

1  
2 **IN THE SUPREME COURT OF THE STATE OF NEVADA**

3 THE NEVADA INDEPENDENT,

4 Appellant,

5  
6 vs.

7 RICHARD WHITLEY, IN HIS  
8 OFFICIAL CAPACITY AS THE  
9 DIRECTOR OF THE NEVADA  
10 DEPARTMENT OF HEALTH AND  
11 HUMAN SERVICES, THE STATE  
12 OF NEVADA, EX REL. THE  
13 NEVADA DEPARTMENT OF  
14 HEALTH AND HUMAN  
15 SERVICES, AND SANOFI-  
AVENTIS U.S. LLC,

Respondent.

No.: 81844

DC No.: A-19-799939-W

Electronically Filed  
Feb 23 2021 10:13 a.m.  
Elizabeth A. Brown  
Clerk of Supreme Court

16  
17  
18 **JOINT APPENDIX**  
19 **VOLUME I**  
20 **PGS. 1-250**  
21

22 MATTHEW J. RASHBROOK  
Nevada State Bar No. 12477  
23 ROBERT L. LANGFORD, ESQ.  
Nevada State Bar No. 3988  
24 ROBERT L. LANGFORD & ASSOCIATES  
25 616 S. Eighth St.  
Las Vegas, NV 89101  
26 (702) 471-6565  
27 *Attorneys for Appellant*  
28 *The Nevada Independent*

AARON D. FORD  
Nevada Attorney General  
Nevada State Bar No. 7704  
HEIDI PARRY STERN  
Nevada State Bar No. 8873  
STEVE SHEVORSKI  
Nevada State Bar No. 8256  
Office of the Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101

1 JOHN R. BAILEY  
 Nevada State Bar No. 137  
 2 DENNIS KENNEDY  
 Nevada State Bar No. 1462  
 3 SARAH E. HARMON  
 Nevada State Bar No. 8106  
 4 REBECCA L. CROOKER  
 Nevada State Bar No. 15202  
 5 BAILEY KENNEDY  
 8984 Spanish Ridge Avenue  
 7 Las Vegas, NV 89148-1302  
 (702) 562-8820  
 8 *Attorneys for Respondent Sanofi-Aventis U.S.*  
 9 *LLC*

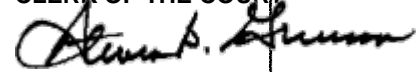
(702) 486-3594  
*Attorneys for Respondents Whitley, and  
 the State of Nevada ex rel. The Nevada  
 Department of Health and Human  
 Services*

## **TABLE OF CONTENTS**

<b><u>VOL.</u></b>	<b><u>DOCUMENT</u></b>	<b><u>DATE</u></b>	<b><u>PAGE NUMBERS</u></b>
I	Petition for a Writ of Mandamus	8/8/2019	JA-000001 – JA-000014
I	Appendix to Petition for a Writ of Mandamus	8/8/2019	JA-000015 – JA-000232
I	Order Setting Hearing re Petition for Writ of Mandamus	8/27/2019	JA-000233 – JA-000234
I	Supplemental Brief in Support of Petition for a Writ of Mandamus	10/15/2019	JA-000235 – JA-000246
I	Opposition to The Nevada Independent’s Petition for Writ of Mandamus and Motion to Dismiss	10/17/2019	JA-000247 – JA-000256
II	Motion to Intervene and to Continue Hearing, on Shortened Time	10/21/2019	JA-000257 – JA-000455
II	Petitioner’s Opposition to Sanofi- Aventis U.S. LLC’s Motion to Intervene and to Continue Hearing	10/31/2019	JA-000456 – JA-000465

II	Sanofi-Aventis U.S. LLC's Reply in Support of Motion to Intervene	11/1/2019	JA-000466 – JA-000472
II	Transcript of Proceedings – Motion to Intervene and to Continue Hearing on Shortened Time	11/5/2019	JA-000473 – JA-000491
II	Errata	11/11/2019	JA-000492 – JA-000520
III	Minute Order	11/14/2019	JA-000521 – JA-000522
III	Sanofi-Aventis U.S. LLC's Supplemental Brief in Support of Motion to Intervene	11/21/2019	JA-000523 – JA-000528
III	Supplemental Brief in Opposition to Motion to Intervene and Reply to Proposed Response	12/5/2019	JA-000529 – JA-000544
III	Minute Order	12/16/2019	JA-000545 – JA-000548
III	Order Granting Sanofi-Aventis U.S. LLC's Motion to Intervene	12/23/2019	JA-000549 – JA-000553
III	Intervenor Sanofi-Aventis U.S. LLC's Response to Petitioner's Petition for a Writ of Mandamus	12/23/2019	JA-000554 – JA-000738
III	Reply to Intervenor's Response	1/3/2020	JA-000739 – JA-000758
IV	Petitioner The Nevada Independent's Witness List	1/17/2020	JA-000759 – JA-000761
IV	Sanofi-Aventis U.S. LLC's Disclosure of Witnesses	1/17/2020	JA-000762 – JA-000764
IV	Defendants' Disclosure of Witnesses	1/17/2020	JA-000765 – JA-000766
IV	Reply in Support of Motion to Dismiss	1/23/2020	JA-000767 – JA-000775
IV	Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	1/30/2020	JA-000776 – JA-000815

IV	Sanofi's Opposition to Petitioner's Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	2/3/2020	JA-000816 – JA-000841
IV	Transcript of Proceedings – Motion to Compel Testimony of James Borneman, or in the Alternative, To Strike his Declaration	2/4/2020	JA-000842 – JA-000890
IV	Motion for Leave to File Brief Amicus Curiae	2/13/2010	JA-000891 – JA-000917
IV	Notice of Non-Opposition	2/14/2020	JA-000918 – JA-000920
IV	Minute Order	2/14/2020	JA-000921 – JA-000922
IV	Notice of Non-Opposition to Culinary union's Motion for Leave to file an Amicus Brief	2/14/2010	JA-000923 – JA-000924
IV	Transcript of Proceedings – Petition for Writ of Mandamus	2/21/2020	JA-000925 – JA-000968
IV	Minute Order	4/21/20	JA-000969 – JA-000973
IV	Order Denying Petition for Writ of Mandamus	9/4/2020	JA-000974 – JA-000984
IV	Notice of Entry of Order	9/9/2020	JA-000985 – JA-000998
IV	Notice of Appeal	9/22/2020	JA-000999 – JA-001001
V	Notice of Appeal (cont.)	9/22/2020	JA-001001



1 **PMAN**  
2 MATTHEW J. RASHBROOK  
3 Nevada State Bar No. 12477  
4 ROBERT L. LANGFORD, ESQ.  
5 Nevada State Bar No. 3988  
6 ROBERT L. LANGFORD & ASSOCIATES  
7 616 S. Eighth Street  
8 Las Vegas, NV 89101  
9 (702) 471-6565  
10 matt@robertlangford.com  
11 robert@robertlangford.com  
12 *Attorneys for Petitioner*  
13 *The Nevada Independent*

CASE NO: A-19-799939-W  
Department 14

14 EIGHTH JUDICIAL DISTRICT COURT  
15 LAS VEGAS, NEVADA

16 THE NEVADA INDEPENDENT,

Case No.:

17 Petitioner,

Dept. No.:

18 vs.

**PETITION FOR A WRIT OF MANDAMUS**

19 RICHARD WHITLEY, in his official  
20 capacity as the Director of the Nevada  
21 Department of Health and Human Services,  
22 and THE STATE OF NEVADA, ex rel. the  
23 NEVADA DEPARTMENT OF HEALTH  
24 AND HUMAN SERVICES;

**Hearing on an expedited basis  
required, pursuant to Nev. Rev. Stat.  
§ 239.011.**

25 Respondents.

26 COMES NOW Petitioner, The Nevada Independent, and hereby petitions this  
27 court for a Writ of Mandamus, directing Respondents Richard Whitley and the State of  
28 Nevada ex rel. the Nevada Department of Health and Human Services ("DHHS") to  
provide Petitioner with certain public records requested by Petitioner, and pay Petitioner its  
reasonable attorney's fees and costs, as provided in Nev. Rev. Stat. § 239.011(2), as  
follows:

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

**Jurisdiction and Venue**

2. The Independent has requested access to certain public records, pursuant to the Nevada Public Records Act (“NPRO”), Nev. Rev. Stat. § 239.001 *et seq.*, in the possession of Respondents. The requests have been unreasonably refused and the corresponding records unreasonably redacted in instances where limited production was offered.

4. The Independent is entitled to be heard on an expedited basis, pursuant to Nev. Rev. Stat. § 239.011(2). (“The court shall give this matter priority over other civil matters to which priority is not given by other statutes.”)

5. The Independent is a 501(c)3 “nonpartisan, nonprofit news and opinion website founded in 2017 . . . focused on ethical, unbiased and transparent journalism . . . [which aims] to gather and disseminate important public information and increase civic engagement.”<sup>1,2</sup>

<sup>2</sup> To that end, The Independent employs a number of reporters, of whom Megan Messerly is one. (See, Affidavit of Jon Ralston and Affidavit of Megan Messerly, true and correct copies of which are attached hereto as Exhibits “Ex.” 1, ¶3, and Ex. 2, ¶4.)

1           7.       The DHHS is a “governmental entity” as that term is defined in Nev. Rev.  
2 Stat. § 239.005(5)(a), with offices at 555 E. Washington Ave, Las Vegas, Nevada 89101.

3 **The Diabetes Epidemic and Insulin Crisis in Nevada and Across the United States and**

4 **Response by the Nevada Legislature**

5           8.       More than 30,000,000 Americans have diabetes. (Ex. 3, p. 2.)

6           9.       A further 84,100,000 Americans have prediabetes, a condition indicated by  
7 increased glucose levels which are presently short of diabetic levels, but which often indicate  
8 a person will develop diabetes. (Ex. 3, p. 7.)

9           10.      Among those aged 65 or older, just over 25% of the population have  
10 diabetes (Ex.3, p. 2), and 48.3% are prediabetic (Ex. 3, p. 7).

11           11.      Diabetes often leads or contributes to heart disease, kidney disease, loss of  
12 limbs and blindness, and is the seventh leading cause of death in the United States.

13           12.      From 2012 to 2016, the price of insulin roughly doubled. (Ex.4, p. 2.) Over  
14 that period, annual insulin spending per person increased by \$2,841. (Ex. 4, p. 3.)

15           13.      However, despite the best efforts of academics and public servants, it is  
16 difficult to gather information regarding medication pricing and profits, in part because  
17 researchers do “not have information on manufacturer rebates or coupons for insulin, because  
18 this information is . . . not publicly available.” (Ex. 4, p. 2.)

19           14.      Average medical expenses for an American with diabetes are estimated  
20 between \$13,700 and \$16,750 per year, of which an estimated \$7,900 to \$9,600 is directly  
21 attributable to diabetes. (Ex. 3, p. 10, Ex. 5, p. 1.)

22           15.      Approximately 291,000 people in Nevada have diabetes. (Ex. 6.)

23           16.      In addition to those with diabetes, approximately 787,000 Nevadans have  
24 prediabetes. (Ex. 6.)

25           17.      Together, the number of diagnosed diabetics and prediabetics represent  
26 approximately half the population of Nevada.

27           18.      “Total direct medical expenses for diagnosed diabetes in Nevada were  
28 estimated at \$2 billion in 2017.” (Ex. 6.) Additionally, a further \$700,000,000 in indirect  
costs were incurred.

          19.      These massive costs are, at least in part, attributable to enormous rises in  
the price of insulin or modern replacements for insulin.

1           20.     In fact, some attribute a significant portion of the rise in the overall cost of  
2 healthcare to the rapid increase in the price of insulin. (Ex. 4, p. 2.)

3           21.     Diabetes appears to disproportionately affect certain groups, most notably  
4 low-income earners, African-Americans, American Indians, Hispanics, Latinos, Asian-  
5 Americans, and Pacific-Islanders. The same groups tend to be over-represented amongst  
6 those who are uninsured or underinsured.

7           22.     In the pharmaceutical marketplace, there are six major players:  
8 manufacturers, wholesalers, insurers, pharmacy benefit managers (“PBMs”), pharmacies,  
9 and the public. (Ex. 7, p. 6.)

10          23.     Manufacturers produce medications and sell them to wholesalers,  
11 wholesalers sell the medications to pharmacies, and pharmacies retail the medications to the  
12 public. (Ex. 7, p. 6.)

13          24.     PBMs may exist as part of insurers, or as a branch or subsidiary of  
14 pharmacies. Roughly, PBMs negotiate discounts and rebates from manufacturers on behalf  
15 of their related pharmacy or insurer.

16          25.     Although many may not realize it, PBMs manage the pharmacy benefits of  
17 about 80% of Americans.

18          26.     In 2017, the largest PBMs had revenues higher than the largest  
19 pharmaceutical manufacturers.

20          27.     Recently, prices for diabetes medications have skyrocketed, and many  
21 attribute the rise to a lack of transparency in the pharmaceutical marketplace.

22          28.     To alleviate the rising cost of diabetes drugs, in 2017 the Nevada Legislature  
23 enacted Senate Bill (“SB”) 539.

24          29.     SB 539, enrolled in significant part at Nev. Rev. Stat. § 439 *et seq.*, has the  
25 effect of requiring pharmaceutical manufacturers and PBMs to disclose to the State certain  
26 information regarding diabetes medication, if the year-over-year price increases for those  
27 medications is greater than the same-year CPI for medical costs.

28          30.     During a hearing on SB 539, Nevada Senators discussed the “unprecedented  
increases in drug prices[,]” and stated specifically that “The intent of S.B. 539 is to . . . further  
increase transparency around the pricing of essential insulin medications[.]” (Ex. 8, p. 3.)

31.     Opinions differ on which actor in the pharmaceutical marketplace is to

1 blame for the staggering increase in insulin prices.

2 32. “You might hear the problem with prices is not the industry and see some  
3 finger-pointing about who is really in charge . . . I would ask that you remember the initial  
4 starting point for price setting begins with the manufacturers[.]”<sup>3</sup> (Ex. 9, p. 33)

5 33. “The PBMs control this market and can require manufacturers to give  
6 rebates, and require insurance companies and retail pharmacies to do their bidding to get the  
7 drugs that their customers need on the formulary. They control the market.” (Ex. 8, p. 10.)

8 34. Commenting on the PBM preference for opacity in their marketplace,  
9 another Nevada Senator said: “I am confident the PBMs will deny the extent to which they  
10 [retain rebates from drug manufacturers]. They conceal this information from their clients,  
11 who are insurance companies and the Employee Retirement Income Security Act of 1974  
12 employers, from retail pharmacies and from the drug manufacturers themselves. If asked by  
13 [the Committee] today, they will conceal this information from this Committee.” (Ex. 8, p.  
14 6.)

15 35. By contrast, those testifying on behalf of PBMs suggested that, in fact, the  
16 leading culprit in high drug prices are the manufacturers. (Ex. 8, p. 23.)

17 36. Those testifying on behalf of the manufacturers suggest however that “The  
18 principal problem we have is that it is not the pharmaceutical manufacturer that determines  
19 what patients pay, it is the PBMs and health insurers.” (Ex. 9, p. 50.)

20 37. Conversely, those studying the price increases suggest “rising insulin prices  
21 were the largest driver of spending growth[.]” (Ex. 4, p. 2.)

22 38. Presently, there is no consensus opinion on why the price of insulin is  
23 increasing so rapidly in Nevada and the United States.

24 39. What can be said with certainty is that the number of diabetes patients in  
25 Nevada is rapidly increasing, and the price they’re paying for medication is skyrocketing at  
26 an even more alarming rate. The 2017 Nevada Legislature passed SB 539 – overwhelmingly,

---

27 <sup>3</sup> This comment was made during a hearing on S.B. 265, which would have created a  
28 similar legislative scheme to that created by S.B. 539, but one that applied to manufacturers  
only. During the 2017 legislative session, the Senate and Assembly both passed S.B. 265.  
However, then-Governor Sandoval vetoed the legislation. Later in the session, a substantial  
part of S.B. 265 was incorporated into S.B. 539; the debate on S.B. 265 is therefore  
relevant.

1 with 17 sponsors and co-sponsors, and bipartisan support in the legislature – and on June 15,  
2 2017, then-Governor Brian Sandoval signed it into law in the hopes of alleviating these  
3 pressing public policy concerns by shining a light and creating transparency in a market  
4 where there is presently nearly none.<sup>4</sup>

**SB 539**

5           40. In pertinent part, SB 539, “requires the Department to compile: (1) a list of  
6 prescription drugs that the Department determines to be essential for treating diabetes in  
7 this State; and (2) a list of such prescription drugs that have been subject to a significant  
8 price increase within the immediately preceding 2 calendar years.” See also, NRS §  
9 439B.630.

10           41. Further, SB 539 “requires the manufacturer of a prescription drug included  
11 on the list of essential diabetes drugs to submit to the Department an annual report that  
12 contains certain information concerning the cost of the drug[.]” including, if applicable, “a  
13 report concerning the reasons for the cost increase.” See also, NRS §§ 439B.635, .640.

14           42. Similarly, SB 539 requires PBMs “to report certain information  
15 concerning essential diabetes drugs to the Department.” See also, NRS § 439B.645.  
16

---

17 <sup>4</sup> “The idea would be to increase the amount of transparency that exists specifically with  
18 diabetes drugs.” (Ex. 9, p. 40.) “Because transparency is minimal in pharmaceutical  
19 pricing, it is very difficult to get to how exactly we choose the best marker . . . As a result  
20 of the lack of transparency, S.B. 265 asks that manufacturers on the list disclose cost-  
21 related information to the DHHS[.]” (Ex. 9, p. 39.) “I believe that getting the most  
22 transparency possible . . . is really the only way that we can actually have a discussion  
23 about every other player in the system.” (Ex. 9, p. 40.) “The premise of this bill is that  
24 transparency will at least help to pinpoint the problem.” (Ex. 9, p. 53.) “Transparency is  
25 required in order to help address this issue . . . The intent of S.B. 539 is . . . to further  
26 increase transparency around the pricing of essential insulin medications[.]” (Ex. 9, p. 3.)  
27 “In addition to the gag rule, S.B. 539 focuses on providing increased transparency[.]” (Ex.  
28 8, p. 5.) “I made it clear that I was in favor of transparency all along the line.” (Ex. 8, p. 8.)  
“We are proposing more transparency today and want to know how much a PBM gets in  
rebates from a drug manufacturer and what the PBM does with those rebates. When we  
have that information, we can identify why these prices continue to go up and why there is  
a problem.” (Ex. 8, p. 13.)

1           43. Under SB 539, any of the information manufacturers, PBMs, or  
2 pharmaceutical sales representatives are required to report to the DHHS are not trade  
3 secrets. NRS § 600A.030(5)(b).

4           44. In short, SB 539 requires pharmaceutical manufacturers to make a  
5 submission to the DHHS detailing the reason for any price increase in essential diabetes  
6 drugs, including detailing what proportion of the price increase was owed to each factor  
7 listed. PBMs must make a similar report. The information submitted is, by law, not a trade  
8 secret.

9           45. Following the enrollment of SB 539, the DHHS set a deadline of January  
10 15, 2019 for manufacturers and PBMs to support the required information.

#### 11                   **Subsequent SB 539 Litigation and DHHS Policy**

12           46. Following the enactment of SB 539, in 2017 the Pharmaceutical Research  
13 and Manufacturers of America (“PhRMA”) – a trade group which represents pharmaceutical  
14 manufacturers – and Biotechnology Innovation Organization (“BIO”) – a biotechnology  
15 trade group – filed suit in the District Court for the District of Nevada, seeking to enjoin the  
16 enforcement of SB 539, in case number 2:17-cv-02315. Plaintiffs PhRMA and BIO asked  
17 the District Court to voluntarily dismiss the suit on or about June 28, 2018, and the suit was  
18 dismissed the same day.

19           47. Whether through a process of negotiations with PhRMA and BIO or  
20 otherwise, Respondents herein established a set of policies to follow when met with public  
21 records requests for information submitted to them by manufacturers, PBMs and others under  
22 SB 539, and codified the policies at NAC §§ 439.730 – 740.

23           48. In pertinent part, the regulation calls for the Department to offer  
24 manufacturers and PBMs an opportunity to seek an injunction from a court before the  
25 Department responds to a public records request by providing records the manufacturer or  
26 PBM has submitted pursuant to SB 539. NAC § 439.735.

#### 27                   **The Public Records Requests and Denials**

28           49. On January 17, 2019, through its reporter Megan Messerly, the  
Independent made a request under the NPRA for the annual reports submitted under Nev.  
Rev. Stat. § 439B.635 and .640 by 97 pharmaceutical manufacturers (and any others who

1 submitted a report), and under Nev. Rev. Stat. § 439B.645 by seven PBMs (and any others  
2 who submitted a report). (Ex. 2-1.)

3 50. On April 3, 2019, the Department responded to Ms. Messerly and the  
4 Independent by advising that, because it believed the information was made confidential by  
5 the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended (“DTSA”), it would  
6 deny the request for public records in every meaningful respect. (Ex. 2-2.)

7 51. On June 11, 2019, through its reporter Megan Messerly, the Independent  
8 made a second request under the NPRA for further annual reports submitted under Nev.  
9 Rev. Stat. § 439B.635 and .640 by 72 pharmaceutical manufacturers (and any others who  
10 submitted a report), and under Nev. Rev. Stat. § 439B.645 by seven PBMs (and any others  
11 who submitted a report). (Ex. 2-3.)

12 52. On June 24, 2019, the Department responded to Ms. Messerly and the  
13 Independent by advising that, because it believed the information was made confidential by  
14 the DTSA, it would deny the request for public records in every meaningful respect.<sup>5</sup> (Ex.  
15 2-4.)

16 53. In each response, the Department agreed to disclose the following from  
17 the “Drug Manufacturer Essential Diabetes Drug Reports” required under Nev. Rev. Stat.  
18 439B.635:

- 19 • Drug Manufacturer Name;
- 20 • Nonproprietary Prescription Drug Name;
- 21 • Proprietary Prescription Drug Name;
- 22 • National Drug Code (“NDC”);
- 23 • Wholesale Acquisition Cost (“WAC”) Price History;
- 24 • Increase in WAC Unit Price; and
- 25 • Date of Increase in WAC Price.

26 However, the Department refused to disclose the following from the Drug Manufacturer  
27 Essential Diabetes Drug Reports:

- 28 • Total Cost of Producing the Drug;
- Total Administrative Expenditures Relating to the Prescription Drug;
- Profit Manufacturer Earned from the Drug;

29 <sup>5</sup> To date, the DHHS has responded by advising Ms. Messerly and The Independent of  
30 what it intends to produce. However, as of the date of this filing, the DHHS has not  
31 produced any records in response to the requests discussed herein.

- Percentage of Manufacturer's Total Profit Attributed to Drug During Marketing Period for Drug Sale;
- Total Amount of Financial Assistance Provided through Patient Prescription Assistance Programs;
- Cost Associated with Consumer Coupons and for Consumer Copayment Assistance Programs;
- Manufacturer Cost Attributable to Redemption of Consumer Coupons and Use of Consumer Copayment Assistance Program; and
- Aggregate of All Rebates Manufacturers Provided to Pharmacy Benefit Managers for Drug Sales in Nevada in Dollars.

54. From the Drug Manufacturer Essential Diabetes Drug Price Increase Reports required under Nev. Rev. Stat. 439B.640, the Department agreed to disclose:

- Drug Manufacturer Name;
- Non-Proprietary Drug Name;
- Proprietary Drug Name; and
- NDC.

However, the Department refused to disclose the following information regarding price increases:

- A Description of the Factor;
- The Percentage of the Influence on any Price Increase; and
- Explanation of Role of Each Factor on the Price Increase.

55. Regarding the PBM Essential Diabetes Drug Reports required under Nev. Rev. Stat. § 439B.645, the Department refused to produce anything other than a list of PBMs that submitted reports, denying all of the following:

- Total amount of all rebates the PBM negotiated with manufacturers during the preceding calendar year for essential diabetes drugs;
- Total amount of all rebates mentioned above that were retained by the PBM;
- Total amount of all rebates that were negotiated for purchases of such drugs for use by recipients of Medicaid;
- Total amount of all rebates that were negotiated for purchases of such drugs for use by persons covered by third parties that are governmental entities but are not Medicaid or Medicare;
- Total amount of all rebates that were negotiated for purchases of such drugs for use by persons covered by third parties that are not governmental entities; and
- Total amount of all rebates that were negotiated for purchases of such drugs for use by persons covered by a plan described in SB 539 § 4.2(2) and (3).

1           56.     Essentially, Respondents refused to disclose any information included in  
2 the reports which is not already in the public domain.

3           57.     The Department's refusal to produce the requested public records is a  
4 violation of the NPRA.

5                   **Nevada Public Records Law Demands Disclosure in this Case**

6           58.     "The purpose of [the NPRA] is to foster democratic principles by providing  
7 members of the public with access to inspect and copy public books and records to the extent  
8 permitted by law[.]" NRS § 239.001(1).

9           59.     The NPRA must therefore "be construed liberally to carry out th[at]  
10 important purpose." NRS § 239.001(2).

11           60.     "Any exemption, exception or balancing of interests which limits or  
12 restricts access to public books and records by members of the public must be construed  
13 narrowly[.]" NRS § 239.001(3).

14           61.     The Supreme Court of Nevada has repeatedly held that a court considering  
15 a claim of confidentiality in response to a public records requests "begin[s] with the  
16 presumption that all government-generated records are open to disclosure." *Reno*  
17 *Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 266 P.3d 623, 628 (2011), citing *Reno*  
18 *Newspapers v. Sheriff*, 126 Nev. Adv. Rep. 23, 234 P.3d 922, 924 (2010); *DR Partners v.*  
19 *Board of County Comm'rs*, 116 Nev. 616, 621, 6 P.3d 465, 468 (2000).

20           62.     Further, to withhold on the basis of claimed confidentiality, the government  
21 "bears the burden to prove that its interest in nondisclosure *clearly outweighs* the public's  
22 interest in access." *Id.* at 880, at 628 (emphasis added), citing *Reno Newspapers v. Sheriff*,  
23 126 Nev. Adv. Rep. 23, 14, 234 P.3d at 927.

24           63.     Following substantial debate, and with bipartisan support specifically  
25 referencing the need for transparency, discussed throughout, see *supra*, ¶¶ 28 – 39, SB 539  
26 was enacted specifically to publicize the records at issue herein.

27           64.     In response, Respondents have created a framework, through administrative  
28 codes and regulations, within which they propose to consider public records requests under  
the NPRA.

1           65.     However, to whatever extent the agency-created regulations at issue conflict  
2 with statutory law, the regulations are invalid. *Division of Ins. v. State Farm Mutual Ins. Co.*,  
3 116 Nev. 290, 293, 995 P.2d 482, 485 (2000).<sup>6</sup>

4           66.     Therefore, if NAC §§ 439.730 – 740 conflict either with SB 539 – and they  
5 do, as SB 539 exempts the information from trade secret status – or, with the NPRA – and  
6 they do, as the NPRA requires these documents be released – NAC §§ 439.730 – 740 must  
7 be invalidated.

8           67.     Substantially, Respondents appear to have based those codes and  
9 regulations on their fear of liability under the DTSA, and further base their denial out of  
10 concern for their potential liability under that federal statute, and claim confidentiality on the  
11 same basis.

12           68.     This, all notwithstanding the fact that the DTSA itself explicitly states it  
13 does not preempt state law, *see* 18 U.S.C. § 1838<sup>7</sup> (“ . . . this chapter shall not be construed  
14 to preempt or displace any other remedies, whether civil or criminal, provided by . . . State .  
15 . . law”), and further states, at 18 U.S.C. 1833(a)(1), that it “does not prohibit or create a  
16 private right of action for any otherwise lawful activity conducted by a governmental entity  
17 of . . . a State[.]”

18           69.     Indeed, this is why the federal District Court for the District of  
19 Massachusetts, presented with a strikingly similar factual scenario, determined that the  
20 DTSA does not provide a cause of action against state governments. *Fast Enterprises, LLC*  
21 *v. Pollack*, 2018 U.S. Dist. LEXIS 161518, 2018 WL 4539685, U.S. Dist. Mass. 16-cv-  
22 12149, Sept. 21, 2018.

---

23  
24 <sup>6</sup> “A court will not hesitate to declare a regulation invalid when the regulation violates the  
25 constitution, conflicts with existing statutory provisions or exceeds the statutory authority  
26 of the agency or is otherwise arbitrary and capricious.” Citing NRS 233B.110; *Clark Co.*  
*Social Service Dep’t v. Newkirk*, 106 Nev. 177, 179, 789 P.2d 227, 228 (1990); *Roberts v.*  
*State*, 104 Nev. 33, 37, 752 P.2d 221, 223 (1988).

27 <sup>7</sup> Notably, in pertinent part, the DTSA, at 18 U.S.C. § 1838, speaks to the public records  
28 context: “ . . . this chapter shall not be construed . . . to affect the otherwise lawful  
disclosure of information by any Government employee under [the Freedom of Information  
Act].”

1           70. In sum, the DTSA states clearly that it does not preempt state law, or have  
2 as its purpose precluding Respondents from complying with the NPRA, and that it does not  
3 provide a cause of action against the State in any case.

4           71. In weighing the policy implications of disclosure or withholding, this Court  
5 should defer to the clearly stated goals of the Legislature in enacting this legislation and  
6 exempting the records at issue from trade secret protection. The stated goal of the legislation  
7 was to get the very information these records contain into the public domain with the specific  
8 purpose of addressing the runaway insulin prices seen in this state and across the country.

9           72. The Nevada Supreme Court acknowledges that many public policy  
10 questions are “better left to the Legislature.” *Renown Health, Inc. v. Vanderford*, 126 Nev.  
11 Adv. Rep. 24, 7, 235 P.3d 614, 616 (2010), citing *Nevada Hwy. Patrol v. State, Dep’t Mtr.*  
12 *Veh.*, 107 Nev. 547, 550 – 51, 815 P.2d 608, 610 – 11 (1991); *Niece v. Elmview Group Home*,  
13 131 Wn.2d 39, 929 P.2d 420, 428 (Wash. 1997) (“[N]oting that the policy decision to expand  
14 the scope of an employer’s liability for an employee’s intentional acts against a person to  
15 whom the employer owes a duty of care ‘should be left to the legislature.’”)

16           73. This is particularly so in areas in which “The Legislature has heavily  
17 regulated,” because courts can safely assume that the Legislature would have codified a  
18 particular result if they’d intended it. *Renown Health, Inc.*, 126 Nev. Adv. Rep. 24, 7, 235  
19 P.3d at 616.

20           74. The Legislature has spoken very clearly in enacting SB 539: their intent was  
21 for the public to benefit from access to these records.

22           75. Respondents have violated the NPRA by refusing to produce the records  
23 requested by Ms. Messerly on behalf of the Independent in unredacted form, and a Writ of  
24 Mandamus should be issued by this Court, directing Respondents to provide The  
25 Independent with the requested records forthwith, together with the reasonable attorney’s  
26 fees and costs incurred in the prosecution of this matter, as required under the NPRA.

27           WHEREFORE, Petitioner respectfully prays for the following relief:

28           76. An expedited hearing of the foregoing Petition, as required by Nev. Rev. Stat.  
§ 239.011;

          77. the opportunity to supplement this Petition with such briefing, evidence, or  
argument as may assist the Court in determining this matter;

1 78. a Writ of Mandamus directing Respondents to provide the Independent with  
2 access to, or copies of, all requested public records, including, but not limited  
3 to:

4 a. unredacted copies of all reports collected by Respondents from  
5 pharmaceutical manufacturers and PBMs pursuant to Nev. Rev. Stat. §§  
6 439B.635, 640, and 645;

7 79. the reasonable attorney's fees and costs incurred in the prosecution of this  
8 Petition, as provided for in Nev. Rev. Stat. § 239.010; and

9 80. such further relief as this Court deems appropriate.

10 All of which is respectfully submitted this 8th day of August, 2019.

11 

12 MATTHEW J. RASHBROOK

13 Nevada State Bar No. 12477

14 ROBERT L. LANGFORD, ESQ.

15 Nevada State Bar No. 3988

16 ROBERT L. LANGFORD &  
17 ASSOCIATES

18 616 S. Eighth Street

19 Las Vegas, NV 89101

20 (702) 471-6565

21 matt@robertlangford.com

22 robert@robertlangford.com

23 *Attorneys for Petitioner*

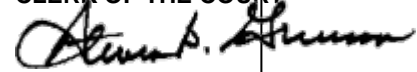
24 *The Nevada Independent*

1  
2  
3  
4  
5  
6  
7  
8  
9  
0  
1  
2  
3  
4  
5  
6  
7  
8  
9  
0  
1  
2  
3  
4  
5  
6  
7  
8

YOU AND EACH OF YOU, PLEASE TAKE NOTICE that the undersigned will bring the foregoing PETITION FOR A WRIT OF MANDAMUS for hearing on the \_\_\_\_\_ day of \_\_\_\_\_, 2019, at \_\_\_\_\_m., or as soon thereafter as counsel may be heard.

DATED this 8th day of August, 2019.

*The Nevada Independent*



1 **APEN**

2 MATTHEW J. RASHBROOK  
3 Nevada State Bar No. 12477  
4 ROBERT L. LANGFORD, ESQ.  
5 Nevada State Bar No. 3988  
6 ROBERT L. LANGFORD & ASSOCIATES  
7 616 S. Eighth Street  
8 Las Vegas, NV 89101  
(702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

CASE NO: A-19-799939-W  
Department 14

9 **EIGHTH JUDICIAL DISTRICT COURT**

10 **LAS VEGAS, NEVADA**

11 THE NEVADA INDEPENDENT,

Case No.:

12  
13 Petitioner,

Dept. No.:

14 vs.

**APPENDIX TO PETITION FOR A WRIT  
OF MANDAMUS**

15 RICHARD WHITLEY, in his official  
16 capacity as the Director of the Nevada  
17 Department of Health and Human Services,  
18 and THE STATE OF NEVADA, ex rel. the  
19 NEVADA DEPARTMENT OF HEALTH  
20 AND HUMAN SERVICES;

21 Respondents.

22 /s/Matthew J. Rashbrook

23 MATTHEW J. RASHBROOK  
24 Nevada State Bar No. 12477  
25 ROBERT L. LANGFORD, ESQ.  
26 Nevada State Bar No. 3988  
27 ROBERT L. LANGFORD &  
28 ASSOCIATES  
616 S. Eighth Street  
Las Vegas, NV 89101  
(702) 471-6565  
*Attorneys for Petitioner*  
*The Nevada Independent*

**TABLE OF CONTENTS TO APPENDIX**

<b><u>Exhibit</u></b>	<b><u>DOCUMENT</u></b>
1	Affidavit of Jon Ralston.
2	Affidavit of Megan Messerly, with sub-exhibits.
2-1	Letter to the Nevada Department of Health and Human Services dated January 17, 2019
2-2	Letter from the Nevada Department of Health and Human Services dated April 3, 2019.
2-3	Letter to the Nevada Department of Health and Human Services dated June 11, 2019
2-4	Letter from the Nevada Department of Health and Human Services dated June 24, 2019.
3	National Diabetes Statistics Report, 2017.
4	Health Cost Care Institute: Spending in Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices.
5	American Diabetes Association: Economic Costs of Diabetes in the U.S. in 2017.
6	American Diabetes Association: The Burden of Diabetes in Nevada.
7	Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain
8	Minutes of the Senate Committee on Health and Human Services, Seventy-ninth Session dated May 26, 2017.
9	Minutes of the Senate Committee on Health and Human Services, Seventy-ninth Session dated March 29, 2017.

# EXHIBIT 1

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 1

Affidavit of Jon Ralston

STATE OF NEVADA       )  
  ) ss.  
COUNTY OF CLARK       )

Jon Ralston, being first duly sworn, hereby deposes and states:

1. I am over 18 years of age and of sound mind.

2. I have personal knowledge of all matters sworn to herein, except for matters specifically stated upon information and belief, and as to those matters, I believe them to be true.

3. I am the Editor of The Nevada Independent, a nonprofit and nonpartisan news and opinion website I founded in 2017.

4. The Nevada Independent employs a number of reporters, of whom Megan Messerly is one.

5. I am informed and believe that in her capacity as a reporter for The Nevada Independent, Ms. Messerly made requests for public records from the Nevada Department of Health and Human Services ("DHHS") on or about January 17, 2019, and June 11, 2019.

///

///

///

///

///

///


///

///

///

6. I am informed and believe that the DHHS, in large part, refused those requests on or about April 3, 2019 and June 24, 2019, respectively.

Further affiant sayeth naught.

  
**Jon Ralston**

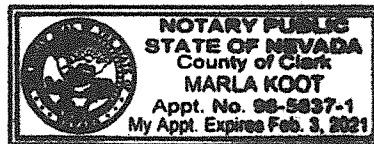
**State of Nevada**  
**County of Clark**

SUBSCRIBED AND SWORN to

before me this 7th day of August, 2019.

Mendel Kost

NOTARY PUBLIC in and for  
STATE OF NEVADA  
COUNTY OF CLARK



# EXHIBIT 2

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 2

Affidavit of Megan Messerly

STATE OF NEVADA       )  
  ) ss.  
COUNTY OF CLARK       )

Megan Messerly, being first duly sworn, hereby deposes and states:

1. I am over 18 years of age and of sound mind.

2. I have personal knowledge of all matters sworn to herein, except for matters specifically stated upon information and belief, and as to those matters, I believe them to be true.

3. On January 17, 2019, on behalf of the Nevada Independent, I sent a request for public records relating to the disclosures required under Nev. Rev. Stat. §§ 439B.600 – 695 to the Nevada Department of Health and Human Services (“DHHS”). A true and correct copy of the letter is attached hereto as Exhibit (“Ex.”) 1.

4. On April 3, 2019, Dr. Scott Jones, of the DHHS replied to me, indicating that the DHHS would, in large part, refuse the request. Ex. 2

5. On June 11, 2019, on behalf of the Nevada Independent, I sent a request for public records relating to the disclosures required under Nev. Rev. Stat. §§ 439B.600 – 695 to the DHHS. Ex. 3.

///

///

///

///


///

///

///

6. In a letter dated June 24, 2019, and e-mailed to me June 27, 2019, Dr. Scott Jones, of the DHHS replied to me, indicating that the DHHS would, in large part, refuse the request. Ex. 4.

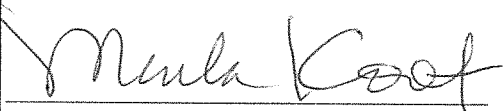
Further affiant sayeth naught.

  
Megan Messerly

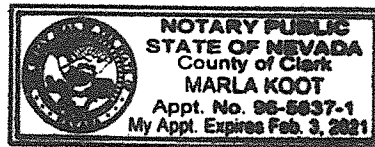
State of Nevada  
County of Clark

SUBSCRIBED AND SWORN to

before me this 8<sup>th</sup> day of August, 2019.



NOTARY PUBLIC in and for  
STATE OF NEVADA  
COUNTY OF CLARK



# EXHIBIT 2-1

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 2-1

Megan Messerly  
The Nevada Independent  
7455 Arroyo Crossing, Suite 200  
Las Vegas, NV 89113

January 17, 2019

Chrystal Main  
Public Information Officer  
Attn: Public Record Request  
Nevada Department of Health and Human Services  
Director's Office  
4150 Technology Way, Suite 200  
Carson City, NV 89706

Dear Ms. Main:

Under the Nevada Public Records Act, I am requesting certain information the department has collected pursuant to the diabetes drug transparency law passed during Nevada's 2017 legislative session, SB539.

Specifically, I am requesting a list of the names of each pharmaceutical manufacturer or pharmacy benefit manager that has submitted a required annual report on the costs associated with essential diabetes drugs by the Jan. 15, 2019 extended deadline.

Additionally, I am requesting the annual reports submitted by the following pharmaceutical manufacturers. Reports requested include those submitted by companies subject to the general manufacturer reporting requirements and also those subject to the additional reporting requirements on price increases, including, but not limited to, those required by NRS §§ 439B.635 and .640.

- Accord Healthcare Inc.
- Actavis Elizabeth
- Actavis Pharma, Inc.
- Aidarex Pharmaceuticals LLC
- American Health Packaging
- Aphenia Pharma Solutions - Tennessee, LLC
- Apotex Corp
- Apotheca Inc.
- Ascend Laboratories, Inc.
- Astrazeneca AB / Astrazeneca Pharmaceuticals, LP
- Aurobindo Pharma
- Avera McKennan Hospital
- AvKARE, Inc.
- Bayer Healthcare Pharmaceuticals, Inc.
- Bionpharma Inc.
- Blenheim Pharmacal, Inc.
- BluePoint Laboratories
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Breckenridge Pharmaceutical, Inc.
- Bristol-Myers Squibb Company
- Bryant Ranch Prepack
- Cadila Healthcare Limited
- Cambridge Therapeutics Technologies, LLC
- Cardinal Health
- Carilion Materials Management
- Carlsbad Technology Inc.
- Citron Pharma LLC
- Clinical Solutions Wholesale
- Contract Pharmacy Services-PA
- Daiichi Sankyo, Inc.
- Dava Pharms, Inc.
- Depomed, Inc.
- DIRECT RX
- Dispensing Solutions, Inc.
- Dr. Reddy's Laboratories Limited

- Eli Lilly and Company
- Epic Pharma LLC
- Gemini Laboratories, LLC
- GlaxoSmithKline, LLC
- Golden State Medical Supply, Inc.
- Greenstone LLC
- Heritage Pharmaceuticals, Inc.
- Hikma
- H.J. Harkins Company, Inc.
- Impax Labs, Inc.
- Ingenus Pharmaceuticals
- International Laboratories, LLC
- Janssen Pharmaceuticals, Inc.
- Kaiser Foundation Hospitals
- Lake Erie Medical & Surgical Supply  
DBA Quality Care Products LLC
- Legacy Pharmaceutical Packaging, LLC
- Liberty Pharmaceuticals, Inc.
- Macleods Pharmaceuticals Limited
- MannKind Corporation
- Major Pharmaceuticals
- MedVantx, Inc.
- Merck Sharp & Dohme Corp.
- Micro Labs Limited
- Mylan / Mylan Institutional Inc. / Mylan  
Pharmaceuticals Inc.
- NCS HealthCare of KY, Inc dba  
Vanguard Labs
- Northwind Pharmaceuticals
- Novartis Pharmaceuticals Corporation
- Novo Nordisk
- NuCare Pharmaceuticals, Inc.
- Paddock Laboratories, LLC
- Par Pharmaceutical, Inc.
- PD-Rx Pharmaceuticals, Inc.
- Pharmadax, Inc.
- Pfizer / Roerig
- Pharmacia and Upjohn Company LLC
- Physicians Total Care, Inc.
- Prasco Laboratories
- Preferred Pharmaceuticals Inc.
- Proficient Rx LP
- Qualitest Pharmaceuticals
- Ranbaxy Pharmaceuticals, Inc
- Rebel Distributors Corp
- RedPharm Drug, Inc.
- REDMEDYREPACK INC.
- Rising Pharmaceuticals, Inc.
- Sandoz, Inc
- Santarus, Inc.
- Sanofi-Aventis U.S., LLC
- Shionogi, Inc.
- Solco Healthcare U.S., LLC
- STAT Rx USA LLC
- State of Florida DOH Central Pharmacy
- St Marys Medical Park Pharmacy
- Sun Pharmaceutical Industries, Inc.
- Takeda Pharmaceuticals America, Inc.
- Teva / Teva Pharmaceuticals USA, Inc.
- Time Cap Laboratories, Inc.
- TYA Pharmaceuticals
- Unit Dose Services
- Validus Pharmaceuticals, LLC
- Virtus Pharmaceuticals
- Wockhardt Limited
- Zydus Pharmaceuticals USA, Inc.
- Any other pharmaceutical manufacturer  
that submitted a report pursuant to  
SB539 of the 2017 legislative session

I am also requesting the required annual reports submitted by the following pharmacy benefit managers, including, but not limited to, those required by NRS §§ 439B.645:

- Express Scripts
- CVS Health
- OptumRx
- Hometown Health
- Cigna
- Humana
- Navitus Health Solutions

- Any other pharmacy benefit manager that submitted a report pursuant to SB539 of the 2017 legislative session

I am also requesting any written opinions, either formal or informal, the attorney general's office has provided the Nevada Department of Health and Human Services relating to the implementation of SB539 of the 2017 legislative session.

If access to the records I am requesting will take longer than a reasonable amount of time, please contact me with information about when I might expect copies or the ability to inspect requested records. If production of the requested records will cost more than \$25, please provide me a written estimate for the production of the records prior to inspection or reproduction. Please provide the records as they become available.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information. Please let me know if you have any questions or need any clarification.

Thank you for handling my request.

Sincerely,

Megan Messerly  
Reporter, *The Nevada Independent*  
megan@thenvindy.com  
(702) 706-6884

# EXHIBIT 2-2

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 2-2

STEVE SISOLAK  
Governor



JULIE KOTCHEVAR  
Administrator

RICHARD WHITLEY, MS  
Director

IHSAN AZZAM, Ph.D., M.D.  
Chief Medical Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way  
Carson City, Nevada 89706  
Telephone (775) 684-4200 • Fax (775) 687-7570  
<http://dpbh.nv.gov>

April 3, 2019

Re: Written Notice of Intent to Disclose Public Records

Dear Ms. Messerly,

The Nevada Department of Health and Human Services (DHHS) received your public records request that seeks disclosure of source reports submitted to DHHS in compliance with NRS 439B.660-695. Your request seeks disclosure of information regarding diabetes drugs defined as essential by DHHS in 2017 for which manufacturers or pharmacy benefit managers (PBMs) have submitted Requests for Confidentiality (RFC). Therefore, DHHS is providing this written notice of the information that DHHS intends to disclose as required by Nevada Administrative Code (NAC) 439.735 (Appendix 1). Appendix 2, included on page four of this notice, provides the data fields that DHHS intends to publicly disclose. DHHS does not intend to disclose any fields from the drug manufacturer and PBM reports not referenced in Appendix 2. DHHS is denying disclosure of the fields not included in Appendix 2 on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act (DTSA) of 2016, 18 U.S.C. § 1836, as amended.

This determination is based on DHHS's review of the DTSA, and on the information provided by drug manufacturers and PBMs in the completed RFCs submitted to DHHS pursuant to NAC 439.735, Subsection 2. Please note that a copy of this letter will be sent to manufacturers and PBMs that submitted an RFC. DHHS will not be able to disclose the information until at least 30 days have elapsed following the date of this written notice. Additionally, if manufacturers or PBMs commence an action within the 30-day period as provided in subsection 6 of NAC 439.735, DHHS will not be able to disclose the information, unless the disclosure is permitted by that subsection. If no legal action is taken during the 30-day period, the information will be shared according to DHHS's determination.

Unless specifically requested otherwise, redacted reports and other requested information will be shared electronically. Price Increase Reports and PBM reported fields will be compiled as lists and will not be redacted original reports unless specifically requested otherwise. Please contact us at [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov) if you have any questions about this process.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott A. Jones".

Scott Jones, PhD  
Manager, Primary Care and Health Workforce Development Office

## Appendix 1

### Nevada Administrative Code (NAC) 439.735

**NAC 439.735 Request by manufacturer or pharmacy benefit manager to keep certain information confidential as a trade secret; procedures for Department to follow upon receipt of public records request for disclosure. ([NRS 439.930](#))**

1. In complying with [NRS 439B.635](#), [439B.640](#) or [439B.645](#), if a manufacturer or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the manufacturer or pharmacy benefit manager may submit to the Department a request to keep the information confidential.

2. A request for confidentiality submitted pursuant to subsection 1 must be divided into the following parts, which must be severable from each other:

(a) The first part of the request for confidentiality must describe, with particularity, the information sought to be protected from public disclosure. Upon a request for public records pursuant to [NRS 239.010](#), the Department will not disclose the description set forth in the request for confidentiality or the information sought to be protected from public disclosure, unless the description and information are disclosed pursuant to subsections 5 and 6.

(b) The second part of the request for confidentiality must include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. Upon a request for public records pursuant to [NRS 239.010](#), the Department will disclose the explanation set forth in the request for confidentiality.

3. If the Department receives a request for public records pursuant to [NRS 239.010](#) seeking disclosure of any information for which a manufacturer or pharmacy benefit manager has submitted a request for confidentiality pursuant to subsection 1, the Department will:

(a) As soon as reasonably practicable after receiving the request for public records, provide the manufacturer or pharmacy benefit manager with:

(1) Written notice of the request for public records and the procedures set forth in this section; and

(2) A copy of the request for public records and the date on which the Department received the request.

(b) Undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. In undertaking its initial review, the Department will consider, as persuasive authority, the interpretation and application given to the term “trade secrets” in Exemption 4 of the federal Freedom of Information Act, 5 U.S.C. § 552(b)(4), as amended.

4. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:

(a) Within the time prescribed by [NRS 239.0107](#), provide the requester of the public records with written notice pursuant to paragraph (d) of subsection 1 of [NRS 239.0107](#) that the Department must deny the request for public records on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended.

(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:

(1) Written notice that the Department denied the request for public records; and

(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.

5. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:

(a) Within the time prescribed by [NRS 239.0107](#), provide the requester of the public records with written notice pursuant to paragraph (c) of subsection 1 of [NRS 239.0107](#) that the Department intends to disclose the information, except that:

(1) The Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and

(2) If the manufacturer or pharmacy benefit manager timely commences an action within the 30-day period as provided in subsection 6, the Department will not be able to disclose the information, unless the disclosure is permitted by that subsection.

(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:

(1) Written notice that the Department intends to disclose the information; and

(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.

6. If, within the 30-day period following the date on which the Department sent the written notice to the requester of public records pursuant to subsection 5, the manufacturer or pharmacy benefit manager:

(a) Does not commence an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will disclose the information.

(b) Commences an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will not disclose the information until final resolution of the action, including any appeals. After final resolution of the action, if the court:

(1) Enjoins the Department from disclosing the information as a trade secret, the Department will not disclose the information so long as the information retains its status as a trade secret.

(2) Does not enjoin the Department from disclosing the information as a trade secret, the Department will disclose the information as soon as reasonably practicable after final resolution of the action.

(Added to NAC by Dep't of Health & Human Services by R042-18, eff. 5-31-2018)

## **Appendix 2**

### *Essential Diabetes Drug Report Data Fields DHHS Intends to Disclose Publicly*

#### **1) Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635)**

- i) Drug Manufacturer Name
- ii) Nonproprietary Prescription Drug Name
- iii) Proprietary Prescription Drug Name
- iv) National Drug Code (NDC)
- v) Wholesale Acquisition Cost (WAC) Price History
- vi) Increase in WAC Unit Price
- vii) Date of Increase in WAC Price

#### **2) Drug Manufacturer Essential Diabetes Drug Price Increase Reports (NRS 439B.640)**

- i) Drug Manufacturer Name
- ii) Non-Proprietary Drug Name
- iii) Proprietary Drug Name
- iv) NDC

#### **3) PBM Essential Diabetes Drug Reports (NRS 439B.645)**

- i) A list of PBMs that submitted reports

# EXHIBIT 2-3

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 2-3

Megan Messerly  
The Nevada Independent  
7455 Arroyo Crossing, Suite 200  
Las Vegas, NV 89113

June 11, 2019

Scott Jones  
Manager, Primary Care and Health Workforce Development Office  
Nevada Department of Health and Human Services  
Division of Public and Behavioral Health  
4150 Technology Way, Suite 300  
Carson City, NV 89706

Dear Mr. Jones:

Under the Nevada Public Records Act, I am requesting certain information the department has collected pursuant to the diabetes drug transparency law passed during Nevada's 2017 legislative session, SB539. Specifically, I am requesting a list of the names of each pharmaceutical manufacturer or pharmacy benefit manager that has submitted their second required annual report on the costs associated with essential diabetes drugs by the April 1, 2019 deadline.

Additionally, I am requesting the annual reports submitted by the following pharmaceutical manufacturers. Reports requested include those submitted by companies subject to the general manufacturer reporting requirements and also those subject to the additional reporting requirements on price increases, including, but not limited to, those required by NRS §§ 439B.635 and .640.

- Accord Healthcare Inc.
- Actavis Pharma, Inc.
- Alvogen, Inc.
- American Health Packaging
- Amneal Pharmaceuticals LLC
- Amneal Pharmaceuticals of New York LLC
- Apotex Corp
- Ascend Laboratories, LLC
- Astrazeneca AB / Astrazeneca Pharmaceuticals, LP
- Aurobindo Pharma
- Bionpharma Inc.
- BluePoint Laboratories
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Bristol-Myers Squibb Company
- Carlsbad Technology Inc.
- Citron Pharma LLC
- Daiichi Sankyo, Inc.
- Dr. Reddy's Laboratories Limited
- Eli Lilly and Company
- Eon Labs, Inc.
- Epic Pharma LLC
- Gemini Laboratories, LLC
- GlaxoSmithKline, LLC
- Glenmark Pharmaceuticals Inc., USA
- Global Pharmaceuticals
- Golden State Medical Supply, Inc.
- Greenstone LLC
- Heritage Pharmaceuticals, Inc.
- Ingenus Pharmaceuticals
- International Laboratories, LLC
- Janssen Pharmaceuticals, Inc.
- Legacy Pharmaceutical Packaging, LLC
- Lupin Pharmaceuticals, Inc.
- Macleods Pharmaceuticals Limited
- MannKind Corporation
- Major Pharmaceuticals
- McKesson Corporation
- Medisca, Inc.
- Merck Sharp & Dohme Corp.
- Method Pharmaceuticals, LLC

- Mylan / Mylan Institutional Inc. / Mylan Pharmaceuticals Inc.
- Nostrum Laboratories, Inc.
- Novartis Pharmaceuticals Corporation
- Novo Nordisk
- Oceanside Pharmaceuticals
- Paddock Laboratories, LLC
- Par Pharmaceutical, Inc.
- Perrigo New York Inc.
- Pharmacia and Upjohn Company LLC
- Physicians Total Care, Inc.
- Prasco Laboratories
- Professional Co.
- Ranbaxy Pharmaceuticals, Inc
- Roerig
- Rising Health, LLC
- Rising Pharmaceuticals, Inc.
- Sandoz, Inc
- Santarus, Inc.
- Sanofi-Aventis U.S., LLC
- Shionogi, Inc.
- Solco Healthcare U.S., LLC
- Strides Shasun Limited
- Sun Pharmaceutical Industries, Inc.
- TAGI Pharma, Inc.
- Takeda Pharmaceuticals America, Inc.
- Teva / Teva Pharmaceuticals USA, Inc.
- Time Cap Laboratories, Inc.
- Torrent Pharmaceuticals Limited
- TruPharma, LLC
- Virtus Pharmaceuticals
- West-Ward Pharmaceuticals Corp
- Zydus Pharmaceuticals USA, Inc.
- Any other pharmaceutical manufacturer that submitted a 2019 report pursuant to SB539 of the 2017 legislative session

I am also requesting the required annual reports submitted by the following pharmacy benefit managers, including, but not limited to, those required by NRS §§ 439B.645:

- Express Scripts
- CVS Health
- OptumRx
- Hometown Health
- Cigna
- Humana
- Navitus Health Solutions
- Any other pharmacy benefit manager that submitted a 2019 report pursuant to SB539 of the 2017 legislative session

If access to the records I am requesting will take longer than a reasonable amount of time, please contact me with information about when I might expect copies or the ability to inspect requested records. If production of the requested records will cost more than \$25, please provide me a written estimate for the production of the records prior to inspection or reproduction. Please provide the records as they become available.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information. Please let me know if you have any questions or need any clarification.

Thank you for handling my request.

Sincerely,

Megan Messerly  
Reporter, *The Nevada Independent*

megan@thenvindy.com  
(702) 706-6884

# EXHIBIT 2-4

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 2-4

STEVE SISOLAK  
Governor



LISA SHERYCH  
Interim Administrator

RICHARD WHITLEY, MS  
Director

IHSAN AZZAM, Ph.D., M.D.  
Chief Medical Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way  
Carson City, Nevada 89706  
Telephone (775) 684-4200 • Fax (775) 687-7570  
<http://dpbh.nv.gov>

June 24, 2019

Re: Written Notice of Intent to Disclose Public Records

Dear Ms. Messerly,

The Nevada Department of Health and Human Services (DHHS) received your public records request that seeks disclosure of source reports submitted to DHHS in compliance with NRS 439B.600-695. Your request seeks disclosure of information regarding diabetes drugs defined as essential by DHHS in 2019 for which manufacturers or pharmacy benefit managers (PBMs) have submitted Requests for Confidentiality (RFC). Therefore, DHHS is providing this written notice of the information that DHHS intends to disclose as required by Nevada Administrative Code (NAC) 439.735 (Appendix 1). Appendix 2, included on page four of this notice, provides the data fields that DHHS intends to publicly disclose. DHHS does not intend to disclose any fields from the drug manufacturer and PBM reports not referenced in Appendix 2. DHHS is denying disclosure of the fields not included in Appendix 2 on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act (DTSA) of 2016, 18 U.S.C. § 1836, as amended.

This determination is based on DHHS's review of the DTSA, and on the information provided by drug manufacturers and PBMs in the completed RFCs submitted to DHHS pursuant to NAC 439.735, Subsection 2. Please note that a copy of this letter will be sent to manufacturers and PBMs that submitted an RFC. DHHS will not be able to disclose the information until at least 30 days have elapsed following the date of this written notice. Additionally, if manufacturers or PBMs commence an action within the 30-day period as provided in subsection 6 of NAC 439.735, DHHS will not be able to disclose the information, unless the disclosure is permitted by that subsection. If no legal action is taken during the 30-day period, the information will be shared according to DHHS's determination.

Unless specifically requested otherwise, redacted reports and other requested information will be shared electronically. Price Increase Reports and PBM reported fields will be compiled as lists and will not be redacted original reports unless specifically requested otherwise. Please contact us at [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov) if you have any questions about this process.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott A. Jones".

Scott Jones, PhD  
Manager, Primary Care and Health Workforce Development Office

## Appendix 1

### Nevada Administrative Code (NAC) 439.735

**NAC 439.735 Request by manufacturer or pharmacy benefit manager to keep certain information confidential as a trade secret; procedures for Department to follow upon receipt of public records request for disclosure. ([NRS 439.930](#))**

1. In complying with [NRS 439B.635](#), [439B.640](#) or [439B.645](#), if a manufacturer or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the manufacturer or pharmacy benefit manager may submit to the Department a request to keep the information confidential.

2. A request for confidentiality submitted pursuant to subsection 1 must be divided into the following parts, which must be severable from each other:

(a) The first part of the request for confidentiality must describe, with particularity, the information sought to be protected from public disclosure. Upon a request for public records pursuant to [NRS 239.010](#), the Department will not disclose the description set forth in the request for confidentiality or the information sought to be protected from public disclosure, unless the description and information are disclosed pursuant to subsections 5 and 6.

(b) The second part of the request for confidentiality must include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. Upon a request for public records pursuant to [NRS 239.010](#), the Department will disclose the explanation set forth in the request for confidentiality.

3. If the Department receives a request for public records pursuant to [NRS 239.010](#) seeking disclosure of any information for which a manufacturer or pharmacy benefit manager has submitted a request for confidentiality pursuant to subsection 1, the Department will:

(a) As soon as reasonably practicable after receiving the request for public records, provide the manufacturer or pharmacy benefit manager with:

(1) Written notice of the request for public records and the procedures set forth in this section; and

(2) A copy of the request for public records and the date on which the Department received the request.

(b) Undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. In undertaking its initial review, the Department will consider, as persuasive authority, the interpretation and application given to the term “trade secrets” in Exemption 4 of the federal Freedom of Information Act, 5 U.S.C. § 552(b)(4), as amended.

4. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:

(a) Within the time prescribed by [NRS 239.0107](#), provide the requester of the public records with written notice pursuant to paragraph (d) of subsection 1 of [NRS 239.0107](#) that the Department must deny the request for public records on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended.

(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:

(1) Written notice that the Department denied the request for public records; and

(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.

5. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:

(a) Within the time prescribed by [NRS 239.0107](#), provide the requester of the public records with written notice pursuant to paragraph (c) of subsection 1 of [NRS 239.0107](#) that the Department intends to disclose the information, except that:

(1) The Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and

(2) If the manufacturer or pharmacy benefit manager timely commences an action within the 30-day period as provided in subsection 6, the Department will not be able to disclose the information, unless the disclosure is permitted by that subsection.

(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:

(1) Written notice that the Department intends to disclose the information; and

(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.

6. If, within the 30-day period following the date on which the Department sent the written notice to the requester of public records pursuant to subsection 5, the manufacturer or pharmacy benefit manager:

(a) Does not commence an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will disclose the information.

(b) Commences an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will not disclose the information until final resolution of the action, including any appeals. After final resolution of the action, if the court:

(1) Enjoins the Department from disclosing the information as a trade secret, the Department will not disclose the information so long as the information retains its status as a trade secret.

(2) Does not enjoin the Department from disclosing the information as a trade secret, the Department will disclose the information as soon as reasonably practicable after final resolution of the action.

(Added to NAC by Dep't of Health & Human Services by R042-18, eff. 5-31-2018)

## **Appendix 2**

### *Essential Diabetes Drug Report Data Fields DHHS Intends to Disclose Publicly*

#### **1) Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635)**

- i) Drug Manufacturer Name
- ii) Nonproprietary Prescription Drug Name
- iii) Proprietary Prescription Drug Name
- iv) National Drug Code (NDC)
- v) Wholesale Acquisition Cost (WAC) Price History
- vi) Increase in WAC Unit Price
- vii) Date of Increase in WAC Price

#### **2) Drug Manufacturer Essential Diabetes Drug Price Increase Reports (NRS 439B.640)**

- i) Drug Manufacturer Name
- ii) Non-Proprietary Drug Name
- iii) Proprietary Drug Name
- iv) NDC

#### **3) PBM Essential Diabetes Drug Reports (NRS 439B.645)**

- i) A list of PBMs that submitted reports

# EXHIBIT 3

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 3

# National Diabetes Statistics Report, 2017

## Estimates of Diabetes and Its Burden in the United States

### Background

The *National Diabetes Statistics Report* is a periodic publication of the Centers for Disease Control and Prevention (CDC) that provides updated statistics about diabetes in the United States for a scientific audience. It includes information on prevalence and incidence of diabetes, prediabetes, risk factors for complications, acute and long-term complications, deaths, and costs. These data can help focus efforts to prevent and control diabetes across the United States. This report was previously known as the *National Diabetes Fact Sheet*.

### Methods

The estimates in this document (unless otherwise noted) were derived from various data systems of CDC, the Indian Health Service (IHS), the Agency for Healthcare Research and Quality (AHRQ), the U.S. Census Bureau, and published studies. The estimated percentages and the total number of people with diabetes and prediabetes were derived from the National Health and Nutrition Examination Survey (NHANES), National Health Interview Survey (NHIS), IHS National Data Warehouse (NDW), Behavioral Risk Factor Surveillance System (BRFSS), United States Diabetes Surveillance System (USDSS), and U.S. resident population estimates.

Numbers and rates for acute and long-term complications of diabetes were derived from the National Inpatient Sample (NIS) and National Emergency Department Sample (NEDS), as well as NHIS. Diagnosed diabetes was determined by self-report among survey respondents and by diagnostic codes for American Indians and Alaska Natives who accessed IHS, tribal, or Urban Indian health facilities that submitted data to the IHS NDW.

Both fasting glucose and hemoglobin A1C (A1C) levels were used to derive estimates for undiagnosed diabetes and prediabetes. An alpha level of 0.05 was used when assessing statistical differences between groups.

Most estimates of diabetes in this report do not differentiate between type 1 and type 2 diabetes. However, because type 2 diabetes accounts for 90% to 95% of all diabetes cases, the data presented are likely to be more characteristic of type 2 diabetes. More detailed information about [data sources and methods](#) is available in the Appendix.



#### Fast Facts on Diabetes

**30.3 million people have diabetes**

(9.4% of the U.S. population)

#### Diagnosed

**23.1 million people**

#### Undiagnosed

**7.2 million**

(23.8% of people with diabetes are undiagnosed)

National Center for Chronic Disease Prevention and Health Promotion  
Division of Diabetes Translation



CS279910-A

## Results

### Prevalence of Both Diagnosed and Undiagnosed Diabetes

- An estimated 30.3 million people of all ages—or 9.4% of the U.S. population—had diabetes in 2015 ([Methods](#)).
- This total included 30.2 million adults aged 18 years or older (12.2% of all U.S. adults), of which 7.2 million (23.8%) were not aware of or did not report having diabetes (Table 1) ([Methods](#)).
- The percentage of adults with diabetes increased with age, reaching a high of 25.2% among those aged 65 years or older (Table 1).
- Compared to non-Hispanic whites, the age-adjusted prevalence of diagnosed and undiagnosed diabetes was higher among Asians, non-Hispanic blacks, and Hispanics during 2011–2014 (see [Table 1a](#) in the Appendix for more details).

**Table 1. Estimated number and percentage of diagnosed and undiagnosed diabetes among adults aged ≥18 years, United States, 2015**

Characteristic	Diagnosed diabetes No. in millions (95% CI) <sup>a</sup>	Undiagnosed diabetes No. in millions (95% CI) <sup>a</sup>	Total diabetes No. in millions (95% CI) <sup>a</sup>
<b>Total</b>	<b>23.0 (21.1–25.1)</b>	<b>7.2 (6.0–8.6)</b>	<b>30.2 (27.9–32.7)</b>
<b>Age in years</b>			
18–44	3.0 (2.6–3.6)	1.6 (1.1–2.3)	4.6 (3.8–5.5)
45–64	10.7 (9.3–12.2)	3.6 (2.8–4.6)	14.3 (12.7–16.1)
≥65	9.9 (9.0–11.0)	2.1 (1.4–3.0)	12.0 (10.7–13.4)
<b>Sex</b>			
Women	11.7 (10.5–13.1)	3.1 (2.4–4.1)	14.9 (13.5–16.4)
Men	11.3 (10.2–12.4)	4.0 (3.0–5.5)	15.3 (13.8–17.0)
	Percentage (95% CI) <sup>b</sup>	Percentage (95% CI) <sup>b</sup>	Percentage (95% CI) <sup>b</sup>
<b>Total</b>	<b>9.3 (8.5–10.1)</b>	<b>2.9 (2.4–3.5)</b>	<b>12.2 (11.3–13.2)</b>
<b>Age in years</b>			
18–44	2.6 (2.2–3.1)	1.3 (0.9–2.0)	4.0 (3.3–4.8)
45–64	12.7 (11.1–14.5)	4.3 (3.3–5.5)	17.0 (15.1–19.1)
≥65	20.8 (18.8–23.0)	4.4 (3.1–6.3)	25.2 (22.5–28.1)
<b>Sex</b>			
Women	9.2 (8.2–10.3)	2.5 (1.9–3.2)	11.7 (10.6–12.9)
Men	9.4 (8.5–10.3)	3.4 (2.5–4.6)	12.7 (11.5–14.1)

CI = confidence interval.

<sup>a</sup> Numbers for subgroups may not add up to the total because of rounding.

<sup>b</sup> Data are crude, not age-adjusted.

Data source: 2011–2014 National Health and Nutrition Examination Survey and 2015 U.S. Census Bureau data.

## Prevalence of Diagnosed Diabetes

### Among people of all ages, 2015 data indicated the following:

- An estimated 23.1 million people—or 7.2% of the U.S. population—had diagnosed diabetes ([Methods](#)) (see [Table 1b](#) in the Appendix for more details).
- This total included:
  - » 132,000 children and adolescents younger than age 18 years (0.18% of the total U.S. population younger than age 18 years).
  - » 193,000 children and adolescents younger than age 20 years (0.24% of the total U.S. population younger than age 20 years).
- About 5% of people with diabetes are estimated to have type 1 diabetes ([Methods](#)).

### Among U.S. adults aged 18 years or older, age-adjusted data for 2013–2015 indicated the following:

- American Indians/Alaska Natives had the highest prevalence of diagnosed diabetes for both men (14.9%) and women (15.3%) (Figure 1) ([Methods](#)). Prevalence varied by region, from 6.0% among Alaska Natives to 22.2% among American Indians in certain areas of the Southwest.
- Overall, prevalence was higher among American Indians/Alaska Natives (15.1%), non-Hispanic blacks (12.7%), and people of Hispanic ethnicity (12.1%) than among non-Hispanic whites (7.4%) and Asians (8.0%) (see [Table 1c](#) in the Appendix for more details).
- Among people of Hispanic ethnicity, Mexicans had the highest prevalence (13.8%), followed by Puerto Ricans (12.0%), Cubans (9.0%), and Central/South Americans (8.5%) (see [Table 1c](#) in the Appendix for more details).
- Among Asians, Asian Indians had the highest prevalence (11.2%), followed by Filipinos (8.9%), and Chinese (4.3%). Other Asian groups had a prevalence of 8.5% (see [Table 1c](#) in the Appendix for more details).
- Prevalence varied significantly by education level, which is an indicator of socioeconomic status. Specifically, 12.6% of adults with less than a high school education had diagnosed diabetes versus 9.5% of those with a high school education and 7.2% of those with more than a high school education (see [Table 1c](#) in the Appendix for more details).



**Figure 1. Estimated age-adjusted prevalence of diagnosed diabetes by race/ethnicity and sex among adults aged ≥18 years, United States, 2013–2015**

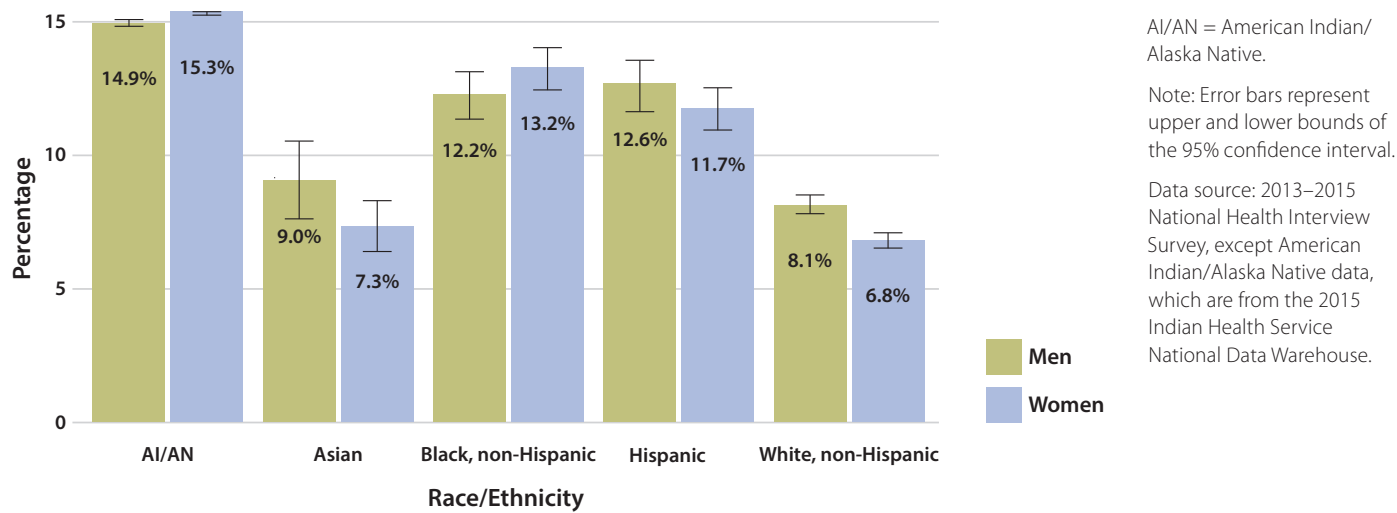
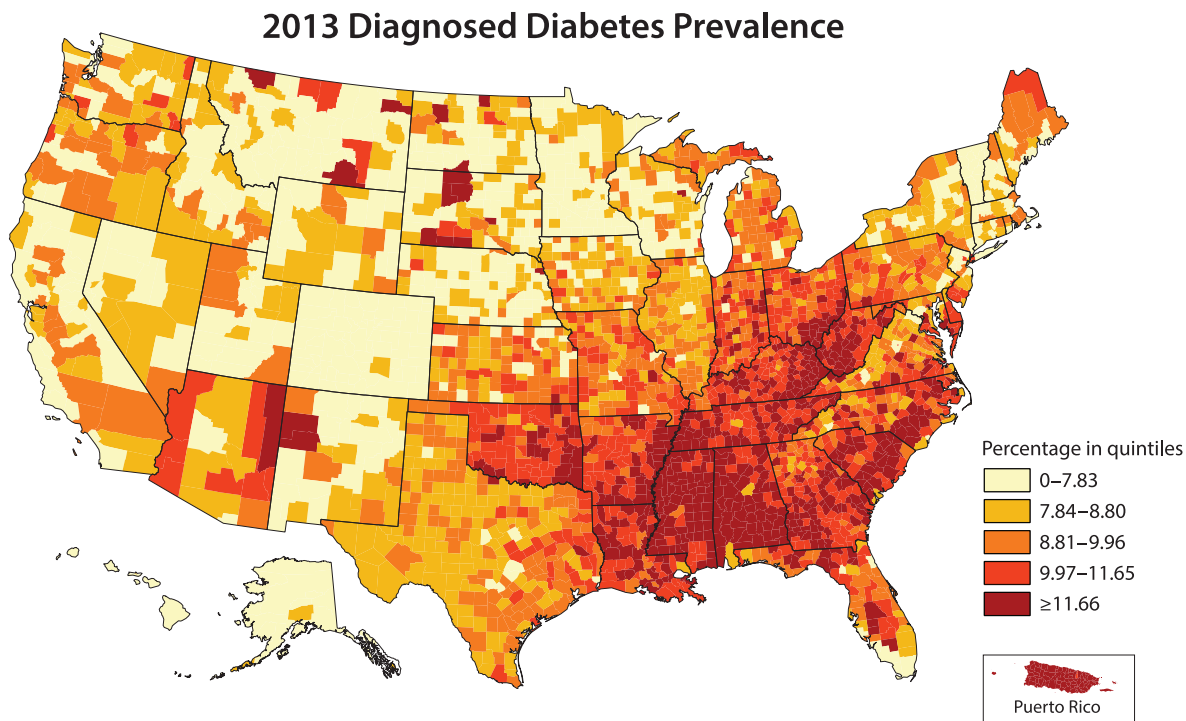


Figure 2 shows model-based county-level estimates of the age-adjusted prevalence of diagnosed diabetes among U.S. adults aged 20 years or older in 2013 ([Methods](#)). Specifically, this figure shows that:

- The median age-adjusted county-level prevalence of diagnosed diabetes was 9.4%, with a range of 3.8% to 20.8%.
- Counties in the southern and Appalachian regions of the United States tended to have the highest prevalence of diagnosed diabetes.

**Figure 2. Age-adjusted, county-level prevalence of diagnosed diabetes among adults aged ≥20 years, United States, 2013**



Data source: United States Diabetes Surveillance System. <https://www.cdc.gov/diabetes/atlas/countydata/atlas.html>

## Incidence of Diagnosed Diabetes

### Incidence Among Adults

- In 2015, an estimated 1.5 million new cases of diabetes (6.7 per 1,000 persons) were diagnosed among U.S. adults aged 18 years or older (Table 2) ([Methods](#)).
- More than half of these new cases were among adults aged 45 to 64 years, and the numbers were about equal for men and women (Table 2).
- Non-Hispanic blacks (9.0 per 1,000 persons) and people of Hispanic origin (8.4 per 1,000 persons) had a higher age-adjusted incidence compared to non-Hispanic whites (5.7 per 1,000 persons) during 2013–2015 (see [Table 2a](#) in the Appendix for more details).
- Age-adjusted incidence was about 2 times higher for people with less than a high school education (10.4 per 1,000 persons) compared to those with more than a high school education (5.3 per 1,000 persons) during 2013–2015 (see [Table 2a](#) in the Appendix for more details).



**Table 2. Estimated incidence of diabetes among adults aged ≥18 years, United States, 2015**

Characteristic	No. in thousands (95% CI) <sup>a</sup>	Rate per 1,000 (95% CI) <sup>b</sup>
<b>Total</b>	<b>1,530 (1,402–1,658)</b>	<b>6.7 (6.2–7.3)</b>
<b>Age in years</b>		
18–44	355 (289–420)	3.1 (2.6–3.8)
45–64	809 (714–905)	10.9 (9.6–12.2)
≥65	366 (310–422)	9.4 (8.0–10.9)
<b>Sex</b>		
Women	787 (694–880)	6.8 (6.0–7.6)
Men	743 (645–840)	6.7 (5.9–7.7)

CI = confidence interval.

<sup>a</sup> Numbers for subgroups may not add up to the total because of rounding.

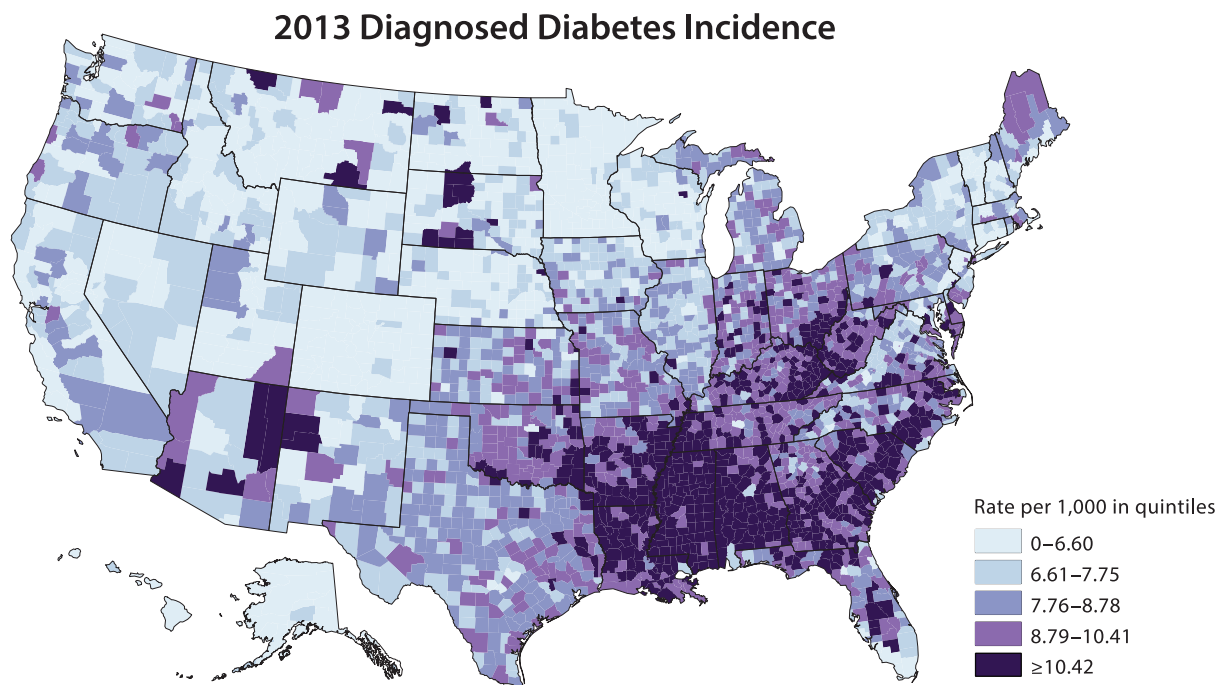
<sup>b</sup> Rates are crude, not age-adjusted.

Data source: 2013–2015 National Health Interview Survey, 2011–2014 National Health and Nutrition Examination Survey, and 2015 U.S. Census Bureau data.

Figure 3 shows model-based county-level estimates of the age-adjusted incidence of diagnosed diabetes among U.S. adults aged 20 years or older in 2013 ([Methods](#)). Specifically, this figure shows that:

- The median age-adjusted county-level incidence of diagnosed diabetes was 8.2 per 1,000 persons, with a range of 3.1 to 21.9 per 1,000 persons.
- Similar to the geographic pattern of the prevalence of diagnosed diabetes, counties in the southern and Appalachian regions of the United States tended to have the highest incidence.

**Figure 3. Age-adjusted, county-level incidence of diagnosed diabetes among adults aged  $\geq 20$  years, United States, 2013**



Note: Data unavailable for U.S. territories.

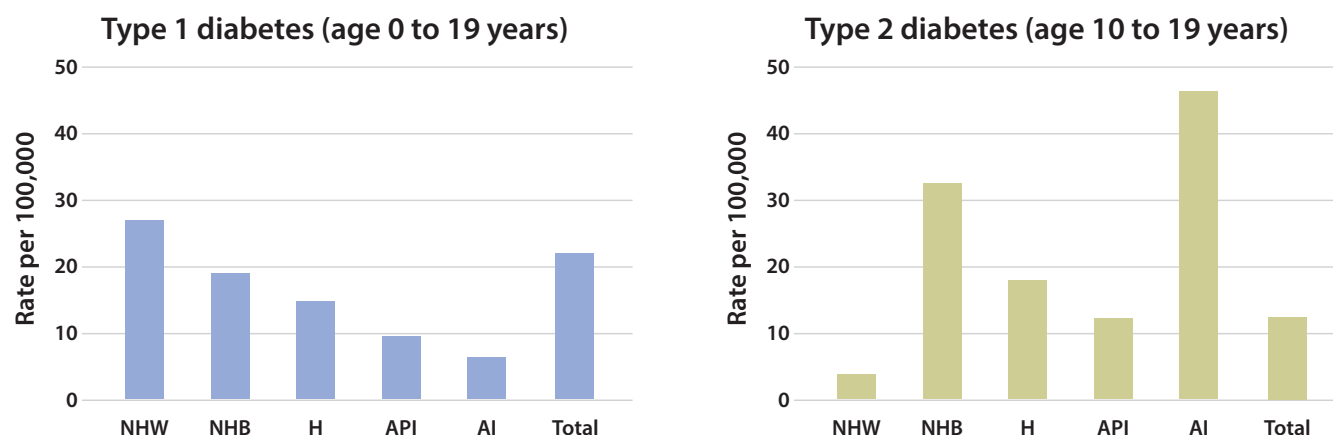
Data source: United States Diabetes Surveillance System. <https://www.cdc.gov/diabetes/atlas/countydata/atlas.html>



### Incidence Among Children and Adolescents

Data from the SEARCH for Diabetes in Youth Study<sup>1</sup> indicated that:

- During 2011–2012, the estimated annual number of newly diagnosed cases in the United States included:
  - » 17,900 children and adolescents younger than age 20 years with type 1 diabetes.
  - » 5,300 children and adolescents age 10 to 19 years with type 2 diabetes.
- Among children and adolescents younger than age 20 years, non-Hispanic whites had the highest rate of new cases of type 1 diabetes compared to members of other U.S. racial and ethnic groups (Figure 4).
- Among children and adolescents aged 10 to 19 years, U.S. minority populations had higher rates of new cases of type 2 diabetes compared to non-Hispanic whites (Figure 4).

**Figure 4. Incidence of type 1 and type 2 diabetes by race/ethnicity, 2011–2012**

NHW = non-Hispanic whites, NHB = non-Hispanic blacks, H = Hispanics, API = Asians/Pacific Islands, AI = American Indians.

Note: American Indian (AI) youth who participated in the SEARCH study are not representative of all AI youth in the United States. Thus, these rates cannot be generalized to all AI youth nationwide.

Data source: SEARCH for Diabetes in Youth Study.

## Prevalence of Prediabetes

- An estimated 33.9% of U.S. adults aged 18 years or older (84.1 million people) had prediabetes in 2015, based on their fasting glucose or A1C level. Nearly half (48.3%) of adults aged 65 years or older had prediabetes (Table 3) ([Methods](#)).
- Among adults with prediabetes, 11.6% reported being told by a health professional that they had this condition (Table 3).
- Age-adjusted data for 2011–2014 indicated that more men (36.6%) than women (29.3%) had prediabetes. Prevalence of prediabetes was similar among racial and ethnic groups (see [Table 3a](#) in the Appendix for more details).

**Table 3. Estimated number, percentage, and awareness of prediabetes among adults aged ≥18 years, United States, 2015**

Characteristic	No. in millions (95% CI) <sup>a</sup>	Percentage (95% CI) <sup>b</sup>	Percentage aware of prediabetes (95% CI) <sup>a,c</sup>
<b>Total</b>	<b>84.1 (78.0–90.4)</b>	<b>33.9 (31.5–36.5)</b>	<b>11.6 (9.9–13.6)</b>
<b>Age in years</b>			
18–44	27.4 (24.5–30.6)	23.7 (21.1–26.4)	8.2 (5.8–11.5)
45–64	34.3 (31.5–37.2)	40.9 (37.5–44.3)	12.9 (10.2–16.1)
≥65	23.1 (21.1–25.1)	48.3 (44.2–52.5)	14.1 (10.5–18.6)
<b>Sex</b>			
Women	39.5 (36.0–43.3)	31.1 (28.3–34.0)	14.1 (11.3–17.6)
Men	44.5 (40.5–48.7)	36.9 (33.6–40.4)	9.4 (6.6–13.3)

CI = confidence interval.

<sup>a</sup> Numbers for subgroups may not add up to the total because of rounding.

<sup>b</sup> Data are crude, not age-adjusted.

<sup>c</sup> Among those with prediabetes.

Data source: 2011–2014 National Health and Nutrition Examination Survey and 2015 U.S. Census Bureau data.

## Risk Factors for Complications

Risk factor data for 2011–2014 for U.S. adults aged 18 years or older with diagnosed diabetes indicated the following ([Methods](#)):

### Smoking

- 15.9% (95% confidence interval [CI], 13.9%–18.1%) of adults were current smokers, and 34.5% (95% CI, 31.7%–37.3%) had quit smoking but had a history of smoking at least 100 cigarettes in their lifetime.

### Overweight and Obesity

- 87.5% (95% CI, 84.8%–89.7%) of adults were overweight or obese, defined as a body mass index (BMI) of 25 kg/m<sup>2</sup> or higher. Specifically:
  - » 26.1% (95% CI, 23.2%–29.3%) of adults were overweight (BMI of 25.0 to less than 30.0 kg/m<sup>2</sup>).
  - » 43.5% (95% CI, 39.6%–47.6%) of adults had obesity (BMI of 30.0 to less than 40.0 kg/m<sup>2</sup>).
  - » 17.8% (95% CI, 14.8%–21.3%) of adults had severe obesity (BMI of 40.0 kg/m<sup>2</sup> or higher).



### Physical Inactivity

- 40.8% (95% CI, 36.8%–45.0%) of adults were physically inactive, defined as getting less than 10 minutes a week of moderate or vigorous activity in each of the physical activity categories of work, leisure time, and transportation.

### High Blood Pressure

- 73.6% (95% CI, 69.9%–77.1%) of adults had systolic blood pressure of 140 mm Hg or higher or diastolic blood pressure of 90 mm Hg or higher, or they were on prescription medication for high blood pressure.

### High Cholesterol (Hyperlipidemia)

- 58.2% (95% CI, 49.7%–66.3%) of adults aged 21 years or older with no self-reported cardiovascular disease but who were eligible for statin therapy were on a lipid-lowering medication (see [Table 4a](#) in the Appendix for more details).
- 66.9% (95% CI, 58.5%–74.4%) of adults aged 21 years or older with self-reported cardiovascular disease who were thus eligible for statin therapy were on a lipid-lowering medication.

### High Blood Glucose (Hyperglycemia)

- 15.6% (95% CI, 13.2%–18.3%) of adults had an A1C value higher than 9%.

## Coexisting Conditions and Complications

### Hospitalizations

In 2014, a total of 7.2 million hospital discharges were reported with diabetes as any listed diagnosis among U.S. adults aged 18 years or older (Table 4) ([Methods](#)). These discharges included the following:

- 1.5 million for major cardiovascular diseases (70.4 per 1,000 persons with diabetes), including:
  - » 400,000 for ischemic heart disease (18.3 per 1,000 persons with diabetes).
  - » 251,000 for stroke (11.5 per 1,000 persons with diabetes).
- 108,000 for a lower-extremity amputation (5.0 per 1,000 persons with diabetes).
- 168,000 for diabetic ketoacidosis (7.7 per 1,000 persons with diabetes).



**Table 4. Number and rate of hospitalizations among adults aged ≥18 years with diagnosed diabetes for selected causes, United States, 2014**

Cause of hospitalization	No. in thousands	Crude rate per 1,000 persons with diabetes (95% CI)
Diabetes as any listed diagnosis	7,155	327.2 (311.3–343.1)
Major cardiovascular disease	1,539	70.4 (66.8–73.9)
Ischemic heart disease	400	18.3 (17.3–19.3)
Stroke	251	11.5 (10.9–12.1)
Lower-extremity amputation	108	5.0 (4.7–5.2)
Diabetic ketoacidosis	168	7.7 (7.3–8.1)

CI = confidence interval.

Data source: United States Diabetes Surveillance System.

### Emergency Department Visits

In 2014, a total of 14.2 million emergency department visits were reported with diabetes as any listed diagnosis among adults aged 18 years or older (Table 5), including:

- 245,000 for hypoglycemia (11.2 per 1,000 persons with diabetes).
- 207,000 for hyperglycemic crisis (9.5 per 1,000 persons with diabetes).

**Table 5. Number and rate of emergency department visits among adults aged ≥18 years with diagnosed diabetes, United States, 2014**

Cause of emergency department visit	No. in thousands	Crude rate per 1,000 persons with diabetes (95% CI)
Diabetes as any listed diagnosis	14,192	648.9 (600.9–696.9)
Hypoglycemia	245	11.2 (10.4–12.1)
Hyperglycemic crisis	207	9.5 (8.8–10.2)

CI = confidence interval.

Data source: United States Diabetes Surveillance System.

## Kidney Disease

- Among U.S. adults aged 20 years or older with diagnosed diabetes, the estimated crude prevalence of chronic kidney disease (stages 1–4) was 36.5% (95% CI, 32.2%–40.8%) during 2011–2012.<sup>2</sup>
- Among those with diabetes and moderate to severe kidney disease (stage 3 or 4), 19.4% (95% CI, 15.5%–23.2%) were aware of their kidney disease during 1999–2012.<sup>3</sup>
- In 2014, a total of 52,159 people developed end-stage renal disease with diabetes as the primary cause. Adjusted for age group, sex, and racial or ethnic group, the rate was 154.4 per 1 million persons.<sup>4</sup>

## Deaths

- Diabetes was the seventh leading cause of death in the United States in 2015. This finding is based on 79,535 death certificates in which diabetes was listed as the underlying cause of death (crude rate, 24.7 per 100,000 persons).<sup>5</sup>
- Diabetes was listed as any cause of death on 252,806 death certificates in 2015 (crude rate, 78.7 per 100,000 persons).<sup>5</sup>

## Cost

- The total direct and indirect estimated cost of diagnosed diabetes in the United States in 2012 was \$245 billion.<sup>6</sup>
- Average medical expenditures for people with diagnosed diabetes were about \$13,700 per year. About \$7,900 of this amount was attributed to diabetes.<sup>6</sup>
- After adjusting for age group and sex, average medical expenditures among people with diagnosed diabetes were about 2.3 times higher than expenditures for people without diabetes.<sup>6</sup>



## Acknowledgments

The following organizations provided content and helped compile data for this report:

- [Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation](#)
- [Indian Health Service, Division of Diabetes Treatment and Prevention](#)
- [National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases](#)

The following organizations collaborated on the content of this report:

- [American Diabetes Association](#)
- [JDRE](#)

## References

1. Mayer-Davis EJ, Lawrence JM, Dabelea D, et al. Incidence trends of type 1 and type 2 diabetes among youths, 2002–2012. *N Engl J Med*. 2017;376:1419–1429.
2. Murphy D, McCulloch CE, Lin F, et al. Trends in prevalence of chronic kidney disease in the United States. *Ann Intern Med*. 2016;165:473–481.
3. Centers for Disease Control and Prevention. Chronic Kidney Disease (CKD) Surveillance Project website. <https://nccd.cdc.gov/CKD/default.aspx>. Accessed June 16, 2017.
4. United States Renal Data System. 2016 *USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States*. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; 2016.
5. Centers for Disease Control and Prevention. About Underlying Cause of Death 1999–2015. CDC WONDER Database. <http://wonder.cdc.gov/ucd-icd10.html>. Updated December 2016. Accessed April 4, 2017.
6. American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. *Diabetes Care*. 2013;36(4):1033–1046.

## Suggested Citation

Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.

# Appendix

## Detailed Tables

This section provides additional data for Tables 1–3, Figure 1, and the High Cholesterol (Hyperlipidemia) section under Risk Factors for Complications of the National Diabetes Statistics Report, 2017.

**Table 1a. Age-adjusted prevalence of diagnosed and undiagnosed diabetes among adults aged ≥18 years, United States, 2011–2014**

Characteristic	Diagnosed diabetes Percentage (95% CI)	Undiagnosed diabetes Percentage (95% CI)	Total Percentage (95% CI)
<b>Total</b>	<b>8.7 (8.1–9.4)</b>	<b>2.7 (2.3–3.3)</b>	<b>11.5 (10.7–12.4)</b>
<b>Sex</b>			
Women	8.5 (7.5–9.5)	2.3 (1.8–3.1)	10.8 (9.8–11.9)
Men	9.1 (8.4–9.9)	3.2 (2.4–4.3)	12.3 (11.3–13.4)
<b>Race/Ethnicity</b>			
Asian, non-Hispanic	10.3 (8.6–12.4)	5.7 (4.0–8.2)	16.0 (13.6–18.9)
Black, non-Hispanic	13.4 (12.2–14.6)	4.4 (3.0–6.2)	17.7 (15.8–19.9)
Hispanic	11.9 (10.3–13.7)	4.5 (3.2–6.2)	16.4 (14.1–18.9)
White, non-Hispanic	7.3 (6.6–8.1)	2.0 (1.5–2.6)	9.3 (8.4–10.2)
<b>Education</b>			
Less than high school	11.4 (9.9–13.1)	4.1 (3.0–5.6)	15.5 (13.5–17.7)
High school	10.3 (8.8–12.0)	3.2 (2.4–4.2)	13.5 (11.9–15.2)
More than high school	7.4 (6.6–8.4)	2.2 (1.6–3.0)	9.6 (8.6–10.7)

CI = confidence interval.

Data source: 2011–2014 National Health and Nutrition Examination Survey.

**Table 1b. Estimated prevalence of diagnosed diabetes among the total population and among children and adolescents, United States, 2015**

Characteristic	No. (95% CI)	Percentage (95% CI)
<b>Total</b>	<b>23,131,000 (22,555,000–23,706,000)</b>	<b>7.20 (7.02–7.38)</b>
<b>Age in years</b>		
<18	132,000 (92,000–172,000)	0.18 (0.13–0.24)
<20	193,000 (140,000–246,000)	0.24 (0.18–0.31)

CI = confidence interval.

Note: Data rounded to nearest thousand and not age-adjusted.

Data source: 2013–2015 National Health Interview Survey and 2015 U.S. Census Bureau data.

**Table 1c. Age-adjusted prevalence of diagnosed diabetes by race/ethnicity, education level, and sex among adults aged ≥18 years, United States, 2013–2015**

Characteristic	Total Percentage (95% CI)	Men Percentage (95% CI)	Women Percentage (95% CI)
<b>Race/Ethnicity</b>			
American Indian/Alaska Native	15.1 (15.0–15.2)	14.9 (14.8–15.0)	15.3 (15.2–15.3)
Asian, non-Hispanic, overall	8.0 (7.3–8.9)	9.0 (7.6–10.5)	7.3 (6.4–8.3)
Asian Indian	11.2 (9.1–13.7)	12.2 (9.1–16.2)	10.0 (7.4–13.3)
Chinese	4.3 (3.2–5.9)	6.2 (4.1–9.1)	2.8 (1.8–4.4)
Filipino	8.9 (7.4–10.8)	9.1 (6.8–11.9)	8.9 (7.1–11.2)
Other Asian	8.5 (7.1–10.0)	8.9 (6.9–11.4)	8.2 (6.5–10.2)
Black, non-Hispanic	12.7 (12.1–13.4)	12.2 (11.3–13.1)	13.2 (12.4–14.0)
Hispanic, overall	12.1 (11.4–12.7)	12.6 (11.6–13.5)	11.7 (10.9–12.5)
Central/South American	8.5 (7.3–10.0)	8.5 (6.6–10.8)	8.8 (7.2–10.7)
Cuban	9.0 (7.1–11.4)	11.6 (8.0–16.5)	5.9 (3.7–9.3)
Mexican	13.8 (13.0–14.8)	14.2 (12.9–15.7)	13.5 (12.5–14.7)
Puerto Rican	12.0 (10.5–13.7)	12.2 (10.0–14.9)	11.8 (9.8–14.1)
White, non-Hispanic	7.4 (7.2–7.6)	8.1 (7.8–8.5)	6.8 (6.5–7.1)
<b>Education</b>			
Less than high school	12.6 (11.9–13.2)	12.2 (11.3–13.1)	13.0 (12.2–13.9)
High school	9.5 (9.1–10.0)	10.1 (9.5–10.8)	9.2 (8.6–9.8)
More than high school	7.2 (7.0–7.5)	7.9 (7.5–8.3)	6.6 (6.3–6.9)

CI = confidence interval.

Data source: 2013–2015 National Health Interview Survey, except American Indian/Alaska Native data, which were from the 2015 Indian Health Service National Data Warehouse.

**Table 2a. Age-adjusted incidence of diagnosed diabetes among adults aged ≥18 years, United States, 2013–2015**

Characteristic	Rate per 1,000 (95% CI)
<b>Race/Ethnicity</b>	
Asian, non-Hispanic	6.0 (4.2–8.6)
Black, non-Hispanic	9.0 (7.4–10.9)
Hispanic	8.4 (7.2–9.8)
White, non-Hispanic	5.7 (5.0–6.4)
<b>Education</b>	
Less than high school	10.4 (8.8–12.4)
High school	7.8 (6.6–9.2)
More than high school	5.3 (4.7–5.9)

CI = confidence interval.

Data source: 2013–2015 National Health Interview Survey and 2015 U.S. Census Bureau data.

**Table 3a. Age-adjusted prevalence of prediabetes among adults aged ≥18 years, United States, 2011–2014**

Characteristic	Percentage with prediabetes (95% CI)	Percentage reporting awareness of prediabetes (95% CI)
<b>Total</b>	<b>33.0 (30.6–35.5)</b>	<b>10.6 (9.0–12.6)</b>
<b>Sex</b>		
Women	29.3 (26.8–31.8)	13.3 (10.0–17.4)
Men	36.6 (33.2–40.0)	8.9 (6.2–12.4)
<b>Race/Ethnicity</b>		
Asian, non-Hispanic	35.7 (33.0–38.5)	9.0 (5.9–13.6)
Black, non-Hispanic	36.3 (33.3–39.4)	10.5 (7.9–13.9)
Hispanic	31.7 (28.4–35.2)	7.5 (4.4–12.5)
White, non-Hispanic	31.5 (28.3–34.9)	11.3 (8.9–14.1)
<b>Education</b>		
Less than high school	37.6 (33.2–42.3)	9.3 (6.7–12.9)
High school	37.0 (33.8–40.3)	12.4 (8.0–18.8)
More than high school	30.4 (27.6–33.4)	10.4 (8.2–13.0)

CI = confidence interval.

Note: Percentage reporting awareness is a subset of adults with prediabetes.

Data source: 2011–2014 National Health and Nutrition Examination Survey.

**Table 4a. Rates of eligibility for statin therapy and treatment with lipid-lowering medication by cardiovascular disease prevention stage among adults aged ≥21 years with diagnosed diabetes, United States, 2011–2014**

Cardiovascular disease prevention stage	Percentage (95% CI) of adults who were eligible for statin therapy	Among eligible adults, percentage (95% CI) on lipid-lowering therapy
Primary <sup>a</sup>	75.2 (68.7–80.8)	58.2 (49.7–66.3)
Secondary <sup>b</sup>	23.3 (18.9–28.3)	66.9 (58.5–74.4)

CI = confidence interval.

<sup>a</sup> Defined as adults aged 40–75 years with no self-reported cardiovascular disease or adults aged 21–39 years with no self-reported cardiovascular disease and a low-density lipoprotein cholesterol level ≥190 mg/dL, according to 2013 guidelines from the American College of Cardiology and American Heart Association.<sup>b</sup> Defined as adults with self-reported cardiovascular disease, according to 2013 guidelines from the American College of Cardiology and American Heart Association.

Data source: 2011–2014 National Health and Nutrition Examination Survey.

## Data Sources and Methods

This section provides additional details about data sources and methods used in the National Diabetes Statistics Report, 2017.

### Prevalence of Both Diagnosed and Undiagnosed Diabetes Among People of All Ages, United States, 2015

#### Data Sources

- 2011–2014 National Health and Nutrition Examination Survey (NHANES), National Center for Health Statistics, Centers for Disease Control and Prevention.
- 2013–2015 National Health Interview Survey (NHIS), National Center for Health Statistics, Centers for Disease Control and Prevention.
- Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2010 to July 1, 2015, Population Division, U.S. Census Bureau.

#### Methods

The total number of people with diabetes is the sum of the number of those aged 18 years or older with diagnosed or undiagnosed diabetes and the number of those younger than age 18 years with diagnosed diabetes. Estimates of undiagnosed diabetes for children and adolescents younger than age 18 years are not available. The 2011–2014 NHANES was used to calculate the percentage of adults aged 18 years or older with diagnosed and undiagnosed diabetes (see next section for detail). The 2013–2015 NHIS was used to calculate the percentage of children and adolescents younger than 18 years with diagnosed diabetes. These percentages were then applied to the corresponding July 1, 2015 U.S. resident population estimates from the U.S. Census Bureau to derive the total number of people with diabetes.

Applying 2011–2014 NHANES estimates to the 2015 U.S. resident population estimates has limitations. This methodology assumes that the prevalence of diabetes in 2015 was the same as it was in earlier periods (2011–2014) and that the prevalence of diabetes in the resident population was identical to those in the civilian, noninstitutionalized population (from NHANES). Deviations from these assumptions may result in overestimated or underestimated numbers and rates.

### Prevalence of Both Diagnosed and Undiagnosed Diabetes Among Adults Aged 18 Years or Older, United States, 2015

#### Data Sources

- 2011–2014 National Health and Nutrition Examination Survey (NHANES), National Center for Health Statistics, Centers for Disease Control and Prevention.
- Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2010 to July 1, 2015, Population Division, U.S. Census Bureau.

#### Methods

The percentage of adults aged 18 years or older with diabetes (diagnosed or undiagnosed) was obtained using 2011–2014 NHANES data. People who self-reported being told by a doctor or health professional that they had diabetes (other than during pregnancy) were classified as having diagnosed diabetes. Those not reporting a history of diagnosed diabetes but who had either a fasting plasma glucose greater than or equal to 126 mg/dl or an A1C level greater than or equal to 6.5% were classified as having undiagnosed diabetes. For consistency with earlier

estimates, fasting glucose values were adjusted using recommended regression equations. People with missing values for either fasting glucose or A1C and pregnant women were excluded. People with diagnosed diabetes from the interviewed sample were combined with people with undiagnosed diabetes from the fasting plasma glucose subsample. Appropriate sampling weights were used so that the sum of the weights added to the total U.S. population.

The age-specific percentages of diagnosed and undiagnosed diabetes for age groups 18–44, 45–64, and 65 years or older were then applied to the corresponding July 1, 2015 U.S. resident population estimates from the U.S. Census Bureau to derive the age-specific numbers of adults with diagnosed and undiagnosed diabetes. These age-specific numbers of adults were added to obtain the estimated total number of adults with diagnosed and undiagnosed diabetes. The same procedure was used to obtain the total number of adults with diagnosed and undiagnosed diabetes by sex. Age-adjusted percentages of diagnosed and undiagnosed diabetes were calculated among adults aged 18 years or older by sex, race/ethnicity, and education level by the direct method to the 2000 U.S. Census standard population, using age groups 18–44, 45–64, and 65 years or older.

## Prevalence of Diagnosed Diabetes, United States, 2015

### Data Sources

- 2013–2015 National Health Interview Survey (NHIS), National Center for Health Statistics, Centers for Disease Control and Prevention.
- Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2010 to July 1, 2015, Population Division, U.S. Census Bureau.

### Methods

The percentage of people with diagnosed diabetes was obtained from 2013–2015 NHIS data. Information on diagnosed diabetes (other than during pregnancy) was obtained from a knowledgeable adult family member residing in the household for children and adolescents younger than age 18 years and was self-reported for people aged 18 years or older. The estimate of diagnosed diabetes was applied to the July 1, 2015 U.S. resident population estimates from the U.S. Census Bureau to derive the number of people with diagnosed diabetes for all age groups and for children and adolescents younger than age 18 years and age 20 years.

No validated method exists to distinguish between types of diabetes in surveys. The proportion of type 1 diabetes was estimated from findings reported in the following journal articles:

- Dall TM, Mann SE, Zhang Y, et al. Distinguishing the economic costs associated with type 1 and type 2 diabetes. *Popul Health Manag.* 2009;12:103–110.
- Fitch K, Weisman T, Engel T, et al. Longitudinal commercial claims-based cost analysis of diabetic retinopathy screening patterns. *Am Health Drug Benefits.* 2015;8(6):300–308.
- Johnson JA, Pohar SL, Majumdar SR. Health care use and costs in the decade after identification of type 1 and type 2 diabetes: a population-based study. *Diabetes Care.* 2006;29:2403–2408.
- Menke A, Orchard TJ, Imperatore G, Bullard KM, Mayer-Davis E, Cowie CC. The prevalence of type 1 diabetes in the United States. *Epidemiology.* 2013;24(5):773–774.
- Ng E, Dasgupta K, Johnson JA. An algorithm to differentiate diabetic respondents in the Canadian Community Health Survey. *Health Rep.* 2008;19:71–79.

## Prevalence of Diagnosed Diabetes by Race/Ethnicity Among Adults Aged 18 Years or Older, United States, 2013–2015

### Data Sources

- 2013–2015 National Health Interview Survey (NHIS), National Center for Health Statistics, Centers for Disease Control and Prevention.
- National Data Warehouse (NDW), Indian Health Service (IHS).

### Methods

With the exception of American Indian/Alaska Native (AI/AN) people, who are not well-represented in national surveys because of small population size, race/ethnicity-specific estimates of diagnosed diabetes by sex were calculated using 2013–2015 NHIS data. Adults aged 18 years or older who self-reported being told by a doctor or health professional that they had diabetes were classified as having diagnosed diabetes. The estimate of diagnosed diabetes for Native Hawaiians and Other Pacific Islanders was not included because of small sample size.

Prevalence of diagnosed diabetes among AI/AN people was calculated using fiscal year 2015 data from the IHS NDW. This data system includes patient registration and encounter data that are received from IHS facilities, tribally operated programs, and urban and contract health systems (I/T/U). These health care facilities serve about 2.2 million AI/AN people who belong to 567 federally recognized tribes in 36 states. Data for active patients (i.e., those with at least one visit to an I/T/U facility during the preceding 3 years) aged 18 years or older were used to calculate these estimates. Diabetes cases among these patients were identified using *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnostic codes 250.0–250.93 from patient visit data. Patients were considered to have a diagnosis of diabetes if they had at least two visits with an ICD 250 diagnosis code reported during fiscal year 2015. Estimates may not be comparable because of differences in the methods used to define diabetes in NHIS and IHS NDW.

Percentages for all U.S. racial and ethnic groups estimated using NHIS and IHS NDW data were age-adjusted, using age groups 18–44, 45–64, and 65 years or older, by the direct method to the 2000 U.S. Census standard population.

## County-Level Prevalence and Incidence of Diagnosed Diabetes Among Adults Aged 20 Years or Older, United States, 2013

### Data Sources

- 2012–2014 Behavioral Risk Factor Surveillance System (BRFSS), National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention.
- Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties, and Puerto Rico Commonwealth and Municipios: April 1, 2010 to July 1, 2014, Population Division, U.S. Census Bureau.
- United States Diabetes Surveillance System (USDSS), National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention.

### Methods

Data from the BRFSS and the U.S. Census Bureau's Population Estimates Program were used to obtain county-level estimates of prevalence and incidence of diagnosed diabetes among adults aged 20 years or older. Three years of data were used to improve the precision of the estimates. For 2013, BRFSS survey data for 2012, 2013, and 2014 were used. County-level estimates for the over 3,200 counties or county equivalents (e.g., parish, borough, municipality) in the 50 U.S. states, Puerto Rico, and the District of Columbia were based on indirect model-dependent estimates using Bayesian multilevel modeling techniques. This model-dependent approach uses a statistical model that “borrows strength” in making an estimate for one county from BRFSS data collected in other

counties. Multilevel Poisson regression models with random effects of demographic variables (age groups 20–44, 45–64, and 65 years or older; race; and sex) at the county level were developed. State was included as a county-level covariate. Rates were age adjusted to the 2000 U.S. Census standard population using age groups 20–44, 45–64, and 65 years or older. More detailed methods are available online at [www.cdc.gov/diabetes/pdfs/data/calculating-methods-references-county-level-estimates-ranks.pdf](http://www.cdc.gov/diabetes/pdfs/data/calculating-methods-references-county-level-estimates-ranks.pdf). Maps and data are posted on the USDSS website.

## Incidence of Diagnosed Diabetes Among Adults Aged 18 Years or Older, United States, 2015

### Data Sources

- 2013–2015 National Health Interview Survey (NHIS), National Center for Health Statistics, Centers for Disease Control and Prevention.
- 2011–2014 National Health and Nutrition Examination Survey (NHANES), National Center for Health Statistics, Centers for Disease Control and Prevention.
- Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2010 to July 1, 2015, Population Division, U.S. Census Bureau.

### Methods

The rate of new cases of diabetes was calculated using 2013–2015 NHIS data on respondents' age at diagnosis and age at interview. Adults who reported being diagnosed with diabetes were asked at what age they were diagnosed. The number of years since diagnosis was calculated by subtracting the person's age at diagnosis from the person's current age. Adults who had a value of zero were identified as having been diagnosed with diabetes within the last year. In addition, half of the adults who had a value of one were classified as having been diagnosed within the last year. To calculate the rate, the numerator included the number of adults who were diagnosed with diabetes within the last year. The denominator was the estimate of the adult population, excluding those who had been diagnosed for more than 1 year and those who were categorized on the NHIS as "refused" or "don't know" or who had missing values on the diabetes status question.

To estimate the number of new cases of diabetes for adults in each age group in 2015, the age-specific rates of new cases from NHIS were applied to the corresponding July 1, 2015 U.S. resident population estimates from the U.S. Census Bureau after excluding the number of adults who had been diagnosed with diabetes for more than 1 year, estimated from NHANES. Age-adjusted incidence of diagnosed diabetes was calculated among adults aged 18 years or older by race/ethnicity and education level by the direct method to the 2000 U.S. Census standard population, using age groups 18–44, 45–64, and 65 years or older.

## Prevalence of Prediabetes Among People Aged 18 Years or Older, United States, 2015

### Data Sources

- 2011–2014 National Health and Nutrition Examination Survey (NHANES), National Center for Health Statistics, Centers for Disease Control and Prevention.
- Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2010 to July 1, 2015, Population Division, U.S. Census Bureau.

### Methods

The percentage of adults aged 18 years or older with prediabetes was estimated using 2011–2014 NHANES data. People without diabetes were classified as having prediabetes if they had fasting plasma glucose values of 100 to 125 mg/dL or A1C values of 5.7% to 6.4%. For consistency with earlier estimates, fasting glucose values were

adjusted using recommended regression equations. People with missing values for either fasting glucose or A1C and pregnant women were excluded. The age-specific percentages of prediabetes for age groups 18–44, 45–64, and 65 years or older were then applied to the corresponding July 1, 2015 U.S. resident population estimates from the U.S. Census Bureau to derive the age-specific numbers of adults with prediabetes. These age-specific numbers of adults were added to obtain the estimated total number of adults with prediabetes. The same method was used for sex-specific numbers.

In addition, age-adjusted percentages were calculated by sex, race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, and Asian), and education level. Age adjustment was done with age groups 18–44, 45–64, and 65 years or older by the direct method to the 2000 U.S. Census standard population. Among those who tested positive for prediabetes, awareness was defined as (1) answered “yes” to the question, “Have you ever been told by a doctor or other health professional that you have any of the following: prediabetes, impaired fasting glucose, impaired glucose tolerance, borderline diabetes or that your blood sugar is higher than normal but not high enough to be called diabetes or sugar diabetes?” or (2) reported having prediabetes when asked whether they had diabetes.

## Reference

American Diabetes Association. Classification and diagnosis of diabetes. *Diabetes Care*. 2017;40(suppl 1):S11–S24.

## Risk Factors for Complications Among Adults Aged 18 Years or Older with Diagnosed Diabetes, United States, 2011–2014

### Data Source

- 2011–2014 National Health and Nutrition Examination Survey (NHANES), National Center for Health Statistics, Centers for Disease Control and Prevention.

### Methods

#### Smoking

The percentage of adults aged 18 years or older with diagnosed diabetes who had a history of smoking was estimated on the basis of self-reported current smoking or a history of smoking at least 100 cigarettes in a lifetime.

#### Obesity

The percentage of adults aged 18 years or older with diagnosed diabetes who were overweight or obese was estimated on the basis of a measured body mass index (BMI) of 25.0 to less than 30.0 kg/m<sup>2</sup> (overweight), 30.0 to less than 40.0 kg/m<sup>2</sup> (obese), or 40.0 kg/m<sup>2</sup> or higher (severely obese).

#### Physical Inactivity

The percentage of adults aged 18 years or older with diagnosed diabetes who were physically inactive was estimated on the basis of self-report of less than 10 minutes per week of moderate or vigorous activity in each of the physical activity categories of work, leisure time, and transportation.

#### High Blood Pressure

The percentage of adults aged 18 years or older with diagnosed diabetes who had high blood pressure was estimated on the basis of the average measured systolic blood pressure of 140 mm Hg or higher or the average diastolic blood pressure of 90 mm Hg or higher or self-reported current use of prescription medication for high blood pressure.

#### High Cholesterol (Hyperlipidemia)

The percentage of adults aged 21 years or older with diagnosed diabetes who were eligible for and being treated with a statin was estimated on the basis of the 2013 cholesterol guidelines from the American College of Cardiology and American Heart Association. People with diabetes who were eligible for primary prevention statin therapy were

defined as those aged 40 to 75 years with no history of cardiovascular disease or those aged 21 to 39 years with no history of cardiovascular disease and a low-density lipoprotein cholesterol level of 190 mg/dL or higher. People with diabetes and cardiovascular disease were eligible for secondary prevention statin therapy.

### ***High Blood Glucose (Hyperglycemia)***

The percentage of adults aged 18 years or older with diagnosed diabetes who had high blood glucose was estimated on the basis of an A1C value higher than 9%.

## **Coexisting Conditions and Complications Among Adults Aged 18 Years or Older with Diabetes**

### **Data Sources**

- 2014 National Inpatient Sample (NIS), Agency for Healthcare Research and Quality.
- 2014 Nationwide Emergency Department Sample (NEDS), Agency for Healthcare Research and Quality.
- 2013–2015 National Health Interview Survey (NHIS), National Center for Health Statistics, Centers for Disease Control and Prevention.
- Chronic Kidney Disease Surveillance System, Centers for Disease Control and Prevention.
- 2015 United States Renal Data System (USRDS) Annual Report.

### **Methods**

The number of hospitalizations for major cardiovascular diseases, lower-extremity amputation, and diabetic ketoacidosis in 2014 were calculated using NIS. The number of emergency department visits for hypoglycemia and hyperglycemic crisis in 2014 were calculated using NEDS. Crude rates were calculated using the proportion of the population with diabetes from NHIS. Prevalence data for chronic kidney disease awareness were from CDC's Chronic Kidney Disease Surveillance System using NHANES data.

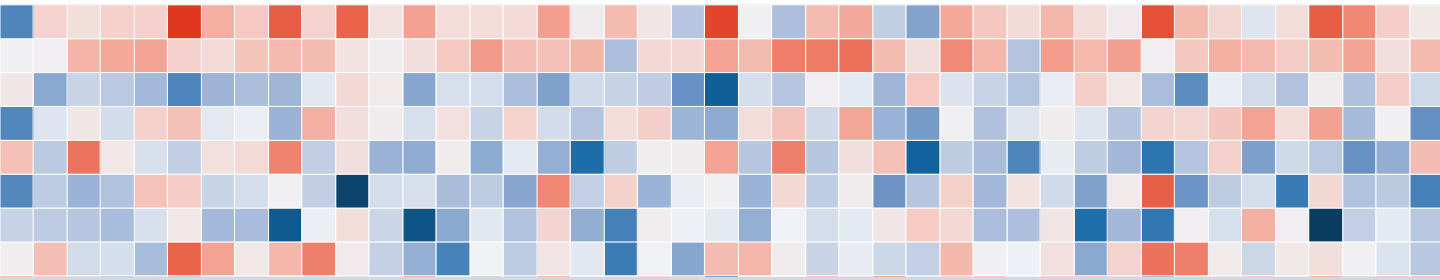
# EXHIBIT 4

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 4



# HEALTH CARE COST INSTITUTE



## Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices



**Authors:**

Jean Fuglesten Biniek  
William Johnson

JA - 000063

January 2019

# Insulin Prices Were the Primary Driver of Rapid Increases In Spending on Type 1 Diabetics

Type 1 diabetes is a chronic condition affecting approximately 1.5 million Americans.<sup>1</sup> In individuals with type 1 diabetes, the pancreas stops producing insulin. Insulin is the hormone that breaks down sugar in the blood so that it can be used by the body's other cells as fuel. As a result, type 1 diabetics must adhere to a lifelong insulin regimen that includes administering insulin through either injections or an insulin pump. Insulin is a complex drug that is not available in generic form, though competing versions are available for some insulin products. The cause of type 1 diabetes is unknown and there is no cure.

There has been a flurry of news reports sharing stories of individuals with diabetes rationing their insulin because they cannot afford higher and higher prices.<sup>2</sup> These anecdotes are consistent with findings of researchers documenting price increases on diabetic therapies, specifically insulin, over the last several years.<sup>3</sup> In response, there has been increased interest in policy circles. In May 2018 the American Diabetes Association testified before Congress on this issue,<sup>4</sup> and in October 2018 the Minnesota Attorney General filed suit against insulin makers for price gouging.<sup>5</sup>

## In This Brief

We used health care claims data to investigate trends in total health care spending on individuals with type 1 diabetes between 2012 and 2016. We found a rapid increase in total health care spending, driven primarily by gross spending on insulin that doubled over the period. During that time insulin use rose only modestly. While the composition of insulins used shifted, the price of all types of insulin and insulin products increased, with point-of-sale prices roughly doubling on average between 2012 and 2016. We conclude that increases in insulin spending were primarily driven by increases in insulin prices, and to a lesser extent, a shift towards use of more expensive products.

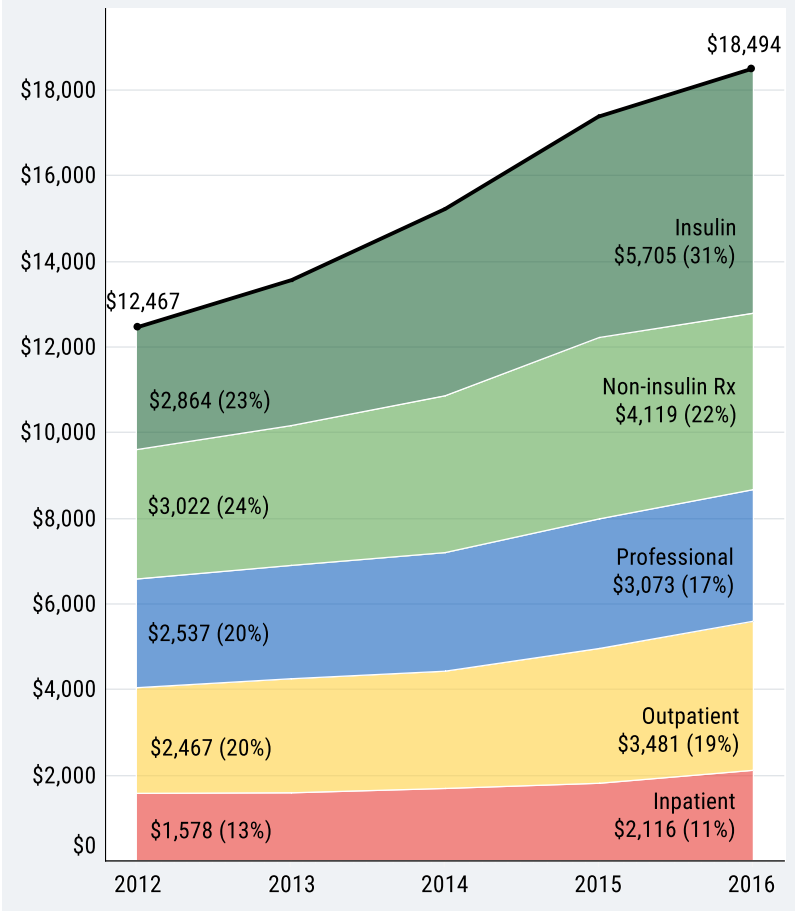
A note on drug rebates and coupons: We did not have information on manufacturer rebates or coupons for insulin, because this information is proprietary and not publicly available. Thus, we measured gross spending using the point-of-sale prices that are reported on a claim for a prescription drug. Rebates and coupons result in lower net spending (for both payers and patients). Although we cannot incorporate data on rebates and coupons into our analysis of total spending or prices, we do provide an illustrative example of their effect – which still indicates that rising insulin prices were the largest driver of spending growth for this population.

# Insulin Drove More Than \$6,000 Increase In Gross Health Care Spending From 2012-2016

We examined gross per-person spending by type of service – inpatient, outpatient, professional procedure, insulin, and non-insulin pharmacy – over 2012 to 2016.

In 2016, individuals with type 1 diabetes spent \$5,705 per-person on insulin.

**Figure 1: Annual Spending per Person for People with Type 1 Diabetes, 2012 to 2016**



- Gross spending on insulin accounted for 31% of the \$18,494 in total per-person spending.
- Per-person spending on non-insulin pharmacy services was \$4,119 (22%), which includes diabetic supplies, as well as other prescription drugs.
- Medical spending accounted for the remaining 47%, and reflected \$2,116 in inpatient (11%), \$3,481 in outpatient (19%), and \$3,073 in professional procedure (17%) spending per person.

Between 2012 and 2016, gross insulin spending per person increased by \$2,841.

- The increase in gross spending on insulin accounted for 47% of the \$6,027 increase in total per-person spending over the period.
- The increase in gross spending on insulin was larger than any other category, nearly doubling between 2012 and 2016.
- Non-insulin prescription drug and outpatient spending per-person had the next largest increases rising \$1,097 and \$1,014, respectively.

# Overview Of Insulin Types

There are two types of insulin: basal (intermediate or long-acting) and mealtime (short or rapid-acting). The amount of insulin an individual requires and the timing of administering each type of insulin varies depending on a person's weight, carbohydrate intake, activity level, and how quickly their body absorbs insulin. Most individuals with type 1 diabetes have insulin regimens that include a basal and a mealtime insulin. There are also combination products, which include both.

Each insulin product contains one active ingredient (except for combination products). There are two broad categories of active ingredients, traditional human insulins and synthetic insulin analogs. Insulin analogs are modified in laboratories to produce formulations that have the potential of providing better blood sugar control.<sup>7</sup>

In general, each active ingredient had exactly one brand name as of 2016. The exceptions are human insulins and the basal insulin glargine, for which follow-on products had been approved. See Table 1 for insulins available as of 2016.

**Table 1: Basal and Mealtime Insulins Available in 2016**

## **Basal Insulins**

### **Traditional human insulins**

- Humulin® N/Novolin® N (NPH)

### **Synthetic insulin analogs**

- Lantus®/Toujeo®/Basaglar® (glargine)
- Levemir® (detemir)
- Tresiba® (degludec)

## **Mealtime Insulins**

### **Traditional human insulins**

- Humulin® R/Novolin® R (regular insulin)

### **Synthetic insulin analogs**

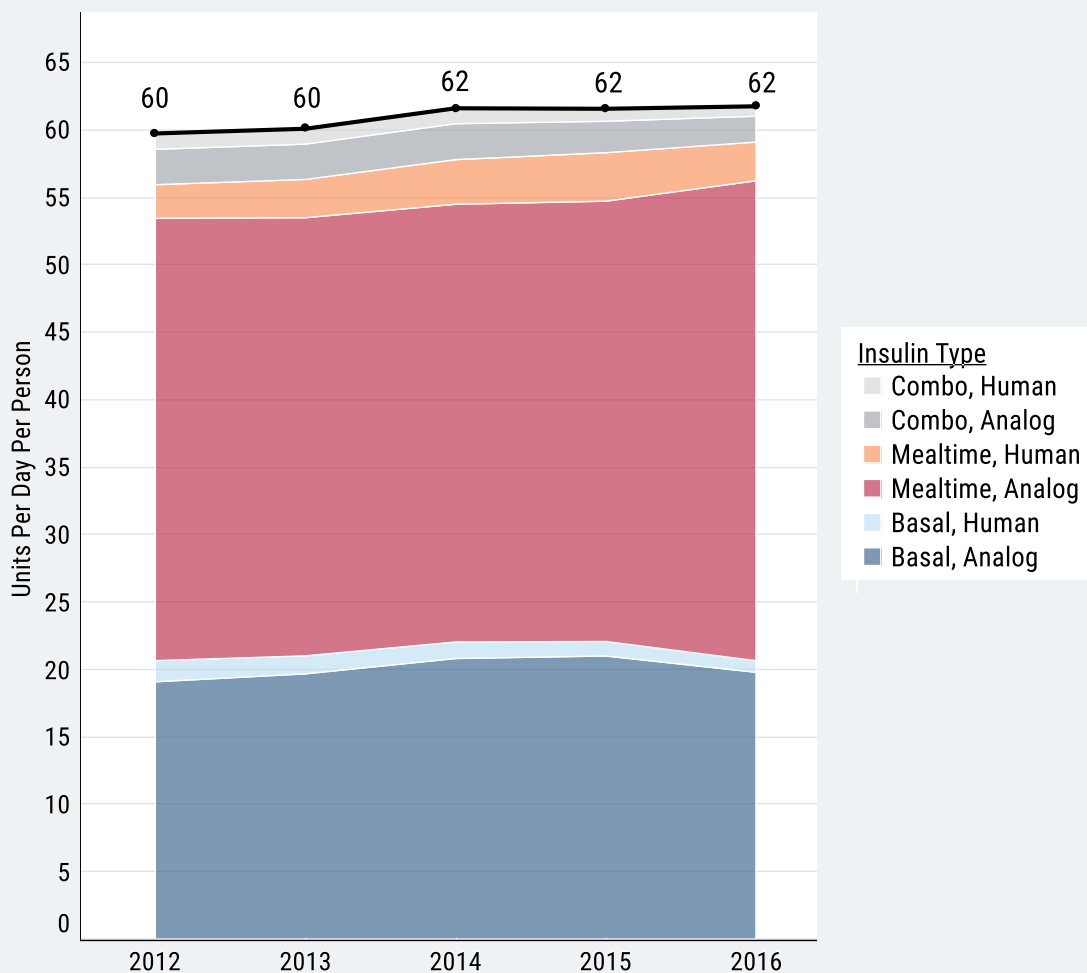
- Apidra® (glulisine)
- Humalog® (lispro)
- Novolog® (aspart)

# Average Daily Insulin Use By Type 1 Diabetics Rose by Only 3%

To measure changes in insulin use, we grouped insulins by type and whether the active ingredient was a human or analog insulin. We then summed the total units across all prescriptions filled in the year. (Insulin units provide a standardized measure that can be used to compare different types and strengths of insulin in a reliable way.) For ease of interpretation, we divided the total units by the number of days in a year to get a daily average.

- In 2016, average daily insulin use was 62 units, a 2 unit (3%) increase from 2012. In comparison, insulin spending per-person just about doubled over the same period.
- Daily usage of mealtime insulins increased by 3 units, whereas units of basal insulin used remained constant, and use of combination insulins decreased by 1 unit.
- Analog insulins accounted for more than 90% of use during each year in the period.
- Use of analog insulins increased slightly from 2012 to 2016.

**Figure 2: Insulin Units per Day per Person with Type 1 Diabetes by Type, 2012 to 2016**



# The Insulin Products Used Changed Over Time: Active Ingredient

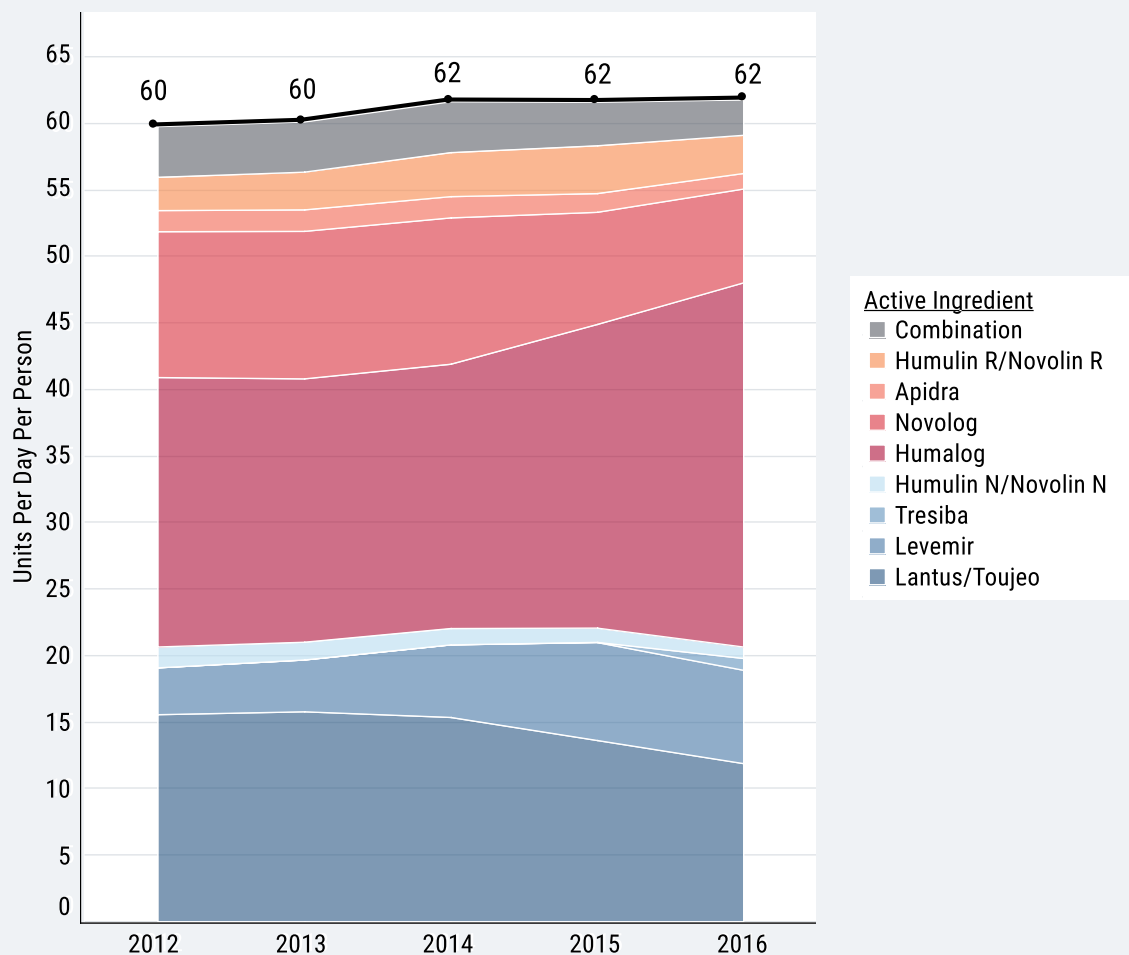
Among basal and mealtime insulins there are several distinct human and analog insulin products. The products differ in their active ingredient and the mechanism used for delivery. To further examine utilization trends, we categorized products along each of these dimensions.

## Active Ingredient

Figure 3 shows the average daily use for each active ingredient. Basal insulins are in the blue shades and mealtime insulins are in the red shades.

- Across the sample, individuals used 7 more units of Humalog® daily in 2016 than in 2012, while daily use of Novolog® declined by 4 units.
- Among basal insulins, daily use of Lantus®/Toujeo® declined by 4 units. This was offset by an increase in use of Levemir® and the adoption of Tresiba®, which came to market in 2015.

**Figure 3: Insulin Units per Day per Person with Type 1 Diabetes by Active Ingredient, 2012 to 2016**



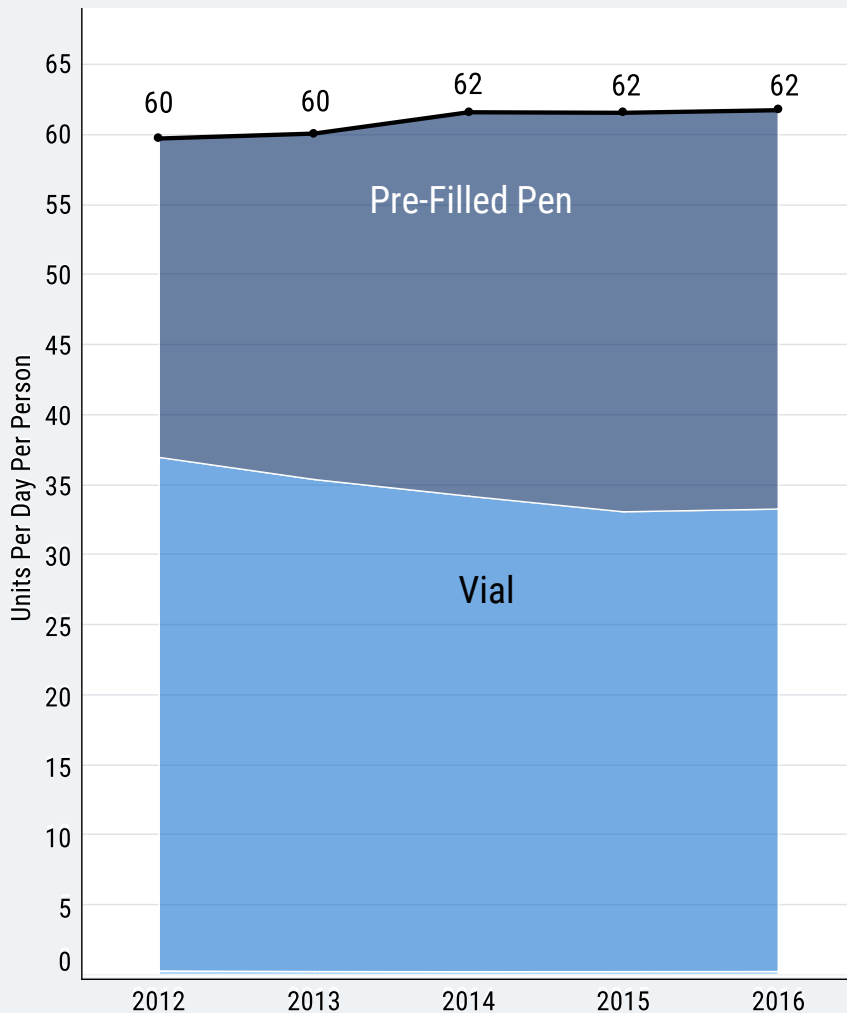
# The Insulin Products Used Changed Over Time: Delivery Mechanism

## Delivery Mechanism

Historically, insulin was available in a vial, and a syringe was used for administration. More recently, pre-filled insulin pens have become available. There are also reusable pens that take cartridges of insulin.

- Vials remained the most common delivery method, making up 53% of use in 2016.
- Use of pre-filled insulin pens increased over the period, rising from 38% of use in 2012 to 46% in 2016.
- Cartridges represented less than 1% of insulin used in each year.

**Figure 4: Insulin Units per Day per Person with Type 1 Diabetes by Delivery Method, 2012 to 2016**  HCCI



# Prices Increased Steadily For All Types Of Insulin Products: Basal Insulins

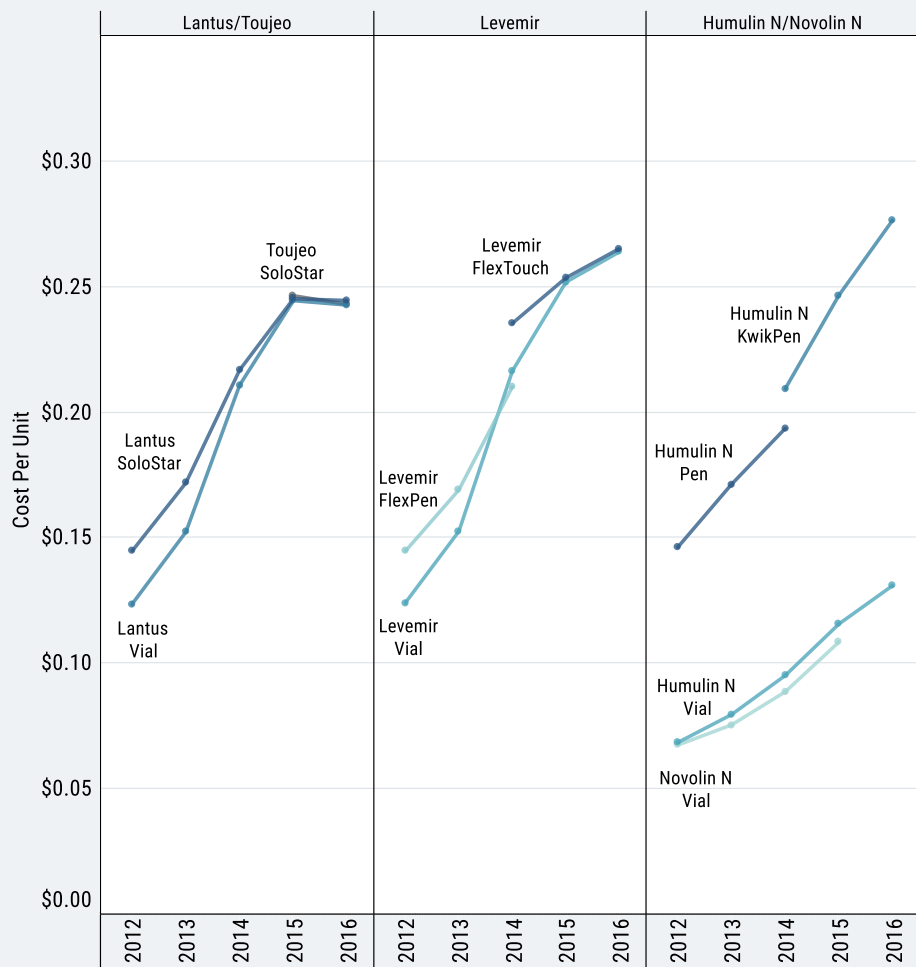
Changes in spending can be driven by changes in use and/or changes in prices. We observed little change in total use over the period but did see the composition of insulins shift. To examine whether use of more expensive products or higher prices drove gross spending increases, we calculated the price per unit of insulin for each NDC code. This standardization allows for comparison across vials and pre-filled pens, which usually contain different amounts of insulin in each package, and across insulins of different concentrations.

The price of all insulin products increased between 2012 and 2016. The average point-of-sale price nearly doubled, rising from \$0.13 per unit to \$0.25 per unit. That translates to an increase from \$7.80 a day in 2012 to \$15 a day in 2016 for someone using an average amount of insulin (60 units per day).

In Figure 5a, the average price per unit for basal insulins are plotted.

- Prices were similar regardless of the delivery mechanism among basal insulins containing the same active ingredient.
- Traditional human insulin products were cheaper than insulin analogs, except for the Humulin® N KwikPen introduced in 2014.
- The unit price did not vary across different concentrations of insulin within the same active ingredient. Toujeo®, which is a more concentrated version of Lantus®, was nearly identical in price.

**Figure 5a: Price per Unit of Insulin by Product Family, 2012 to 2016 (Basal Insulins)**

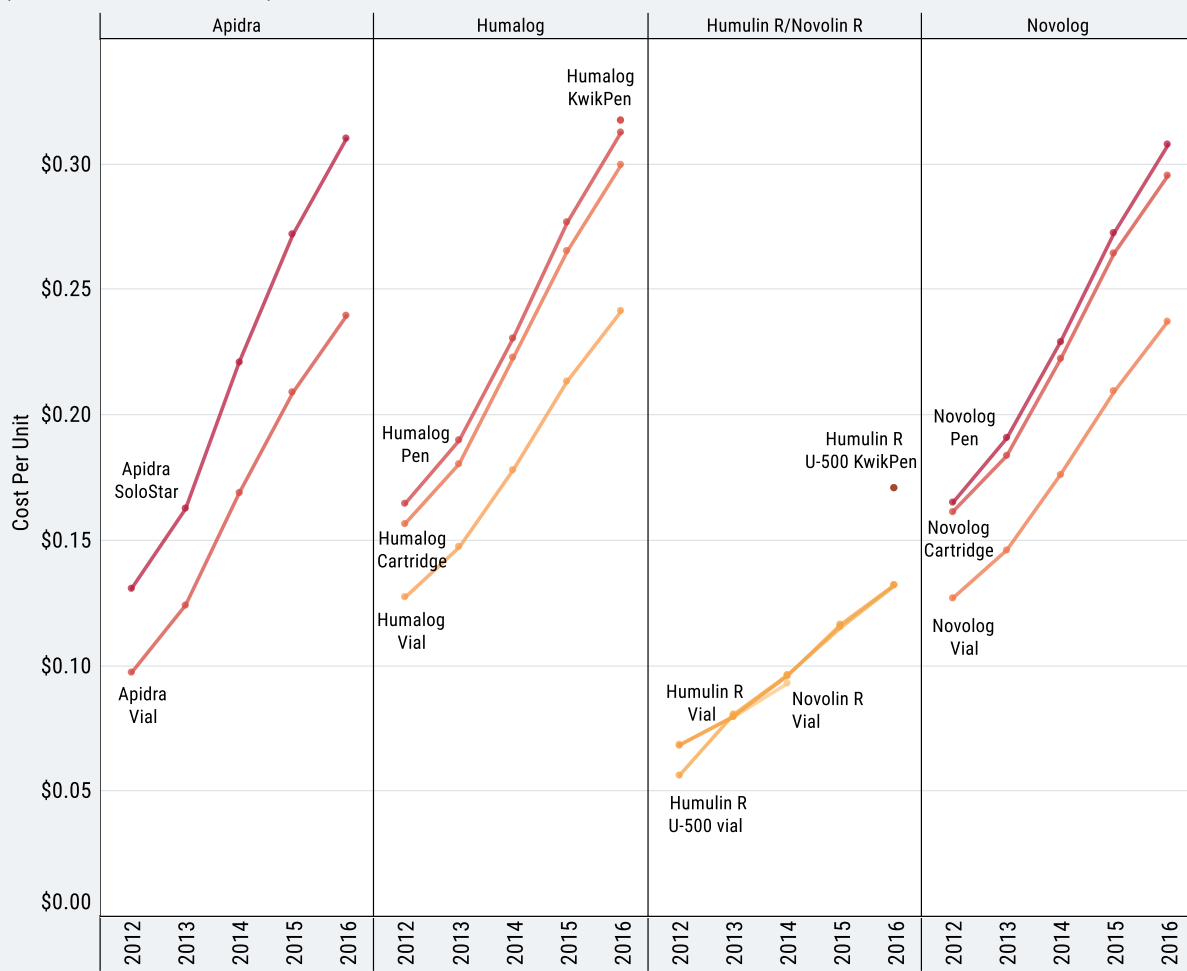


# Prices Increased Steadily For All Types Of Insulin Products: Mealtime Insulins

We performed the same analysis for mealtime insulins, calculating the price per unit for each NDC code. In Figure 5b, the average price per unit for mealtime insulins are plotted. Trends for mealtime insulins were similar to those observed for basal insulins.

- Among mealtime insulins, vials were cheaper than insulin packaged in other types of delivery mechanisms.
- Traditional human insulin products were cheaper than insulin analogs.
- The unit price did not vary across different concentrations of insulin within the same active ingredient. Vials of Humulin® R and Humulin® R U-500, which is five times more concentrated, were similarly priced per unit of insulin.

**Figure 5b: Price per Unit of Insulin by Product Family, 2012 to 2016 (Mealtime Insulins)**



# What Do Changes In Insulin Prices Look Like From A Patient Perspective?

To illustrate how an individual might have been impacted by insulin price increases, consider a person with the following insulin regimen:

- Once or twice a day basal insulin: Lantus® SoloStar, 30 units total on average
- Mealtime insulin at meals: Humalog® Pen, 30 units total on average throughout the day

This person would use one Lantus® and one Humalog® pen every 1-2 weeks and require at least seven boxes of each over the year. In 2012, their annual insulin spending would have been approximately \$3,200, growing to \$5,900 in 2016.<sup>8</sup> Table 2 provides the average point-of-sale prices for the most common products in our sample. Table 2 also provides the 5-year percent change for products available in all years. The median price increase among these products was 92 percent.

**Table 2: Prices for Common Insulin Products, 2012 to 2016**

	Product	Delivery	Description	Average Price per Product (\$)					5-yr Chg. (%)
				2012	2013	2014	2015	2016	
Basal	Humulin N	Vial	10mL, 100 units/mL	68	79	95	116	131	93%
		Pen	5 pens, 3mL each, 100 units/mL	219	257	290			
		KwikPen	5 pens, 3mL each, 100 units/mL			314	370	415	
	Novolin N	Vial	10mL, 100 units/mL	67	75	89	108		
	Lantus	Vial	10mL, 100 units/mL	123	152	211	244	243	98%
		SoloStar Pen	5 pens, 3mL each, 100 units/mL	217	258	325	368	367	69%
	Levemir	Vial	10mL, 100 units/mL	124	152	216	252	264	113%
		FlexPen	5 pens, 3mL each, 100 units/mL	217	253	315			
		FlexTouch	5 pens, 3mL each, 100 units/mL			353	380	398	
	Toujeo	SoloStar Pen	3 pens, 1.5mL each, 300 units/mL				333	328	
Mealtime	Tresiba	U-100 Pen	5 pens, 3mL each, 100 units/mL					440	
		U-200 Pen	3 pens, 3mL each, 200 units/mL					524	
	Humulin R	Vial	10mL, 100 units/mL	68	80	96	116	132	94%
		U-500 Vial	20mL, 500 units/mL	563	804	961	1152	1319	134%
		U-500 KwikPen	2 pens, 3mL each, 500 units/mL					513	
	Novolin R	Vial	10mL, 100 units/mL	68	79	93			
	Apidra	Vial	10mL, 100 units/mL	97	124	169	209	240	147%
		SoloStar Pen	5 pens, 3mL each, 100 units/mL	196	244	332	408	466	138%
	Humalog	Vial	10mL, 100 units/mL	127	147	178	213	241	90%
		Cartridge	5 cart., 3mL each, 100 units/mL	235	271	334	398	449	91%
		Pen	5 pens, 3mL each, 100 units/mL	247	285	346	415	469	90%
		KwikPen	2 pens, 3mL each, 200 units/mL					381	
	Novolog	Vial	10mL, 100 units/mL	127	146	176	209	237	87%
		Cartridge	5 cart., 3mL each, 100 units/mL	242	275	333	397	443	83%
		FlexPen	5 pens, 3mL each, 100 units/mL	247	286	344	409	461	87%

# How Might Manufacturer Rebates and Coupons Affect Spending Analysis?

Recognizing manufacturer rebates and coupons are not trivial,<sup>6</sup> we considered a case where rebates and coupons offset 50% of the gross cost of insulin in each year. This implicitly assumes that the costs offset by coupons or rebates change proportionately with any changes in the point-of-sale cost of insulin. In this case:

- The net increase in total spending per person would be \$4,606, reflecting a \$1,421 increase in spending on insulin.
- Increased spending on insulin net of rebates and coupons would account for 31% of the total increase in spending and would still be the category with the largest increase.
- On net, the average price of insulin would still have doubled between 2012 and 2016.

**Table 3: Per-Person Spending by Category, 50% Rebate for Insulin, 2012 and 2016**

Category	2012	2016	Change	Share of Change
Inpatient	\$1,578	\$2,116	\$538	11.7%
Outpatient	\$2,467	\$3,481	\$1,014	22.0%
Professional	\$2,537	\$3,073	\$536	11.6%
Non-insulin Rx	\$3,022	\$4,119	\$1,097	23.8%
Insulin	\$1,432	\$2,853	\$1,421	30.8%
Total	\$11,035	\$15,641	\$4,606	

# Data and Methods

**Analytic Sample:** We studied individuals aged 18-64 with employer sponsored health insurance. We identified individuals with type 1 diabetes by adapting the classification tree model presented by Lo-Ciganic and colleagues.<sup>9</sup> Because we wanted to measure spending on medical care over a full calendar year, we restricted our sample to individuals with full-year of medical and prescription drug coverage. Given the important role of insulin in the treatment and management of type 1 diabetes, we further limited the sample to individuals who had at least one prescription for an insulin product in the year. This methodology resulted in between 13,800 and 16,200 type 1 diabetics per year in our sample.

**Measure of Use:** The days supplied field in the claims data is not a reliable measure of insulin use because use can vary widely day-to-day. We instead combined information on the insulin strength (units per mL) with the quantity field (expressed as mL of insulin) to calculate the total number of units a person obtained in a calendar year. We excluded prescriptions for Afrezza<sup>®</sup> (inhaled insulin) because the units are not equivalent to injected insulins. There were less than 200 fills for Afrezza<sup>®</sup> over the period in our sample.

**Price Calculation:** To calculate the point-of-sale price of individual insulin products, we used a subset of all filled prescriptions. First, we excluded combination products and restricted the analysis to the most common NDC code for each active ingredient and delivery mechanism. Next, we restricted the analysis to products that had at least 100 fills in a year. Therefore, some products that were available for purchase are not included, because we did not observe a sufficient number of fills in the year. We then summed the payments (allowed amounts) and units by year for each NDC code. To calculate the price per unit, we divided the total payments by the total units. We constructed prices per product by multiplying the unit price by the number of units in the package.

# Limitations

It is possible that manufacturer rebates and coupons for insulin have increased as a share of list prices over the study period. In Medicare Part D, manufacturer rebates increased from 11.7% of total drug costs in 2012 to 19.9% of total drug costs in 2016.<sup>10</sup> Additionally, a report by the U.S. Department of Health & Human Services Office of Inspector General found that rebates offset approximately 20% of spending increases in Part D from 2011 to 2015.<sup>11</sup> If similar patterns exist for insulin products, our findings will overstate the percent change in spending and prices. Note, the analysis reflects claims from individuals with employer-sponsored insurance coverage. Individuals without insurance coverage would not benefit from lower prices resulting from manufacturer rebates.

In addition, we only have data on prescriptions filled where the individual reported their insurance coverage. If individuals purchased insulin over-the-counter or used an insulin discount program that cannot be combined with insurance when filling their prescription, it will not be reflected in our data, and therefore, excluded from this analysis.

Finally, several new insulin products have been approved since the end of the period of this study. In addition, products approved near the end of the period have likely increased in use. We are unable to assess the effects of these changes in the landscape of products available on spending, prices, and use in 2017 and 2018. That is, the trends reported in this brief cannot be reliably extrapolated to more recent years.

# End Notes

1. American Diabetes Association, "American Diabetes Association Releases White Paper by Insulin Access and Affordability Working Group at Hearing of Senate Special Committee on Aging." 5/8/2018. <http://www.diabetes.org/diabetes-basics/type-1/>
2. For example, see: Sable-Smith, Bram. "Insulin's High Cost Leads to Lethal Rationing." NPR 9/1/2018. <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>
3. Luo J, Kesselheim AS, Greene J, and Lipska KJ. Strategies to improve the affordability of insulin in the USA. The Lancet Diabetes & Endocrinology. Published 2/8/2017
4. American Diabetes Association, <http://www.diabetes.org/newsroom/press-releases/2018/insulin-affordability-white-paper-release.html>
5. Raymond, Nate. "Minnesota accuses insulin makers of deceptive drug pricing." Reuters 10/16/2018. <https://www.reuters.com/article/us-minnesota-lawsuit-insulin/minnesota-accuses-insulin-makers-of-deceptive-drug-pricing-idUSKCN1MQ20A>
6. The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, "2018 Annual Report of the Board of Trustees of Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds." June 5, 2018 and U.S. Department of Health & Human Services Office of the Inspector General, "Increases in Reimbursement for Brand-Name Drugs in Part D."
7. Diabetes Teaching Center at the University of California, San Francisco. "Insulin Analogs." <https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/insulin-analogs/>
8. These back of the envelop calculations here are slightly above the averages we calculated for our sample, because the products used for our calculations are more expensive than average.
9. Lo-Ciganic W, Zgibor JC, Ruppert K, Arena VC, Stone RA. Identifying type 1 and type 2 diabetic cases using administrative data: a tree-structured model. J. Diabetes Sci Technol. 2011; 5(3): 486-93. Published 2011 May 1.
10. The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, "2018 Annual Report of the Board of Trustees of Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds." June 5, 2018.
11. U.S. Department of Health & Human Services Office of the Inspector General, "Increases in Reimbursement for Brand-Name Drugs in Part D."

# EXHIBIT 5

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 5



# Economic Costs of Diabetes in the U.S. in 2017

American Diabetes Association

<https://doi.org/10.2337/dci18-0007>

## OBJECTIVE

This study updates previous estimates of the economic burden of diagnosed diabetes and quantifies the increased health resource use and lost productivity associated with diabetes in 2017.

## RESEARCH DESIGN AND METHODS

We use a prevalence-based approach that combines the demographics of the U.S. population in 2017 with diabetes prevalence, epidemiological data, health care cost, and economic data into a Cost of Diabetes Model. Health resource use and associated medical costs are analyzed by age, sex, race/ethnicity, insurance coverage, medical condition, and health service category. Data sources include national surveys, Medicare standard analytical files, and one of the largest claims databases for the commercially insured population in the U.S.

## RESULTS

The total estimated cost of diagnosed diabetes in 2017 is \$327 billion, including \$237 billion in direct medical costs and \$90 billion in reduced productivity. For the cost categories analyzed, care for people with diagnosed diabetes accounts for 1 in 4 health care dollars in the U.S., and more than half of that expenditure is directly attributable to diabetes. People with diagnosed diabetes incur average medical expenditures of ~\$16,750 per year, of which ~\$9,600 is attributed to diabetes. People with diagnosed diabetes, on average, have medical expenditures ~2.3 times higher than what expenditures would be in the absence of diabetes. Indirect costs include increased absenteeism (\$3.3 billion) and reduced productivity while at work (\$26.9 billion) for the employed population, reduced productivity for those not in the labor force (\$2.3 billion), inability to work because of disease-related disability (\$37.5 billion), and lost productivity due to 277,000 premature deaths attributed to diabetes (\$19.9 billion).

## CONCLUSIONS

After adjusting for inflation, economic costs of diabetes increased by 26% from 2012 to 2017 due to the increased prevalence of diabetes and the increased cost per person with diabetes. The growth in diabetes prevalence and medical costs is primarily among the population aged 65 years and older, contributing to a growing economic cost to the Medicare program. The estimates in this article highlight the substantial financial burden that diabetes imposes on society, in addition to intangible costs from pain and suffering, resources from care provided by nonpaid caregivers, and costs associated with undiagnosed diabetes.

*This report was prepared under the direction of the American Diabetes Association by Wenya Yang (The Lewin Group, Inc., Falls Church, VA), Timothy M. Dall (IHS Markit, Washington, DC), Kaleigh Beronjia (The Lewin Group, Inc.), Janice Lin (The Lewin Group, Inc.), April P. Semilla (IHS Markit), Ritashree Chakrabarti (IHS Markit), and Paul F. Hogan (The Lewin Group, Inc.).*

Address correspondence to Matthew P. Petersen, [mpetersen@diabetes.org](mailto:mpetersen@diabetes.org).

This article contains Supplementary Data online at <http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dci18-0007/-/DC1>.

This ADA statement was reviewed and approved by the American Diabetes Association Professional Practice Committee in March 2018 and ratified by the American Diabetes Association Board of Directors in March 2018.

© 2018 by the American Diabetes Association. Readers may use this article as long as the work is properly cited, the use is educational and not for profit, and the work is not altered. More information is available at <http://www.diabetesjournals.org/content/license>.

See accompanying articles, pp. XXXX, XXXX, XXXX, XXXX, XXXX, XXXX, XXXX, XXXX, and XXXX. 000078

Diabetes imposes a substantial burden on society in the form of higher medical costs, lost productivity, premature mortality, and intangible costs in the form of reduced quality of life. The estimated economic burden associated with diagnosed diabetes in the U.S. in 2012 was \$245 billion in the form of higher medical costs (\$176 billion) and reduced productivity (\$69 billion) (1). The population diagnosed with diabetes has continued to grow, by ~700,000 people annually between 2012 and 2015, with prevalence projected to continue rising over time as the population grows and ages (2,3). Furthermore, there continue to be changes in the demographics of the population with diabetes, health care use and delivery patterns, technology, medical costs, insurance coverage, and economic conditions that affect the economic burden associated with diabetes. This study updates previous estimates, with the goal to quantify the economic burden of diabetes at the national and state levels in 2017. Such information can help inform and motivate strategies to reduce diabetes prevalence and burden.

## RESEARCH DESIGN AND METHODS

The methodology used is similar to that of previous diabetes burden studies sponsored by the American Diabetes Association (1,4), with updated data sources and modifications to refine the analyses where appropriate. Although the primary focus of this analysis is the national economic burden of disease, the national estimates are calculated by summing the state-level estimates that reflect variation across states in demographics, health risk factors and lifestyle choices, prices, and economic outcomes. (State-level estimates of diabetes prevalence and costs are provided in Supplementary Table A-16.) All cost and utilization estimates are extrapolated to the U.S. population in 2017, with cost estimates calculated in 2017 dollars using the hospital services, physician services, and prescription drug components of the medical consumer price index or total consumer price index (5).

Inputs to the study include both state-level and national-level data. Sources for state-level data include the American Community Survey (ACS), Behavioral Risk Factor Surveillance System (BRFSS), Medicare Current Beneficiary Survey (MCBS), and Long Term Care Minimum

Data Set (MDS). Sources for national data (which are extrapolated to the state level) include the Current Population Survey (CPS), OptumInsight de-identified Normative Health Information (dNHI) database, Medical Expenditure Panel Survey (MEPS), National Ambulatory Medical Care Survey (NAMCS), National Hospital Ambulatory Medical Care Survey (NHAMCS), National Home and Hospice Care Survey (NHHC), National Health Interview Survey (NHIS), National (Nationwide) Inpatient Sample (NIS), and Medicare 5% sample Standard Analytical Files (SAFs). We use the most recent year's data available for each of these data sources, though for certain analyses we combine multiple years of data to increase sample size. Supplementary Table A-1 describes how these data sources are used along with their respective strengths and limitations as pertinent to this study.

## Estimating the Size of the Population With Diabetes

For each of the 50 states and the District of Columbia, we estimate the prevalence of diagnosed diabetes for 480 population strata defined by age-group (<18, 18–34, 35–44, 45–54, 55–59, 60–64, 65–69, and ≥70 years), sex, race/ethnicity (non-Hispanic white, non-Hispanic black, non-Hispanic other, and Hispanic), insurance status (commercial; government, including Medicare, Medicaid, Children's Health Insurance Program, Veterans Health Administration, and other government-sponsored coverage; and uninsured), and whether residing in the community, a residential care facility, or a nursing home. (Government employees and military personnel and dependents with insurance are counted under private insurance.) The reason for modeling the large number of strata reflects differences in diabetes prevalence and costs across these strata and that different data sources are used to estimate diabetes prevalence for people residing in the community, in a residential care facility, or in a nursing home.

The population database starts with the 2016 ACS, which contains state-level population estimates by age, sex, race/ethnicity, whether the person has medical insurance, and whether the person resides in a group setting. We use random sampling with replacement to statistically match each person in the 2016 ACS with a similar person in a file containing patient health information and risk factors. ACS individuals residing in the community are

matched to a similar individual in the 2015–2016 BRFSS of the same age, sex, race/ethnicity, state, family income level, and insurance type. ACS individuals residing in residential care facilities and nursing homes are matched to a person of similar age, sex, race/ethnicity, and state from the 2015 MDS and 2013 MCBS, respectively.

Diabetes status in the MDS and MCBS is based on clinical diagnosis, whereas diabetes status in the BRFSS is based on respondents answering “yes” to the question, “Have you EVER been told by a doctor or health professional that you have diabetes or sugar diabetes?” The prevalence estimates exclude gestational diabetes mellitus. These sources do not contain diabetes status for children. Therefore, we combined the 2014–2016 NHIS files to estimate national diabetes prevalence rates for children—based on self-report (6) like the BRFSS information—which we then extrapolated to the state population files by age (6–12 and 13–17 years), sex, and race/ethnicity.

To estimate diabetes prevalence in 2017, we scaled the state estimates based on population growth between 2016 and 2017 by demographic group. For validation, when we apply prevalence rates for each strata (demographic, insurance, state) to the 2015 population, our national estimate of diagnosed diabetes is slightly higher than that reported by the Centers for Disease Control and Prevention (CDC) (23.4 million vs. 23.0 million). Our higher estimate possibly reflects that our analysis incorporates data from residential care and nursing facilities, whereas the CDC estimate is based on a representative sample of the noninstitutionalized population.

## Estimating the Direct Medical Cost Attributed to Diabetes

We estimate health resource use among the population with diabetes in excess of resource use that would be expected in the absence of diabetes. Diabetes increases the risk of developing neurological, peripheral vascular, cardiovascular, renal, endocrine/metabolic, ophthalmic, and other complications (see Supplementary Appendix 2 for a more comprehensive list of medical conditions and ICD-9 and ICD-10 codes). Diabetes also increases the cost of treating general conditions that are not directly related to diabetes. Therefore, only the relevant portion of health care expenditures for these medical conditions is attributed to diabetes.

The approach used to quantify the excess health resource use associated with diabetes was influenced by four data limitations: 1) absence of a single data source for all estimates, 2) small sample size in some data sources, 3) correlation of both diabetes and its comorbidities with other factors such as age and obesity, and 4) underreporting of diabetes and its comorbidities in certain data sources such as the NIS, NAMCS, and NHAMCS. Because of these limitations, we estimate diabetes-attributed costs using one of two approaches for each cost component.

For cost components estimated solely from MEPS (ambulance services, home health, podiatry, diabetes supplies, and other equipment and supplies), we use a comparison of annual per capita health resource use for people with and without diabetes controlling for age, sex, and race/ethnicity. For nursing/residential facility use (which is not captured by MEPS) and for cost components that rely on analysis of medical encounter data (hospital inpatient, emergency care, and ambulatory visits), we employ an attributed risk methodology often used in disease burden studies that relies on population etiological fractions (7). Etiological fractions estimate the excess use of health care services among the diabetes population relative to a similar population that does not have diabetes. Both approaches used in this study are equivalent under a reasonable set of assumptions. However, the first approach cannot be used with some national data sources analyzed—e.g., visit/hospital discharge-level files such as NIS, NAMCS, and NHAMCS, which may not identify the patient as having diabetes even if the patient does indeed have diabetes.

The attributable fraction approach combines etiological fractions ( $\varepsilon$ ) with total projected U.S. health service use ( $U$ ) in 2017 for each age-group ( $a$ ), sex ( $s$ ), medical condition ( $c$ ), and care delivery setting ( $H$ ), which includes hospital inpatient, emergency department, and ambulatory service (physician office visits and hospital outpatient/clinic visits):

$$\text{Attributed health resource use}_{H,a,s,c} = \sum_{age} \sum_{sex} \sum_{\substack{medical \\ condition}} \varepsilon_{H,a,s,c} \times U_{H,a,s,c}$$

The etiological fraction is calculated using the diagnosed diabetes prevalence ( $P$ ) and the relative rate ratio ( $R$ ):

$$\varepsilon_{H,a,s,c} = \frac{P_{a,s} \times (R_{H,a,s,c} - 1)}{P_{a,s} \times (R_{H,a,s,c} - 1) + 1}$$

The rate ratio for hospital inpatient days, emergency visits, and ambulatory visits represents how annual per capita health service use for the population with diabetes compares to the population without diabetes:

$$R_{H,a,s,c} = \frac{\text{annual per capita use for people with diabetes}_{a,s,c}}{\text{annual per capita use for people without diabetes}_{a,s,c}}$$

Diabetes and its comorbidities are correlated with other patient characteristics such as demographics and body weight. To mitigate bias caused by correlation, we estimate age/sex/setting-specific etiological fractions for each medical condition. The primary data sources for calculating etiological fractions are the 2015 OptumInsight dNHI data and the 2014 Medicare 5% sample SAF. The dNHI data contain a complete set of medical claims for more than 31 million commercially insured beneficiaries in 2015 and allows patient records to be linked during the year and across health delivery settings. This allows us to identify people with a diabetes ICD-9 (250.xx) or ICD-10 diagnosis code in at least one of their inpatient medical claims or in two or more separate noninpatient claims during the year. The Medicare 5% sample SAF contains claims data filed on behalf of Medicare beneficiaries under both Part A and Part B, and as with the dNHI data, we identify people with diabetes based on diabetes ICD-9 diagnosis codes. The large size of these two claims databases enables the generation of age/sex/setting-specific rate ratios for each medical condition that are more stable than the rates estimated using MEPS.

Unlike the MEPS data, the dNHI data and Medicare 5% claims data do not contain race/ethnicity and select patient characteristics that could affect both patient health status and health-seeking behaviors. For the 10 medical conditions that are the largest contributors to the overall cost of diabetes—general medical condition, other chronic ischemic heart disease, myocardial infarction, heart failure, hypertension, conduction disorders and cardiac dysrhythmias, cellulitis, occlusion of cerebral arteries, end-stage renal disease (ESRD), and renal failure and its sequelae—we estimate two multivariate Poisson regressions, using data from

2011–2015 MEPS, to determine the extent to which controlling only for age and sex might bias the rate ratios. First, we estimate a naive model that produces diabetes-related rate ratios for hospital inpatient days, emergency visits, and ambulatory visits controlling for age and sex only. Then, we estimate a full model that includes diabetes status as the main explanatory variable and various known predictors of health service utilization including age, sex, education level, income, marital status, medical insurance status, and race/ethnicity as covariates.

For the full model, our focus is not on the relationship between health care use and the covariates (other than diabetes); instead, these covariates are included to control for patient characteristics not available in medical claims data that could be correlated with both medical conditions and health-seeking behavior. The full model omits indicators for presence of coexisting conditions or complications of diabetes (e.g., hypertension), since including such variables could downward bias the estimated relationship between diabetes and health care use for each of the 10 medical conditions. The rate ratio coefficients for the diabetes flag variable in the naive and full models are then compared. The findings suggest statistically significant overestimates of the rate ratios for eight condition categories for both emergency visits and inpatient days when using the naive model. For ambulatory visits, we find significant overestimates in the rate ratios for five condition categories from the MEPS-based naive model compared with the full model.

To remedy the relative risk overestimation for these condition categories, we scaled the rate ratios estimated from dNHI and Medicare 5% sample SAFs using the regression results from the MEPS analysis by applying a scalar (with the scalar calculated as the full model rate ratio divided by the naive model rate ratio). For emergency department visits, claims-based rate ratios are scaled down for other chronic ischemic heart disease (scale = 0.89), myocardial infarction (0.89), heart failure (0.86), hypertension (0.63), cellulitis (0.89), occlusion of cerebral arteries (0.94), chronic renal failure–ESRD (0.73), and renal failure and its sequelae (0.77). For inpatient days, claims-based rate ratios are scaled down for

chronic ischemic heart disease (0.99), myocardial infarction (0.92), heart failure (0.81), hypertension (0.69), cellulitis (0.85), occlusion of cerebral arteries (0.98), chronic renal failure–ESRD (0.72), and renal failure and its sequelae (0.64). Physician office visits are scaled down for myocardial infarction (0.98), heart failure (0.76), hypertension (0.87), occlusion of cerebral arteries (0.93), and renal failure and its sequelae (0.25). We did not find a significant overestimate of the rate ratios for general medical conditions for any of the three health service delivery settings comparing the MEPS-based naive model and the full model. However, a comparison of the claims-based rate ratios with the rate ratios calculated from the MEPS-based naive model finds that the claims-based rate ratios for general conditions are significantly higher than the MEPS-based rate ratios for emergency department visits and inpatient days. Therefore, to be conservative in our cost estimates, we downward adjusted claims-based rate ratios for emergency department visits (0.52) and inpatient days (0.50) for the general condition group by applying a scalar calculated as the MEPS-based naive model rate ratio divided by the claims-based rate ratio.

Estimates of health resource use attributed to diabetes are combined with estimates of the average medical cost per unit of health care utilization, in 2017 dollars, to compute total medical costs attributed to diabetes. For hospital inpatient days, office visits, emergency visits, and outpatient visits, we use the average cost per visit/day specific to the medical conditions modeled. We pooled the 2011–2015 MEPS files to estimate average cost per unit of health care utilized. Although MEPS contains both inpatient facility and professional expenditures and NIS contains only facility charges (which are converted to costs using hospital-specific cost-to-charge ratios), the NIS has a much larger sample ( $n = \sim 7$  million discharges in 2014) and also contains five-digit diagnosis codes. Therefore, we use the 2014 NIS data to estimate inpatient facility costs and use the pooled 2011–2015 MEPS files to estimate the cost for professional services. Average costs per event or day by medical condition are shown in Supplementary Table A-3.

Utilization of prescription medication (excluding insulin and other antidiabetes agents) for each medical condition is

estimated from medications prescribed during physician office, emergency department, and outpatient visits attributed to diabetes. Average number of medications prescribed during a physician office visit for each age/sex/race stratum is estimated using data from the 2013–2015 NAMCS along with 2012–2014 NHAMCS for emergency department visits and 2009–2011 NHAMCS for outpatient visits. We calculate the total number of people with diabetes who use insulin and other antidiabetes agents by combining diabetes prevalence and the rate of use for these antidiabetes agents obtained from the 2013–2015 NHIS. Average cost per prescription filled, yearly average cost per insulin user, and yearly average cost per oral agent and other antidiabetes agent user are obtained from the 2013–2015 MEPS. We combined the utilization of these medications with the average cost per prescription to estimate the cost by age, sex, race/ethnicity, and insurance status. Average per capita cost for diabetes supplies by age/sex/race stratum is calculated from MEPS (excluding over-the-counter medications owing to lack of data on whether diabetes increases use of such medications).

The 2012 cost study estimated prevalence of diagnosed diabetes among the population in nursing homes by demographic using the 2004 National Nursing Home Survey (NNHS) data but scaled the diabetes prevalence estimates to be consistent with an estimated 32.8% prevalence among nursing home residents obtained from the existing literature (8). In this iteration of the study, we use the 2015 Centers for Medicare & Medicaid Services (CMS) MDS data to estimate diabetes prevalence among this population and find that the estimated prevalence of diagnosed diabetes is 25% among the nursing home population in 2017.

Nursing/residential facility use attributed to diabetes is estimated using an attributable risk approach where the prevalence of diabetes among residents is compared with the prevalence of diabetes among the overall population in the same age/sex stratum. The analysis is conducted separately for long-stay and residential facility residents to estimate total days of care. Unlike the 2012 study, due to data unavailability there is no separate analysis done for short stays at nursing/residential facilities. Similar to the previous studies, cost per day per

resident is obtained from a geographically representative cost of care survey for 2017 (9).

Hospice days attributed to diabetes represent a combination of length of stay and diabetes prevalence among hospice residents. The 2007 NHHCS is used to calculate the number of hospice residents with diabetes and those that have a primary diagnosis of diabetes along with the average length of stay for each age/sex/race stratum. Based on more recent estimates available from the National Hospice and Palliative Care Organization (NHPCO) on diabetes prevalence among hospice residents (10), the 2007 NHHCS-based prevalence estimates for the various strata are adjusted and updated to impute the 2017 diabetes prevalence. Cost per hospice resident per day is based on the 2017 report from NHPCO (11) and is combined with hospice days attributed to diabetes to estimate total cost of hospice care attributed to diabetes.

The 2011–2015 MEPS files are pooled to increase sample size to analyze use of home health, podiatry, ambulance services, and other equipment and supplies. These cost components are estimated by comparing annual per capita cost for people with and without diabetes, controlling for age. Due to small sample size, sex and race/ethnicity are not included as a stratum when calculating costs per capita.

### Estimating the Indirect Cost Attributed to Diabetes

The indirect costs associated with diabetes include work days missed due to health conditions (absenteeism), reduced work productivity while working due to health conditions (presenteeism), reduced workforce participation due to disability, household productivity losses, and lost productivity due to premature mortality (12). The approach mirrors that used in the 2012 study but with more recent data.

- **Absenteeism** is defined as the number of work days missed due to poor health among employed individuals, and prior research finds that people with diabetes have higher rates of absenteeism than the population without diabetes. Estimates from the literature range from no statistically significant diabetes effect on absenteeism to studies reporting 1–6 extra missed work days (and odds ratios of 1.1 to 1.6) (13,14).

from 1.5 to 3.3) (12–14). Analyzing 2014–2016 NHIS data and using a negative binomial regression to control for overdispersion in self-reported missed work days, we estimate that people with diabetes have statistically higher missed work days—ranging from 1.0 to 4.2 additional days missed per year by demographic group, or 1.7 days on average—after controlling for age-group, sex, race/ethnicity, diagnosed hypertension status (yes/no), and body weight status (normal, overweight, obese, unknown). Diabetes is entered as a dichotomous variable (diagnosed diabetes = 1; otherwise 0) as well as an interaction term with age-group. Controlling for hypertension and body weight produces more conservative estimates of the diabetes impact on absenteeism, as comorbidities of diabetes are correlated with body weight status and a portion of hypertension is attributed to diabetes.

- **Presenteeism** is defined as reduced productivity while at work among employed individuals and is generally measured through worker responses to surveys. These surveys rely on the self-reported inputs on the number of reduced productivity hours incurred over a given time frame. Multiple recent studies report that individuals with diabetes display higher rates of presenteeism than their peers without diabetes (12,15–17). We model productivity loss associated with diabetes-attributed presenteeism using the estimate (6.6%) from the 2012 study—which is toward the lower end of the 1.8–38% range reported in the literature.

- **Inability to work** associated with diabetes is estimated using a conservative approach that focuses on unemployment related to long-term disability. Logistic regression with 2014–2016 NHIS data suggests that people aged 18–65 years with diabetes are significantly less likely to be in the workforce than people without diabetes. It is unclear to what extent people with diabetes voluntarily leave the workforce or do so because of diabetes. Therefore, we use a conservative approach (which likely underestimates the cost associated with inability to work) to estimate the economic burden associated with reduced labor force participation. Using logistic regression, we estimate the relationship between diabetes and receipt of Supplemental Security Income (SSI) payments for disability—controlling for age-group, sex, race/ethnicity, hypertension status, and body weight status (normal, overweight, obese). Diabetes status is included in the regression both as a separate variable and interacted with age-group to provide age-specific impacts. Study results suggest that people with diabetes have a 3.1 percentage point higher rate of being out of the workforce and receiving disability payments compared with their peers without diabetes. The diabetes effect increases with age and varies by demographic—ranging from 2.1 percentage points for non-Hispanic white males aged 60–64 years to 10.6 percentage points for non-Hispanic black females aged 55–59 years. The average daily earnings estimated from

the CPS for those in the workforce are used as a proxy for the economic impact of reduced employment due to chronic disability. SSI payments are considered transfer payments and therefore are not included in the cost estimates.

- **Reduced productivity for those not in the workforce** is included in our estimate of the national burden. This population includes all adults aged <65 years who are not employed (including those voluntarily or involuntarily not in the workforce). The contribution of people not in the workforce to national productivity includes time spent providing child care, household activities, and other activities such as volunteering in the community. We use per capita absenteeism estimates for the working population as a proxy for reduced productivity days among the nonemployed population in a similar demographic. Whereas each work day lost due to absenteeism is based on estimated average daily earnings, there is no readily available measure of the value of a day lost for those not in the workforce. Some studies use minimum wage as a proxy for the value of time lost, but this may underestimate the value of time. Using average earnings for their employed counterparts will overestimate the value of time. Similar to the 2012 study, we use 75% of the average earnings for people in the workforce as a productivity proxy for those aged <65 years not in the labor force (which is close to the midpoint between minimum wage and average hourly wage earned by a demographic

**Table 1—Health resource use in the U.S., by diabetes status and type of service, 2017 (in millions of units)**

Health resource	Population with diabetes				Incurred by population without diabetes	U.S. total*
	Attributed to diabetes		Incurred by people with diabetes			
	Units	% of U.S. total	Units	% of U.S. total		
Institutional care						
Hospital inpatient days	22.6	13.9	40.3	24.8	122.2	162
Nursing/residential facility days	57.3	7.5	200.0	26.1	567.3	767
Hospice days	0.3	0.3	14.2	12.7	97.8	112
Outpatient care						
Physician office visits	121.6	12.5	208.6	21.5	760.4	969
Emergency department visits	7.2	5.2	16.8	12.2	121.1	138
Hospital outpatient visits	13.5	11.7	22.2	19.2	93.0	115
Home health visits	10.1	5.0	43.0	21.2	159.9	203
Medication prescriptions	664.4	16.6	1,092.8	27.4	2,898.0	3,991

Data sources: NIS (2014), CMS MDS (2013), NAMCS (2013–2015), NHAMCS (2012–2014), MEPS (2011–2015), and NHHCS (2007), OptumInsight dNHI (2015), and Medicare 5% SAFs (2014). \*Numbers do not necessarily sum to totals because of rounding.

**Table 2—Health care expenditures in the U.S., by diabetes status and type of service, 2017 (in millions of dollars)**

Cost component	Population with diabetes				Population without diabetes	Total*
	Attributed to diabetes		Total incurred by people with diabetes			
	Dollars	% of U.S. total	Dollars	% of U.S. total		
Institutional care						
Hospital inpatient	69,661	14	122,729	25	362,855	485,584
Nursing/residential facility	6,439	7	24,484	25	71,934	96,419
Hospice	64	0.3	3,180	13	21,933	25,114
Outpatient care						
Physician office	29,990	12	51,882	21	190,024	241,906
Emergency department	7,990	5	18,651	12	133,894	152,545
Ambulance services	332	8	700	17	3,356	4,056
Hospital outpatient	12,049	10	21,012	18	98,872	119,884
Home health	3,388	5	14,479	21	53,824	68,303
Podiatry	252	10	607	25	1,835	2,442
Outpatient medications and supplies						
Insulin	14,981	100	14,981	100	0	14,981
Diabetes supplies	3,723	100	3,723	100	0	3,723
Other antidiabetes agents†	15,855	100	15,855	100	0	15,855
Prescription medications	71,235	17	117,160	27	310,697	427,856
Other equipment and supplies‡	1,310	4	4,564	16	24,796	29,360
Total	237,269	14	414,427	24	1,277,908	1,692,335

Data sources: NIS (2014), CMS MDS (2013), NAMCS (2013–2015), NHAMCS (2012–2014), MEPS (2011–2015), NHHCS (2007), NHIS (2014–2016), OptumInsight dNHI (2015), and Medicare 5% SAFs (2014). \*Numbers do not necessarily sum to totals because of rounding. †Includes oral medications and noninsulin injectable antidiabetes agents such as exenatide and pramlintide. ‡Includes but is not limited to eyewear, orthopedic items, hearing devices, prosthesis, bathroom aids, medical equipment, and disposable supplies.

similar to the unemployed aged <65 years).

- **Premature mortality** associated with diabetes reduces future productivity (and not just the current year productivity). Ideally, to model the value of

lost productivity in 2017 associated with premature mortality, one would calculate the number and characteristics of all people who would have been alive in 2017 but who died prior to 2017 because of diabetes. Data

limitations prevent using this approach. Instead, we estimate the number of premature deaths associated with diabetes in 2017 and calculate the present value of their expected future earnings. To estimate the total

**Table 3—Health care expenditures attributed to diabetes in the U.S., by age-group and type of service, 2017 (in millions of dollars, with percentages in parentheses)**

Cost component	Age (years)		
	<65 (N = 13.7 million)	≥65 (N = 11.0 million)	Total* (N = 24.7 million)
<b>Institutional care</b>			
Hospital inpatient	24,835 (36)	44,826 (64)	69,661
Nursing/residential facility	2,568 (40)	3,871 (60)	6,439
Hospice	6 (9)	58 (91)	64
<b>Outpatient care</b>			
Physician office	9,591 (32)	20,399 (68)	29,990
Emergency department	4,258 (53)	3,732 (47)	7,990
Ambulance services	105 (32)	227 (68)	332
Hospital outpatient	5,322 (44)	6,728 (56)	12,049
Home health	2,588 (76)	801 (24)	3,388
Podiatry	94 (37)	158 (63)	252
<b>Outpatient medications and supplies</b>			
Insulin	8,850 (59)	6,132 (41)	14,981
Diabetes supplies	2,272 (61)	1,452 (39)	3,723
Other antidiabetes agents†	8,456 (53)	7,399 (47)	15,855
Prescription medications	21,702 (30)	49,534 (70)	71,235
Other equipment and supplies‡	783 (60)	527 (40)	1,310
<b>Total*</b>	<b>91,428 (39)</b>	<b>145,841 (61)</b>	<b>237,269</b>
<b>Average cost per person with diabetes (actual dollars)</b>	<b>6,675</b>	<b>13,239</b>	<b>9,601</b>

Data sources: NIS (2014), CMS MDS (2013), NAMCS (2013–2015), NHAMCS (2012–2014), MEPS (2011–2015), NHHCS (2007), NHIS (2014–2016), OptumInsight dNHI (2015), and Medicare 5% SAFs (2014). \*Numbers do not necessarily sum to totals because of rounding. †Includes oral medications and noninsulin injectable antidiabetes agents. ‡Includes but is not limited to eyewear, orthopedic items, hearing devices, prosthesis, bathroom aids, medical equipment, and disposable supplies.

**Table 4—Health care expenditures attributed to diabetes in the U.S., by demographic**

Characteristics	Diabetes prevalence	Total direct cost (\$, millions)	Average cost per person with diabetes (\$, actual)
<b>Age (years)</b>			
<18	110,000	860	7,510
18–34	1,020,000	6,850	6,740
35–44	1,920,000	10,510	5,480
45–54	4,060,000	26,140	6,440
55–59	3,050,000	22,600	7,400
60–64	3,530,000	24,460	6,920
65–69	3,590,000	46,710	13,030
≥70	7,430,000	99,140	13,340
<b>Sex</b>			
Male	12,810,000	128,830	10,060
Female	11,900,000	108,450	9,110
<b>Race/ethnicity</b>			
White, non-Hispanic	15,080,000	150,260	9,800
Black, non-Hispanic	4,030,000	42,240	10,470
Other, non-Hispanic	1,890,000	14,880	7,890
Hispanic	3,710,000	29,900	8,050

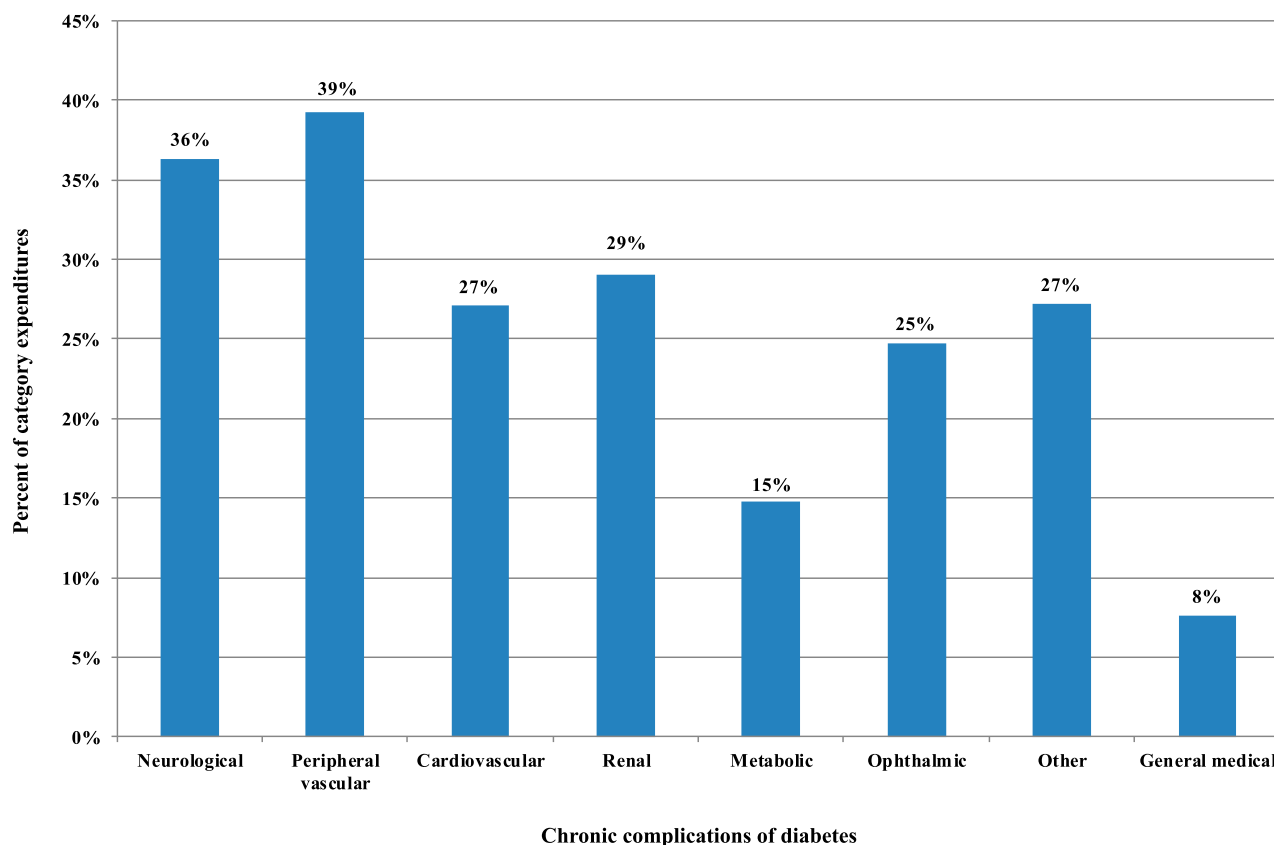
Data sources: NIS (2014), CMS MDS (2013), NAMCS (2013–2015), NHAMCS (2012–2014), MEPS (2011–2015), NHHCS (2007), NHIS (2014–2016), OptumInsight dNHI (2015), and Medicare 5% SAFs (2014).

number of deaths attributable to diabetes, we analyzed the CDC's 2015 Mortality Multiple Cause File to obtain mortality data by age, sex, and race/

ethnicity for cardiovascular disease, cerebrovascular disease, renal failure, and diabetes. We use the same estimates as our previous study: ~16%

of cardiovascular disease (excluding cerebrovascular disease) deaths can be attributed to diabetes, and ~28% of deaths listing cerebrovascular disease as the primary cause and ~55% of deaths listing renal failure as the primary cause can be attributed to diabetes. To generate 2017 estimates, we grow the 2015 CDC mortality data using the annual population growth rate from 2015 to 2017 for each age, sex, and race/ethnicity group.

Productivity loss associated with early mortality is calculated by taking the net present value of future productivity (PVFP) for men and women by age and race/ethnicity using the same discount rate (3%), assumptions, and equation outlined in the 2008 American Diabetes Association report (4). We combined average annual earnings from the CPS, expected mortality rates from the CDC, and employment rates from the CPS by age, sex, and race/ethnicity to calculate the net present value of future earnings of a person who dies prematurely.



**Figure 1—Percent of medical condition-specific expenditures associated with diabetes.** Data sources: NIS (2014), CMS MDS (2013), NAMCS (2013–2015), NHAMCS (2012–2014), MEPS (2011–2015), NHHCS (2007), NHIS (2014–2016), OptumInsight dNHI (2015), and Medicare 5% SAFs (2014). See Supplementary Appendix 2 for diagnosis codes for each category of medical condition.

Employment rates for 2015 are used to calculate PVFP.

We do not count productivity loss for the population aged <18 years. While children constitute a small proportion of the population with diabetes, omitting productivity loss associated with diabetes among children could bias low the cost estimates. For example, the economic cost associated with parents who take time off from work to take their children to the doctor for diabetes-related visits is omitted from these cost estimates.

## RESULTS

In 2017, an estimated 24.7 million people in the U.S. are diagnosed with diabetes, representing ~7.6% of the total population (and 9.7% of the adult population). The estimated national cost of diabetes in 2017 is \$327 billion, of which \$237 billion (73%) represents direct health care expenditures attributed to diabetes and \$90 billion (27%) represents lost productivity from work-related absenteeism, reduced productivity at work and at home, unemployment from chronic disability, and premature mortality. Particularly noteworthy is that excess costs associated with medications constitute 43% of the total direct medical burden. This includes nearly \$15 billion for insulin, \$15.9

billion for other antidiabetes agents, and \$71.2 billion in excess use of other prescription medications attributed to higher disease prevalence associated with diabetes.

### Health Resource Use Attributed to Diabetes

Table 1 shows estimates of health resource utilization attributed to diabetes and incurred by people with diabetes as a percentage of total national utilization. For example, of the projected 162 million hospital inpatient days in the U.S. in 2017, an estimated 40.3 million days (24.8%) are incurred by people with diabetes, of which 22.6 million days are attributed to diabetes. About one-fourth of all nursing/residential facility days are incurred by people with diabetes. About half of all physician office visits, emergency department visits, hospital outpatient visits, and medication prescriptions (excluding insulin and other antidiabetes agents) incurred by people with diabetes are attributed to their diabetes.

### Health Care Expenditures Attributed to Diabetes

Health care expenditures attributed to diabetes reflect the additional expenditures the nation incurs because of diabetes. This equates to the total health care expenditures for people with diabetes

minus the projected level of expenditures that would have occurred for those people in the absence of diabetes. Table 2 summarizes national expenditure for the cost components included, accounting for nearly \$1.7 trillion in projected expenditure for 2017. Approximately \$414 billion of the total is incurred by people with diabetes, reflecting 1 in 4 (24%) of all health care dollars. Costs attributed to diabetes exceed \$237 billion, or 57% of total medical costs incurred by people with diabetes. For the cost components included, 1 in every 7 health care dollars (14%) is attributed to diabetes.

National health-related expenditures are projected to exceed \$3.5 trillion in 2017 (18), but slightly less than half of these expenditures are included in our analysis. These cost estimates omit national expenditures (and any portion of such expenditures that might be attributable to diabetes) for administering government health and private insurance programs, investment in research and infrastructure, over-the-counter medications, disease management and wellness programs, and office visits to nonphysician providers other than podiatrists (e.g., dentists and optometrists).

The largest contributors to the cost of diabetes are higher use of prescription

**Table 5—Annual per capita health care expenditures in the U.S., by diabetes status, 2017 (in actual dollars)**

Cost component	Unadjusted			Adjusted for age and sex		
	With diabetes (\$)	Without diabetes (\$)	Ratio with to without diabetes	Without diabetes (\$)	Ratio with to without diabetes	Attributed to diabetes (\$)*
<b>Institutional care</b>						
Hospital inpatient	4,966	1,202	4.1	2,147	2.3	2,819
Nursing/residential facility	991	238	4.2	730	1.4	261
Hospice	129	73	1.8	126	1.0	3
<b>Outpatient care</b>						
Physician office	2,099	629	3.3	886	2.4	1,213
Emergency	755	443	1.7	431	1.7	323
Ambulance services	28	11	2.5	15	1.9	13
Hospital outpatient and freestanding ambulatory surgical center	850	327	2.6	363	2.3	488
Home health	586	178	3.3	449	1.3	137
Podiatry	25	6	4.0	14	1.7	10
<b>Outpatient medications and supplies</b>						
Insulin	606	NA	NA	NA	NA	606
Diabetes supplies	151	NA	NA	NA	NA	151
Other antidiabetes agents†	642	NA	NA	NA	NA	641
Prescription medications	4,741	1,029	4.6	1,858	2.6	2,882
Other equipment and supplies‡	185	82	2.2	132	1.4	53
<b>Total*</b>	<b>16,752</b>	<b>4,220</b>	<b>4.0</b>	<b>7,151</b>	<b>2.3</b>	<b>9,601</b>

Data sources: NIS (2014), CMS MDS (2013), NAMCS (2013–2015), NHAMCS (2012–2014), MEPS (2011–2015), NHHCS (2007), NHIS (2014–2016), OptumInsight dNHI (2015), Medicare 5% SAFs (2014), and U.S. Census Bureau (2017). NA, not applicable. \*Numbers do not necessarily sum to totals because of rounding. †Includes antidiabetes agents such as exenatide and pramlintide. ‡Includes but is not limited to eyewear, orthopedic items, hearing devices, prosthesis, bathroom aids, medical equipment, and disposable supplies.

**Table 6—Indirect burden of diabetes in the U.S., 2017 (in billions of dollars)**

Cost component	Productivity loss	Total cost attributable to diabetes (\$)	Proportion of indirect costs*
Work days absent	14 million days	3.3	3.7%
Reduced performance at work	114 million days	26.9	29.7%
Reduced productivity days for those not in labor force	14 million days	2.3	2.6%
Reduced labor force participation due to disability	182 million days	37.5	41.7%
Mortality	277,000 deaths	19.9	22.1%
Total		89.9	100%

Data source: analysis of the NHIS (2014–2016), CPS (2016), CDC mortality data, and U.S. Census Bureau population estimates for 2016 and 2017. \*Numbers do not necessarily sum to totals because of rounding.

medications beyond antihyperglycemic medications (\$71.2 billion), higher use of hospital inpatient services (\$69.7 billion), medications and supplies to directly treat diabetes (\$34.6 billion), and more office visits to physicians and other health providers (\$30.0 billion).

Approximately 61% of all health care expenditures attributed to diabetes are for health resources used by the population aged  $\geq 65$  years, much of which is borne by the Medicare program (Table 3). Dividing total attributed health care expenditures by the number of people with diabetes, we estimate the average annual excess expenditures for the population aged  $< 65$  years and  $\geq 65$  years, respectively, at \$6,675 and \$13,239. Health care expenditures attributed to diabetes generally increase with age, although among younger people, average costs are slightly higher likely due to a higher proportion of these cases being type 1 versus type 2 diabetes, are slightly higher for men (mainly due to men having higher attributable fractions on several key measures), and are highest for the non-Hispanic black population due to a higher use of emergency care and hospital outpatient care (Table 4).

Figure 1 summarizes the proportion of medical expenditures attributed to diabetes for each chronic complication over total U.S. health care expenditure, combining

expenditures for hospital inpatient, hospital outpatient, emergency department, and physician and other provider office visits as well as prescription medications. For patients with diabetes who receive care for peripheral vascular conditions, 39% of these expenditures are attributed to diabetes. For the general medical conditions category (which includes all care not included in the other categories), 8% of expenditures incurred by people with diabetes are attributed to their diabetes.

The population with diabetes is older and sicker than the population without diabetes, and consequently annual medical expenditures are much higher (on average) than for people without diabetes (Table 5). When we compare expenditures for people with diabetes to expenditures for a population of similar age and sex, people with diabetes have health care expenditures that are 2.3 times higher (\$16,752 vs. \$7,151) than expenditures would be expected for this same population in the absence of diabetes. This suggests that diabetes is responsible for an estimated \$9,601 in excess expenditures per year per person with diabetes. This 2.3 multiple is unchanged from the 2007 and 2012 studies.

After adjusting for inflation, the total cost of insulin and other medications to control blood glucose increased by 45%

from 2012 to 2017, to a total of \$31 billion. The inflation-adjusted cost of insulin increased by 110% during the same period. These increases are attributable to both an increase in the number of people using these medications and the cost of the medications themselves.

#### Indirect Costs Attributed to Diabetes

The total indirect cost of diabetes is estimated at \$89.9 billion (Table 6). Major contributors to this burden are reduced employment (\$37.5 billion), presenteeism (\$26.9 billion), and premature mortality (\$19.9 billion). Work days absent (\$3.3 billion) and reduced productivity for those not in the workforce (\$2.3 billion) represent a relatively small portion of the total burden.

Of the estimated 24.7 million people with diagnosed diabetes, analysis of NHIS data suggests that  $\sim 8.1$  million are in the workforce. If people with diabetes participated in the labor force at rates similar to their peers without diabetes, there would be  $\sim 2$  million additional people aged 18–64 years in the workforce. However, using a more conservative approach (described previously) where reduced labor force participation is associated with receiving disability payments, we estimate 756,000 fewer working-age adults in the workforce in 2017—equivalent to 182 million lost

**Table 7—Mortality costs attributed to diabetes, 2017**

Primary cause of death	Total U.S. deaths (thousands)*	Deaths attributed to diabetes		
		Deaths (thousands)	% of U.S. deaths in category	Value of lost productivity (\$, billions)
Diabetes	85	85	100	8.5
Renal disease	72	39	54	1.9
Cerebrovascular disease	150	42	28	1.9
Cardiovascular disease	689	111	16	7.6
Total	NA	277	NA	19.9

\*Data source: CDC National Vital Statistics Reports for total deaths in 2015 by primary cause of death, scaled to 2017 using the annual diabetes population growth rate from 2015 to 2017 for each age, sex, and race/ethnicity group. NA, not applicable.

work days. While disability payments themselves are a cost to the government, from a societal perspective they are considered transfer payments and thus not included in the burden estimates.

The cost of missed work days due to absenteeism is estimated at \$3.3 billion, representing 14 million days. If people not in the workforce had similar rates of days where they are unable to work due to poor health as their employed peers, this would equate to 14 million excess sick days with estimated productivity loss valued at \$2.3 billion.

Reduced performance at work (presenteeism) accounted for 30% of the indirect cost of diabetes. The estimate of a 6.6% annual decline in productivity attributed to diabetes equates to 114 million lost work days per year.

The estimated number of deaths in 2017 attributable to diabetes is 277,000 (Table 7); for 85,000 deaths, diabetes is listed as the primary cause. Of the 689,000 deaths where cardiovascular disease is listed as the primary cause, ~111,000 (16%) are attributable to diabetes. Approximately 42,000 cases where cerebrovascular disease is listed as the primary cause of death are attributable to diabetes, and 39,000 cases where renal disease is listed as the primary cause of death are attributable to diabetes. The average cost per premature death declines with age (reflecting fewer remaining expected working years), and across all premature deaths, cost averaged ~\$71,700 per case.

#### Trends in Diabetes Costs, 2007–2017

Between 2012 and 2017, we estimate that medical costs associated with diabetes increased by 26% (from \$188 billion to \$237.3 billion) when adjusted for general inflation (Fig. 2). Adjusting for both inflation and growth in diabetes prevalence, the excess medical cost per person with diabetes grew by 14% (from \$8,417 to \$9,601 in 2017 dollars) (Fig. 5).

The indirect costs of diabetes grew by 23% when adjusted for general inflation (Fig. 3), which on a per capita basis reflects 11% growth (from \$3,283 to \$3,640 per person in 2017 dollars) (Fig. 5).

Combined, the inflation adjusted total economic burden of diabetes increased from ~\$261 billion in 2012 to \$327.3 billion in 2017 (or 25% growth) (Fig. 4). Adjusted for inflation and growth in diabetes

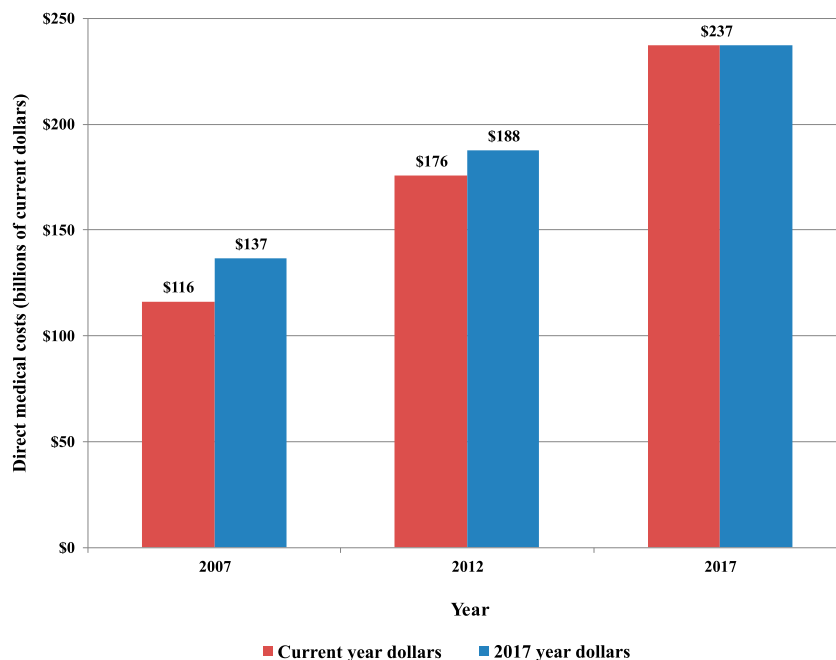


Figure 2—Total direct costs of diabetes, 2007–2017.

prevalence, the average economic cost associated with diabetes increased from \$11,700 to \$13,247 (in 2017 dollars), or 13% growth (Fig. 5).

#### CONCLUSIONS

This study estimates ~24.7 million people (~9.7% of adults) had diagnosed diabetes in the U.S. in 2017. Diabetes costs

the nation ~\$327 billion, which includes \$237 billion in direct medical cost and \$90 billion in lost productivity. Similar to estimates in 2007 and 2012, after adjusting for age and sex, annual per capita health care expenditure is 2.3 times higher for people with diabetes compared with those without diabetes. A large portion of medical costs associated with diabetes costs is for comorbidities.

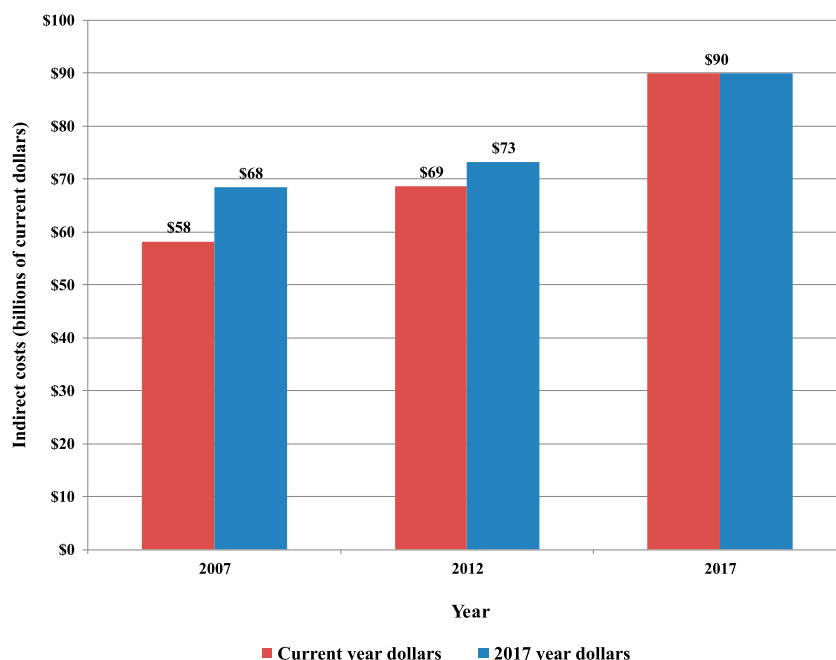
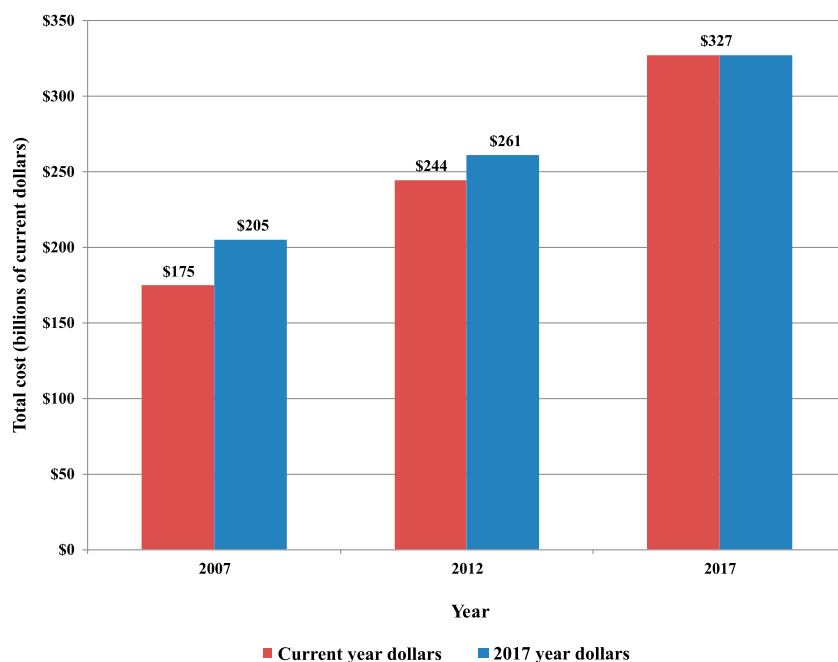


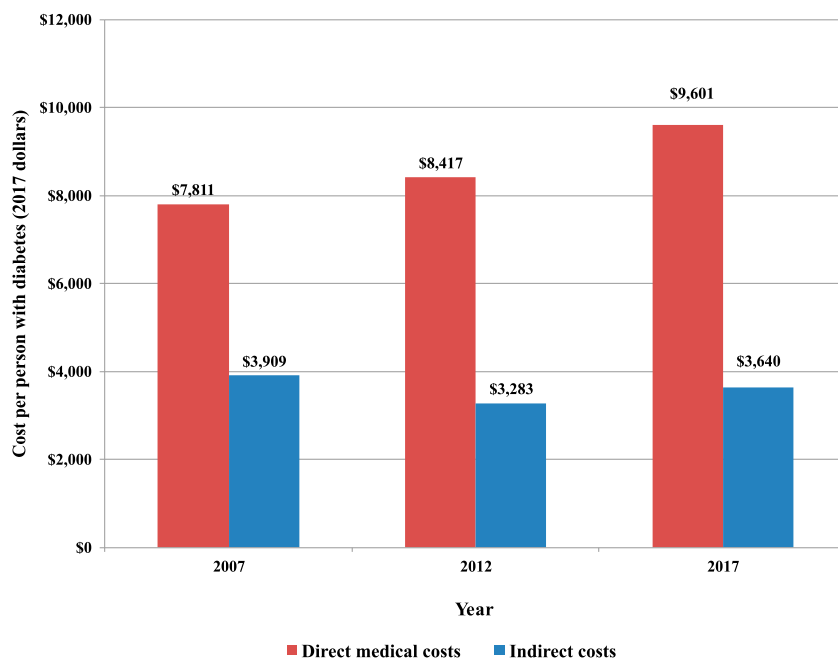
Figure 3—Total indirect costs of diabetes, 2007–2017.



**Figure 4**—Total economic cost of diabetes, 2007–2017.

For costs that include hospital and office-based services as well as prescription medications and supplies, the costs to directly treat diabetes are estimated at \$29.3 billion. An estimated \$37.3 billion in cardiovascular-related spending is associated with diabetes (with the presence of diabetes contributing to higher medical expenditures among patients seeking cardiovascular-related care). Outside of

the chronic complication categories modeled, the presence of diabetes is associated with greater use of health care services in general—including longer stays in the hospital regardless of primary reason for hospitalization. This underscores that simply aggregating all costs associated only with diabetes diagnosis codes grossly underestimates the medical costs directly attributable to diabetes.



**Figure 5**—Average cost of diabetes, 2007–2017 (in 2017 dollars).

While much of the cost of diabetes appears to fall on insurers (especially Medicare) and employers (in the form of reduced productivity at work, missed work days, and higher employer expenditures for health care), in reality such costs are passed along to all of society in the form of higher insurance premiums and taxes, reduced earnings, and reduced standard of living.

Comparing the 2017 estimates with those produced for 2012, the overall cost of diabetes appears to have increased by ~25% after adjusting for inflation, reflecting an 11% increase in national prevalence of diagnosed diabetes and a 13% increase in the average annual diabetes-attributed cost per person with diabetes.

Study limitations include the following:

- Due to data limitations, we omitted from this analysis potential increase in the use of over-the-counter medications and optometry and dental services. Diabetes increases the risk of periodontal disease, so one would expect dental costs to be higher for people with diabetes. Small sample size in MEPS data prevented meaningful analysis of these cost components. We also omitted expenditures for prevention programs targeted to people with diabetes, research activities, and health administration costs. These omissions underestimate the full medical costs associated with diabetes.
- The study omits lost productivity associated with care for diabetes of family members (e.g., time off from work to care for a child or an elderly parent with diabetes). The value of informal care and personal aides is excluded from our cost estimate. Time and costs associated with traveling to doctor visits and other medical emergencies are omitted. These omissions underestimate the indirect costs associated with diabetes.
- Also omitted from the cost estimates are the intangible costs of diabetes such as pain, suffering, and reduced quality of life.
- A complicating factor in estimating costs attributed to diabetes is that health behavior that affects both the presence of diabetes and the presence of other comorbidities, unless controlled for, could result in an overestimate of the link between diabetes and use of health resources. Controlling for demographics helps to control for this correlation. In addition, for the top 10 cost drivers we conducted

additional analysis controlling for other important explanatory variables using MEPS data, and based on the results we reduced the etiological fractions for several diabetes complications and for the general medical conditions group—depending on care delivery setting. This potential limitation also applies to the estimates of indirect costs attributed to diabetes, especially the estimated productivity loss due to presenteeism, potentially biasing these estimates high.

- Other study limitations discussed previously include small sample size for some data sources used, the use of a data source (dNHl) that overrepresents the commercially insured population for the population younger than age 65 years, and the need to use different approaches to model different cost components because of data limitations. Another limitation common to claims-based analysis is the possibility of inaccurate diagnosis codes. Claims data tend to be less accurate than medical records in identifying patients with specific conditions due to reasons such as rule-out diagnosis, coding error, etc. The direction of such bias on our risk ratio calculations is unknown, although it is anticipated to be small as there is no reason to believe that the coding of comorbidities would be significantly different for people with and without diabetes.

Using a methodology that is largely consistent with our previous studies conducted in 2007 and 2012, with updated national survey and claims data from previous data sources, we estimate the total burden of diabetes in 2017. The estimates presented here show that diabetes places an enormous

burden on society and has increased over time—both in the economic terms presented here and in reduced quality of life.

**Duality of Interest.** No potential conflicts of interest relevant to this article were reported.

## References

1. American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. *Diabetes Care* 2013;36:1033–1046
2. Centers for Disease Control and Prevention. National Diabetes Statistics Report [Internet], 2017. Available from <https://www.cdc.gov/diabetes/data/statistics/statistics-report.html>. Accessed 30 November 2017
3. Boyle JP, Thompson TJ, Gregg EW, Barker LE, Williamson DF. Projection of the year 2050 burden of diabetes in the US adult population: dynamic modeling of incidence, mortality, and prediabetes prevalence. *Popul Health Metr* 2010;8:29
4. American Diabetes Association. Economic costs of diabetes in the U.S. in 2007. *Diabetes Care* 2008;31:596–615
5. U.S. Bureau of Labor Statistics. Consumer Price Index (CPI) databases [Internet]. Available from <https://www.bls.gov/cpi/data.htm>. Accessed 30 November 2017
6. Okura Y, Urban LH, Mahoney DW, Jacobsen SJ, Rodeheffer RJ. Agreement between self-report questionnaires and medical record data was substantial for diabetes, hypertension, myocardial infarction and stroke but not for heart failure. *J Clin Epidemiol* 2004;57:1096–1103
7. Benichou J. A review of adjusted estimators of attributable risk. *Stat Methods Med Res* 2001;10:195–216
8. Dybiczy SB, Thompson S, Molotsky S, Stuart B. Prevalence of diabetes and the burden of comorbid conditions among elderly nursing home residents. *Am J Geriatr Pharmacother* 2011;9:212–223
9. Genworth Financial, Inc. Compare long term care costs across the United States [Internet], 2017. Available from <https://www.genworth.com/about-us/industry-expertise/cost-of-care.html>. Accessed 4 December 2017
10. National Hospice and Palliative Care Organization. Hospice policy compendium [Internet], 2016. Available from [https://www.nhpco.org/sites/default/files/public/public\\_policy/Hospice\\_Policy\\_Compendium.pdf](https://www.nhpco.org/sites/default/files/public/public_policy/Hospice_Policy_Compendium.pdf). Accessed 5 December 2017
11. National Hospice and Palliative Care Organization. Facts and figures: Hospice care in America [Internet], 2016. Available from [https://www.nhpco.org/sites/default/files/public/Statistics\\_Research/2016\\_Facts\\_Figures.pdf](https://www.nhpco.org/sites/default/files/public/Statistics_Research/2016_Facts_Figures.pdf). Accessed 5 December 2017
12. Breton M-C, Guénette L, Amiche MA, Kayibanda J-F, Grégoire J-P, Moisan J. Burden of diabetes on the ability to work: a systematic review. *Diabetes Care* 2013;36:740–749
13. Asay GRB, Roy K, Lang JE, Payne RL, Howard DH. Absenteeism and employer costs associated with chronic diseases and health risk factors in the US workforce. *Prev Chronic Dis* 2016;13:E141
14. Gallup-Sharecare Well-Being Index. State of American well-being: The cost of diabetes in the U.S.: Economic and well-being impact [Internet], 2017. Available from [https://info.healthways.com/hubfs/Gallup-Sharecare%20State%20of%20American%20Well-Being\\_Cost%20of%20Diabetes%20FINAL.pdf?t=1510870191218&\\_\\_hstc=56314740.d054ffd56b854b6aed2c4302f7119e90.1512068793130.1512068793130.1512068793130.1&\\_\\_hssc=56314740.5.1512068793131&\\_\\_hsfp=436238590](https://info.healthways.com/hubfs/Gallup-Sharecare%20State%20of%20American%20Well-Being_Cost%20of%20Diabetes%20FINAL.pdf?t=1510870191218&__hstc=56314740.d054ffd56b854b6aed2c4302f7119e90.1512068793130.1512068793130.1512068793130.1&__hssc=56314740.5.1512068793131&__hsfp=436238590). Accessed 30 November 2017
15. DiBonaventura M, Link C, Pollack MF, Wagner JS, Williams SA. The relationship between patient-reported tolerability issues with oral antidiabetic agents and work productivity among patients having type 2 diabetes. *J Occup Environ Med* 2011;53:204–210
16. Loeppke R, Taitel M, Haufle V, Parry T, Kessler RC, Jinnett K. Health and productivity as a business strategy: a multiemployer study. *J Occup Environ Med* 2009;51:411–428
17. Rodbard HW, Fox KM, Grandy S; Shield Study Group. Impact of obesity on work productivity and role disability in individuals with and at risk for diabetes mellitus. *Am J Health Promot* 2009;23:353–360
18. Centers for Medicare & Medicaid Services. National health expenditure data: projected [Internet], 2017. Available from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>. Accessed 30 November 2017

# EXHIBIT 6

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 6

# The Burden of Diabetes in Nevada



**Diabetes is an epidemic in the United States.** According to the Centers for Disease Control and Prevention (CDC), over 30 million Americans have diabetes and face its devastating consequences. What's true nationwide is also true in Nevada.

## NEVADA'S DIABETES EPIDEMIC:

Approximately **291,000 people in Nevada**, or 12.6% of the adult population, **have diabetes**.

- Of these, an estimated **75,000 have diabetes but don't know it**, greatly increasing their health risk.
- In addition, **787,000 people in Nevada**, 38.5% of the adult population, **have prediabetes** with blood glucose levels higher than normal but not yet high enough to be diagnosed as diabetes.
- **Every year** an estimated **14,000 people in Nevada** are diagnosed with diabetes.

**Diagnosed diabetes costs an estimated \$2.8 billion in Nevada each year.**

The serious complications include heart disease, stroke, amputation, end-stage kidney disease, blindness—and death.

## DIABETES IS EXPENSIVE:

People with diabetes have **medical expenses approximately 2.3 times higher** than those who do not have diabetes.

- Total **direct medical expenses** for diagnosed diabetes in Nevada were estimated at **\$2 billion in 2017**.
- In addition, another **\$700 million** was spent on **indirect costs** from lost productivity due to diabetes.

## IMPROVING LIVES, PREVENTING DIABETES AND FINDING A CURE:

In 2018, the **National Institute of Diabetes and Digestive and Kidney Diseases** at the National Institutes of Health invested **\$3,443,015** in diabetes-related research projects in Nevada.

The **Division of Diabetes Translation** at the CDC provided **\$964,532** in diabetes prevention and educational grants in Nevada in 2018.

### Sources include:

- Diabetes Prevalence: 2015 state diagnosed diabetes prevalence, [cdc.gov/diabetes/data](http://cdc.gov/diabetes/data); 2012 state undiagnosed diabetes prevalence, Dall et al., "The Economic Burden of Elevated Blood Glucose Levels in 2012", *Diabetes Care*, December 2014, vol. 37.
- Diabetes Incidence: 2015 state diabetes incidence rates, [cdc.gov/diabetes/data](http://cdc.gov/diabetes/data)
- Cost: American Diabetes Association, "Economic Costs of Diabetes in the U.S. in 2017", *Diabetes Care*, May 2018.
- Research expenditures: 2018 NIDDK funding, [projectreporter.nih.gov](http://projectreporter.nih.gov); 2018 CDC diabetes funding, [www.cdc.gov/fundingprofiles](http://www.cdc.gov/fundingprofiles)

# EXHIBIT 7

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

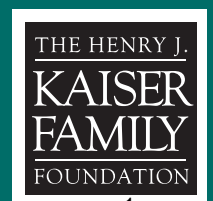
# EXHIBIT 7

# Follow the Pill:

## Understanding the U.S. Commercial Pharmaceutical Supply Chain

Prepared for The Kaiser Family Foundation by:  
The Health Strategies Consultancy LLC

March 2005



JA - 000093

## **Table of Contents**

- I. Executive Summary**
- II. The Flow of Goods from Manufacturers to Consumers in the U.S. Pharmaceutical Supply Chain**
  - Pharmaceutical Manufacturers*
  - Wholesale Distributors*
  - Pharmacies*
  - Pharmacy Benefit Managers (PBMs)*
- III. The Flow of Money and Key Financial Relationships in the U.S. Pharmaceutical Supply Chain**
  - Pharmaceutical Manufacturers*
  - Wholesale Distributors*
  - Pharmacies*
  - Pharmacy Benefit Managers (PBMs)*
- IV. Conclusion**
- V. Appendix**
  - A. Special Pricing Rules Applicable to Federal Programs**
    - Medicaid*
    - Department of Veteran Affairs, Department of Defense, Public Health Service, Coast Guard*
    - Section 340B Drug Pricing Program*
  - B. Other Stakeholders in the U.S. Commercial Supply Chain**
    - Physicians*
    - Large Employers*
    - Health Plans*
- VI. Key Acronyms and Glossary of Key Terms**



## I. Executive Summary

The pharmaceutical supply chain is the means through which prescription medicines are delivered to patients. Pharmaceuticals originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price negotiations and processed through quality and utilization management screens by pharmacy benefit management companies (PBMs); dispensed by pharmacies; and ultimately delivered to and taken by patients. There are many variations on this basic structure, as the players in the supply chain are constantly evolving, and commercial relationships vary considerably by geography, type of medication, and other factors.

The intent of this paper is to demystify the U.S. pharmaceutical supply chain. The first section of the paper describes each of the key players (i.e., industry segments) involved in the process of supplying prescription drugs to consumers. The section begins with a discussion of what each player does and the role that it plays in the flow of pharmaceuticals from manufacturer to patient. The second section of the paper describes the financial relationships between each of these key players and how the dollars flow between and among the segments, including the consumer.

Highlights from this paper about the key players and their financial relationships include:

### *Pharmaceutical Manufacturers:*

- A relatively few large, multinational firms comprise the bulk of the brand pharmaceutical manufacturing industry today – the 10 largest pharmaceutical corporations, as measured by U.S. sales, accounted for almost 60 percent of total U.S. sales in 2004.
- Pharmaceutical manufacturers have the most influence over pharmaceutical prices, assessing expected demand, future competition, and projected marketing costs to establish the wholesale acquisition cost (WAC), which is the baseline price at which wholesale distributors purchase drug products. Discounts and rebates may be applied, based on market share, volume, and prompt payment.

### *Wholesale Distributors:*

- The wholesale distribution industry has consolidated in the last 30 years, with the number of wholesale distributors in the U.S. declining from approximately 200 in 1975 to fewer than 50 in 2000. The top 3 wholesale distributors account for almost 90 percent of the wholesale market.
- Wholesale distributors typically sell drugs to pharmacies at WAC plus some negotiated percentage. They may facilitate discounts negotiated between manufacturers and other customers.

### *Pharmacies:*

- Although comprising a small overall percentage of total prescriptions filled (approximately 6.1 percent in 2004), mail-order pharmacy sales were the fastest-growing sector of the U.S. prescription drug retail market in 2004, increasing by 18 percent over the previous year.

- Pharmacies may negotiate with manufacturers or wholesalers for discounts and rebates based on volume sales or market share, and they may negotiate with PBMs for inclusion in their networks and for their reimbursement (drug cost plus dispensing fee).

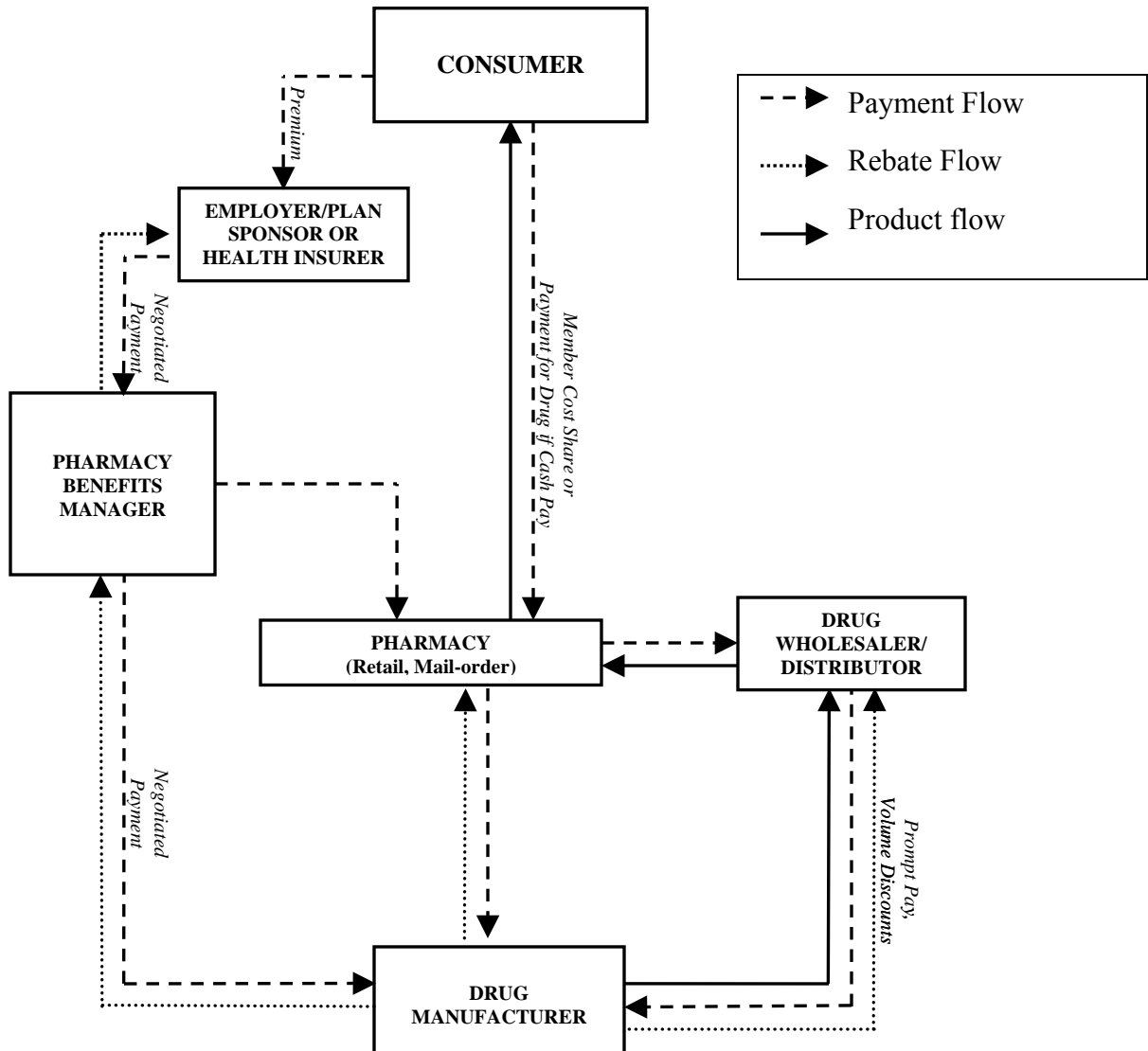
*Pharmacy Benefit Managers (PBMs):*

- Approximately two-thirds of all prescriptions written in the U.S. are processed by a PBM.
- PBMs may achieve savings for their customers by negotiating discounts and through cost containment programs, including use of formularies and cost sharing.

The Appendix briefly describes: (A) special pricing rules applicable to Medicaid and some other federal programs, and (B) the roles physicians, large employers, and health plans have in the pharmaceutical supply chain.

The pharmaceutical supply system is complex, and involves multiple organizations that play differing but sometimes overlapping roles in drug distribution and contracting. This complexity results in considerable price variability across different types of consumers, and the supply chain is not well understood by patients or policymakers. Increased understanding of these issues on the part of policymakers should assist in making rational policy decisions for the Medicare and Medicaid programs.

**Exhibit 1. Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain**



Source: The Health Strategies Consultancy LLC

## **II. The Flow of Goods from Manufacturers to Consumers in the U.S. Pharmaceutical Supply Chain**

### ***Pharmaceutical Manufacturers***

Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs (e.g., Pfizer, Merck, and Novartis) and manufacturers of generic drugs (e.g., Mylan, Roxane, and Barr). There are a few pharmaceutical companies that participate in both the branded and generic parts of the industry, and both models focus on the manufacturing and packaging of pharmaceutical products, but there are other important differences. Most brand manufacturers devote a portion of their expenses to the scientific research and development of new drug therapies. Generic drug manufacturers typically do not develop new drug therapies, but instead manufacture generic compounds that compete directly with the original branded version of a drug once the brand product's patent protection has expired.

Manufacturers manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, and some health plans. Manufacturers may also distribute products directly to government purchasers, such as the Veterans Administration, AIDS Drug Assistance Programs (ADAPs), and Vaccines for Children (VFC), which typically receive the largest price discounts. In a few rare cases, a manufacturer may distribute drugs directly to a self-insured employer with an on-site pharmacy, but the typical employer-sponsored plan does not follow this path. Wholesale distributors are the manufacturers' largest purchasers. Very few drugs are distributed directly to consumers.

At the most basic economic level, a pharmaceutical manufacturer supplies a quantity of its products that is equal to the demand for its products from consumers/patients (of course, consumer demand in this market is expressed through the medium of a prescribing physician or other licensed health care provider). Manufacturers also play roles in stimulating demand for drug products through underwriting clinical studies designed to demonstrate the value proposition of pharmaceutical treatments compared to one another or compared to no clinical treatment at all; by engaging in the promotion and marketing of products to health care providers (including health plans and PBMs) and direct-to-consumer advertising; and by administering patient assistance programs that provide the firm's products at nominal cost to low-income consumers.

Manufacturers also play an important role in ensuring the safety of the pharmaceutical supply chain by producing informational labeling for prescribers and consumers that is consistent with the terms and conditions of a drug's approval by the U.S. Food and Drug Administration (FDA), and by using electronic bar-coding technology on drug packaging that may be used to track individual production lots, and to prevent prescribing errors.

## *Overview of Pharmaceutical Manufacturing Industry*

Pharmaceutical manufacturing is a large global industry. In 2003, worldwide pharmaceutical industry sales totaled \$491.8 billion, an increase in sales volume of 9 percent over the preceding year.<sup>1</sup> The U.S. represents the largest single national market for pharmaceuticals, accounting for 44 percent of global industry sales in 2003, or a total of \$216.4 billion, which was an increase of approximately 12 percent from the previous year's figure.<sup>2</sup>

After a decade of significant mergers and acquisitions by drug companies, a relatively few large, multinational firms comprise the bulk of the brand pharmaceutical manufacturing industry today. The ten largest pharmaceutical corporations, as measured by U.S. sales, accounted for almost 60 percent of total U.S. sales in 2004:

### **Exhibit 2. Top 10 Pharmaceutical Corporations by U.S. Sales, 2004**

<b>Rank</b>	<b>Corporation</b>	<b>U.S. Sales (\$ Billions)</b>	<b>% Growth Over Previous Year</b>	<b>% Market Share</b>
1	Pfizer	\$30.7	5	13.1
2	GlaxoSmithKline	18.8	1	8.0
3	Johnson & Johnson	16.2	7	6.9
4	Merck & Co.	15.0	8	6.4
5	AstraZeneca	11.3	12	4.8
6	Novartis	10.2	7	4.3
7	Sanofi-Aventis	10.0	13	4.3
8	Amgen	9.5	23	4.1
9	Bristol-Myers Squibb	9.2	-4	3.9
10	Wyeth	8.2	11	3.5
	Total, Top 10	139.1	--	59.3

Source: IMS Health, IMS National Sales Perspectives,<sup>TM</sup> February 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891374,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891374,00.html)

<sup>1</sup>IMS Health, "Bruised But Triumphant," *Medical Marketing and Media*, May 2004, accessed at [http://www.imshealth.com/vgn/images/portal/cit\\_40000873/23/12/55250930BruisedTriumphant081804.pdf](http://www.imshealth.com/vgn/images/portal/cit_40000873/23/12/55250930BruisedTriumphant081804.pdf)

<sup>2</sup>IMS Health, "IMS Reports 11.5 Percent Dollar Growth in '03 U.S. Prescription Sales," February 17, 2004, accessed at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_3665\\_44771558,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_44771558,00.html). Prescription sales figures reported by IMS Health represent manufacturer prices.

When measured by prescription volume, the “top 10” list is similar but not identical, as a few generic drug manufacturers appear on the list:

**Exhibit 3. Top 10 Pharmaceutical Corporations by Total U.S. Dispensed Prescriptions, 2004**

Rank	Corporation	U.S. Prescriptions (Millions)	% Growth Over Previous Year	% Market Share
1	Pfizer	360.7	-4	10.2
2	Novartis	225.5	-2	6.4
3	Teva*	221.2	7	6.3
4	Mylan Labs*	215.2	4	6.1
5	Watson*	175.6	7	5.0
6	GlaxoSmithKline	138.8	-13	3.9
7	Merck & Co.	129.5	3	3.7
8	AstraZeneca	100.4	11	2.9
9	Johnson & Johnson	95.6	-9	2.7
10	Abbott	91.5	-4	2.6
	Total, Top 10	1754.0		49.8

\* Generic drug manufacturers

Source: IMS Health, National Prescription Audit™Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913574,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913574,00.html)

Exhibit 4 provides a description of the generic pharmaceutical market:

**Exhibit 4. Top 10 Generic Manufacturers by Total Global Sales, 2003**

Rank	Corporation	Global Sales (\$ Millions)	% Growth Over Previous Year
1	Sandoz	\$4,004.0	
2	Teva Pharmaceutical Industries Limited	3,276.4	30.1
3	IVAX Corporation	1,420.3	18.6
4	Mylan Laboratories Inc.	1,269.2	15.0
5	Alpharma Inc.	1,297.3	4.8
6	Andrx Corporation	1,046.3	35.7
7	Barr Pharmaceuticals, Inc.	902.9	-24.1
8	Par Pharmaceutical Companies, Inc.	661.7	73.4
9	American Pharmaceutical Partners, Inc.	351.3	26.6
10	Eon Labs, Inc.	329.5	34.9

Source: Hoover's, Inc. Hoover's Online, accessed 1/03/2005.

To convey the size of the pharmaceutical manufacturing industry from the perspective of individual products, the following tables present data on the biggest selling pharmaceutical products in the United States in 2004, measured by prescriptions dispensed and by sales in dollars. Exhibits 5 and 6 are for individual drug products, while Exhibits 7 and 8 are for broader therapeutic classes of drugs.

**Exhibit 5. Top 10 Products by Total U.S. Dispensed Prescriptions, 2004**

Rank	Product	Manufacturer	Prescriptions (Millions)	% Growth Over Previous Year	% Market Share
1	Lipitor	Pfizer	74.8	9	2.1
2	HYCD/APAP	Mallinckrodt	49.5	12	1.4
3	Synthroid	Abbott	47.4	-5	1.3
4	Norvasc	Pfizer	38.3	5	1.1
5	Toprol-XL	AstraZeneca	35.0	18	1.0
6	Zoloft	Pfizer	33.1	1	0.9
7	Zocor	Merck	29.6	1	0.8
8	HYCD/APAP	Watson	29.0	-2	0.8
9	Albuterol	Warrick	26.8	0	0.8
10	Amoxicillin	Teva	26.2	-5	0.7

Source: IMS Health, National Prescription Audit™ Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913594,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913594,00.html)

**Exhibit 6. Top 10 Products by U.S. Sales, 2004**

Rank	Product	Manufacturer	U.S. Sales (\$ Billions)	% Growth Over Previous Year	% Market Share
1	Lipitor	Pfizer	\$7.7	14	3.3
2	Zocor	Merck	4.6	4	1.9
3	Prevacid	TAP	3.8	-5	1.6
4	Nexium	AstraZeneca	3.8	23	1.6
5	Procrit	Ortho Biotech	3.2	-3	1.4
6	Zoloft	Pfizer	3.1	8	1.3
7	Epogen	Amgen	3.0	-4	1.3
8	Plavix	Sanofi-Synthelabo	3.0	33	1.3
9	Advair Diskus	GlaxoSmithKline	2.9	26	1.2
10	Zyprexa	Eli Lilly	2.8	-10	1.2

Source: IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2-28-05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69890133,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69890133,00.html)

**Exhibit 7. Top 10 Therapeutic Classes by Total U.S. Dispensed Prescriptions, 2004**

Rank	Therapeutic Class	Total Prescriptions (Millions)	% Growth over Previous Year	% Market Share
1	Codeine	157.6	5	4.5
2	SSRIs/SNRIs	147.4	4	4.2
3	ACE Inhibitors	143.8	5	4.1
4	HMG-COA Reductase Inhibitors (Statins)	139.8	11	4.0
5	Beta Blockers	120.6	7	3.4
6	Proton Pump Inhibitors	93.1	-2	2.6
7	Thyroid Hormone, Synthetic	90.0	6	2.6
8	Calcium Blockers	88.4	0	2.5
9	Seizure Disorders	84.8	7	2.4
10	Oral Contraceptives	82.5	-3	2.3

Source: IMS Health, National Prescription Audit™ Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68914714,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68914714,00.html)

### Exhibit 8. Top 10 Therapeutic Classes by U.S. Sales, 2004

Rank	Therapeutic Class	U.S. Sales (\$ Billions)	% Growth Over Previous Year	% Market Share
1	HMG-COA Reductase Inhibitors (Statins)	\$15.5	12	6.6
2	Proton Pump Inhibitors	12.5	-3	5.3
3	SSRIs/SNRIs	11.0	1	4.7
4	Antipsychotics, Other	9.1	12	3.8
5	Seizure Disorders	8.2	19	3.5
6	Erythropoietins	8.0	8	3.4
7	Antiarthritics, COX-2 Inhibitors	5.3	0	2.3
8	Calcium Channel Blockers	4.4	1	1.9
9	Angiotensin II Antagonists	4.4	24	1.9
10	Ace Inhibitors	3.9	-5	1.7

Source: IMS Health, IMS National Sales Perspectives,<sup>TM</sup> February 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891394,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891394,00.html)

### Wholesale Distributors

Wholesale distributors purchase pharmaceutical products from manufacturers and distribute them to a variety of customers, including pharmacies (retail and mail-order), hospitals, and long-term care and other medical facilities (e.g., community clinics,

physician offices and diagnostic labs). Some wholesalers sell to a broad range of potential clients while others specialize in sales of particular products (e.g., biologic products) or sales to particular types of customers (e.g., nursing homes).

#### Exhibit 9. Wholesale Distribution Industry

In 2004, the wholesaler distributor industry is valued at approximately \$212 billion in annual U.S. sales. The following three wholesalers represent 88% of the market:

##### 1) McKesson

- Merged with health-care software giant HBO & Co. in 1998
- Rolling 12-month sales as of September 2004: \$72.2 billion; Market Share: 34.1%

##### 2) Cardinal Health

- From 1999 – 2002, Cardinal merged with many other wholesalers including Allegiance Corporation and Bindley Western Industries
- Rolling 12-month sales as of September 2004: \$63.3 billion; Market Share: 29.9%

##### 3) AmerisourceBergen

- Began operations in August 2001 following merger of AmeriSource Health Corporation and Bergen Brunswig Corporation
- Rolling 12-month sales as of September 2004: \$52.4 billion; Market Share: 24.8%

Source: *GICS Sub-Industry Revenue Share (09/04/2004)*.  
Copyright © 2004 Standard & Poor's.

In the past, wholesalers limited their operations to a traditional distribution function. They provided the link between manufacturers and pharmacies (and other entities, e.g., government sites and physicians) by warehousing products and managing inventory. While “traditional” distribution services remain the cornerstone of the business, the industry has developed a more comprehensive list of services in response to the evolving

marketplace. Today, wholesale distributors provide a number of specialized services, including specialty drug distribution, drug repackaging, electronic order services, reimbursement support, and drug buy-back programs.<sup>3</sup>

The wholesale distribution industry has gone through significant change and consolidation in the last 30 years, due in part to the increasing pressures to lower costs. Between 1975 and 2000, the number of wholesale distributors in the U.S. declined from approximately 200 to fewer than 50.<sup>4</sup> The top three wholesale distributors, McKesson, Cardinal Health, and Amerisource-Bergen, account for almost 90 percent of the entire wholesale drug market.<sup>5</sup>

This consolidation has forced the industry to change its revenue model, evolving its core distribution business into a low-margin enterprise that makes money by maximizing economies of scale, creating physical efficiencies in the distribution system (such as “just-in-time” deliveries to customers), and realizing financial efficiencies (such as retaining discounts for prompt payment). The industry has also extended and augmented its business model by moving into specialty pharmacy and disease management services.

### ***Pharmacies***

Pharmacies are the final step on the pharmaceutical supply chain before drugs reach the consumer/patient. Pharmacies purchase drugs from wholesalers, and occasionally directly from manufacturers, and then take physical possession of the drug products. After purchasing pharmaceuticals, pharmacies assume responsibility for their safe storage and dispensing to consumers. Pharmacy operations include maintaining an adequate stock of drug products, providing information to consumers about the safe and effective use of prescription drugs, and facilitating billing and payment for consumers participating in group health benefit plans.

Pharmacies also serve as a vital information link between PBMs, drug manufacturers, and wholesale distributors. Unlike most other sectors of the health care delivery system in the U.S., the pharmaceutical supply chain is highly automated and virtually all claims transactions are handled electronically, rather than on paper. Since they are the final point of sale for pharmaceuticals and the interface between the supply chain and the consumer, pharmacies generate the prescription drug claims information that PBMs, as well as health plans, employers, governments, and other payers, rely upon to measure consumer activity. Other types of information, both quality-focused (e.g., drug-drug interaction warnings) and utilization management-based (e.g., formulary compliance

---

<sup>3</sup> Drug buy-back programs are offered by manufacturers and are facilitated by wholesale distributors. Buy-back programs are intended to minimize the financial risk that pharmacies must assume in stocking products by allowing them to sell unused products or products with near-term expiration dates back to the manufacturer.

<sup>4</sup> Goldman Sachs Industry Report: Health Care Technology & Distribution, February 27, 2003.

<sup>5</sup> Standard & Poor's, *GICS Sub-Industry Revenue Share*, September 4, 2004.

messaging) can originate from other parts of the supply chain, in particular from PBMs, to the pharmacy as a prescription is being dispensed. As the final actor in the supply chain, it is up to the pharmacy to take action based on the information provided. For example, the pharmacy is expected to contact the prescribing physician if the drug prescribed is not on the patient's health plan's formulary or if a lower-cost therapeutic alternative is available.

There are several types of pharmacies, including independent pharmacies, chain drug stores, pharmacies in supermarkets and other large retail establishments, and mail-order pharmacies. Most pharmacies purchase their drug supply from a wholesale distributor, although in some cases, large institutional and retail chain pharmacies, specialty pharmacies, and mail-order pharmacies obtain drugs directly from a manufacturer. These organizations can deal directly with manufacturers because they already possess the operational infrastructure necessary to bypass wholesalers – warehousing facilities, distribution vehicles, and inventory control systems. Once a pharmacy takes possession of the drug products, it distributes the products to physicians or directly to consumers. In addition, there are specialty pharmacies, which specialize in the distribution of high-cost and more complex drug therapies (e.g., self-injectable drugs and biologics).

In 2003, there were 55,000 community retail pharmacies, including 19,000 independent drug stores, 21,000 chain drug stores, and 16,000 pharmacies in supermarkets and other retail merchants.<sup>6</sup> In 2004, there were 3.5 billion prescriptions dispensed in the United States through community pharmacies, including about 1.8 billion filled at chain drug stores, 780 million filled at independent pharmacies, and 470 million filled in supermarkets. Another 214 million prescriptions were filled through the mail.<sup>7</sup>

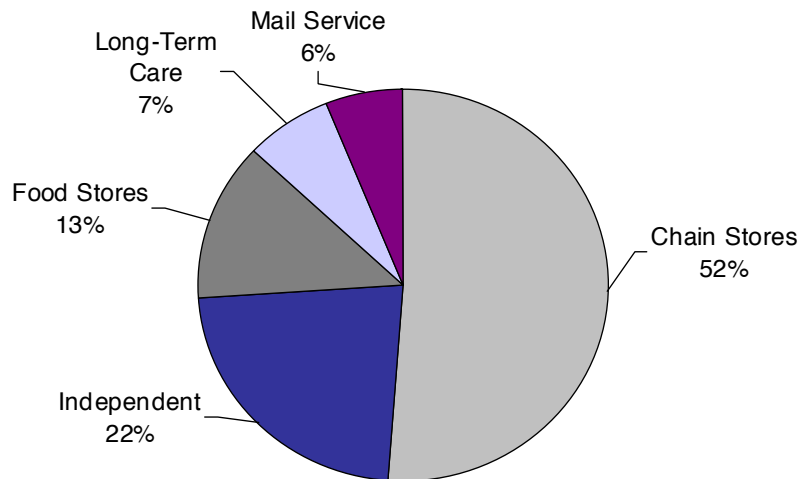
---

<sup>6</sup> National Association of Chain Drug Stores, [http://www.nacds.org/user-assets/PDF\\_files/Retail\\_Outlets2003.pdf](http://www.nacds.org/user-assets/PDF_files/Retail_Outlets2003.pdf).

<sup>7</sup> IMS Health, National Prescription Audit™ Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913551,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html)

Exhibits 10 and 11 depict the distribution of pharmaceuticals in the U.S. through the various types of “retail” pharmacy channels:

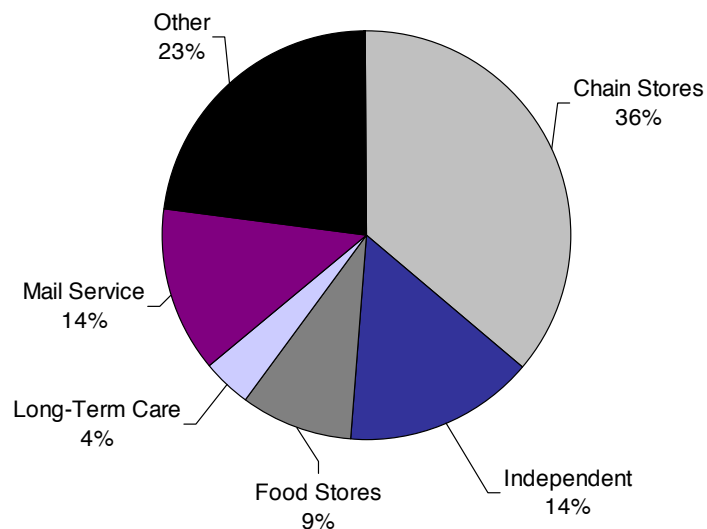
**Exhibit 10. Number of Prescriptions by Pharmacy Distribution Channel, 2004**



Note: Represents total dispensed prescriptions, including insulin dispensed through chain, food store, independent, long term care, and mail service pharmacies.

Source: IMS Health, National Prescription Audit™ Plus, January 2005, accessed 2/28/05 at [www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913551,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html)

**Exhibit 11. Drug Sales by Pharmacy Distribution Channel, 2004**



Note: Represents wholesale prices. Sales include prescription products only.

Source: IMS Health, IMS National Sales Perspectives,™ February 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891354,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891354,00.html)

Like all other parts of the pharmaceutical supply chain, the pharmacy industry has gone through significant consolidation as well as diversification of its businesses over the past five to ten years. Several retail pharmacy chains have merged, primarily as a way to gain buying power for use in negotiations with drug manufacturers and wholesale distributors.

As shown in Exhibit 12, Walgreens, CVS, and Rite Aid were the top three retail pharmacy chains based on market capitalization:

**Exhibit 12. Top 5 Retail Pharmacy Chains in the U.S., By Market Capitalization**

Rank	Pharmacy Chain	2004 Market Cap
1	Walgreens Company	\$35.2 bil.
2	CVS Corporation	\$16.1 bil.
3	Rite Aid	\$2.6 bil.
4	Longs Drug Stores	\$0.7 bil.
5	Duane Reade	\$0.4 bil.
	Total for Industry	\$103.0 bil.

Source: Health Strategies Consultancy analysis of Pharmacy/Drug Store Industry based on market cap data obtained from Dow Jones (factiva.com)<sup>8</sup>

In addition to traditional retail pharmacy services, consumers have increasingly been using specialty and mail-order pharmacies over the past several years. Growth in the use of these types of pharmacies is expected to increase rapidly for the foreseeable future, as more payers adopt the view that these specialized retail distribution channels can be important components of their strategies to manage the rate of growth in their pharmacy benefit expenditures. Residents of long-term care facilities (LTC) rely almost exclusively on dedicated LTC pharmacies.

- **Specialty pharmacies** serve patients with chronic diseases by dispensing high-cost biotechnology drugs. Specialty pharmaceuticals typically are administered by injection or infusion (intravenously), and often, are administered by a clinical professional in a doctor's office. The diseases treated with specialty pharmaceuticals range from relatively common conditions, some of which are treated with multiple drug therapies, such as HIV/AIDS, multiple sclerosis, cancer, and rheumatoid arthritis, to rare diseases that are treated with a single drug therapy, such as hemophilia and growth hormone deficiency. The specialty pharmacy industry today is dynamic, with new companies entering continuously. Types of firms in the market range from publicly-traded stand-alone firms to subsidiaries of PBMs, retail pharmacies, and home health companies.<sup>9,10</sup>

<sup>8</sup> Market capitalization is the value of a company's outstanding shares of stock, which is measured by multiplying the number of shares outstanding by the current share price. Speaking very generally, the larger the market capitalization, the more financially stable the company.

<sup>9</sup> Credit Suisse First Boston, "Pharmacy Benefit Managers and Specialty Pharmacies: Initiating Coverage," July 14, 2003, p. 22.

<sup>10</sup> Raymond James & Associates, Inc., "Specialty Drug Distribution," July 16, 2002, p. 3.

- **Mail-order pharmacies** receive prescriptions by mail, fax, phone, or Internet at a central location; process the prescription in large, mostly automated centers; and mail the prescribed drugs back to the consumer. An aging population, convenience, and the recent upswing in pharmaceutical treatments for common chronic ailments, such as diabetes and depression, are some of the driving forces behind the rapid growth in the use of mail-order pharmacies.<sup>11</sup> While representing a small overall percentage of total prescriptions filled (approximately 6.1 percent in 2004<sup>12</sup>), mail-order pharmacy sales remained the fastest-growing sector of the U.S. prescription drug retail market in 2004, increasing by 18 percent over the previous year.<sup>13</sup> The majority of mail-order facilities are owned and operated by PBMs, and a number of the large retail pharmacy chains also own mail-order pharmacies.<sup>14</sup>
- **Long-term care pharmacies**, sometimes called institutional pharmacies, are a third type of specialized retail pharmacy. Long-term care pharmacies address the special needs of nursing homes, providing packaging for controlled administration (called unit-dose supply or bubble packs), and special services that are more extensive than those provided by retail pharmacies. These special services include: quality assurance checks, emergency drug kits and medication carts, regular and emergency (24-hour-a-day) delivery services, and in-service training programs for nurse aides, nurses, and other professional nursing facility staff. Four national chains provide the bulk of institutional pharmacy services to nursing homes: Omnicare, PharMerica, NeighborCare, and Kindred Healthcare. In 2003, these four chains served over two-thirds of all nursing home beds and had collective revenues of more than \$6 billion.<sup>15</sup> The two largest national long-term care pharmacies, Omnicare and PharMerica (which is a subsidiary of AmerisourceBergen, a wholesale distributor), provide drugs to over half of the nursing home beds in the United States. Omnicare is the largest provider with over \$3 billion in 2003 revenues.<sup>16</sup>

### ***Pharmacy Benefit Managers (PBMs)***

According to one leading report on the PBM industry, PBMs currently manage prescription drug benefits for as much as 57 percent of the U.S. population,<sup>17</sup> and the

<sup>11</sup> National Health Policy Forum, *The ABCs of PBMs*, October 1999.

<sup>12</sup> IMS Health, National Prescription Audit<sup>TM</sup>Plus, January 2005, accessed 2/28/05 at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695974\\_68913551,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695974_68913551,00.html)

<sup>13</sup> IMS Health, IMS National Sales Perspectives,<sup>TM</sup> February 2005, accessed 2/28/05, at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_49695983\\_69891354,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891354,00.html)

<sup>14</sup> California Health Care Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.

<sup>15</sup> Long-Term Care Pharmacy Association, 2003.

<sup>16</sup> Omnicare Annual Report, 2003.

<sup>17</sup> Atlantic Information Services (AIS), Inc., *A Guide to Drug Cost Management Strategies (2<sup>nd</sup> Edition)*, 2004, p. 329. AIS states that its data are based on a quarterly survey that the firm has been using to track all publicly-traded and privately-held PBMs since 2000.

National Association of Chain Drug Stores estimates that approximately two-thirds of all prescriptions written in the U.S. are processed by a PBM.<sup>18</sup> While not a direct link in the physical supply chain for pharmaceutical products (PBMs in most instances do not take possession or control of prescription drugs), PBMs have become an integral part of most consumer drug purchases. PBMs work with third party payers (private insurers, self-funded employers and public health programs) to manage consumer drug purchases by defining which drugs will be paid for and the amounts that the pharmacy will receive and the consumer must pay out-of-pocket when the prescription is filled.

PBMs have evolved over the last three decades from basic claims administrators to more complex organizations offering a wide range of prescription drug management tools. In addition to offering their basic services – claims processing, record keeping, and reporting programs – PBMs offer their customers a wide range of services including drug utilization review, disease management, and consultative services. PBMs also assist clients with establishing their benefit structure. Options for plan design include: developing and maintaining a prescription drug formulary; developing a network of pharmacy providers; and providing mail order fulfillment services. A PBM's core services and tools include:

- **Formularies:** PBMs use formularies to negotiate deeper price discounts with manufacturers, set cost-sharing levels to influence beneficiary utilization rates, and encourage beneficiaries to use a mix of preferred or lower-cost covered products.
- **Rebates:** PBMs negotiate with pharmaceutical manufacturers for rebates on products selected for the formulary. Rebate amounts are based on the contracts negotiated between the PBM and plan sponsors and the PBM and manufacturers. Typically, contracts are structured so that PBMs retain a portion of the rebate in exchange for developing the formulary and negotiating with manufacturers.
- **Pharmacy Networks:** Pharmacy networks consist of pharmacies that have agreed to dispense prescription drugs and provide pharmacy services to a health plan's enrollees under specified terms and conditions. Pharmacy networks can be broad or narrow. These networks allow PBMs to lower prescription drug prices by negotiating the reimbursement rate and dispensing fee with pharmacies.
- **Mail-Order Pharmacy Service:** Almost all PBMs offer mail-order pharmacy service, especially targeted toward individuals with chronic medical conditions who take maintenance medications. The medications are dispensed typically in 90-day amounts per prescription, as opposed to the usual 30-day supply per prescription dispensed by a retail pharmacy. PBMs are able to lower the cost of pharmaceuticals to consumers and payers by using mail-order services to more successfully drive market share for particular products, based on the terms of

---

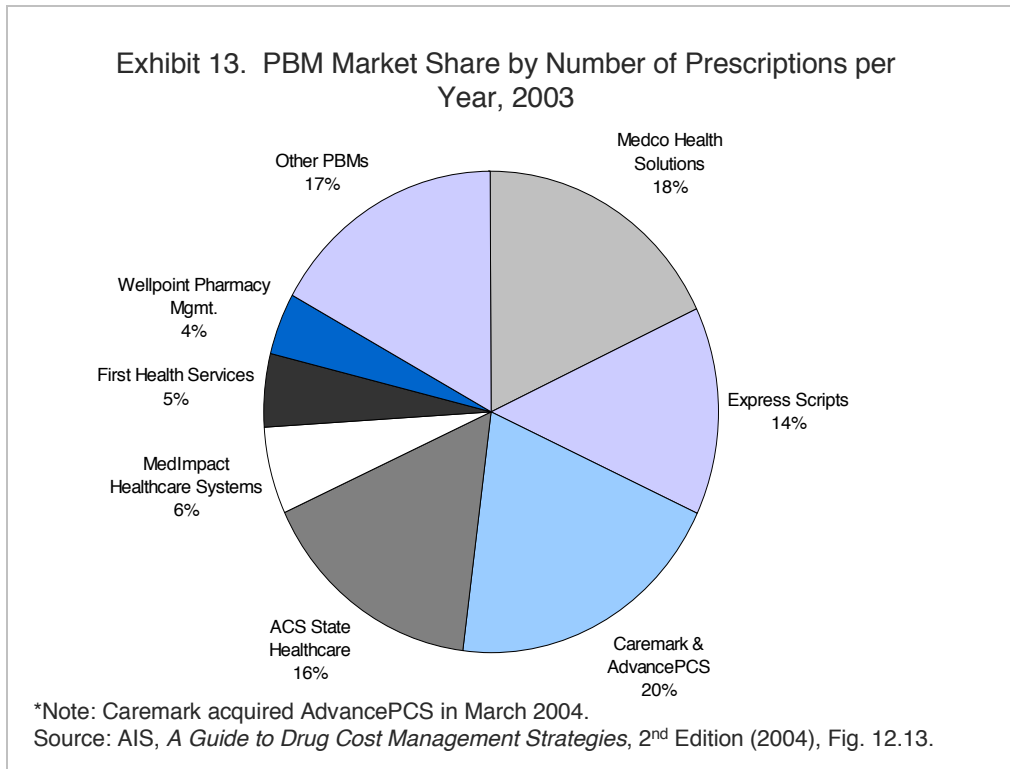
<sup>18</sup> Ibid., p. 331.

contracts negotiated with pharmaceutical manufacturers (e.g., encouraging generic and branded therapeutic substitution and other forms of managing formulary compliance), and (relative to the typical retail pharmacy operation) by automating dispensing processes.

- ***Claims Adjudication:*** All PBMs use a real-time, point-of-sale system linked to retail and mail-order pharmacies and distribution centers. This process provides verification of coverage, formulary restrictions, drug interactions, and individual co-pay information. This process also provides prescription drug information back at the PBM data warehouse, where it can be used for customized reporting and quality-focused clinical and intervention programs.
- ***Generic and Therapeutic Substitution:*** Generic substitution promotes the shift from brand to chemically equivalent generic drugs as a cost savings device. Therapeutic interchange programs promote the use of preferred drugs (i.e., drugs on a plan's formulary) that are determined to be clinically similar.
- ***Quality-Focused Programs:*** PBMs develop programs that provide disease management, compliance strategies, and other clinical expertise promoting the safe, educated use of prescription drugs.

PBMs generally do not take physical possession of prescription drugs when performing their core pharmaceutical management functions. However, in their mail-order and specialty-pharmacy businesses, PBMs buy drugs from wholesalers or manufacturers and dispense them directly to patients in a manner similar to other pharmacies.

During the 1990s, there was a great deal of jockeying within the PBM market, a highly penetrated market compared to just a decade ago. In order to remain competitive, PBMs have merged and acquired new businesses. Most recently, in March 2004, Caremark acquired AdvancePCS; in 2001, Express Scripts acquired National Prescription Administrators; in 2000, Medco Health Solutions acquired Provantage; and in 1998, Express Scripts acquired Value Rx. As shown in Exhibit 13, the PBMs that controlled the most market share measured by prescriptions per year in 2003 were Medco Health Solutions, ACS State Healthcare, AdvancePCS/Caremark, and Express Scripts.<sup>19</sup>



<sup>19</sup> Atlantic Information Services, Inc., *A Guide to Drug Cost Management Strategies*, 2<sup>nd</sup> Edition, 2004.

### **III. The Flow of Money and Key Financial Relationships in the U.S. Pharmaceutical Supply Chain**

The flow of money between manufacturers and end-users is more complex than the physical distribution of drugs. The manufacturer typically interacts with three primary entities when dealing with price: wholesale distributors, retail pharmacies, and pharmacy benefit managers. Pharmaceutical manufacturers negotiate separate contracts with these entities and offer various discounts and rebates based largely on the entities' varying ability to influence the quantity of drugs that are sold. This section looks at these financial relationships and charts the flow of funds among the key players, starting with manufacturers, who play by far the most important role in establishing prices.

#### ***Pharmaceutical Manufacturers***

Manufacturers have the most influence over pharmaceutical prices. They develop algorithms to account for expected demand for the product, future competition for the product, and projected marketing costs, and use those algorithms to establish the “wholesale acquisition cost” (WAC), which is the baseline price at which wholesale distributors purchase products. After the WAC is established, the average wholesale price (AWP), or the retail list price, is established either by the manufacturer or by one of the companies that publishes price compendia. The AWP, and sometimes the WAC, is listed in drug compendia published by a small number of private firms, such as the Red Book, published by Thomson Medical Economics, and First DataBank. The AWP has two purposes: (1) it is often used by public and private third-party payers as the basis for reimbursement, and (2) it often serves as the base price for negotiations between manufacturers and private sector purchasers of drugs (e.g., health plans, pharmacy benefit managers, self-insured employers, etc.).

The negotiation process and the price points on which negotiations are based are different for brand and generic manufacturers. Brand manufacturers typically offer discounts based on a percentage of AWP or WAC, depending upon the purchaser. End purchasers can typically acquire brand drug products for a price in a range of AWP minus 5 to 40 percent, depending upon their purchasing power or that of their designated agent, such as a PBM. Generic pharmaceutical manufacturers operate in a more aggressive and dynamic negotiation environment than brand manufacturers and thus the prices for generic drugs change much more frequently, sometimes daily, in response to market forces. The most common kinds of discounts and rebates include: retroactive rebates based on market share (i.e., rebates paid by the manufacturer to the pharmacy or PBM based on its ability to direct consumers to certain products); volume discounts (discounts that are triggered when predetermined sales volume targets are met); and “prompt pay” discounts (discounts that are triggered when the purchaser reimburses the manufacturer in an expedited fashion).

Pricing for prescription drugs purchased and dispensed by certain federal programs, including Medicaid and the Veterans Administration, are subject to special rules which

generally result in those programs getting lower prices than other purchasers. These rules are outlined in the Appendix.

#### **PRICING TERMS DEFINED**

- **Average Manufacturer Price (AMP):** The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. AMP was a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available. (See Appendix for additional discussion of pharmaceutical pricing in Medicaid).
- **Average Sales Price (ASP):** The weighted average of all non-Federal sales to wholesalers net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to ASP.
- **Average Wholesale Price (AWP):** Although not defined in statute, AWP is recognized as retail list price (sometimes referred to as a “sticker” price) and is currently used by some public and private third-party payers as the basis for reimbursement (e.g., AWP minus 5 or 25 percent). AWP has been widely criticized as a price that is (1) not reflective of the true market price, and (2) easily manipulated. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to average sales price (ASP).
- **Estimated Acquisition Cost (EAC):** EAC is a state Medicaid Agency’s best estimate of the price generally paid by pharmacies for a particular drug.
- **Maximum Allowable Cost (MAC):** MAC lists are designed to cap reimbursement for certain generic and multi-source brand products. States and private payers with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which the program will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing for drugs on a MAC list.
- **Wholesale Acquisition Cost (WAC):** The price paid by a wholesaler for drugs purchased from the wholesaler’s supplier, typically the manufacturer of the drug. Publicly disclosed or listed WAC amounts may not reflect all available discounts.

#### ***Wholesale Distributors***

Wholesale distributors purchase drugs from manufacturers. For branded products, the purchase price is fairly uniform, with little negotiation on the part of the wholesale distributor. The distributor typically purchases branded products for a discounted rate off of WAC. Examples of discounts for branded products include volume discounts, prompt pay discounts, and discounts related to the sale of short-dated products (because the wholesaler is assuming a risk that the product will expire before it can be resold). The wholesale distributor then sells the product to its end consumer, typically a pharmacy, at WAC plus some negotiated percentage.

For generic products, the purchase price is highly variable, largely depending upon competition in the class and the ability of the wholesale distributor to drive market share or increase the volume sold. In this case, wholesale distributors play a larger role in the negotiation of the price of the product. The price to the end consumer also is highly elastic depending upon the negotiated contracts with the retail pharmacies.

In some cases, the wholesale distributor may facilitate discounts negotiated between manufacturers and other customers. For example, wholesaler A may distribute drugs to pharmacy B based on negotiations between pharmacy B and manufacturer C. Although wholesaler A directly distributes the drugs to pharmacy B, it plays a minimal part in pricing negotiations for these drugs. In this case, wholesalers use an important pricing mechanism, *chargeback*, which allows them to carry products destined for customers paying very different prices to manufacturers. The wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then “charges back” the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler’s cost of goods (WAC).

### ***Pharmacies***

Payment for prescription drugs flow from the pharmacy to the manufacturer according to a negotiated contract involving manufacturers, PBMs, and pharmacies. Retail pharmacies negotiate with manufacturers for discounts and rebates based on the pharmacy’s ability to sell specific volumes of certain drugs or achieve a certain share of a specified market. As discussed in the wholesale distributor section, pharmacies may be able to negotiate discounts with manufacturers that are more substantial than the wholesale distributor’s cost. In these instances, the wholesale distributor facilitates the discount and “charges back” the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler’s cost of goods (WAC). Pharmacies also negotiate with PBMs for inclusion in a PBM’s pharmacy network and for reimbursement for the cost of the drug plus dispensing fees.

Manufacturers may offer volume discounts on selected drugs to pharmacies when they achieve predetermined market share targets. These discounts provide an incentive for pharmacists to work with patients and physicians to switch products from a prescribed non-preferred drug to a preferred drug.

Pharmacies contract with PBMs to join their pharmacy network. This structure provides pharmacies with guaranteed, stable reimbursement from private payers and access to a greater number of customers. The network consists of a group of retail and independent pharmacies and serves to offer plan members with lower prescription drug costs. As part of the pharmacy network contract, retail pharmacies must agree to a guaranteed reimbursement formula for prescription drugs. For brand-name medications, the reimbursement formula is usually determined by subtracting a negotiated percentage from the drug’s AWP and adding the dispensing fee. For generic drugs, reimbursement may be determined in the same way as for a brand drug (for less competitive generic drug classes), but more often is based on an amount specified referred to as the maximum allowable cost (MAC).

Smaller retail stores, such as independent pharmacies and smaller retail chains, either purchase directly from wholesalers – at a price significantly higher than retail pharmacies – or join group-purchasing organizations (GPOs). As members of a GPO, small

pharmacies receive the benefits of volume purchasing by leveraging their combined purchasing power to negotiate discount pricing from wholesalers or even in some cases from manufacturers. Some of these groups further reduce their costs through direct rebate deals offered by manufacturers.

Mail-order and specialty pharmacy services are increasingly becoming a more attractive and demanded option for health plan sponsors and other payers seeking to rein in pharmaceutical expenditures for their members. Mail-order and specialty pharmacies are able to generate increased savings by driving market share, streamlining the distribution chain, and automating drug dispensing processes.

- **Specialty Pharmacy:** Most specialty pharmacy providers manage the cost of specialty pharmaceuticals by negotiating directly with manufacturers and by running quality-focused programs intended to improve patient care and lower costs. Large PBMs or retail pharmacy chains own a number of the specialty pharmacies, and in some cases these entities are able to negotiate greater discounts with manufacturers.<sup>20</sup> Nearly all specialty pharmacies also administer programs designed to enforce patient compliance. Industry representatives claim that these programs save the patient and health plan money by averting acute incidences.
- **Mail-Order Pharmacy:** In 2000, the U.S. Department of Health and Human Services estimated that mail-order pharmacies were able to generate savings between two and 35 percent compared to retail pharmacies.<sup>21</sup> Representatives from the mail-order industry attribute these savings to their ability to “manage” prescriptions because the majority of mail-order prescriptions are filled in 90-day units (the equivalent of three prescriptions).<sup>22</sup> The considerable lead time associated with filling a 90-day prescription gives the pharmacists and other clinical staff at a mail-order pharmacy the time to analyze whether the prescribed drug is on the client’s (i.e., insurer’s or health plan’s) approved formulary, if there is a generic equivalent available, and if there are any potential interactions of the prescribed drug with other medications the member’s physician or physicians may have also prescribed.
- **Long-Term Care Pharmacy:** LTC pharmacies have long-term, almost exclusive contracts with nursing homes to provide medications and services for residents. LTC pharmacies capture a large volume of customers in this way. LTC pharmacy chains have developed formularies and use them in many states that do not have Medicaid preferred drug lists (PDLs) applicable in the nursing home setting. The large LTC pharmacy chains negotiate rebates with manufacturers in exchange for

---

<sup>20</sup> Berg, Kevin I. “Health Care Industry Report: The Down Low,” *First Albany Corporation* 6 (2003): 1-153.

<sup>21</sup> Department of Health and Human Services, *Report to the President: Prescription Drug Coverage: Spending Utilization and Prices*, April 2000.

<sup>22</sup> California HealthCare Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.

moving market share on their formularies. In addition to receiving rebates, many pharmacies are reimbursed at higher rates than acquisition costs, because they purchase drugs through wholesalers and group purchasing organizations.

### ***Pharmacy Benefit Managers (PBMs)***

Although PBMs are a relatively unknown entity to the end consumer, they play a fundamental role in negotiating the price that is ultimately paid for the product through their relationships with other entities in the supply chain.

PBMs contract with health plans to manage their prescription drug costs. Each contract is different between health plans and PBMs; however, there are generally three basic components of the payment negotiated between PBMs and their sponsors. First, PBMs receive payment for the services they provide. These services may include claims adjudication processing and disease management services. Second, PBMs typically assume some type of performance risk in the contracts they negotiate. Performance metrics can include: customer service (e.g., adequacy of pharmacy networks, timeliness of reporting), clinical quality measures (e.g., the number of people averted from taking inappropriate medications), and cost management techniques (e.g., the number of generic substitutions made in a given time period). Third, PBMs also retain a portion of rebates they secure from manufacturers.

PBMs do not typically assume full insurance risk for drugs. This type of risk is assumed when an insurer takes full or partial financial responsibility for claims incurred under a specified benefit. Insurance risk can further be segmented into three sub-categories: price, utilization, and selection risk. PBMs do not typically guarantee either the unit prices of drugs, the volume of drugs (utilization) or the kinds of patients that sign up for the drug plan (selection). Insurance risk for drugs is often assumed by self-insured entities in the context of a full medical benefit. For an entity to assume insurance risk, the entity must demonstrate that it has adequate financial reserves, be licensed and overseen by state insurance regulators, and be prepared for underwriting cycles.

While performance risk arrangements are very common for PBMs, insurance risk arrangements are not. During the mid-1990s, some PBMs experimented with risk contracts. ValueHealth, PCS, and Medco had contracts in which the PBM assumed full insurance risk. The contracts typically contained actuarial carve-outs for new biotechnology products and unexpected changes in demographics, but put the PBM at risk for other drug utilization and cost. Many of these contracts were with large manufacturing clients who were self-insured, concerned about drug spending, and bid out the pharmacy benefit competitively to multiple vendors. The experience was uniformly negative from the PBM perspective. The PBMs consistently lost money because they under-estimated the development and diffusion of new technology. Many were able to negotiate out of these contracts, but some contracts persisted until the late 1990s. Most, if not all, are now gone.

PBM relationships with manufacturers are governed under guidance from the Department of Health and Human Services (HHS) Office of the Inspector General, and subject to oversight by the Department of Justice for compliance with federal anti-kickback statutes. PBMs are further regulated in many states under consumer protection statutes. In recent years, some industry practices, for example switching of medications and associated pricing issues, have come under scrutiny by state Attorneys General and the Department of Justice. Allegations have also included accepting undisclosed incentives from pharmaceutical manufacturers, not passing manufacturer rebates through to plan sponsors, and driving beneficiaries unnecessarily to mail-order services for the benefit of the PBM. False Claim Act lawsuits also have been filed by the federal government and several states. Medco Health Solutions settled in April 2004 with twenty State Attorneys General on a case involving therapeutic interchange and price disclosure. While this legal scrutiny has focused on a few industry practices, the typical business practices of PBMs have also been heavily scrutinized by plan sponsors, such as health plans and self-insured employers. Further guidance from the HHS Office of the Inspector General on PBM operations and safe harbors under the anti-kickback statute is expected.<sup>23</sup>

According to a January 2003 study conducted by the federal Government Accountability Office (GAO), PBMs achieved significant discounts for drugs purchased at retail pharmacies (in comparison to cash-paying customers) and offered even greater discounts for their mail-order services.<sup>24</sup> However, cost savings are largely driven by how restrictive or open the cost-containment programs are. This is a point usually negotiated between the health plans and PBMs. For example, open formularies (where consumers are free to access all prescription drugs) typically yield lower cost savings than closed formularies (where consumers are limited to certain drugs). Cost sharing differences by the type of formulary also increase members' sensitivity to prescription drug costs and provides an incentive to use lower-cost or preferred products on the formulary. Common private-sector, cost sharing tools include flat copayments, percent copayments with a minimum/maximum dollar amount, and front-end deductibles with a benefit maximum and/or stop loss.<sup>25</sup>

- ***Manufacturer-PBM Relationship:*** As discussed above, the relationship between manufacturers and PBMs is centered around inclusion of a drug on a plan's formulary and the PBM's ability to increase a manufacturer's market share for certain drugs through inclusion or exclusion on a formulary. Manufacturers pay rebates to PBMs retroactively based on the PBM's ability to meet both of these goals. These rebates are passed in whole or in part back to the employer. According to the California HealthCare Foundation, PBMs are often able to secure rebates of 5-25 percent for branded drugs.<sup>26</sup>

---

<sup>23</sup> For more information about the Medco settlement, see *The Pink Sheet*, May 3, 2004, pages 22-30.

<sup>24</sup> U.S. Government Accountability Office, "Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies," GAO-03-196, January 2003.

<sup>25</sup> Joanne Sica, "Managing prescription drug costs," *Employee Benefits Journal*, March 2001, pp. 35-40.

<sup>26</sup> California HealthCare Foundation, *Navigating the Pharmacy Benefits Marketplace*, January 2003.

- ***PBM-Pharmacy Relationship:*** As discussed above, PBMs negotiate with pharmacies for drug reimbursement and dispensing. The pharmacies negotiate for inclusion in a PBM's pharmacy network. There is often significant tension between the two entities because (1) in general, pharmacies are reimbursed by PBMs at levels below uninsured cash-paying customers and other government payers, like Medicaid, and (2) pharmacies are often required to perform more administrative tasks when filling a prescription for a PBM customer.

## IV. Conclusion

Pharmaceuticals are a vital part of patient care, and their importance will only grow as the population ages and pharmaceutical innovation continues. Understanding current pharmaceutical issues (including the sources of prescription drugs, pricing and discounts, cost containment methods, and brand/generic questions) requires knowledge about the various actors in the supply chain. State and federal policymakers increasingly are looking to private sector financing strategies to shape the ways in which individuals with public coverage receive medications. Passage of the Medicare Modernization Act of 2003 (MMA) makes knowledge about the pharmaceutical chain even more important as the large public Medicare program and its beneficiaries begin to access the chain, and pharmaceutical chain entities make changes in response to the new coverage.

The pricing of prescription drugs and the flow of money among the various links in the pharmaceutical supply chain is more complex than the physical distribution of drugs through the chain. This complexity can result in substantial variations in what different purchasers pay for the same drugs. As we have shown, the price of prescription drugs paid by the consumer is determined by a constellation of negotiated contracts between manufacturers, PBMs, wholesale distributors, pharmacies, and plan sponsors. The price charged by each entity in the chain is largely driven by the ability of contracting entities to sell specific volumes of certain drugs or achieve a certain share of a specified market. It is also affected by the value each entity brings to the subsequent actors in the supply chain.

Rapid increases in spending on pharmaceuticals in recent years have led policymakers to more closely scrutinize drug pricing and the relationships among key actors in the marketplace, and the greatly enhanced federal role in the market brought about through the MMA will only intensify public interest in these areas. Experiences with the Medicare price comparison website for the drug discount card has increased consumer and government interest in internet-based price comparisons. The price differences highlighted by these and other analyses lead to questions about the basis for these pricing differentials. Medicare's activities to detect and remedy fraud and abuse will also require continued oversight and need for transparency and fiscal accountability. Public policy discussions regarding transparency and price disclosure are thus likely to continue to be active over the coming years.

## **V. Appendix**

This Appendix briefly describes: (A) special pricing rules applicable to Medicaid and some other federal programs, and (B) the roles physicians, large employers, and health plans have in the pharmaceutical supply chain.

### **A. Special Pricing Rules Applicable to Federal Programs**

Several federal programs that are significant purchasers of prescription drugs have special rules for pricing.

#### **Medicaid**

Federal rules require that states pay for brand name prescription drugs based on the lower of (1) the estimated acquisition cost (EAC) of a drug (the method most states use); or (2) the usual or customary charge to the public. Most Medicaid programs use a drug's AWP to calculate the EAC, generally AWP minus some percentage. An additional limit, known as the Federal Upper Limit (FUL), applies to the purchase of generic drugs. Manufacturers who want to have their drugs covered by Medicaid also must provide rebates to state Medicaid programs. For brand name drugs, the basic rebate is the larger of (1) 15.1% of the AMP (the average price paid to manufacturers by wholesalers for drugs distributed to retail pharmacies; the AMP is usually lower than the AWP); or (2) the difference between the AMP and the lowest price the manufacturer offers to most other purchasers. An additional rebate is required if the price of brand name drugs rises faster than the change in Consumer Price Index. Rebates for generic drugs are calculated by multiplying the AMP by 11%.

#### **Department of Veterans Affairs, Department of Defense, Public Health Service, Coast Guard**

The Department of Veterans Affairs (VA) administers a program known as the Federal Supply Schedule (FSS), through which the VA and certain other government agencies can purchase prescription drugs at prices that are equal to or lower than the prices that drug manufacturers charge their "most-favored" private customers. In addition, manufacturers must sell brand-name drugs to these agencies at a minimum of 24% off the AMP (known as the federal ceiling price).

#### **Section 340B Drug Pricing Program**

Section 340B of the Public Health Service Act requires drug manufacturers, as a condition of having their drugs covered by Medicaid, to provide prescription drugs to certain nonfederal entities (public and disproportionate share hospitals, community health centers, certain grantees of Federal agencies, and health centers that serve migrant, homeless, public housing, and Native American populations)

at prices that are equal to or below the AMP reduced by the applicable Medicaid rebate percentage.

## **B. The Role of Physicians, Employers and Health Plans in Supply Chain**

### **Physicians**

Physicians play an important role in the pharmaceutical supply chain. They are the first to interact with the consumer (i.e., patient), the end-user in the supply chain. Doctors typically diagnose a patient's illnesses and prescribe a medication. The physician is also responsible for ensuring the appropriate quantity and dosage of the prescribed medication. If the prescribed drug is not covered under the patient's health plan, the physician may have to submit additional information substantiating the necessity of the specific medication for the treatment of the injury or illness. This is called "prior authorization." Once a drug is prescribed, patients typically fill prescriptions at their local retail pharmacies. In some cases, the physician may administer the drug in their office (e.g., chemotherapy).

Historically, patient compliance with whatever treatment the doctor ordered was assumed as part of the physician-patient relationship; increasingly, however, patients are becoming more proactive in their interaction with physicians, particularly in the area of prescription drug treatment decisions. Greater access to health information (fueled, in part, by widespread use of the Internet), the loosening of "direct-to-consumer" (DTC) advertising restrictions on drug manufacturers, and a general increase in the public's awareness of health care issues have helped transform many once-passive patients into inquiring and demanding consumers.<sup>27</sup> This trend has affected physician choices of specific medications prescribed and the modes of delivery used, and it has increased the complexity of the information transmitted to physicians and consumers. Now more than ever, physicians and patients/consumers play a large role in driving the market demand for pharmaceuticals.

### **Large Employers**

Large employers that self insure their employees for health benefits generally negotiate contracts with PBMs (and sometimes with specialty pharmacy companies as well) to provide pharmaceutical coverage to employees. Employers exercise control over the supply chain through the contracts they set with PBMs. The contracts govern the prices of pharmaceuticals paid by the employer, the cost sharing to the insured population, the type of formularies that will be applied, the network standard for pharmacies, and what types of drug utilization review will be applied. Employers pay PBMs either on an administrative services basis, or by

---

<sup>27</sup> *Health Affairs*, March/April 2000.

allowing the PBMs to retain a portion of manufacturer rebates. Employers retain audit rights to exercise oversight of PBM operations.

### **Health Plans**

Health plans employ the use of a range of strategies to manage prescription drug benefits, most of which involve the use of a PBM or PBM-like strategies. There are a few remaining plans that compensate pharmacies on a fee-for-service basis, but plans are using this method less frequently, as it does not allow for use of cost-containment strategies to lower prescription drug costs. More commonly, plans do one of the following: (1) outsource management to an external PBM, (2) operate their own PBM, or (3) outsource claims administration only. Notable exceptions include certain group models, such as that of Kaiser Permanente, which has maintained control of pharmaceutical procurement. Kaiser streamlines the distribution process by purchasing pharmaceuticals from manufacturers and dispensing the medications to consumers at on-site pharmacies.

Regardless of the strategy used, health plans often influence the cost-containment strategies utilized by PBMs. For example, managed care organizations may negotiate a more restrictive formulary or more competitive pharmacy networks. Managed care companies have a greater ability to enforce formulary compliance and to drive consumers to a smaller number of pharmacies.

## VI. Key Acronyms and Glossary of Key Terms

**AMP** – Average Manufacturer Price

**ASP** – Average Sales Price

**AWP** – Average Wholesale Price

**EAC** – Estimated Acquisition Cost

**MAC** – Maximum Allowable Cost

**PBM** – Pharmacy Benefit Manager

**WAC** – Wholesaler Acquisition Cost

**Average Manufacturer Price (AMP)** – The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. AMP was a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available.

**Average Sales Price (ASP)** – The weighted average of all non-Federal sales to wholesalers net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer. The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from AWP to ASP.

**Average Wholesale Price (AWP)** – A national average of list prices charged by wholesalers to pharmacies. AWP is sometimes referred to as a "sticker price" because it is not the actual price that larger purchasers normally pay.

**Estimated Acquisition Cost (EAC)** – EAC is a state Medicaid Agency's best estimate of the price generally paid by pharmacies for a particular drug

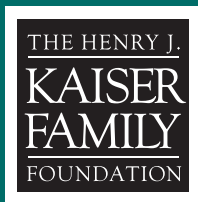
**Maximum Allowable Cost (MAC)** – MAC is a cap set by payers on reimbursement for certain generic and multi-source brand products. States and private payers with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which the program will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing for drugs on a MAC list.

**Medicaid Best Price** – The lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts, or other pricing adjustments, excluding nominal prices. Best price is a variable used in the Medicaid rebate statute to calculate manufacturer rebates owed to State Medicaid agencies. Prices charged to certain governmental purchasers are statutorily excluded from best price including prices charged to the Veterans Administration, Department of Defense, Indian tribes, the Federal Supply Schedule, State Pharmaceutical Assistance Programs, Medicaid, Public Health Service "340B" entities, and Medicare Part D prescription drug plans (starting in 2006). Best price data are reported by manufacturers to CMS, but are not publicly available.

**Reference Pricing** – System of fixed reimbursement for pharmaceuticals, in which the government or other third party payers establish a level at which they are willing to reimburse “interchangeable” products. Manufacturers may charge above the reference price, but patients must pay the excess cost.

**Wholesale Acquisition Cost (WAC)** – The price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. Publicly disclosed or listed WAC amounts may not reflect all available discounts.





## The Henry H. Kaiser Family Foundation

2400 Sand Hill Road, Menlo Park, CA 94025  
Phone: 650-854-9400 Fax: 650-854-4800

Washington Office:  
1330 G Street, NW Washington, DC 20005  
Phone: 202-347-5270 Fax: 202-347-5274

[www.kff.org](http://www.kff.org)

Individual copies of this publication (#7296) are available on the Kaiser Family Foundation's website at [www.kff.org](http://www.kff.org)

*The Kaiser Family Foundation is a non-profit, private operating foundation dedicated to providing information and analysis on health care issues to policymakers, the media, the health care community, and the general public. The Foundation is not associated with Kaiser Permanente or Kaiser Industries.*

# EXHIBIT 8

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 8

**MINUTES OF THE  
SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES**

**Seventy-ninth Session  
May 26, 2017**

The Senate Committee on Health and Human Services was called to order by Chair Pat Spearman at 3:25 p.m. on Friday, May 26, 2017, in Room 2149 of the Legislative Building, Carson City, Nevada. The meeting was videoconferenced to Room 4412 of the Grant Sawyer State Office Building, 555 East Washington Avenue, Las Vegas, Nevada. [Exhibit A](#) is the Agenda. [Exhibit B](#) is the Attendance Roster. All exhibits are available and on file in the Research Library of the Legislative Counsel Bureau.

**COMMITTEE MEMBERS PRESENT:**

Senator Pat Spearman, Chair  
Senator Julia Ratti, Vice Chair  
Senator Joyce Woodhouse  
Senator Joseph P. Hardy  
Senator Scott Hammond

**GUEST LEGISLATORS PRESENT:**

Senator Heidi S. Gansert, Senatorial District No. 15  
Senator Michael Roberson, Senatorial District No. 20

**STAFF MEMBERS PRESENT:**

Megan Comlossy, Policy Analyst  
Eric Robbins, Counsel  
Martha Barnes, Committee Secretary

**OTHERS PRESENT:**

DuAne Young, Chief, Behavioral Health and Pharmacy Services, Division of Health Care Financing and Policy, Department of Health and Human Services  
Khanh Pham, Nevada Pharmacist Association  
Julie Kotchevar, Deputy Administrator, Director's Office, Department of Health and Human Services  
John Jones, Pharmaceutical Care Management Association

Senate Committee on Health and Human Services  
May 26, 2017  
Page 2

Nick Vassiliadis, Pharmaceutical Care Management Association  
Elizabeth MacMenamin, Retail Association of Nevada  
Elyse Monroy, Policy Analyst, Office of the Governor

CHAIR SPEARMAN:

We will open the hearing on Assembly Bill (A.B.) 473.

**ASSEMBLY BILL 473 (1st Reprint)**: Temporarily provides for the continued inclusion of certain drugs on the list of preferred prescription drugs to be used for the Medicaid program. (BDR 38-977)

DUANE YOUNG (Chief, Behavioral Health and Pharmacy Services, Division of Health Care Financing and Policy, Department of Health and Human Services):

Assembly Bill 473 extends the sunset language of *Nevada Revised Statutes* 422.4025 until 2019 and allows the Nevada fee-for-service Medicaid program to continue to manage its atypical and typical antipsychotic medications, anticonvulsant medications and antidiabetic medications on the preferred drug list.

The Governor-appointed Pharmacy and Therapeutics Committee consisting of pharmacists and physicians from Nevada reviews and manages Nevada's Medicaid's preferred drug list (PDO). The PDO is not a closed or tiered formulary. The drugs are either preferred or non-preferred. If a non-preferred drug is requested, the prescribing physician is asked to choose a preferred drug unless there is a clinical rational as to why the non-preferred drug is needed. We have implemented measures to allow those to receive non-preferred medications through either treatment failures or continuity of care mechanisms.

CHAIR SPEARMAN:

I will close the hearing on A.B. 473 and open the hearing on Senate Bill (S.B.) 539.

**SENATE BILL 539**: Revises provisions relating to prescription drugs. (BDR 40-1217)

SENATOR HEIDI S. GANSERT (Senatorial District No. 15):

Over the last few years, the news has highlighted unprecedented increases in drug prices without information to support the increases. Transparency is required in order to help address this issue.

I want to acknowledge Senator Yvanna D. Cancela for her work on S.B. 265. Senator Cancela recognized the need for transparency around prescription drugs essential for treating diabetes and S.B. 265 has gone a long way to create it.

**SENATE BILL 265:** Revises provisions relating to prescription drugs.  
(BDR 40-809)

Patients afflicted with diabetes are captive consumers. I have witnessed first-hand the plight of these patients when visiting Nevadans who have suffered from diabetes or who have family members who are impacted. It was clear that their well-being was dependent on insulin-based drugs and they were facing uncertain costs for medications they cannot live without. Thankfully, insulin products are continually improving, leading to a better quality of life for patients. The retail price paid by patients is unpredictable and can escalate to unaffordable levels over short periods. The pricing scheme from drugmakers to wholesalers, to pharmacies and to the formulary approval process, by a pharmacy benefit manager (PBM), is complex and confusing. They are shrouded in secrecy and the final price paid by a patient may be higher than the actual net cost. Simply stated, pricing is uncertain and poorly understood.

The intent of S.B. 539 is to complement the work by Senator Cancela to further increase transparency around the pricing of essential insulin medications and eliminate the “gag rule” pharmacists are required to follow. The “gag rule” precludes pharmacists from working with patients to identify the best price for life-saving medications.

Senate Bill 539 places requirements in statute to provide greater transparency with respect to drugs that are used to treat diabetes sold in this State and to provide regulation for PBMs. I will read from our mock-up of S.B. 539 which shows Proposed Amendment 5037 in conceptual form ([Exhibit C](#)).

In section 4 of [Exhibit C](#), the Department of Health and Human Services (DHHS) is required to compile a list of prescription drugs used to treat diabetes and which have undergone a significant increase in the wholesale acquisition cost.

Section 4 also requires a manufacturer of a drug included on the list to prepare a report that explains the reasons for the increase in the wholesale acquisition cost of the drug and submit the report to the DHHS. Finally, section 4 requires a manufacturer of any drug, sold or marketed for sale in the State for the treatment of diabetes, to report annually to the DHHS the wholesale acquisition cost of the drug. The DHHS is required to analyze the information by the manufacturers and compile a report of the reasons for the increase and the effect of the price increase on the costs to residents in the State.

Section 6 of [Exhibit C](#) requires the DHHS to place the report on its Website so the public will have access to the information.

Section 8 of [Exhibit C](#) provides a penalty if a manufacturer doing business in the State fails to provide the information to the DHHS.

Section 9 of [Exhibit C](#) excludes the information that a manufacturer or PBM is required to report under this bill from the definition of trade secrets, but only to the extent that the information is required to be disclosed.

Sections 11 to 21 of [Exhibit C](#) have specific requirements for a PBM. A PBM is defined in section 11 as an entity that manages pharmacy benefits that are provided as part of a health care plan offered by an insurer.

Section 18 of [Exhibit C](#) prohibits a PBM from operating in this State without a license issued by the Insurance Commissioner and provides the procedure for obtaining a license.

Section 19 of [Exhibit C](#) places a fiduciary duty on a PBM with respect to any insurer with which the PBM has a contract to manage pharmacy benefits.

Section 20 of [Exhibit C](#) prohibits a PBM from engaging in certain acts that restrict pharmacies and pharmacists. For example, it prohibits restricting a pharmacy or pharmacist from providing certain information to an insured about an alternative drug. It prohibits a PBM from penalizing a pharmacist or pharmacy for providing certain information for less expensive drugs, and it prohibits other conduct that interferes with the conduct of a pharmacy or pharmacist.

Sections 8.4 to 8.8, 26.1, 26.2, 26.25 and 26.4 to 26.9 of [Exhibit C](#) prohibit insurers, including public insurers, from engaging in such conduct.

Section 21 of [Exhibit C](#) requires a PBM to post the rate at which the PBM reimburses each pharmacy in the State for each prescription drug used to treat diabetes that is covered by a plan and managed by the PBM on a publicly available Website that it maintains. In addition, section 21 requires the PBM to submit a report to the Division of Insurance (DOI) each year which includes certain information regarding rebates that the PBM negotiates on prescription drugs used to treat diabetes.

Senate Bill 539 will provide greater transparency regarding the cost of drugs to treat diabetes that are sold in the State and ensure that PBMs are not the sole entities benefiting from rebates provided from the sale of drugs in this State. In addition, S.B. 539 will eliminate the “gag rule” to ensure that pharmacists and pharmacies are not prohibited from discussing less expensive drugs that will meet the needs of the patient.

I would like to show a short video, “How PBMs Lead to Higher Prescription Drug Prices.”

SENATOR MICHAEL ROBERSON (Senatorial District No. 20):

The video you just watched illustrates the problem of the gag rule as it applies to the concept of “spread pricing” the PBMs put on retail pharmacists. Spread pricing prevents pharmacists from helping consumers identify alternative low cost drugs or find the same drug for a lower cost.

Section 20 of [Exhibit C](#) would eliminate the ability of PBMs to impose a gag rule in the State. Whether it is through this bill or the bill of your choosing, if you do nothing else, I hope you will take action to eliminate the PBM gag rule in our State.

In addition to the gag rule, S.B. 539 focuses on providing increased transparency with regard to rebates received by PBMs from drug manufacturers and who ultimately benefits from those rebates. Forty-three states in this Country have passed laws or regulations addressing PBM transparency. To date, Nevada has done nothing to make PBMs transparent.

The PBMs control the distribution of pharmaceutical drugs in this Country by telling drug manufacturers that they will not sell their drugs or include their drugs in their formularies unless they get rebates off the list prices. This is known as the wholesale acquisition price.

It is my understanding that the rebates extracted by PBMs can equal 50 percent to 70 percent of the list price on many diabetes drugs. The question is, what do the PBMs do with the rebates? Do they make sure they are passed on to the consumer to lower the costs of diabetes drugs or do they pocket the rebates themselves?

A study in January of 2017 from the Centers for Medicare and Medicaid Services reported that while drug companies are paying increasingly larger rebates to PBMs, the PBMs are keeping the money rather than converting the proceeds into lower costs for consumers and government health care programs.

In "How PBMs make the drug price problem worse" in *The Hill* newspaper, David Balto, a former policy director in the Office of Policy and Evaluation for the Federal Trade Commission's Bureau of Competition notes:

A large portion of PBM profits are derived from rebates they receive from the drug manufacturers, but don't pass on to their consumers. How big is the difference? Unfortunately, we don't know because the information has not been disclosed to the public ... .

If there was transparency when prices increase employers could 'follow the money,'—they could figure out what rebates are being paid and who received them. Giving them that information would enable employers to bargain effectively and secure lower prices. That's the way markets are supposed to work.

This is what S.B. 539 aims to accomplish.

I am confident the PBMs will deny the extent to which they do this. They conceal this information from their clients, who are insurance companies and the Employee Retirement Income Security Act of 1974 employers, from retail pharmacies and from the drug manufacturers themselves. If asked by you today, they will conceal this information from this Committee.

There are other issues with the PBMs that this Legislature needs to look at. There is a real problem with vertical integration with regard to the PBMs owning pharmacies, specialty pharmacies, and mail order pharmacies. David Balto continued:

PBMs own and operate mail order and specialty pharmacies, but considering their purpose is to control drug dispensing costs, it's hard to believe the fox can guard the henhouse. In a PBM's perfect world, there would be no independent pharmacy and no local pharmacist advocating to make sure patients do not overpay for drugs.

There is also a problem concerning generic drugs with the Maximum Allowable Cost (MAC) lists transparency used by PBMs or other payers. It includes prescription drug products that have an upper limit or maximum allowed reimbursement of generic drugs or brand drugs that have a generic version.

The problem is the PBMs use a MAC list as a revenue stream, typically by using aggressively low MAC pricing to pay their pharmacy networks and another MAC list with higher prices to bill their clients, who are the plan sponsors. This is called "the spread." Many states have addressed MAC transparency. We do not address MAC transparency, the spread or vertical integration in S.B. 539.

I knew nothing about this going into this Session, and since I do not serve on this Committee, I did not follow the deliberations as closely as others did. However, once Senator Gansert and others in the building started to look at this problem, it has become truly disturbing. There are 43 states that have started to do something and Congress is debating what to do.

Whether you pass this bill or put portions of this bill into another vehicle, in the waning days of this Session, I hope you do something at a minimum with the gag rule the PBMs place on pharmacists in the State and look at increased transparency on the rebates that PBMs receive.

SENATOR HARDY:

Are the insulin and diabetic products less expensive in Nevada than in the other 43 states?

SENATOR ROBERSON:

I do not know the answer to that question.

SENATOR HARDY:

I believe this is important and is an opportunity to do something that will allow a person to get a less expensive medicine.

SENATOR ROBERSON:  
I would agree.

SENATOR HAMMOND:  
When we had this discussion a while ago and talked about the whole process of getting the drug manufactured to getting the drug into the consumer's hands, I made it clear that I was in favor of transparency all along the line. In your estimation, without this, where does it leave the consumer?

SENATOR ROBERSON:  
Clearly, nothing will change with regard to what the PBM does or does not do. It is not a complete solution without looking at transparency on PBMs. The very least we can do is prevent PBMs from continuing to put a gag order on pharmacists in our State. A pharmacist should be able to explain to customers how they can get a drug cheaper if they pay cash, or that there is an alternative drug that would cost less.

I also support S.B 265 because we have to address every part of this situation and bring transparency to every part of the supply chain. The middleman in this situation is the PBM, and the PBM is the most opaque part of the supply chain. If we really want to make a difference this Session, with the short amount of time left, we can try to lower costs for diabetic patients in this State. To make a difference and lower the costs of drugs, we must do something with regard to the transparency of the PBM.

SENATOR RATTI:  
Does the gag rule portion of this bill only apply to diabetic drugs?

SENATOR GANSERT:  
No. It is for any medication.

SENATOR RATTI:  
It was very important in other hearings to connect the rebates back to the consumer, and I do not see the connection back to the consumer. How does this help the patients in the "doughnut hole" on Medicaid?

SENATOR GANSERT:  
The PBMs control what is on the formulary for a benefit plan, and they receive the rebates. To put a drug on a plan, the PBM can get a rebate, but that rebate

is not necessarily passed on to the consumer. Therefore, consumers are captive and do not have a choice.

The lack of transparency is from the manufacturer, to the wholesaler, to the PBM who is saying what is going to be on a formulary, to the pharmacy. The middleman, the PBM, is controlling what the price ultimately is.

SENATOR ROBERSON:

The client for a PBM is typically an insurance carrier or a self-insured employer. If there is no transparency between the PBM and its client, then the client does not know that the PBM is getting the rebates. Those rebates are not going to the insurer. If those rebates do not go to the insurer, then the insurer cannot reduce the price of the drug for its enrollees, whether it is for the copay or the premium.

SENATOR RATTI:

This Session I have learned that health care issues are complex, and we need to make sure that we are not having unintended consequences with what is an incredibly complex system. Would you please explain the stakeholder process?

SENATOR ROBERSON:

We have been having discussions for well over a month, if not longer. I have spoken with Senator Cancela and with Barbara Richardson, the head of the Division of Insurance, the Legislative Counsel Bureau, and practically every representative, both of the manufacturers and the PBMs in this building. To be clear, the PBMs do not like this and will vehemently oppose S.B. 539.

SENATOR RATTI:

You have spoken to the pharmaceutical companies and PBMs. Have you spoken with the insurers, the hospitals, the medical associations, retail pharmacists and all of the other players who have an interest?

SENATOR ROBERSON:

Yes, I have spoken to all of those groups and talked to all of them about trying to get to a point where we can get some agreement or common ground on this issue. We have spoken to a retail pharmacist in Las Vegas who has very strong opinions on the PBMs and how they work and would like to testify.

SENATOR RATTI:

Is there still a \$200,000 fiscal note on this bill?

SENATOR ROBERSON:

The fiscal note was removed when we took out the provision that required at least 80 percent of the rebates to be passed on to the consumer.

SENATOR RATTI:

Is the DOI willing to absorb the costs of the collecting and publishing the data?

SENATOR ROBERSON:

Yes.

CHAIR SPEARMAN:

Who made the gag rule?

SENATOR ROBERSON:

The PBMs require the gag rule when contracting with retail pharmacy networks. It is a requirement of doing business with the PBMs.

The PBMs control this market and can require manufacturers to give rebates, and require insurance companies and retail pharmacies to do their bidding to get the drugs that their customers need on the formulary. They control the market.

SENATOR RATTI:

The video that Senator Gansert presented suggested that insurance companies were also a significant part of the challenge. What was the thinking behind focusing on this piece?

SENATOR ROBERSON:

Insurance companies are the most regulated part of the supply chain. A PBM contracts with an insurer, charging a significantly higher price to a health plan, and then enters into a separate agreement with a retail pharmacy network. Essentially, the PBM tells an insurance company this is the price for the drugs in this formulary, and then separately makes agreements with retail pharmacies at a different price. The price they charge in the health plans is larger than the retail pharmacies, and they pocket the difference, which is spread pricing.

SENATOR RATTI:

My point is the video was specifically pointing at insurance companies, and we are not addressing that piece.

SENATOR ROBERSON:

No. It was pointing at PBMs and not insurance companies. The insurance company charges a copay based on what they have to pay for the drugs from the PBM.

SENATOR GANSERT:

On the video, it showed a copayment of \$20, but the price for the drug is only \$1.75. Insurance companies probably have to average out the cost of medications, and they charge a flat fee as a copayment trying to cover all costs.

The PBM actually controls what medications are on a formulary for an insurance company and to do that, it gets rebates and deals with the manufacturers and insurance companies. If you are a manufacturer and want a drug on a formulary that the insurance company defines, a certain price has to be paid and the PBM holds this money. The insurance companies are highly regulated and are trying to flatten the out cost so consumers have an expectation of what the cost will be.

SENATOR RATTI:

I understand the explanation and appreciate the detail. During this Session, I have learned that the insurance companies control step therapy, which drugs a patient is allowed to have at a low cost, or no cost, and what the direct cost is going to be to them. This is just a different form of a gag rule, saying a patient cannot use this drug, but can use another drug. It could be this is being done for cost management. I would argue that insurance companies have just as much influence over which drugs patients are getting and the cost of those drugs as PBMs have.

SENATOR GANSERT:

I think it is the entire supply chain. We are striving to complement S.B. 265, so all of the pieces of the supply chain, not just parts of it and the PBMs are a critical piece of that supply chain, can be seen.

SENATOR RATTI:

Contracts have been an issue that you have spoken quite a bit to, and others have spoken to me and say that the contracts actually require the pharmacist to tell a patient when there is a less expensive drug. Some contracts require pharmacists to say there is a generic available. There have been a lot of conversations this Session about contraception, step therapy and the steps folks are taking to manage costs. In those conversations, I wanted to accomplish many things that were not possible because of an insurance company or perhaps a PBM telling a pharmacy it must use a certain drug in all those steps because it is the most cost-effective drug.

I am having a hard time reconciling what I have learned about the system pushing people to the lowest cost drug, even when it is not the most effective drug, with what you are saying.

SENATOR GANSERT:

There are no generics for diabetes medication and insulin-based products. Pharmacists are to tell patients or consumers about generics if they are available, but in this class of medications and insulin-based medications, there are no generics. The gag rule applies to other types of medications that could be used which are less expensive and are not necessarily generics.

SENATOR ROBERSON:

We decided to focus on PBMs because they appear to have the least transparency. Whether a PBM or insurers are telling a retail pharmacist to suggest one drug versus another or whether it is generic or brand, it always comes back to which drugs are on the formulary. There is a profit incentive for the PBM to push the drugs on its formulary with the retail pharmacist.

SENATOR RATTI:

How does it work when the insurance company owns the PBM?

SENATOR ROBERSON:

That gets into the problem of vertical integration, whether it is a PBM, an insurance company or in the case of a PBM and pharmacy chains or specialty pharmacies or mail order pharmacies owned by the same company.

SENATOR RATTI:

Can you tell me about the history of how the PBM became the middleman? What happened before there were PBMs?

SENATOR ROBERSON:

I am not proposing to be an expert; I did read that in 1968, the PBMs were started with the idea that the end user would have lower priced drugs. That has changed over the years.

This is a complicated problem, and there are a lot of less-than-good actors in this system. We are proposing more transparency today and want to know how much a PBM gets in rebates from a drug manufacturer and what the PBM does with those rebates. When we have that information, we can identify why these prices continue to go up and why there is a problem.

CHAIR SPEARMAN:

Senator Parks had a bill in the Senate Committee on Commerce and Labor earlier this Session, and the bill was to allow people who were diagnosed with Stage 4 cancer to not have to do the step therapy. The patients could go straight to the drugs their doctors felt would benefit them the most. We heard from insurers during the course of that hearing that if that bill were to pass, it would not be something they could accommodate, particularly the self-insurers, because the drugs would be too costly. I do not remember hearing from the PBMs. After several questions, we finally were told the price really starts with the manufacturer. Whatever the manufacturer establishes then, that is the price that everyone else has to deal with. I believe it was described as the wholesale acquisition cost. You said you worked with stakeholders; did you talk to a PBM or representatives here in the building?

Senator Gansert, you said there were no generics for diabetic drugs and that is what Senator Cancela's bill deals with because diabetic drug costs are escalating through the roof. I want to put aside the diabetic drugs. Of the other drugs, if the cost originates with the manufacturer, and by the time it gets to the PBM, it is your assertion that they do not tell or cannot tell the consumer that there is a cheaper drug and they keep whatever is rebated. Would not the PBMs have to report this on their income tax?

SENATOR ROBERSON:

I think we are talking about different things here, the issue with the gag rule affects all drugs not just the diabetes drugs.

CHAIR SPEARMAN:

I want to address everything but the diabetic drugs. Your statement was that the PBM gag rule prevents pharmacists from telling the consumer there is a cheaper drug. They keep the money from the discounts and do not give the consumers the discounts. My question is how do they report the money? How do we know that the PBM is keeping the money? The money has to show up either on their income taxes or it has to show up somewhere.

SENATOR ROBERSON:

We are talking about two different things; I am not talking about a gag rule. I believe we are talking about rebates, and the rebates have nothing to do with the gag rule. I am talking about the diabetic patients.

CHAIR SPEARMAN:

No, I took the diabetics drugs out. I specifically said, Senator Gansert said there is no generic for diabetics, so I said we are going to take them off the table and we are not going to talk about them. I am talking about every other drug, not diabetic drugs.

SENATOR ROBERSON:

You are talking about rebates, correct?

CHAIR SPEARMAN:

Yes. I am talking about the rebates.

SENATOR ROBERSON:

The rebates are between the manufacturers and the PBMs. There are three PBMs that take up 80 percent of the market. These PBMs have control over whether manufacturers can ultimately sell their drugs to the end user. The PBMs demand rebates from the wholesale acquisition cost or the list price. In many cases, the rebates are 30 percent, 50 percent or 70 percent of the list price.

The health plans that have contracts with the PBMs do not have any idea how much the PBMs are getting in rebates from the manufacturers. The original

concept of a PBM was to help a health plan keep the drug prices low so the health plans could offer the lowest prices to their enrollees. There has been a breakdown in the system with the middleman. It is so opaque, the health plans do not know what the PBMs are actually paying for the drugs from the manufacturers versus the price being charged to the health plans for those drugs. There is no transparency, and this is why Anthem is suing Express Scripts for \$15 billion.

SENATOR HARDY:

We are facing two problems in the real world of patients and medicines. Senator Cancela's bill, which focuses on insulin, is something that can actually be done. We read enough in the newspapers to know the cost of medicines that have been around for a long time are going up from \$10 one day to \$100 another. It was not because the cost of manufacturing went up, but because the middleman is charging more money. We also know that when a company sells its rights to a particular medicine, the new company increases the price.

The concept of looking at the manufacturing is wise. The manufacturers' costs are going up 3 percent, 2 percent or 1 percent. This proposal is looking at where the other 100 percent to 500 percent has gone. The insurers are clear on where their money is going. The pharmacy is stuck and has to sell the drugs at the price they can sell them for.

If we focus on insulin, we will get something done. If we focus on the whole world, I do not believe we will be able to get anything done.

SENATOR GANSERT

Section 19 of [Exhibit C](#) creates a fiduciary relationship between the PBMs and insurance companies which does not exist now. A PBM has a fiduciary duty to a third party with which the PBM has entered into a contract. We are requiring it to have a fiduciary responsibility to the insurer and I think that is important.

KHANH PHAM (Nevada Pharmacist Association):

I am a pharmacist and a certified diabetes educator. I am the voice of the patient, your constituent, who you do not see on a daily basis. I commend you for looking into this issue. I see patients who are fully insured and patients who are on Medicaid.

The patients who are in Medicare/Medicaid are well taken care of. But the patients who make a dollar above Medicaid level are not qualified for Medicaid and are the ones who suffer. I see the homeless walking on the street not knowing where to go for their prescriptions. Senate Bill 539 is a common sense bill and will help reduce the financial burden for the patients I serve.

As stated by Senator Roberson, 43 states in this Country already have some transparency to cover this division. I would like to ask you to make it a reality so my patients can benefit from it. A lot of people blame the drugmakers because they do not understand the PBM structure or the way it functions.

The PBMs created the pharmacy network. Pharmacists have to sign a contract with the PBM with a gag order, and if we violate the gag order, we will be kicked out of the network. If you pass this bill, it will reduce the burden for all of us as pharmacists and the patients.

I submitted evidence ([Exhibit D](#)) for you to see that the PBM pockets all the money instead of passing the rebates back to the employer or the consumer. For example, last year in November, I had an elderly patient with Alzheimer's disease who is insulin dependent. Right now, everybody is geared towards type 3 diabetes and it is insulin resistant in the brain. The patient's home was foreclosed on and his wife told me his copay was all the money they had, and she did not want her husband to go without his medication. She has severe arthritis and can barely move, but wanted her husband to be taken care of. I had a \$75 coupon, but I was not allowed to use it for a patient who is on Medicare because it violates the law. Nobody talks about this. I could have saved them money, but I had to look the other way.

I had a child diagnosed with type 1 diabetes three weeks ago. The parents have insurance but it does not cover enough; when the copayment came back as \$800, the mom cried and the dad cried in front of me. I used a voucher coupon given to me by the drugmaker and was able to take care of the child for one and a half months.

The PBMs claim they cover everything that insurance does. I do not know the relationship between the two of them, but I know that my patients suffer and know that the patient's actual out-of-pocket cost is a 169 percent increase according to the Center for Medicare/Medicaid Services. The PBMs mandate patients go through their very own mail order services and have created over

30 percent of waste. The waste is due to a 90-day supply being renewed, the doctor changes the medication and the patient cannot use the old 90-day prescription. Another problem was when my patients tried to stop the prescriptions from being shipped, they kept sending them, and my patients are stuck with the bills and have nowhere to go to resolve the issues.

Today, PBMs control 78 percent of all the prescription benefit transactions in the U.S. Their profit is 600 percent, and they are bigger than Walt Disney, McDonalds and Adidas combined. They delay valued treatment and change the formulary without notifying pharmacists in time to act. The PBMs demand prior authorization or deny medical treatments without any explanation.

When patients go without the necessary treatment, they often end up in the emergency room and have increased hospital stays. I have the statistics for Nevada and will be more than happy to provide them to you.

The cost of hospital stays dating back to 2008 to 2010 for a type 1 or a type 2 diabetes patient was between \$98,000 and \$102,000 per hospital stay. I do not know why the cost is so high in our State when the cost is \$55,000 everywhere else.

CHAIR SPEARMAN:

I am uncomfortable saying that they pocket the money without having some tangible evidence. If there is tangible evidence that the PBMs are pocketing the money, it needs to be presented.

It is the price at the beginning that is high. If drug prices were just made affordable, you would not need to have coupons. Senate Bill 394 was passed authorizing insurance companies to provide HIPAA-compliant information to the PBM for a group.

[Senate Bill 394 \(2nd Reprint\)](#): Revises provisions relating to health insurance.  
(BDR 57-950)

Without sources, and I would say this to anybody, I am just uncomfortable without a source that saying something is the truth. Without some type of source, we are casting an aspersion that we have not yet justified the statements for.

SENATOR ROBERSON:

To be clear, I am not saying this, I am sourcing, when I referenced the Centers for Medicare and Medicaid Services that was from an article from Alan G. Rosenbloom, President and CEO of the Senior Care Pharmacy Coalition. When I mentioned that the reports from the Centers for Medicare and Medicaid Services found that the PBMs were pocketing the rebates, I referenced David Balto, former policy director of the Office of Policy and Evaluation for the Federal Trade Commission's Bureau of Competition, where he talks about and I quoted him that "they are pocketing rebates." If the PBMs come to the table, they will not dispute that they pocket rebates. The question is how much and what percentage of the rebates.

I also want to make clear there is a distinction between manufacturer coupons that are given to the customer at the pharmacy and PBM rebates. They are very different concepts, and I want to steer away from the coupons, which are not what we are talking about. We are talking about rebates that are demanded by the PBMs in order for the PBMs to agree to sell the drugs to include the manufacturer's product in their formulary.

I believe we have presented to the Committee an article by Business Insider ([Exhibit E](#)). I know that you are not going to make a decision right this moment, but I would encourage all of you to spend ten minutes on Google and find source after source that talks about the rebates received by the PBMs and what they do with them. None of us know exactly how much of those rebates are put into their own pockets. They do not want anyone to know, even their own clients. I will give you one more citation, by the National Community Pharmacists Association. They prepared a presentation detailing many common PBM practices that drive up health care cost. This is from the National Community Pharmacists Association.

According to this association,

Some of the more prominent examples of common PBM practices include classifying certain generic drugs as brand drugs and then charging brand prices. Promoting drugs based on the rebate the PBM obtains, not on the consumer's best interest. PBMs will prefer brands from which they get the highest rebate even if there is an equally well or better-suited drug that is cheaper for the consumer. Sometimes PBMs will even switch patient's prescriptions without

the knowledge of the patient just so that the PBM can receive the rebate!

Utilizing spread pricing, and that gets back to what happens where the PBM charges the health plan one price for a drug and a different price will be charged by the PBM to the pharmacy network, and then the PBM claws back the difference, or they keep the spread.

The presentation goes on to state,

They utilize spread pricing by charging health plans more than they reimburse pharmacies and pocketing the difference. And finally, using abusive audit practices and penalizing pharmacies for minor typographical errors on claims, forcing them to forgo reimbursement due to small errors that post no consequence to the claim.

Those are not my allegations; those are the claims of the National Community Pharmacists Association. I want to be clear, everything I have said today has been based on research and using credible nationally recognized sources.

SENATOR HARDY:

Are the 43 states studying this able to find a trend that they can save money for the consumer or the end user of the product?

MS. PHAM:

We are at your mercy as pharmacists. At the pharmacy level, we do not have any authority to make any decisions. All we are allowed to do is dispense the drug. I always, to the best of my ability, use the best medication available for the patient based on what they can afford. Because I know, it cost \$2.6 billion to bring one drug on the market. It takes 10 to 20 years to come up with one compound to apply to the Federal Drug Administration. During that time, the drugmakers still have to pay for the scientists, the janitor, and the medical equipment to have the drug come out on the market. The drugmaker has never employed me and I am not speaking on its behalf. I just learned why the drug is expensive.

SENATOR HARDY:

My question is more on the 43 states that are doing the transparency on the PBMs. Have they shown a decrease in the money charged to the patient with anything that they have been able to do in the other states? In other words, when you go to Utah, Arizona or one of the other 43 states, is the insulin cheaper? Is Nevada different or are we in the same challenging time and no one has figured this out yet?

MS. PHAM:

I know for a fact through all the research that I have read there is no increase in cost. However, you can buy a vial of insulin for \$25 to \$50 for the NPH Insulin R. I know my patients pay \$100 out of pocket for one single pen of the sophisticated analog insulin such as Toujeo, Lantis or Tresiba.

I do not know where the claim of a few thousand dollars a month came from. I advise my patients they always have the option to choose a better insurance plan. The cash price for what we have here is standard. With a coupon, the cost can come down \$15 or \$25 for a month supply.

SENATOR HARDY:

As a physician, somebody will say these are coupons, but they are only good for private insurance not good for cash pay or for Medicare or Medicaid patients. Is this part of the gag rule you are talking about?

MS. PHAM:

I am not allowed to use the coupons for patients who are on Medicare or Medicaid because that is against the law. I have used the coupon for the insulin directly for cash paying patients.

JULIE KOTCHEVAR (Deputy Administrator, Director's Office, Department of Health and Human Services):

We have reviewed the bill and are able to provide the analysis requested without incurring a fiscal impact.

SENATOR RATTI:

Can you speak to the interrelation between the reporting that would be required between S.B. 265 and S.B. 539?

Ms. KOTCHEVAR:

Senate Bill 539 requests a different reporting and specifically asks the manufacturers to issue a report explaining why there was an increase if they are on the list of the named drugs that had an increase. Senate Bill 265 asked for specific information about costs related to the manufacturing of drugs. It would be reported to the Department of Health and Human Services and the Department would analyze the information and then an issue a report on the impact of those costs on the overall pricing of the drugs.

SENATOR RATTI:

Does this bill only pertain to an increase versus S.B. 265, which is for all costs?

Ms. KOTCHEVAR:

Senate Bill 539 requests the Department to compile a list of drugs that specifically have had an increase of certain amounts based on the Consumer Price Index Medical Care Component. Senate Bill 265 requests a list of essential diabetes drugs and any costs related to them.

SENATOR RATTI:

Senate Bill 539 is focused on an increase. If there is a drug that is already expensive and does not increase significantly, then the transparency provision does not kick in?

Ms. KOTCHEVAR:

I do not believe so.

CHAIR SPEARMAN:

You mentioned the manufacturers' pricing, and that is what I was trying to say during the hearing of S.B. 265. All pricing starts with the manufacturers. Do you remember what you just said about manufacturers' pricing?

Ms. KOTCHEVAR:

I believe the manufacturers had to report the costs related to their pricing. In S.B. 265, the manufacturers have to report specific costs that would apply to the pricing. In S.B. 539, the manufacturers are asked for an explanation if there was a price increase.

SENATOR HARDY:

Has there been a cost increase to the State's budget for the insulin products?

MS. KOTCHEVAR:

That would be better answered specifically by Medicaid. My understanding is the pharmaceutical costs have increased overall. Whether or not there is data specific to the types of drugs would probably need to come from our Medicaid Services section.

SENATOR HARDY:

Are they here?

MS. KOTCHEVAR:

They are here, but I do not know if they will have the information you are requesting.

JOHN JONES (Pharmaceutical Care Management Association):

I am a pharmacist and have a history of working for health plans in PBM agreements for the last 20 years.

Pharmacy benefit management companies exist because businesses and peers for pharmacy benefits need their services. Typically, if you have a drug card and get a prescription filled, it is through the operations of a PBM.

The National Community Pharmacists Association is the trade group for retail pharmacies. The retail pharmacies are contracted with PBMs and the PBMs strike the best deals possible for their clients. The PBMs' clients include the government, through Medicaid and Medicare, insurers, health plans, unions, large employers, small employers and so on. The clients select their PBMs by use of consultants. The consultants know the business and often have worked for the PBMs.

There are about 60 PBMs throughout the Nation; 3 of them are the largest and command 70 percent to 80 percent of the market. If a health plan, an insurer or a union wants to get a different PBM, they simply select another PBM.

SENATOR RATTI:

Please take us back to the basics. What is the value of a PBM and why are they needed?

MR. JONES:

Pharmacy benefit management companies started in the 1980s as claim processors for prescription benefits. At first, they just paid claims, which were submitted on paper. When electronics came in support of the industry, the PBM would process the claims electronically. Large employers, small employers and so on started to demand more services from the PBMs to manage the drugs that were available to the members of those programs. The PBMs rose to the task of getting a formulary of drugs for the lowest prices possible from the manufacturers for the physicians and pharmacists.

The question was asked as to where do the rebate dollars go. This is intensely negotiated via contract, and in the vast majority of contracts, the rebates are going back to the payer at 100 percent. Whether it is a union or an insurance company, the money goes back to them four and six months after the prescription is filled.

The manufacturers ask why should we pay PBMs. If you have their product and shift the market share to their product, it is worth dollars to the manufacturer. The manufacturer is not going to pay the rebate up front because if its product is not shifted to the market share, why should it? Instead, manufacturers are going to ask you to show them how much of certain prescriptions have shifted to their drug, and they will give rebates on a graduated scale according to how much the market has shifted to their product. The only way this can be done is through a rebate and after the fact. Typically, 90 percent on average goes back to the payer. How they distribute the money is up to them and is nothing the PBM has control over.

Why are the drugs so expensive? Because manufacturers set the price, PBMs do not set the price. We can negotiate for a more aggressive rebate and if those prices go up, we try to get as much in the way of discounts and rebates as possible. That is what our clients demand.

How the clients pay the PBMs varies. Different clients want to pay in different ways. Some clients want to pay an administrative fee and other clients want to share a percentage of rebates. It is up to the client, and the market will determine how the PBMs are paid.

Ninety percent is the average that goes to the payer from the PBM. The PBMs are audited. Every contract that I have ever seen with a client involves auditing

of the PBM so they can determine how many dollars the PBM collected from the manufacturer and how the money was distributed according to the terms of the contract.

CHAIR SPEARMAN:  
Please repeat what you just said.

MR. JONES:  
The PBM has a contract with whatever payer it is giving services to. That includes the network rate, the rebate amounts, and performance standards. Unless it is a state organization, the contract is private between the contracting entities. It is a public document if the PBM has a contract with Medicaid. It is not considered a public document if it is a commercial document and considered a confidential document. This holds true when you contract with a manufacturer for what you are going to get back in rebates.

The Federal Trade Commission (FTC) and the Congressional Budget Office (CBO) have both said it is necessary that these documents are confidential, otherwise everyone will ask for the same price and there will not be any incentive for the manufacturers to give the lowest price. Why would the manufacturers give you their lowest price? If they give the same price to another client or PBM, it devolves one price for everyone and there would not be any competition.

When the hepatitis C drugs first came out, the cost was \$84,000 for a treatment. Once there was a competitor on the scene, the PBM could force the manufacturers to the table to negotiate and demand a significant reduction in price. We did better than the European Union as far as the price discount for those drugs. This was done through the competitive market and competitive bidding. Once a second product came onto the market, there was about a 40 percent reduction in the cost of those drugs. This is aggregate, and it would be defended as a private contract between the manufacturer and the PBM. When looking at Medicare Part D, the FTC and the CBO would agree not to disclose these contracts or the contract between the payer and the PBM. It is a confidential document. Once you disclose the contracts, you will not get the same discounts, and the cost of care would go up.

I talked about the National Community Pharmacists Association (NCPA) which is a trade group. I represent the Pharmaceutical Care Management Association

(PCMA), which is a trade group for the PBMs. The NCPA is a trade group for the Independent pharmacies and they do not like the PBMs because the PBMs drive hard bargains.

The sponsor talked about David Balto, who is a consultant for the NCPA. Mr. Balto is not going to say kind things about PBMs and it has been a long time since he has been at the FTC.

SENATOR RATTI:

We have heard a lot about the gag rule, how does that work in practice?

MR. JONES:

A pharmacy will have a contract with its PBM, and how the PBM pays the pharmacy is confidential. It is not public information to tell every pharmacy what is given to another pharmacy. I have listened to the references to the gag rule. I have not personally had a contract where it says you cannot talk to the patient about his or her therapy.

SENATOR RATTI:

What is a typical profit margin for a PBM, and where do the PBM Chief Executive Officers (CEO) rank in the top paid CEO scale?

MR. JONES:

Of the total dollars, PBMs are 4 percent, pharmacies are 7 percent, wholesalers are 1 percent and the manufacturers are 88 percent.

The PBMs drive hard bargains with the manufacturers and the manufacturers do not like that. The manufacturers point fingers back at the PBMs saying if not for PBMs, their products would cost less. That is not true. If it was not for the PBMs, they would cost more.

SENATOR HAMMOND:

Your last statement is very interesting. We are saying there has to be transparency all along the line. It is understood that in order to do business you have to keep some things proprietary.

It is true that there can be more disclosure with government contracts and the PBMs do not want to share all their numbers. Would it hurt to disclose some of the numbers for the rebates, and would it not hurt to give some disclosure in

the aggregate as to what these transactions are and how much money is coming back to the consumer or how much money is sent back to the manufacturers? If there were a little bit more disclosure from the PBMs and the manufacturers, we would have a better idea of what is going on.

MR. JONES:

Ninety percent of the rebates going back is an aggregate statement, and that was through a study of PBMs and rebating practices. Some clients do not want any fees up front and want all of the fees taken through rebates. It varies, but 90 percent is the average number that goes back to the payer.

SENATOR HARDY:

I am still interested in the consumer. How much of the rebate goes back to the consumer? How does the consumer benefit? What is the role of the PBM to the consumer? How do you interface with the consumer to give them assurance they can afford their insulin?

MR. JONES:

Our contract is a business-to-business contract with the payer, whether it is a union or insurer. The payers benefit in the way it is structured, the way the dollars are used, and we have no control over it. Premiums and copays could be decreased; there are any number of ways, but that is up to the payer. There is no way a PBM would have any influence over that.

SENATOR HARDY:

You do not have a gag rule that precludes the pharmacist from telling a consumer they can get the drug cheaper or telling them this insurance would be better than that insurance?

MR. JONES:

Over the years whether I was working for a health plan or a PBM, I did not see any contracts that with that level of granularity in pharmacist-to-patient interaction. Being a pharmacist myself, I always looked out for my patients when I was dispensing.

SENATOR HARDY:

Do I understand correctly that you do not mind the transparency concept?

MR. JONES:

The PCMA understands transparency and supports it to the extent that it is good for the consumer. The minute transparency is driven down to where you cannot get good deals with manufacturers as far as their costs or a pharmacy as far as costs, it then becomes more expensive. The PBMs are there to reduce the cost of things for our clients, not increase those costs.

SENATOR HARDY:

That is your objection to the transparency in S.B. 539, that it would allow private negotiating, decreasing your ability to drive the bargain so that you have a fiduciary responsibility for your client, as well as to make sure your salary still is paid?

MR. JONES:

Yes, the FTC and the CBO agree with that.

SENATOR HARDY:

Would you see a commerce clause issue with this bill?

MR. JONES:

The states where they have pushed for this type of disclosure have found it to be challenged under federal law or repealed. Maine had a law for a while, and it was repealed because they were not getting the reduction.

You asked about which of the 43 states got a reduction. All 43 states are still dealing with the original price of the drug set by the manufacturer.

SENATOR HARDY:

If you were a manufacturer, would you have the same challenges you are having as the PBM sitting here? Is the PBM in favor of S.B. 265?

MR. JONES:

Our organization has not taken a position on S.B. 265. Members of our organization have to negotiate with the pharmaceutical industry on a regular basis, and they look for every angle to reduce those costs.

SENATOR HARDY:

Pretend it is somewhat transparent; are your contracts on a flat fee or percentage of the cost?

MR. JONES:

Every client wants something different. Some clients want great rebates and most clients want the lowest net cost. Some clients want to share a percentage of the rebates to pay the fees and some clients do not want to share any of the rebates to pay the fees. Some clients want everything and want to give a flat fee for administering a program. The reality is the customer is king and the larger the customer, the greater the king.

SENATOR HARDY:

Does the PBM decide the formulary?

MR. JONES:

Would you please restate your question, I want to be sure I answer it correctly.

SENATOR HARDY:

If you are in charge of the formulary and contracting with an insurance company or payer to be able to do the formulary, is there an economic advantage to you to have a formulary that you gain more from than the formulary that would be less?

MR. JONES:

I would say no in the market of today. The customers are very sophisticated and the health plans have their own medical directors and chief pharmacy officers who look closely at a PBM formulary and decide whether to accept that formulary. They understand both the therapeutics and the financials, and do not have to accept the formulary. The customers can depart from that formulary, and some do, but most do not.

It is imperative that the PBM have a high integrity process so the customer adopts the formulary that the PBM has put out there. Typically, people who are not employed by the PBM as full-time employees who are practicing physicians and practicing pharmacists are making those decisions independently and the PBM wants to be able to stand behind their decisions and not say it was a business decision. Therapeutics comes first and then pricing after the therapeutics. If a customer says, "We need this drug on the formulary," you take that and then negotiate your best price.

SENATOR HARDY:

With the competitive market and low margins on insulin, are you putting insulin on your formularies?

MR. JONES:

Insulin has three large manufacturers. You try to get the best price for the products that you need to have on a formulary to serve that population.

CHAIR SPEARMAN:

Is there a specific part of the bill you are opposed to?

NICK VASSILIADIS (Pharmaceutical Care Management Association):

We are opposed to the bill in its entirety. We would be open to discuss the bill as a matter of philosophy.

CHAIR SPEARMAN:

Did you meet with the sponsor of S.B. 539?

MR. VASSILIADIS:

My boss met with the sponsor.

SENATOR HAMMOND:

When you were talking about the gag rule, you said you were unaware of any kind of gag rule, is that correct?

MR. JONES:

The terms of contracts are confidential. I cannot say that I have seen every contract because I have not, but the ones I am aware of do not say you cannot talk to the patients.

SENATOR HAMMOND:

Mr. Jones, you are aware it is a problem. You may not be aware of it in any contract, but surely you have to be aware of the problem.

After you had made that statement, I went online and Googled a few words to find out. I have come up with approximately 20 different articles that talk about how call backs and gag rules are definitely contributing to the higher prices that are occurring among the consumers. I just ran into 10 or 15 articles talking

about the millions being saved by CEOs of companies from PBMs. To be less than aware is maybe a little short of what we need to tell.

MR. JONES:

The people who are writing those articles have a different interpretation on what they can and cannot say. They may have multiple contracts that they are looking at, I am not aware of anyone that cannot describe any therapeutic alternatives. Again, a lot of the people who have complained, are also parties to the contract that are concerned about their reimbursement.

SENATOR HAMMOND:

I will leave with this; I listened to the testimony of a pharmacist who has to be on the front line with the consumer and cannot explain ways for the consumer to save money. These people are the most vulnerable. The elderly woman whose husband is definitely dependent on this medicine and she cannot tell them. The pharmacist's testimony is very compelling when she talks about the 600 percent increase in salary among PBMs being higher than McDonalds, Adidas and Walt Disney combined. Yet, she cannot explain to the person who cannot afford the insulin that they could probably get it cheaper somewhere else. Now you know that there may be a problem out there.

MR. JONES:

In response to the increasing costs of the drugs, a number of the payers have looked at other ways to keep those costs in alignment. Deductibles are one way and that puts a burden of cost on the patient. It comes down to whether the drug is overly priced and we could come to some agreement and say it should be that high. That is the price that has been increased into the market. I can understand why that is a burden for most people when the first \$1,000 is your deductible.

SENATOR HAMMOND:

Since you claim the manufacturer sets the price, there is not much you can do to help on the back end when they are selling the drug. If you actually prohibit somebody from explaining that there is a lower cost option, the competition goes away. If I were buying a cheaper drug repeatedly, then whoever is selling it higher would start to think that they need to lower their price to compete. I think that is a major part of this issue now.

CHAIR SPEARMAN:

You raise a valid point. There was another bill where pharmacists were asking permission to talk with their patients and discuss medications because they see the patient more than the doctors. Those who represent doctors in the medical field were against the bill because they did not want pharmacists talking to patients about medications. It is one thing to say here is a lower costing drug, but at the same time, that drug may have a different composition and might not work well with another. The doctors do not want pharmacists talking to patients and telling them what to take.

You said that it is more of what is in a contract in terms of what can be disclosed because the contents of contracts are proprietary information. The manufacturer sets the price and everything after that is a consequence of what happens at that price setting.

ELIZABETH MACMENAMIN (Retail Association of Nevada):

That was the collaborative practice of pharmacy in which pharmacists will work through a doctor and with a doctor in order to help patients manage their drug therapy.

For the record, my personal pharmacist is more than willing to work with me and always lets me know what the cheaper drug is. I had a very expensive drug prescribed to me a couple of years ago, and my pharmacist told me my copay was going to be \$80. We went through the whole process, which is the pharmacist's role. The pharmacists always try to get the patient on a cheaper drug that is just as effective.

CHAIR SPEARMAN:

Would you please repeat the name of the bill we passed?

MS. MACMENAMIN:

It is S.B. 260, the collaborative practice of pharmacy, and it passed the Assembly on May 25.

**SENATE BILL 260 (2nd Reprint)**: Establishes requirements for engaging in the collaborative practice of pharmacy. (BDR 54-973)

SENATOR ROBERSON:

You have heard a lot of denials from the PBM industry. If they have nothing to hide, they should be willing to be more transparent. I just looked at another article from February of 2017 by Bloomberg. If Mr. Jones has not heard of a gag rule or a gag order, then he did not hear that Arkansas passed a law in 2015 prohibiting PBMs and pharmacies from charging customers more than the pharmacy will be paid. This is your claw back issue. In 2016, Louisiana passed a law allowing pharmacists to tell customers how to get the cheapest price for drugs, trumping contract gag clauses. This is a Bloomberg article from February 22, 2017 and is not from big Pharma or the retail pharmacy community.

This Committee is in charge of making policy with regard to health care matters. I am surprised that this has not come up before in previous sessions or early this Session. I know it is late in the Session and you will or will not do whatever you want with this bill. I promise you this, if nothing is done in the next ten days, one of you on this Committee will become more informed on this issue and probably champion this issue in 2019. If Congress has not addressed it by then, I am quite sure you will. Take ten minutes and use Google. You will learn what Mr. Jones does not want you to learn.

CHAIR SPEARMAN:

We are closing the hearing on S.B. 539 and will begin the work session with A.B. 474.

**ASSEMBLY BILL 474 (1st Reprint)**: Makes various changes relating to drug overdoses and prescribing and using drugs. (BDR 40-1102)

MEGAN COMLOSSY (Policy Analyst):

Assembly Bill 474 makes various changes relating to drug overdoses and prescribing and using drugs. It was heard in this Committee on May 17, and sponsored by the Assembly Committee on Health and Human Services on behalf of the Office of the Governor.

The A.B. 474 work session document ([Exhibit F](#)) revises certain provisions concerning the prescription drug monitoring program for controlled substances. This bill authorizes certain occupational licensing boards to access the prescription drug monitoring program database and requires such boards to review and evaluate certain information and impose disciplinary action. The

measure permits such an occupational licensing board to suspend the authority of a practitioner to prescribe, administer, or dispense a controlled substance in certain circumstances. In addition, the bill revises various provisions governing the accessibility of health care records in certain investigations.

The bill requires a practitioner, other than a veterinarian, who intends to prescribe or dispense a controlled substance listed in schedule II, III or IV to consider certain factors, take certain actions, and document certain information before initiating such a prescription. Additionally, the bill revises the required contents of certain written prescriptions and requires certain persons to make a report of a drug overdose or suspected drug overdose to the State's Chief Medical Officer. No amendments were proposed for this measure.

CHAIR SPEARMAN:

Would someone please come to the table to clarify the intent in section 51?

ELYSE MONROY (Policy Analyst, Office of the Governor):

During the hearing, there were questions from Senator Hardy regarding confusion with section 51. We want to make sure that the record is clear on our intent with section 51.

We changed the definition of initial prescription, which was added in statute with S. B. No. 459 of the 78th Session.

The sentence added in section 51 is, "The term does not include any act concerning an ongoing prescription that is issued by a practitioner to continue a course of treatment for a new or existing patient of the practitioner." The new language to the definition of initial prescription is to better clarify that if there is a continuation of an existing course of treatment by a new provider and that continuation would not be considered an initial prescription. We are trying to ensure that there is a continuity of care.

SENATOR HARDY MOVED TO DO PASS A.B. 474.

SENATOR RATTI SECONDED THE MOTION.

THE MOTION CARRIED UNANIMOUSLY.

\* \* \* \* \*

CHAIR SPEARMAN:

What is the pleasure of the Committee with regard to A.B. 473 for continuation of certain drugs on the preferred list for the Medicaid program?

SENATOR RATTI MOVED TO DO PASS A.B. 473.

SENATOR HARDY SECONDED THE MOTION.

THE MOTION CARRIED UNANIMOUSLY.

\* \* \* \* \*

Page intentionally left blank; signature page to follow

Senate Committee on Health and Human Services  
May 26, 2017  
Page 35

CHAIR SPEARMAN:

There being no public comment and no further business before this Committee,  
the meeting is adjourned at 5:27 p.m.

RESPECTFULLY SUBMITTED:

---

Tammy Lubich  
Committee Secretary

APPROVED BY:

---

Senator Pat Spearman, Chair

DATE: \_\_\_\_\_

<b>EXHIBIT SUMMARY</b>				
<b>Bill</b>	<b>Exhibit / # of pages</b>		<b>Witness / Entity</b>	<b>Description</b>
	A	1		Agenda
	B	4		Attendance Roster
S.B. 539	C	17	Senator Michael Roberson	Proposed Amendment 5037
S.B. 539	D	30	Khanh Pham / Nevada Pharmacist Association	Lift veil on pharmacy benefit managers, reduce prescription costs
S.B. 539	E	7	Senator Michael Roberson	Business Insider Article
A.B. 474	F	1	Megan Comlossy	Work Session Document

# EXHIBIT 9

ROBERT L. LANGFORD & ASSOCIATES  
ATTORNEYS AT LAW  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101

# EXHIBIT 9

**MINUTES OF THE  
SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES**

**Seventy-ninth Session  
March 29, 2017**

The Senate Committee on Health and Human Services was called to order by Chair Pat Spearman at 3:39 p.m. on Wednesday, March 29, 2017, in Room 2149 of the Legislative Building, Carson City, Nevada. The meeting was videoconferenced to Room 4412 of the Grant Sawyer State Office Building, 555 East Washington Avenue, Las Vegas, Nevada. [Exhibit A](#) is the Agenda. [Exhibit B](#) is the Attendance Roster. All exhibits are available and on file in the Research Library of the Legislative Counsel Bureau.

**COMMITTEE MEMBERS PRESENT:**

Senator Pat Spearman, Chair  
Senator Julia Ratti, Vice Chair  
Senator Joyce Woodhouse  
Senator Joseph P. Hardy  
Senator Scott Hammond

**GUEST LEGISLATORS PRESENT:**

Senator Nicole J. Cannizzaro, Senatorial District No. 6  
Senator Yvanna D. Cancela, Senatorial District No. 10

**STAFF MEMBERS PRESENT:**

Megan Comlossy, Policy Analyst  
Eric Robbins, Counsel  
Debbie Carmichael, Committee Secretary

**OTHERS PRESENT:**

Sheila Leslie, Social Services, Washoe County  
Travis Warren, Police Officer, Police Department, City of Reno  
Shawn Marston, Deputy Sheriff, Sheriff's Office, Washoe County  
Brandi Planet, Dignity Health – St. Rose Dominican  
Marlene Lockard, Nevada Women's Lobby; Human Services Network; Service Employees International Union Local 1107 Nevada  
Trey Delap, Group Six Partners

Amy Roukie, Deputy Administrator of Clinical Services, Division of Public and Behavioral Health, Department of Health and Human Services  
Jodi Tyson, Three Square  
Shane Piccinini, Food Bank of Northern Nevada  
Jon Sasser, Washoe Legal Services; Legal Aid Center of Southern Nevada  
Denise Tanata, Executive Director, Children's Advocacy Alliance  
Edwina Richardson, Macedonia Outreach Social Enrichment Services  
Mary Finch, Three Square  
Steve H. Fisher, Administrator, Division of Welfare and Supportive Services, Department of Health and Human Services,  
Barbara Buckley, Executive Director, Legal Aid Center of Southern Nevada  
Mekhi Overton-Jackson  
Stephanie Mahler  
Elliot Brittain  
James Conway, Executive Director, Washoe Legal Services  
Jesse Fredzess  
Yolanda T. King, County Manager, Office of the County Manager, Clark County  
Jodi Stephens, Wynn Resorts, Limited  
Kevin Schiller, Assistant County Manager, Washoe County  
Praveen Jayakumar, M.D., Medical Director, Culinary Health Fund  
Bobette Bond, Executive Director, Nevada Healthcare Policy, Unite Here Health  
Kevin Hooks  
Tanya George  
Rita Neanover  
Bonnie Jean Sedich  
Peggy Lear Bowen  
Christopher Hughes  
Keith Lee, Nevada Association of Health Plans  
Rusty McAllister, Nevada State AFL-CIO  
Jim Sullivan, Culinary Workers Union Local 226  
Stacie Sasso, Health Services Coalition  
Matt Morrison, Executive Director, Healthcare Operations, MGM Resorts International  
Ruben R. Murillo, Nevada State Education Association  
Ryan Beaman, Clark County Firefighters Union Local 1908  
Todd Ingalsbee, Professional Firefighters of Nevada  
Priscilla Maloney, AFSCME - Retirees  
Russell Rowe, Boyd Gaming Corp.  
Mike Alonso, Caesars Entertainment

Senate Committee on Health and Human Services  
March 29, 2017  
Page 3

Rachel Gumpert, AFSCME International  
Randy Soltero, International Alliance of Theatrical Stage Employees  
Fran Almaraz, Teamster Local 986; Teamster Local 631  
Jeanetta Williams, President, NAACP Tri-State Conference Idaho-Nevada-Utah  
Beth Handler, Chief, Bureau of Child, Family and Community Wellness, Division  
of Public and Behavioral Health, Department of Health and Human  
Services  
DuAne Young, Chief, Behavioral Health and Pharmacy Services, Division of  
Health Care Financing and Policy, Department of Health and Human  
Services  
Kipp Snider, Pharmaceutical Research and Manufacturers of America  
Brian Warren, Biotechnology Innovation Organization  
Jeff Buel, Johnson & Johnson Services, Inc.  
Chris Ferrari, Pfizer, Inc.

CHAIR SPEARMAN:  
I will open the hearing on Senate Bill (S.B.) 192.

**SENATE BILL 192**: Establishes required hours of operation for certain mobile  
mental health units. (BDR 39-816)

SENATOR NICOLE J. CANNIZZARO (Senatorial District No. 6):  
The reason why S.B. 192 came to my attention deals in part with what I do for  
a living, which is I am a prosecutor with the Clark County District Attorney's  
Office. All too often, we struggle when we encounter individuals who are in the  
court process by virtue of the fact that they have an unaddressed mental illness,  
or they have not had the resources to intervene to ensure that they are getting  
the help that they need. Instead, they become the subject of one of the Clark  
County District Attorney's Office cases. Frankly, it is very difficult for them to  
encounter those individuals to address with the criminal justice system. I had  
discussions on how can we better address this situation, so we are not using  
our criminal justice resources on individuals who deserve treatment. This issue  
started to percolate, which is the existence of what we have now in Clark  
County, Washoe County, Lyon County and Carson City, which are mobile  
mental health units (MMHU). What came out of the discussions was the  
suggestion that if these MMHUs were more readily available, that we might be  
able to combat this situation. While S.B. 192 is quite short, its impact could be  
substantial. Senate Bill 192 requires that any facility within the Department of  
Health and Human Services (DHHS) in the Division of Public and Behavioral

Health (DPBH), which provides mobile mental health services in Clark and Washoe Counties to ensure the mobile unit is available to provide those services from at least 8:00 a.m. until midnight, 7 days a week, 365 days a year. Currently, this requirement would apply to the mobile outreach safety team (MOST), a program that pairs a behavioral health professional with a law enforcement officer to respond to calls, and provide intervention for those in mental health crises.

In February of 2017 alone, MOST served more than 200 clients statewide including 158 clients in northern Nevada, 15 clients in southern Nevada and 28 in Carson City and Lyon County. This program is extremely popular among law enforcement and the behavioral health community as evidenced by its expansion from Washoe County to rural areas of the State, and in 2015, to southern Nevada. The goal of S.B. 192 is to expand on an already successful program in order to increase the access to much needed services, because mental health crises are not limited to 9:00 a.m. to 5:00 p.m., Monday through Friday. By providing mobile mental health services outside of regular business hours, the State will be able to serve many more Nevadans in crisis when they need care most. This is an important step in that direction, just to require that these services are available, to engage in intervention and to help those individuals who really do need help, and are not receiving it from other sources. One thing that struck me when this issue came up was it only operated during business hours. If you talk to anyone in this building, there are loved ones or family or people they know who have a mental illness or mental health issue and it does not restrict itself or turn on or off at 9:00 a.m. Oftentimes, it can become a larger problem during hours when these services are not available. Mental health is a huge issue not only in this State and I think this is a good way to start to address it. Senate Bill 192 is quite short in terms of policy and is to increase the access of these particular services. There is a fiscal note on S.B. 192 and this is something we will have to address and combat.

SENATOR HAMMOND:

I have questions that may be addressed during the next expert testimonies, but I will ask them now in hopes of them being covered. What divisions will do this right now? How many of the mobile units are deployed right now? What are the limitations to expanding the hours? Who sets the hours now? Why are they those hours? Is it financial or other considerations? I would be interested in seeing the fiscal note.

SENATOR CANNIZZARO:

There are at least four different areas, Washoe County, Clark County, Lyon County and Carson City, which are working within the constructs of mobile mental health units. Senate Bill 192 just addresses the MOST program in Washoe County and Clark County. The limitations are part fiscal and part lack of service providers, which I know is another issue that has been before this Committee and the Legislature, and is an ongoing and important discussion. Even though we are asking to expand the MOST program, we can also work on ways that qualified individuals can be identified and brought to Nevada so we can get some of the services in place.

SHEILA LESLIE (Social Services, Washoe County):

Washoe County Social Services support S.B. 192. I will give you a brief history of the MOST program. In 2009, this legislation came forward in the money committees as a pilot project. The idea came from the Reno Police Department. The officer who is behind "Million-Dollar Murray" brought the idea forward. "Million-Dollar Murray" is a *The New Yorker* article about a homeless man and really tells why Nevada needs MOST teams. Senator Raggio was the Chair of the Senate Committee on Finance at the time, and at the very end he came forward and said this is very important, and we are going to carve out some money and give it a try. It was established as a pilot project in Reno. It was so successful in Reno that it has been replicated, in a slightly different model in Las Vegas and the rural counties.

TRAVIS WARREN (Police Officer, Police Department, City of Reno):

I have been running the MOST team for the last four and a half years. The MOST is a crisis intervention unit that was developed by the Reno Police Department in partnership with Northern Nevada Adult Mental Health Services (NNAMHS). In 2008, as a police department, we started recognizing that we were encountering individuals on the street in calls for service that were in crisis, mental health or situational. Our only tools were either taking them to jail or the hospital. We were limited in what to do for them and recognized we could do something better. We worked with NNAMHS and developed a program called MOST, which pairs a mental health counselor with law enforcement to respond in a first responder type setting. When we encounter these individuals in crisis by the time they get to the hospital, most of the crises have subsided, and the doctors may not see what we are encountering on the street. The person may not get the treatment he or she needs.

Since that time, we have two mental health counselors employed by the State that work alongside both the Reno Police Department, the Washoe County Sheriff's Office and the Sparks Police Department. During my time in the unit we have been able to expand the program to Carson City. Last year we were able to contact over 1,400 people in Washoe County with just 2 mental health counselors, ranging from mental health follow-ups from our detectives to our victims unit to calls for service from police officers on the street who encountered these individuals in crisis. Our working hours are 6:00 a.m. to 4:00 p.m., so the officers working swing shift or graveyard hours do not have the benefit of having these mental health intervention specialists work alongside them. This is due to funding. One area of growth we have identified is expansion of the crisis intervention units into those hours. For the Washoe County area, which includes all three major law enforcement agencies, Pyramid Lake Police Department, Tribal Police Department and the University of Nevada Reno Police Department, a lot of our mental health and suicidal subjects' calls we are encountering are from 10:00 a.m. to midnight. We see a large spike during the late afternoon into evening hours, which is generally when the mental health counselors are not available. While some officers have crisis intervention training it is really important to have a mental health specialist with them to develop the rapport with the individual and help them navigate through the system.

SENATOR HAMMOND:

Does a unit consist of a police officer and a mental health specialist in a car driving around?

MR. WARREN:

Reno is unique in the sense that the Reno Police Department fully funds the position of the MOST coordinator. There is an officer that is strictly assigned to the MOST team. Other agencies, based on availability of officers, deputies or personnel, can mold and shape this program to however it fits best. The primary focus is that the mental health counselor is in the vehicle, responding to the crisis call when it is occurring. The most timely and beneficial services can be provided to get the individual navigated away from the criminal justice system and away from the emergency services into something that will benefit them in the long term.

SENATOR HAMMOND:

I am trying to figure out how the MOST operation works. The number of beds taken by these individuals in emergency rooms where there is no MOST team must be problematic. Is this something you are trying to avoid?

MR. WARREN:

Yes, that is correct. We may go on a call where the person is starting to show signs of crisis, but the key is when the mental health specialist is in the car with us, he or she can identify some of the things before it may become a situation where law enforcement or emergency services has to respond, and take them to the hospital or incarcerate them. There is also the early intervention piece that is really important that helps reduce the calls for service and unnecessary contacts. One thing we try to do is reduce the impact on the community and on the individuals who are in crisis.

SHAWN MARSTON (Deputy Sheriff, Sheriff's Office, Washoe County):

I highly support the MOST program. I am a MOST liaison for the Sherriff's Office. The mental health specialists are primarily assigned to the Reno Police Department. The City of Sparks and the Washoe County Sheriff's deputies need those resources available to them which they do not have, other than on a limited basis. Officer Warren would respond, when he could, into the unincorporated areas of Washoe County and try to assist or I would pick up a MOST worker and go out to the call. When a deputy is out on a call and there are no resources, it is extremely frustrating, especially when the deputy keeps going back to the same house time and time again. We had one incident in Sun Valley, for example, where the deputies had to Taser the mentally ill person. He was living with mom and dad and the incident happened right after payday. The parents were the caretakers and they pulled their hair out because they did not have the resources available to help their son. The following month when payday hit, the same incident occurred and the deputies went out there. Because the deputies only know how to do their job and they did not have knowledge about mental illness, they were actually sending the person and his family on a course of destruction. The MOST worker and I responded to a call at the same home. The MOST worker helped the individual and the family, and connected them to resources to get them back on track. The expansion of the MOST team is needed as we need to fan and farm out the resources to handle these types of calls.

SENATOR RATTI:

Is the intent of S.B. 192, if the \$2.9 million fiscal note is met, that the MOST team would be an on-call resource during those hours for anybody within Washoe County or Clark County?

MS. LESLIE:

Washoe County Social Services is in the process of subcontracting with the State so they will have more local control. It has been a concern because there is so much need and so much competition for the resources. Sparks is involved in the regional group and I know they would like to expand as well. The MOST workers are State workers and they are transitioning to be county workers but that has not been completed. With the expansion of money we will sit down with the three jurisdictions to figure out what is the best way to spread the resources and I am not sure how it will look.

SENATOR RATTI:

Senate Bill 192 says there will be at least one MOST worker available during these hours within Washoe County and Clark County.

MS. LESLIE:

Yes, that is my understanding that we will at least expand the hours to be 8:00 a.m. to midnight, seven days a week with one MOST worker.

CHAIR SPEARMAN:

During the Interim, a presentation was made and a figure was shown on what it would cost if the MOST team had not been there, the avoided cost. There is a \$3 million fiscal note but sometimes if things are done up front it looks huge but without it what would the cost be?

MR. MARSTON:

In the past six years we have built a program called Crossroads which targets mentally ill homeless people. Our statistics show nationally a mental illness co-occurring disorder is around 55 percent. In our program the male population is 76 percent and the female population is 90 percent. We conducted a one-year look-back from each one of the clients who came into the program, and those individuals on average cost the community \$250,000 on average per year.

CHAIR SPEARMAN:

Is that \$250,000 per person or \$250,000 aggregate?

MR. MARSTON:

Yes, that is \$250,000 per year for emergency response. The University of Nevada, Reno did a study showing when police, fire and medical personnel respond to an incident what the cost would be to the taxpayer. Transport to the hospital and emergency room visit is over \$10,000, the arrest and other costs equates to \$250,000 per person.

CHAIR SPEARMAN:

Are there any trends in terms of presenting problems? If all of the money is not obtained, is there one thing or a combination of things that we can look at proactively to lessen or mitigate the \$250,000 per person?

MR. WARREN:

One of the things we have identified is the implementation of a comprehensive case manager. When we have initial contact with an individual, it may be a week or longer before another contact is made with them because of availability of resources. If there was a comprehensive case manager that we could do a warm handoff to, then the case manager could continue to work with the individual throughout the case. There would always be a degree of contact, so the individual does not fall through the cracks. That would be a positive impact in the community.

SENATOR HAMMOND:

Where are the cost savings? Maybe in some cases we do not have to add resources, but shift resources if we know where we are saving the money. Is the \$250,000 truly per person?

MR. MARSTON:

It is \$250,000 per individual that we encounter and do wrap-around services for. Some of the clients we did the study on were \$120,000 per year and some reached up to \$1 million. The calls for services that we encounter are for the mentally ill treating themselves with drugs and alcohol.

MS. LESLIE:

This program actually saves lives. Many of the calls law enforcement goes on are active suicides, people who are trying to commit suicide by cop, lots of people who are in horrendous psychotic crisis situations. It is very important for early intervention, but the program provides a vital crisis intervention role and it

helps law enforcement to have these specially trained people with them at the scene.

BRANDI PLANET (Dignity Health – St. Rose Dominican):

Dignity Health – St. Rose Dominican is committed to the principle that health care is a basic human right for all and is in support of S.B. 192.

MARLENE LOCKARD (Nevada Women’s Lobby; Human Services Network):

The Nevada Women’s Lobby and the Human Services Network strongly support S.B. 192. The mental health needs in our State are astronomic and every little bit we can do to help is gratefully appreciated.

TREY DELAP (Group Six Partners):

Group Six Partners supports S.B. 192. All the areas of my work which is youth mental health first aid, adult mental health first aid and public awareness of suicide intervention has one common thread. It is connecting people to the correct service with the right level of care at the right time. It is interesting to think that this type of service is not available every day. When people are bottled up in the emergency room they are not getting the definitive care that they need for mental health. This program by connecting people to the right kind of care starts them on the path of recovery and reduces the impact into the other systems. There is a lot of support nationally and many states do this differently and there are many collaborative funding mechanisms and accommodation of grants, but all of this points to what has been presented here today. It works by connecting people to the right services at the right time.

AMY ROUKIE (Deputy Administrator of Clinical Services, Division of Public and Behavioral Health, Department of Health and Human Services):

The Division of Public and Behavioral Health is neutral on S.B. 192. Conceptually, the DPBH does support the MOST program. The funds do come to DPBH and it is in the process of sub-granting the funding to Washoe County for local control. The DPBH already does the same in Clark County. The fiscal note that is defined is based solely on increased hours that would be needed in order to cover the new service delivery times. The DPBH is in agreement that crises do not occur between 9:00 a.m. and 5:00 p.m. and this conceptually works very well in the places where it has been expanded and has proven to be very worthwhile. The DPBH is getting requests from other areas of the State saying they need more of this kind of service. The DPBH is here to support the concept. Although the fiscal note is high, it is worth the time. I have worked in

the community with the MOST team, on the provider side, and they are lifesavers. I highly recommend that the program is continued and enhanced in any way possible.

CHAIR SPEARMAN:

I will close the hearing on S.B. 192 and open the hearing on S.B. 323.

**SENATE BILL 323**: Revises provisions governing the Supplemental Nutrition Assistance Program. (BDR 38-627)

SENATOR YVANNA D. CANCELA (Senatorial District No. 10):

Senate Bill 323 has the potential to make an impact on many lives in Nevada. In 2018, the Supplemental Nutrition Assistance Program (SNAP) is going to undergo some significant changes in the State and S.B. 323 is crafted to make sure that some of our most vulnerable recipients of SNAP benefits are protected and the program functions at its best.

JODI TYSON (Three Square):

We are talking about one specific group of people who receive SNAP benefits, not the entire program. First, I will take you through the program as a whole, then move into the specific pieces that we are talking about in S.B. 323. I have submitted a presentation (Exhibit C) to the Committee. The changes I will talk about relate to the 1996 welfare reform issues that deal with time limits and work requirements. To be eligible for the SNAP benefits, an individual has to meet a certain income means-tested application. It is an entitlement program, and individuals have to apply for a benefit and meet a certain amount of income. Page 2 of Exhibit C shows the maximum amount an individual can make in Nevada to qualify for the SNAP benefits. As the individual's income is closer to the maximum amount, the lower the SNAP benefit will be. There are individuals who apply for benefits and are approved but their benefit amount is zero or maybe \$12, because their income is too high. The SNAP benefits are like a step program.

Page 3 of Exhibit C shows in fiscal year 2016-2017, 441,646 Nevadans will benefit during the year from SNAP. All individuals do not stay on the program for the entire year and this is a really important aspect of SNAP. Before the start of the recession, the average amount of time individuals stayed on SNAP was about eight months. During the recession, that went up to about 10 months. By the end of December 2017, we expect to serve 224,436 individuals as shown

on page 4 of [Exhibit C](#) and what this shows is individuals do not stay on the program for the whole year. A portion of the 441,646 individuals are seen each month throughout the course of the year.

The part of SNAP that is affected by [S.B. 323](#) deals with able-bodied adults without dependents (ABAWD) and page 5 of [Exhibit C](#) gives the criteria. If the individual falls within the affected category, he or she cannot receive SNAP benefits for more than 3 months within a 36-month period of time. There are some groups of individuals who are part of the affected group but can be exempted. Groups of individuals can be exempted when the Division of Welfare and Supportive Services (DWSS) requests a waiver from the United States Department of Agriculture (USDA) for geographic areas that exceed 10 percent unemployment or 20 percent higher than the national average. Nevada has had for the last eight years a statewide exemption waiver because our unemployment rate has been high.

Nevada has had small geographic area waivers because of high unemployment. For example, some of the tribal reservations have been exempted as well as a county here and there when a mine pulls out. We can also request waivers for geographic areas that lack sufficient jobs. If the unemployment rate is below 10 percent but there is no job market that would allow individuals to work, then a waiver can be requested for that area. There are programs or opportunities to exempt those who are in work training or workfare through State-sanctioned programs. Only 15 percent of recipients that are subjected to ABAWD waivers can be exempted because they encounter significant barriers to work. People that are homeless or mentally ill are automatically exempted. States are coming back to ABAWDs in droves. In 2016, there were 19 states that came back to ABAWDs and during this time period, it is estimated through the Center on Budget and Policy Priorities that between one-half million and one million SNAP recipients will lose their benefit as the states shown on page 6, [Exhibit C](#), roll back onto the program. Nevada will reinstate ABAWDs on January 1, 2018, and that is when the time clock will start for the three-months benefit. The recipients will have to meet one of the exemptions or they will no longer have SNAP benefits for the next 33 months.

The return of ABAWDs means there will be a significant drop within certain populations that receive SNAP benefits. A few examples that come from the Center on Budget and Policy Priorities are shown on page 7 of [Exhibit C](#). When Kansas brought ABAWDs back, the level of SNAP recipients, around 325,000,

significantly dropped off to about 285,000. That relates to those who came off the program due to time limits and work requirements.

Nevada's statewide waiver for ABAWDs will expire on December 31, 2017, and will be reinstated on January 1, 2018. That starts the three-month clock for SNAP recipients and means the recipients could start losing benefits on April 1, 2018. The USDA has not informed Nevada exactly how many individuals will be subjected to ABAWDs, or how many within the 15 percent we could look to exclude. Some initial estimates are that about 59,000 SNAP recipients will be subject to ABAWD waivers and somewhere around 10,000 will be the amount of exemptions we could provide. Of those who are subjected to ABAWDs, the DWSS has the ability to exempt about 15 percent due to significant barriers to employment but those determinations are made on a case-by-case basis. It means that the DWSS will need to meet with thousands of people across the State to determine whether or not they may be eligible for one of the exemptions.

Nationwide, the ABAWDs subjected individuals encounter major barriers to employment as shown on page 9 of [Exhibit C](#). Senate Bill 323 looks at those who have significant barriers to employment and provides guidance to the DWSS for exemptions. Those who are subjected to ABAWDs are among the very low incomes. Some of these individuals are seasonal workers and when they hit a low season, their income is very low. These are things we want people to keep in mind. People may not be working 20 hours a week but have a job and hope to be able to work 20 hours if they can stay in their jobs.

For the food banks, ABAWDs will increase demand as 44 percent of food pantry clients have SNAP benefits right now. Nevadans who lose SNAP benefits will turn to food banks for nutrition assistance. Three Square Food Bank and the Food Bank of Northern Nevada are estimated to serve 502,200 people per month per year and have distributed a combined amount of 56.7 million pounds of food in 2016. The work at the food banks is already significant and the amount of unfunded demand that will come to the food bank because individuals losing their SNAP benefits will be significant.

Senate Bill 323 seeks to mitigate some of the negative impacts of ABAWDs to the level to which the State can address them. This bill, including the friendly amendments, seek to address six areas in which ABAWDs can fix the administrative policy. I will take the Committee through S.B. 323 but will be

referring to the proposed friendly amendment ([Exhibit D](#)) for clarification. Section 2 of [Exhibit D](#) sets a statewide fixed clock, which is advantageous to those who will not have benefits starting on April 1, 2018 until January 1, 2021. The reason for the statewide fixed clock is so that everyone is subjected to the same clock rather than an individual clock that is reset for every individual person. Let us say the statewide clocks starts on January 1 and ends on December 31. An individual applies for benefits in 2019 and receives three months of benefits. The statewide fixed clock starts again in 2021 and the individual is eligible for the next three months. The individual does not necessarily have to wait an entire 36 months in order to get his or her benefit back. Section 2 also affirms that the DWSS has the ability to request statewide or geographic waivers under specific circumstances relating to unemployment or insufficient job markets. The last thing section 2 of [Exhibit D](#) does is establish priority groups for potential exemption within the State's 15 percent discretion due to the significant barriers the individual experiences for unemployment. Those employment barriers include employees who are working less than 20 hours a week, those who are recently discharged from the military who may need more of an adjustment time than 3 months, caregivers who are unpaid who are caring for a family member that resides outside of their home and non-custodial parents who are required to provide child support. Remember the State already exempts homeless individuals who are mentally ill.

Section 3 of [Exhibit D](#) establishes a voluntary workfare program at a rate equivalent to the State minimum wage. If the individual is in a SNAP employment or training or a Workforce Innovation and Opportunity Act (WIOA) program and has 20 hours or more of job training, the individual can be exempted out of the work requirements. Nevada does not have nearly enough of those work training programs to meet all of the individuals looking for work that are within that group of individuals. We are talking about possibly 60,000 people. A workfare program is an allowable work opportunity through the USDA that individuals can come work at nonprofit organizations like the food bank but instead of getting paid minimum wage they would be clocking in and out as a volunteer, learning job skills and responsibilities, setting their own volunteer hours and what activities they will do. They are responsible to show up and we calculate the hours, and provide them printouts whenever they need them. This helps recipients and also helps nonprofit organizations whose demand for workfare would go up and decrease the nonprofits' burdens when trying to meet volunteer request demands.

Section 4 guides the DWSS to consider contracts with appropriate individuals or entities to interview tens of thousands of ABAWD subjected recipients. For example, the DWSS already contracts with several different nonprofit organizations including both of the food banks in Nevada to do SNAP outreach. Many of the people who may be subjected to time limits on SNAP actually might have applied for their benefits through the food banks or through SNAP outreach programs. They never walked into a welfare office. These individuals may be less inclined, even if they have a potential exemption, to walk into a physical welfare office, which is only open from 8:00 a.m. to 5:00 p.m. They may have applied for benefits in the evening or weekend through programs like SNAP outreach. We would want to provide as much flexibility to DWSS to make sure that they have all opportunities to meet with as many of these ABAWD subjected individuals as possible to make recommendations on who may be eligible for an exemption.

Section 4 of [Exhibit D](#) also brings stakeholders to the table with DWSS to discuss ABAWD implementation for a set period of time. For about 18 months after ABAWD comes to be, we would have regular communication with them so we are all on the same page about the challenges and the successes of returning to the time limits.

Section 5 of [Exhibit D](#) establishes the effective and end dates of each section and provision of [S.B. 323](#) to be in alignment with the new sections.

SHANE PICCININI (Food Bank of Northern Nevada):

[Senate Bill 323](#) is a helping hand for the unpaid caregivers, the seasonal workers, the construction and building trades or people in the tourist-based economy who need this as a bridge. The food banks would have a hard time trying to meet the needs of those workers, and [S.B. 323](#) goes a long way in helping keep people in food security.

JON SASSER (Washoe Legal Services; Legal Aid Center of Southern Nevada):

Washoe Legal Services and the Legal Aid Center of Southern Nevada support [S.B. 323](#).

DENISE TANATA (Executive Director, Children's Advocacy Alliance):

The Children's Advocacy Alliance supports [S.B. 323](#).

EDWINA RICHARDSON (Macedonia Outreach Social Enrichment Services):

The Macedonia Outreach Social Enrichment Services (MOSES) operates a food pantry in connection with Three Square and receives support from other organizations and businesses in Las Vegas. We serve about 300 families per week and last year distributed 500,000 pounds of food to those in need. The implementation of S.B. 323 would help MOSES significantly as we provide one to two days of food per week. Many individuals are in the category of construction workers or seasonal to the extent that they are underemployed, like working in the gaming or tourist industry and may have lost their jobs. If MOSES is now providing one or two days of food for a family, we are then put in a position of where we are required to provide perhaps seven days worth of food. That more than triples our workload and triples our need to find sources of food to meet this need. When a family cannot receive what they need through a single pantry, they will go to multiple pantries, so the impact on the community is the same whether it is a single pantry or multiple pantries. The Macedonia Outreach Social Enrichment Services support S.B. 323.

MARY FINCH (Three Square):

Three Square supports S.B. 323 as it will allow our veterans to receive the benefits they need once they are discharged after serving our Country, and pending employment and retirement.

STEVE H. FISHER (Administrator, Division of Welfare and Supportive Services, Department of Health and Human Services):

I want to thank Senator Cancela for meeting with us this week and working with us on the amendments for S.B. 323. Because of the amendments to S.B. 323 we are removing the fiscal note.

CHAIR SPEARMAN:

I think it is easy sometimes for people to say derogatory things about individuals who are having a tough time or people who may not have the type of income that they have. Having the presentation helps us to appreciate the struggles of the people who are trying to make it.

SENATOR CANCELA:

The intent of S.B. 323 is to make individuals who are struggling have the help they need, and that we are as prepared as possible for the kick in of the 2018 changes.

CHAIR SPEARMAN:

I close the hearing on S.B. 323 and open the hearing on S.B. 305.

**SENATE BILL 305**: Revises provisions regarding certain proceedings concerning children. (BDR 38-926)

SENATOR JULIA RATTI (Senatorial District No. 13):

Best practices, recent case law and new guidelines from the U.S. Department of Health and Human Services agree that children have a constitutional due process right to counsel in foster care cases. Currently, only some children in the Nevada foster care system are being appointed counsel, subject to the judge's discretion and the available resources. Today, 87 percent of children in Clark County, which is 3,073 kids, and 50 percent of children in Washoe County are receiving representation. Washoe Legal Services is also contracted to represent children in Lyon, Elko, Humboldt and Pershing Counties.

Senate Bill 305 will require that all children have an attorney in a *Nevada Revised Statutes* (NRS) 432B foster care case and in any related NRS 128 termination of parental rights case. These attorneys give children a voice and an advocate to help them navigate one of the hardest and most confusing times in their lives, creating better outcomes for children. These changes bring Nevada in line with best practices and the national norm. Thirty states have solidified this right to counsel for children, thirteen states have a qualified right and only seven states, including Nevada, only have a discretionary appointment of counsel for children. Our experiences show that attorneys ensure children's voices are heard in court, protect children from unnecessary removals from their homes, help children succeed in school, ensure children have access to medical and dental care, monitor and ensure appropriate use of psychotropic medication, and ensure children who have to testify in court are protected. We are prepared to share examples of each of these positive outcomes.

The proposed amendment ([Exhibit E](#)) provides a funding source for the counties to meet the mandate. The funding source will be an increase in recording fees from \$3 to \$6. The proposed amendment enables the county commission to implement the fee to fund the programs.

BARBARA BUCKLEY (Executive Director, Legal Aid Center of Southern Nevada):

The Legal Aid Center of Southern Nevada is a nonprofit organization that provides free legal representation to vulnerable communities. Among those are children who are abused or neglected. About 18 years ago, I received a phone call from the Clark County Manager's Office, who said we are one of the last organizations in the metropolitan areas in the nation that does not provide independent legal representation to kids and this needs to change. Forty years ago, kids were thought of as property or an afterthought in abuse and neglect. The parent accused of abuse got an attorney, there was an attorney for the child welfare agency, there was a court appointed special advocate (CASA), but who let the court know what the child thought? Who represented their interest? The Children's Attorneys Project (CAP) in Clark County was born after the phone call. We received our first seed grant, hired our first lawyer and took our first case. Fast forward to today, we are representing over 3,000 children with 20 staff attorneys and 300 volunteer attorneys. These volunteer attorneys are some of the best lawyers in the State. They come from big firms, small firms and general counsel. We give them a crash course training and then assign them to one of our lawyers to be a mentor. We put all the pleadings they may need on a Website and then they are introduced to the clients. One memorable conversation I had was with Justice Hardesty, Justice Douglas and a managing partner of a construction defense firm said his CAP case is the most meaningful thing in his legal career, nothing he is doing compares to representing a kid in the foster care system. Now is the time to take Nevada off the list of seven discretionary states. Due to the collaborative work with Clark and Washoe Counties, the children's programs in both jurisdictions, through the judges appointing private counsel and Washoe Legal Services in the rural communities, we are almost there. This funding will get us through the last mile.

SENATOR HAMMOND:

The proposed amendment doubles the fees collected for recording a document. Those fees were originally set at \$3 when A.B. No. 192 of the 76th Session passed. I remember Ms. Buckley testifying that we could cover all the children in the State for \$3. Has the number of children doubled?

MS. BUCKLEY:

It has not doubled, but it has gone up. The amount of money was not sufficient. In 2013, we were at 1,225 children. Today, we are at 3,033 children. Senate Bill 305 does create an unfunded mandate. We went to the counties and worked out an amendment. The language on the proposed amendment says up

to \$3. In Clark County, we estimate that \$1 to \$1.50 would get us to 100 percent. In Washoe County, they estimate \$3 to get to 100 percent. One of the questions Clark County asked us was if we would dismantle the pro bono program if they were supportive of the raised fees. The answer is no, we would not dismantle the pro bono program. It is helpful for our lawyers to get involved as they see the unmet legal needs for children. We have had attorneys adopt kids. We like having the attorneys involved in the system.

SENATOR HAMMOND:

The increase of the fee from \$3 to \$6 does not mean the county recorder's office will charge \$6, but can charge up to \$6. Is that correct? The proposed amendment says impose by ordinance a fee of not more than \$6. So the fee is being increased 100 percent.

Ms. BUCKLEY:

Yes, that is correct. The proposed amendment allows up to \$6 but it does not require that. It allows the local communities to determine their own needs. Clark County does not need the full \$3 increase.

SENATOR HAMMOND:

In 2011, you testified that the \$3 would cover the attorneys for every child in the State, but that has not happened even though we have fewer foster care children. Is that correct?

Ms. BUCKLEY:

I do not think we have fewer children in foster care. In 1999, when the program was set up there were 1,600 children in care. Today, there are 3,500 children in care, and that counts the kids that are between 18 and 21 years old, but the caseloads have gone up as the population has gone up.

SENATOR HAMMOND:

What about in 2011, when you came to us and asked for the \$3?

Ms. BUCKLEY:

I will provide the number because I do not want to misquote it as it is not off the top of my head.

SENATOR HAMMOND:

The one part of S.B. 305 that does give me pause is section 2, subsection 1, paragraph (c) as it states the attorney must not be an attorney appointed to represent the child pursuant to NRS 432B.420. Are we talking about a guardian ad litem?

Ms. BUCKLEY:

Yes, that is correct.

SENATOR HAMMOND:

In 2015, attorneys were allowed to be guardian ad litem when S.B. No. 394 of the 78th Session passed. In two years we are changing the language. Is there a reason for this? Are attorneys guardians ad litem in other states? If they are allowed in other states, why are we not allowing attorneys to be guardians ad litem?

Ms. BUCKLEY:

The American Bar Association (ABA) and its section for children and the law recommend that attorneys represent children as their lawyers, to represent their wishes. The National Association of Counsel for Children (NACC) does as well. In Nevada, we have settled on a guardian ad litem program and it is called the CASA program. There are CASA programs in different counties in the State. The court-appointed special advocates recruit volunteers to serve as the guardians ad litem for children. The volunteers represent the children's best interest, to visit them in their homes and to give a court report on what they have seen. Some states use lawyers for that. In some states two lawyers are used to represent the child. In Nevada that does not make sense as we have limited resources and we have a guardian ad litem program. The Blue Ribbon For Kids Commission is unanimous in its support of the work CASAs do. That is why an attorney representing a child cannot be a guardian ad litem and to recognize the importance of the CASA programs.

SENATOR HAMMOND:

I do not agree with the reasoning as I do not mind having an attorney be a guardian ad litem as well. There are the wishes of the child and there is the best interest of the child, and those are two different things. This is one part of S.B. 305 that I have a problem with and I would be happy to speak with the ABA about it.

SENATOR RATTI:

I want to clarify that S.B. 305 does not stop attorneys from being guardians ad litem, it only stops the attorney who is appointed to represent that child from also being that child's guardian ad litem. We are making sure the child has both a guardian ad litem and an attorney. Senate Bill 305 just makes sure that the child's attorney does not play both roles.

SENATOR HAMMOND:

I understand that, but here is the pause, section 2, subsection 1, paragraph (c) states, "Must not be an attorney appointed to represent the child pursuant to NRS 432B.420" and paragraph (d) states, "Is not entitled to compensation or payment for expenses." The amount of people who can do the job is cut down and not many attorneys will be willing to do that.

Ms. BUCKLEY:

We have 350 attorneys representing 888 children pro bono. This is an amazing number, probably one of the highest in the nation. If a lawyer is told he or she will get paid by the county, if a bill to do guardian ad litem work is submitted, it interferes with the model of volunteerism that has been developed and grown to an incredible level. One of the reasons why the ABA and the NACC are so strong on this is lawyers are trained to be lawyers. They are trained to listen to clients, to represent the clients' wishes in court and to present evidence but they are not very good at substituting their own opinions, judgements and morals in a situation. The reason these organizations have recommended this model so strongly, and they have convened groups around the Nation to study and debate this, is because they think lawyers have a role and they should stick to that role. I am happy to share all the studies with the Committee.

SENATOR HAMMOND:

I would like to see the studies. I keep going back to two years ago when we had a particular bill in the Senate Committee on Health and Human Services and an attorney you are familiar with said sometimes they do not care what the children need, they care about what they want. When there is a nonverbal child, it is important to represent the need. That is why I like a guardian ad litem that is also a lawyer. Then the lawyer can do both and bring a different perspective. It is admirable that there are so many lawyers that do pro bono work, and come from one perspective, but I think there is room for another as well. When we are talking about kids, it is certainly not a disadvantage to have two lawyers representing two different viewpoints. For years, parents had lawyers, almost

everyone else had lawyers, the only ones who did not were children. They are the ones who are the most vulnerable. I certainly do not want to take away the ability to have someone who is a guardian ad litem with the training of a lawyer. That is why I am adamant about it.

SENATOR HARDY:

Ms. Buckley came into my office this morning and we talked about the best interest of the child. Just because you are the attorney for the child does not mean you quit caring for the best interest of the child even. When the attorney and the guardian ad litem were married together, the best interest of the child took precedence. I do not understand the proposed amendment where it states if an attorney is paid through the legal services program in a county, that attorney is not entitled to compensation under this statute. Are we are talking about increasing a fee so we can pay the attorneys, but we are not allowed to pay them if they are being paid?

Ms. BUCKLEY:

Right now, the compensation for lawyers in this system is they would bill the county, similar to what is done in criminal defense. We have never utilized that in Clark County or Washoe County, but they do utilize that process in the rural counties. If instead we are able to develop this fee mechanism and the county gives a contract, for example, to a legal services organization, then that legal services organization attorney cannot bill the county under the criminal rate. That is all that it does, to make sure the services are only paid for once.

With regard to best interest, that is still the standard and it is in the law now. When we first started CAP, I thought we would be representing a lot of positions the kids had that were not in their best interest. That hardly ever happens. What kids want is not to be separated from their brothers or sisters or to go to the high schools they have been going to for all these years.

SENATOR HARDY:

If an attorney is being paid, he or she cannot be paid under this statute. Is that correct? For me, that is counterintuitive of what we are doing.

SENATOR RATTI:

The key point is if the attorney is being paid through a legal services program. We do not want to impact a county that does not have the benefit of a legal service program today. It was mentioned that there is coverage in Clark County

and Washoe County, and Washoe Legal Services also provides services in four other counties. In the counties that do not have the benefit of a legal aid organization, we are leaving them the flexibility to be able to pay for services the way they are paying for services now. The key phraseology is if the attorney is paid through a legal services program. That is what we are carving out.

SENATOR HARDY:

Where is the money going?

SENATOR RATTI:

The county commission has the ability to enable the fee and retains the authority over its budgeting process. In Clark County, Washoe County and the other counties where Washoe Legal Services has a program, a contract is entered into between the county and legal aid organization through the local government budgeting process. In the counties that do not have a legal aid program, the \$3 fee could be used to pay an attorney directly at the order of a judge.

SENATOR HARDY:

I am going to provide a scenario. I live in Clark County and I have a document recorded and the cost is \$6. The \$6 goes to the county and the county commission gives it to the legal aid society and the legal aid society pays the attorney \$6 cumulative. The legal aid society cannot do that if the proposed amendment to S.B. 305 says the attorney is not entitled to compensation under this statute.

SENATOR RATTI:

I understand your point and we will work to add language to the proposed amendment to make the intent more clear. The intent is really what Ms. Buckley said, as we do not want attorneys to double-dip.

CHAIR SPEARMAN:

Could you complete this sentence? The fee that is collected does...

MS. BUCKLEY:

The fee that is collected does allow every child in the foster care system in the State to finally have a voice and to have an advocate in court.

CHAIR SPEARMAN:

This morning in another committee, we heard S.B. 406 regarding court reporters.

**SENATE BILL 406**: Revises provisions relating to court reporters and court reporting firms. (BDR 54-949)

The question I asked at the time was, how many attorneys are doing pro bono work? One group said they typically do pro bono work and the other group said there are times when they also do pro bono work. Attorney's fees and court fees are going up. I have researched the cost of living and the cost for legal counsel in 2009, 2011, 2015 and 2017. It appears during the recession, 2009 and 2011, the costs were not quite as steep, but coming out of the recession, the costs have begun to escalate. I understand why there is a proposed fee increase. We have talked about the care for children, and the cost of incarceration. If S.B. 305 does not happen, what is the cost of incarceration? Is it \$6 or less?

MS. BUCKLEY:

The cost of incarceration is \$10,000 or more. One of the saddest studies I ever saw on Nevada kids in foster care was done by Dr. Tom Riley, when he was at the University of Nevada, Las Vegas. He did an exit survey of kids in foster care and found an alarming number in jail, prison and homeless. One kid was rationing his insulin and died. That is when all the reforms started. We wanted to give a bridge to kids from 18 years old to 21 years old. We started representing kids in foster care to make sure they had a voice so they were not so traumatized. So they felt like someone listened to them. Now, of course, they have Medicaid under the Affordable Care Act. We have made progress, but if we do not invest in our kids now, we pay for it later, which is your point.

CHAIR SPEARMAN:

If a child was not in foster care and the parent could afford an attorney, would the child still have the same option or is it just children that are in foster care that we are having a difficult time with?

MS. BUCKLEY:

Most of the families in foster care are poor. Occasionally, we have families of means, but mostly they are in the sexual abuse cases, where we represent the kids. They are usually girls, and we are so fortunate to have a female attorney

that is all she does, and she is nationally certified. Regardless of the parent's means, we represent the child. The judge might assess fees against the parents, but we go in from day one. We get the kids into counseling as quickly as possible. It is so imperative, and sometimes it does not happen because of bureaucratic reasons, so we are there right away to say the child needs counseling.

CHAIR SPEARMAN:

The fee is paid so every child in Nevada can have attorney representation. The cost of incarceration is in excess of \$10,000 and we have not even talked about the cost of life, the quality of life. So \$6 for the fee or \$10,000 for incarceration seems like an easy decision. I am trying to reconcile the difference between the lenses of family values and valuing families.

MEKHI OVERTON-JACKSON:

I am 19 years old. I was originally put into the foster care system when I was 15 years old. It was a result of my mother having a serious alcohol problem and having a really abusive boyfriend that would lash out at me and my younger brother. It took my mom kicking me out of the house before I made my way to my grandmother's house and called Child Protective Services (CPS) to tell them what was going on. From then on, I stayed in the foster care system until I turned 18 years old and aged out. Before my lawyer Janice came into my life, things were essentially going nowhere. I battled depression when I was going through the system. I was separated from my younger brother constantly. I bounced between homes. My life was going nowhere. I felt the caseworker I had at the time did not serve my best interest. I was breathing, had a home, and had necessities, but whether I was happy at these homes or if I was thriving was not the caseworker's goal. When Janice came into my life and took charge, the caseworker was removed and replaced with a new one. I was placed with my grandmother, found work and went back to school. Things got back on the right track after I was able to vocalize and make things known to people. Before, when I said things and needed things, it was disregarded because I was a child. I was too young to know what I wanted or I did not have the right state of mind. Once Janice came into my life and became my voice, things started taking a turn for the better. I feel no kid should have to go through the things I went through when I was in foster care. I believe the lawyer was the first step in me being able to take control of my future. I support S.B. 305.

STEPHANIE MAHLER:

I am 14 years old. Since I was real young I watched my mom being abused by my stepfather. Both my mom and step-dad used drugs, and there was a lot of violence between them. One time, when I was 5 years old, they were fighting on the stairs, and I tried to stop my step-dad from hitting my mom. He tripped me and I fell down the stairs. This was the first time CPS entered my life. They did an investigation, but I was not removed from the home. My mom and step-dad later broke up, and my mom got a new boyfriend, who was even more abusive to us both. He was violent all the time. They were both using drugs everyday too. Eventually, they both lost their jobs, and we ended up living in a weekly motel. I was really scared at first, but after a while I got used to living that way. Then one time, when I was 6 years old, my mom left me with a stranger all day. Finally after midnight she called and asked my grandmother to go pick me up, but she could not remember where the person lived, and did not have her phone number. My grandmother was very scared for me, and she drove around the neighborhood for hours where my mom had dropped me off. My grandmother finally found me walking along the street with the person. My grandmother was desperate to keep me safe, and wanted to take me home with her, but first had to start the process. She went to the police to report what had happened, and they called CPS. Legally, my mom still had custody, so I had to go back to her. At least this got CPS to open another investigation into how my mom was treating me.

My grandmother took classes to become my guardian, and I was placed with her from when I was 6 years old until I was 9 years old. I felt really safe with my grandmother. For once I got to sleep in a bed instead of a couch pushed up against the motel room door, but at the same time I had gotten so used to the constant violence and chaos, I could never really relax and believe this was the life I should have been living all along. During this time, my mom completed rehabilitation and came to live with my grandmother and me. I had two different caseworkers with the Clark County Department of Family Services, and they decided my mom had qualified to take custody of me again. No one told me about this change or asked me what I wanted. One day she started making decisions for me again. She met another boyfriend and they got married. I was forced to move away from my grandmother and live with my mom and new step-dad. They were both openly using drugs. My mom got pregnant with twins, a boy and a girl, and my step-dad was very abusive to all of us. The babies were bruised all the time, so someone finally called and reported it to CPS. A new case was opened for the three of us. This time I was able to go

back to my grandmother, and get a lawyer of my own through the Legal Aid Center of Southern Nevada.

My lawyer's name is Denise. It was weird to be around my lawyer at first, because I never had anyone who would stand up for me in court, be my voice and fight for my rights. I thought she would be like every other caseworker who said they cared, but really did not. I went to court with Denise on my fourteenth birthday, and I fully expected they would send me back to my mom, and this whole mess would repeat once again. Denise was like a total savior and warrior for me. She fought for what I wanted, which was to stay with my grandmother for good. I was so surprised when the court agreed, and my wish came true. It was the best birthday present I could ever have hoped for. It was a gift that will truly stay with me forever. I will be 15 years old this year, and I am out of care now as my grandmother has guardianship over me. I am so happy living with her. I was accepted into Advanced Technologies Academy where I am majoring in graphic design. I want to study other languages and become an interpreter, especially sign language for the deaf. I support S.B. 305.

ELLIOT BRITTAIN:

I am a University of Nevada, Las Vegas student who is interested in helping those with mental illness and substance addiction. I was born and raised in Las Vegas, and proud to say I am a native Nevadan. From my earliest memories, I remember only a few situations in which I lived with my mother. I never met my father or knew much about him, only his name. I remember living in some neighborhoods that were unsafe, and as a young child, I would wander about without much supervision. One day my mother, who I have a relationship with today and love dearly, was drinking heavily and I ended up getting hurt. She had given me a black eye. For that day on, at the age of four or five years old, I lived with my grandparents, not through foster care. I grew up with them and they ensured that I would grow up happy and become an aspiring young man. I did not think much about growing up with them instead of with my mother or father.

When I was 17 years old, my life changed. My grandfather fell ill and passed away suddenly, followed by my grandmother a few months later. I was not prepared for such a turn in circumstances. I soon became a fostered youth. Though I was almost considered to be an adult, I was still quite young and unprepared to begin my life. When I was called to court to determine if my biological father was really my father I did not feel prepared, or ready to meet

this man. That is when I was connected to the foster care system and found many amazing mentors who have helped me become who I am today. Among them was my CAP attorney who helped me navigate the court system. I had been called to court to meet a man I had never seen before and only known by name. I was to see him face-to-face in court for the first time to determine if he was really my father. My CAP attorney walked me through the process. I felt nervous and uneasy at the prospect of showing up to court and meeting this man but my attorney had the knowledge of the court system and provided me the emotional support I needed. My story is similar to other foster youth. I see the benefit of having attorneys on the side of the children who need them most. I am grateful that such a resource existed for me. Senate Bill 305 ensures that all foster kids have access to attorneys. It is through all the cumulative efforts of my mentors that I have gotten to where I am today and I urge your support of S.B. 305.

JAMES CONWAY (Executive Director, Washoe Legal Services):

Washoe Legal Services provides child advocacy services in Washoe, Elko, Lyon, Humboldt and Pershing Counties. Washoe Legal Services is in support of S.B. 305.

JESSE FREDZESS:

Growing up, I faced many forms of abuse at the hands of my parents. Please let your imagination go wild because you would not be wrong. My parents took everything from me including my voice. My voice was taken and suppressed for years until I entered the foster care system. There, an attorney from Washoe County Legal Services was appointed to me. My attorney was the first to speak up for me, listened to every word I had to say, articulated them with the force I was afraid to and the skill I did not know. My attorney was the first of many to give me back my voice. As I learned and gained courage, I reclaimed my voice. I am so thankful for my attorney and everything done for me. I am surprised such a service is not yet in the law. I saw my attorney more than I saw my social worker. My attorney really knew my needs and communicated them for me. Representation for vulnerable children is a just pursuit supporting the well-being of every child in Nevada. We need to be the voice these children do not have because no one else will be. Passing S.B. 305 will be helping the children of Nevada, especially those most vulnerable to gain back their voices. This is exactly what the activity supported by S.B. 305 did for me.

SENATOR HAMMOND:

When the young people testified today and told their stories and backgrounds as to why the need is there, I feel compelled to tell them some things. Because I have asked questions some of you might assume that I might be against the bill. I have had good conversations with Mekhi, Stephanie, Elliot and Jesse and I have told them a little bit about my background so they know where I am coming from. I want them to know the questions that have been asked are necessary, especially the one about the child's best interest.

Mekhi, Stephanie, Elliot, Jesse and I spoke off-line. I am going to pretend that nobody else is here, except the four of you. I have been in your positions; my mother was married at least three times, that I know of. I know she made bad choices, and of course, I had to suffer through those bad choices. I still have a nose that was hit hard enough to break it, and I left it that way as a reminder throughout my life of what I went through. I want you four to know as we are debating S.B. 305, it is not that I do not understand where you coming from, because I do. I spent time in another home that I told you about. My nose is a reminder for me, but I also want you all to know that is not your story. Your story is not done. You know that. You guys are going someplace and your story is not done yet. You do not know what you can be someday. Some people will say you need to be a State Senator, and I do not think that is anything great. It just means I get to represent some people and that is awesome. When we are debating S.B. 305 we are trying to figure out the language of the bill to make it the best we can. I understand your stories and I am grateful you all had attorneys that had your back. I am looking at having your back plus I want to make sure we are covering the interest of us, the ones who have gone through this.

MS. TANATA:

The Children's Advocacy Alliance supports S.B. 305.

YOLANDA T. KING (County Manager, Office of the County Manager, Clark County):

The reference to: If an attorney is paid through the legal services program in a county, that attorney is not entitled to compensation under the statute, is confusing. Looking at the proposed amendment before that statement, there is reference to the same compensation and payment for expenses from the county as provided in NRS 7.125 and NRS 7.135. Those particular statutes outline a fee that is paid to an appointed attorney. The fee for noncapital cases is \$100.

The intent of the language is to state if legal aid services is providing a program, that fee of \$100 does not apply to that legal aid service or program. As Ms. Buckley stated, currently they are not charging \$100. I wanted to ensure going forward, in order to keep the cost down associated with representation, that the \$100 does not apply to the legal aid services. Clark County does support S.B. 305 based on the proposed amendment.

As Senator Ratti and Ms. Buckley stated, without the additional fee increase, there would be an additional cost. It would be an unfunded mandate to the counties. In an effort to keep those costs down, there are a couple of items that we brought to the attention of Senator Ratti, as well as Ms. Buckley. The first is the reference to the attorney's fee of \$100. I did not want in the future for fees to be charged because the statute allows those fees to be charged, which would increase the cost for representation, and thereby would obviously need to have an increase in the recording fee. The second part has to do with the recording fee and what that looks like going forward. Although Clark County does not need the full \$3, there will be a caseload increase. We have seen it just from when the fee was initially imposed. Our preference is to have a little bit of leeway to be able to increase the fee over time if there is an increase in caseload. Obviously, an increase in caseload will definitely mean that there would be an increase in the cost, and therefore could be an additional unfunded mandate to Clark County or any of the other counties. That was the intent of including a fee that would allow us to accommodate or pay for a caseload increase as well as limit the amount of money that is paid to those attorneys. If we look at payment of the representation to those children in Clark County, it would not be Clark County's intent to charge a fee to the maximum of the \$3. We anticipate that we will need approximately \$1 to represent the remaining children. Ms. Buckley stated she would continue to maintain the pro bono services. If we have a complement of the legal aid programs as well as pro bono services, that will in fact also limit the cost going forward. Ms. Buckley and I have worked on having language within our contracts whereby she would continue to maintain those pro bono services. Ms. Buckley, Senator Ratti, Washoe County and I have worked through some of these issues that would limit the cost and I do not anticipate that the full \$3 is needed in Clark County. However, I understand it is needed in Washoe County.

SENATOR HARDY:

The extra money is going to the attorney but also to the county to deal with the other charges the county will be faced with due to the increased caseload. Is that correct?

MS. KING:

It would address future caseload increases. The intent would be for the Clark County Board of Commissioners to increase the fee that is necessary to address the remaining caseload, and if in the future, that fee needs to be increased to address additional costs associated with caseload growth. That would give the Board of Commissioners the ability to increase the fee as needed.

SENATOR HARDY:

Is the silo legal? Is it going to be used for the caseload issues, administration and all the things that go with the increased caseload?

MS. KING:

The way the language is written in S.B. 305, it is specific to legal representation for foster care children. I believe it is written tight enough where it is nondiscretionary in terms of how the dollars can be used.

SENATOR HARDY:

Are you saying because of the \$100 cap and increasing the caseload legal fees, you will have legal aid hire more lawyers to take care of the increased caseload?

MS. KING:

Yes, that is correct.

JODI STEPHENS (Wynn Resorts, Limited):

Wynn Resorts, Limited supports S.B. 305 to ensure the children have a voice.

KEVIN SCHILLER (Assistant County Manager, Washoe County):

Washoe County supports S.B. 305. About 16 years ago, Washoe County was part of the initiation of this program. Washoe County operates very similarly to Clark County in terms of contracts. Washoe County has a contract where it pays a portion of the fee and the rest is offset with the \$3 filing fee. Washoe County is at about 50 percent represented on a full caseload. It has been said several times that Washoe County needs the full additional \$3. It is enabling language, as it will be a slow titration to the 100 percent mark. We are looking

at a 2-year period and may not go to the additional \$3, as we are budgeting as it is a priority for Washoe County. It is an issue in child welfare cases and the need for representation, which often helps us with permanency and with reunification. In many cases it actually provides some level of cost saving when we are getting to permanency and representing children correctly in conjunction with public defenders and the Washoe County District Attorney. Washoe County funds this outside of the filing fee and will continue to do so and will approach this from an enabling perspective in terms of what is needed.

SENATOR RATTI:

I want to thank the young adults who came today to share what it was like for them to be in foster care, and in particular, what an impact it made on their lives when they had access to legal counsel. This is our obligation. Every child who is in foster care deserves the right to legal counsel. If the government had to bear the full weight of the cost, we would have a very challenging conversation. We are lucky in Nevada that we have some very talented and innovative legal aid organizations, which through a combination of philanthropy, pro bono work and government contracts are bringing that cost down significantly to the State government to take care of these children. The \$3 fee we had before, plus the additional \$3 fee, does not come anywhere close to paying 100 percent of the costs. How we get to the 100 percent of the costs is a stellar partnership with the legal aid organizations who are carrying the bulk of the weight. It is our job to get us to the finish line so that every single child in the foster care system has access to legal counsel as they should. I encourage the Committee to support S.B. 305 and it is well past time this happens.

SENATOR HAMMOND:

Ms. King mentioned caseload, and Mr. Schiller said they need to be represented correctly. What are the national best practices? What are the caseloads right now? Are we trying to maintain the caseloads or lower them a little bit with this increase? Do we reach anything close to the national best practices?

MS. BUCKLEY:

One of the goals in providing an attorney for every child is to lower the caseload. Government is a terrible parent, even the best intended workers are no substitute for a loving parent. Whether it is complying with the Adoption and Safe Families Act of 1997 to give parents a chance, if they can; if not, relatives; if not, adoption. That is the goal of permanency in child welfare. If that happens and a lawyer pushes to make that happen, deadlines are met, and

kids get out of the system and caseloads can go down. That is the way it should be. Kids should not be raised in foster care, as it is not healthy.

SENATOR HAMMOND:

Can we talk off-line about the national best practices and the current caseloads?

Ms. BUCKLEY:

Yes, we can do that.

CHAIR SPEARMAN:

I close the hearing on S.B. 305. Senate Bill 325 will not be heard today and will be rescheduled to another day.

**SENATE BILL 325**: Revises provisions governing medical assistance to certain children. (BDR 38-941)

I open the hearing on S.B. 265.

**SENATE BILL 265**: Revises provisions relating to prescription drugs. (BDR 40-809)

SENATOR YVANNA D. CANCELA (Senatorial District No.10):

Senate Bill 265 is intended to address the rapidly increasing cost of diabetes care in Nevada. Twelve percent of all Nevadans are diabetic, thirty eight percent are prediabetic. The total diabetic population of Nevada is on path to double by 2030. Meanwhile, the cost of insulin has inflated across the Country, and certainly here in Nevada, so much so, that the three makers of insulin have been sued for fixing prices in a Massachusetts federal court. You will hear from doctors, who are diabetes experts and experts on the rising cost of insulin and drug purchasing and you will hear about the impact on families and the importance of consumer protection. I suspect you will also hear some of the same arguments that have been advanced in other states as legislatures have attempted to put legislation forward to address the rapidly increasing costs of pharmaceuticals. You might hear the problem with prices is not the industry and see some finger-pointing about who is really in charge. Is it the pharmaceutical benefit managers? Is it the insurance companies? I would ask that you remember the initial starting point for price setting begins with the manufacturers, which is why they are the major target of S.B. 265. You might also hear that spending on diabetes medications reduces other health care costs

such as hospitalization and that is true if folks are able to access diabetes medications. You might hear transparency in prescription drug pricing will stifle innovation. To that, I would say it may be true for other drugs, it is not true for a 95-year-old drug like insulin. You might hear that price gouging is an isolated incident, that there are some bad actors, but the reality is that we have seen price increases across the board in insulin nationally for almost two decades.

PRAVEEN JAYAKUMAR, M.D. (Medical Director, Culinary Health Fund):

The insulins of today are different from the insulins from 95 years ago. The most potent and long-acting insulins were discovered in the year 2000 and all of those are unaffordable if you do not have health insurance. The insulin you can get for \$25 at Walmart and Target is called NPH 70/30 and these are combinations that were made in the 1980s. This is the only option for our patients who do not have insurance coverage and it is 2017. Diabetes is a silent killer. Type 1 diabetes affect young children and young adults, and they get to know the symptoms sooner, and they need to be on insulin. Most of the time folks who get diabetes later as a metabolic issue do not know they have diabetes until complications set in. The reason diabetes is such a public health issue is that elevated blood sugars, when uncontrolled for long periods of time, affects every single part of the body. It starts by affecting the microvessels of the nerves, kidneys and the eyes which ultimately leads to kidney damage, loss of vision and loss of sensation in the feet. Ultimately, it affects the large vessels and leads to diseases such as heart disease, heart failure and stroke. It is a silent killer in the folks who do not realize the complications until it is too late. The way progression and complications of diabetes is controlled is through intensively controlling the blood sugar levels. That is where the role of insulin comes in. In the course of my clinical practice, I have treated hundreds of diabetics in Nevada. For these patients, at some point in time, either early on in the course of treatment or later, they all end up on insulin at some point.

I would like to share a story of one of my patients called Jose, who first came to see me when I worked at Lied Clinic at the University of Nevada, Las Vegas, School of Medicine, which is the county hospital. Jose was 46 years old, hardworking, and worked in the fast food sector. He came to see me and his main complaint was he was tired all the time and it was affecting his work. I ran some lab work and found out he had diabetes, his blood sugars were uncontrolled. They were so high, and the guidelines suggested he go on insulin right away. He could not take oral drugs because of how high his blood sugar levels were. We discussed diet, lifestyle changes and other medications but

ultimately he needed to be on insulin. He did not have health insurance, so he ended up having to take the lower cost insulin that was available. The problem with these types of insulins, that you get for \$25 at Walmart and other places, is that the blood sugar control is not optimal. It goes up and down based on the type of formulation the doctor gives. One of the big side effects of these types of insulin is the patient's blood sugar can drop to a critical low level at which point it becomes a medical emergency. Anyone who has been through that process will never forget it. It makes treating the disease even more difficult because folks get scared of taking insulin with the fear of that one episode of low blood sugar. In the case of Jose, he had that one episode of hypoglycemia when he was at work. He collapsed and had to be taken to the emergency room. I saw him in the hospital later and discussed how he could avoid this with the type of insulin he had. The best option was to cut down the dose of the insulin, help him work with his diet and try to make that work with his work schedule. I did not see Jose for the next year. The last time I saw him was when he was admitted to the hospital and I was performing rounds with my resident team. Jose had developed a foot ulcer which had gotten infected and had gone to his bone. Luckily his foot was saved, but he needed to be on intravenous antibiotics for six weeks. That was six weeks he could not work to support his family and get more in debt.

The team of researchers in Toronto, Canada who discovered insulin in 1921 patented it for \$3. They were troubled by the idea of profiting from a drug, which quickly transformed a disease that was a death sentence back then to a manageable disease. The first longer acting insulin was released in 2000, yet the only affordable insulin that is available today are the ones from the 1980s. Unfortunately, for many of Nevada residents, the price of effective long acting insulin today make diabetes a slow but certain death. I wholeheartedly support S.B. 265 and appreciate the opportunity to represent all the thousands of individuals like Jose who live among us.

BOBETTE BOND (Executive Director, Nevada Healthcare Policy, Unite Here Health)  
My role has been to try to figure out how we are going to help manage our prescription costs in a strategic way over the long haul in our fund as they increase. That led us to the issue we are seeing with insulin and diabetes management. The cost of insulin has been consistently rising, it has tripled between 2002 and 2013, but this is not the case in other countries. The transparency in S.B. 265 will help us get a better handle on why that is. In the 95 years since insulin was developed and the \$3 patent was sold,

manufacturers have been competing for insulin. There have been continual revisions to insulin. Part of the reason is to keep it under patent status, so the patent does not expire and become eligible for generic versions. That is why it has taken 95 years for generics to hit the market. Manufacturers have been competing, which is what they are supposed to do, but competition has not led to lower prices. In fact it has had the opposite effect. We would like to know why prices are going up when competition is in place.

Each of the three dominant insulin producers has been able to tweak its insulin products to remain in patent status and that market is now just beginning to develop. You may hear this year about new biologics coming online that are insulin. Eli Lilly, Novo Nordisk and Sanofi, collectively referred to in our world as the Big Three, dominate the global insulin market in terms of revenue. Earlier this year, the Big Three were subject to a class action suit filed on behalf of 11 diabetic patients, which accuses the companies of unlawfully raising the prices of insulin products, and in doing so violating the Racketeer Influenced and Corrupt Organizations Act and various state consumer protection and antitrust statutes. They have denied these allegations and the review is continuing. A review of recent U.S. Securities and Exchange Commission filings reveals that insulin is a money maker. Diabetes is profitable. Novo Nordisk sold \$9.2 billion in insulin products, Sanofi posted \$7.5 billion in sales, and Eli Lilly sold \$2.8 billion in Humalog and \$1.4 billion in humulin. That is almost \$21 billion worth of insulin products in 1 year. These competitors appear to be raising their prices in step with one another, which is the opposite of what good competition allows. It appears they are syncing price hikes that result in raised profit, and it seems collaborative with what we would call price gouging.

Meanwhile, the cost for Medicaid patients and those with limited insurance makes insulin compliance unattainable. Without transparency in the pharmacy industry, we will likely never know how the patents are being extended, how prices are being synchronized, if they are, why generics are not being developed more quickly and if prices are set. We support S.B. 265 as an excellent step towards transparency and hopefully long-term affordability. The other parts of S.B. 265 are compilations of strategies that we support to address prescription drug costs.

KEVIN HOOKS:

I am a managed care clinical pharmacist and have been practicing since 1986. On the graphs ([Exhibit F](#)) that I have submitted to the Committee, you can see

that insulin costs have risen 387 percent from 2006 to 2013 and it is a proven fact that we live with every day, patient compliance has a direct reflection on the relationship to the cost of the medication. Regardless of whether the patient does or does not have insurance, the costs of these medications are passed on to the patient, and ultimately is a direct reflection on the compliance of the patient. The associated medical costs related to these noncompliant patients is staggering across the board. The United States is paying the bulk of the cost of medications. One basic reason for that is in foreign countries that do not have a political system, no different than we would negotiate for a car, they negotiate a drug based on the drug, the patient outcome and the ultimate best price. In other words, there may be two competing drugs. Both drugs have the same proven outcome, and the cost of that drug in a foreign country would be less based on a bid process they put together. It is completely political here, which has led to an opaque and a complex system. This system has created an environment ripe for profiteering in many ways, not only with the pharmaceutical industry but with other health care players, such as the pharmacy benefit management (PBM). In 1986, I was a retail pharmacist and the system had few pricing benchmarks. There were no formularies, no PBMs, and no rebates. There was nothing to add to the cost of the drug. It was a simple average wholesale price or maybe a wholesale acquisition cost. You understood it and the wholesalers understood it and the doctors for the most part understood it. Today we have over a dozen pricing benchmarks that have created an opaque system. It is an environment ripe for profiteering across the board, starting with the pharmaceutical industry.

Senate Bill 265 has selected wholesale acquisition costs (WAC), which means it is the most recognized spoken-about term in the industry related to pharmacy but it is the list price from the manufacturer to the drug wholesaler. It is pretty simple, well understood and that is why S.B. 265 attaches to WAC pricing. Without question, the pharmaceutical industry has a direct responsibility on how drugs are priced from the time the drugs are approved. This is important when folks think you are picking on the pharmaceutical industry. You can pick anywhere on the plant, the leaves and say this is the problem, that is the problem, but the root of the problem is how the drug is priced from the beginning. As a pharmacist, certain aspects of S.B. 265 hit directly to the root of the problem and I believe pharma will react accordingly with rebate dollars and trying to unwind what has been done to be able to meet the terms of what S.B. 265 puts out.

SENATOR HAMMOND:

You talked about the difference between the WAC and the foreign acquisition costs. How will the foreign price be determined?

MR. HOOKS:

The foreign price is negotiated as they do not use the WAC. It is basically a committee. Each country may be somewhat different, but it is not political. It is negotiating the best price for a drug based on the clinical outcome. If all things are equal, it will be a bid process. Someone will say what the price of the drug is. You probably heard that the U.S. pays for the research and development costs for the world, which is partially true. If pharma is put in a situation where it is forced to change or forced to meet these particular terms, I think that is where we may end up and I do not think it will affect new drugs to the market. They can live within that particular circle.

SENATOR CANCELA:

I will go through a brief overview ([Exhibit G](#)) of S.B. 265. The key part of this bill is that the Department of Health and Human Services will compile a list of essential diabetes drugs, insulin and biguanides, and that list will be updated every year. From the list of drugs, the manufacturers included on that list will design a reimbursement process if one of two situations happens. The first situation is when the WAC of the drug exceeds the highest price paid in foreign countries, as looked at through the Organization for Economic Cooperation and Development (OECD). The OECD was started in 1960 that specifically does economic development work and is comprised of 35 developed countries. The second trigger would be when the manufacturer increases the WAC of a drug during the previous calendar year by a percentage larger than the percentage increase in the Consumer Price Index (CPI) medical care component for that year.

There have been a lot of interested folks who have talked to me about this process. I have made a commitment to work through the logistics of how this process works, as it is specifically vague in the bill in order to allow for that process to be laid out by stakeholders. There is a difference for reimbursement if the individual is on a high deductible plan where the reimbursement should go to the individual versus if the individual is on a different kind of health insurance and the reimbursement should go to the insurer. In addition, a manufacturer must post the essential medications on its Website listing all the drugs that are eligible for this reimbursement.

Because transparency is minimal in pharmaceutical pricing, it is very difficult to get to how exactly we choose the best marker. Some people say it is the WAC, some people say it is other things. The starting point is the WAC because it seems to be universal across the different health care entities involved in prescription costs. As a result of the lack of transparency, S.B. 265 asks that manufacturers on the list disclose cost-related information to the DHHS by May 1 of every year and that the list includes things like research and development costs and preclinical and clinical studies, so we have a full picture of how we arrive at these costs. It is language that is also in Assembly Bill 215.

**ASSEMBLY BILL 215**: Requires the reporting of certain information relating to prescription drugs. (BDR 57-284)

There are three other pieces that are related to transparency and that are also in S.B. 265. The first deals with nonprofit organizations in the health care field. It asks that they disclose the amount of each contribution from a manufacturer and what percentage of their overall budget that contribution makes up. It is unfortunate that we end up in situations where folks who are advocating for patients are pressured by donors to not give the most accurate information and we want to make sure that is not happening out there. The DHHS will register pharmaceutical representatives. This is modeled off a program that was passed in the Chicago City Council in response to the opioid crisis there. The intention is to have information on pharmaceutical representatives and their relationships with doctors. The reporting would include information about health care providers they contacted, the drugs they marketed and free samples they provided, among other things. There is no fee for the registration, but DHHS would keep a list and make sure the reports are turned in every year.

The last piece deals with self-medication for diabetic patients. Today, this part includes both employers and private schools. The intention is to strip out the language that is related to employers so it just deals with schools. We are not sure if that language actually protects folks or undermines what is in federal statute. That is the part of S.B. 265 that is being actively worked on.

SENATOR HAMMOND:

The most sensitive part of S.B. 265 is where it is asking for information from private companies in an industry that is very competitive. These companies price things based on several different parts of the business like marketing or how much is put into research and development or transportation costs. There

are many different factors. I am worried that S.B. 265 is asking for specific things. Why not ask more for the aggregate? Are you afraid you will not get the answers you need?

SENATOR CANCELA:

You are right that generally asking for more information in the private sector can be an uncomfortable space. In health care there is already a series of requirements put on almost every other entity that operates within the health care field. Hospitals have to disclose a ton of information, insurers have massive reports that go to the Division of Insurance every year and that is not true for pharma today. The idea would be to increase the amount of transparency that exists specifically with diabetes drugs.

SENATOR HAMMOND:

Is the information you are asking for more in the aggregate or is it very detailed?

SENATOR CANCELA:

Senate Bill 265 does not require any information from hospitals or insurers. It is fairly specific information that is being requested from the manufacturer. I am open to different kinds of information but I believe that getting the most transparency possible and how prices are set is really the only way that we can actually have a discussion about every other player in the system.

SENATOR HAMMOND:

Over the years of listening to several bills, the one thing that sets one business apart from another is the proprietary information of how they set prices. Someone may have found the key to transporting their product more efficiently, and as soon as they disclose that, then the competitors figure out how they can do the same thing.

SENATOR CANCELA:

The intent of S.B. 265 is not to ask for disclosures on every single drug in a portfolio. We are not asking for everything but a very narrow disclosure on a small set of specific drugs.

SENATOR HARDY:

My question pertains to section 6 of S.B. 265. How does a patient know he or she needs a rebate? How does the Health Insurance Portability and Accountability Act of 1996 apply to these people?

SENATOR CANCELA:

These are the kind of questions that the working group will be figuring out to define the exact process. It is left intentionally somewhat vague to allow for those discussions to happen.

TANYA GEORGE:

I support S.B. 265 and have provided my written testimony ([Exhibit H](#)) to the Committee.

RITA NEANOVER:

I support S.B. 265 and have provided my written testimony ([Exhibit I](#)) to the Committee.

BONNIE JEAN SEDICH:

I support S.B. 265 and have provided my written testimony ([Exhibit J](#)) to the Committee.

PEGGY LEAR BOWEN:

I support S.B. 265. My best friend of 50 years is in the process of dying because of price gouging on diabetic medication. She was a State employee for 27 years and thought her health insurance would cover her diabetic medication. Unfortunately, because she worked for another company that paid into social security, her insurance benefits with the State were switched to a different company. My friend would test her blood sugar levels prior to eating and then take her insulin, but because the insurance company covered less, my friend stopped eating because she could not afford the insulin. She was recently admitted to the hospital because of complications with her diabetes. The gouging, lack of insurance coverage and the greed involved in diabetic medication are outrageous.

CHRISTOPHER HUGHES:

When I was 15 months old, I became sick and was hospitalized. The doctors told my parents that I was a Type 1 diabetic. To survive, I need to take shots and use my insulin pump to deliver it. I take care of my diabetic supplies on my own and I am on top of the latest technologies. I have never had to worry about whether the supplies would be there, they just were. My mom has explained the cost of the supplies and how lucky I am to have good insurance because if I did not, my parents could not afford all the supplies that I need to live.

I have friends who do not have everything I have. One day I asked a friend how come he was not feeling well and he said he was not able to test for three weeks, all because he simply could not afford the supplies. I asked my mom if my friend could borrow my supplies since we have the same meter and test strips. She explained that laws protect companies, and there is a large number of people who are affected, and cannot afford the insulin at all. She showed me the receipt for the insulin. It was \$1,200 a month and that is a lot of money for something I physically cannot live without. My mom and I have talked about what I want to do when I grow up. This was a you can be anything you want kind of talk, except I cannot. I need a job with good health insurance because of the cost of insulin. Now I worry about others who will not have the same opportunities as I do. I worry about the others who will not be able to afford insulin ever and about the possibility that my insurance company has a right to quit on me. The bottom line is insulin needs to be affordable and that is why I support S.B. 265.

KEITH LEE (Nevada Association of Health Plans):

The Nevada Association of Health Plans supports S.B. 265. The Nevada Association of Health Plans is comprised of the major health insurers in the State as well as America's Health Insurance Plans, which is the national trade association for the health insurance companies. The America's Health Insurance Plans has submitted a letter ([Exhibit K](#)) to the Committee. The Nevada Association of Health Plans is part of the work group Senator Cancela referred to about dealing with the reimbursement issues, to sort out and minimize, if not completely do away with, the unintended consequences.

RUSTY McALLISTER (Nevada State AFL-CIO):

The Nevada State AFL-CIO and its 220,000 members have some form of health insurance trust fund or health insurance fund which are negotiating for health care increases. There is not enough money to continue to do this. Senate Bill 265 will not solve the problem, but it is a good first step. We are always talking about the new Nevada and education, but people will not want to come here if they cannot get health care, if it is so expensive they cannot afford it. Let us make the new Nevada cover everything.

JIM SULLIVAN (Culinary Workers Union Local 226):

The Culinary Workers Union Local 226 supports S.B. 265. I will read a statement from the Secretary-Treasurer, Geoconda Arguello-Kline:

In Nevada today, approximately 280,000 adults or 12.54 percent have diabetes, including 75,000 who do not know they have the disease. Another 787,000 of Nevada adults or 38.5 percent have prediabetes. According to recent estimates, during their lifetime, at least one in three adults will develop diabetes by 2050. Half of all Latinos and half of American African women nationally are projected to develop the disease. Children who develop the disease face a lifetime of medication and disease management. Diabetes is a public health epidemic that costs Nevadans \$2.4 billion every year in medical costs. Prescribed retail pharmaceuticals account for an estimated 57.6 percent of total diabetes health care spending. Insulin, the primary drug for controlling diabetes, was discovered 95 years ago, but drug companies have raised insulin prices as much as 450 percent beyond inflation since 1996.

The Culinary Health Fund, which is sponsored by the union and Las Vegas area employers, provides the health insurance coverage for over 143,000 Nevadans, the culinary union's 57,000 members and their dependents. Through the health fund the culinary union is one of the largest health care consumers in the State. The culinary union has thousands of members who are impacted by the diabetes epidemic. The high prices of pharmaceutical drugs, like insulin, drive up the costs of health care, and this affects not just our members and their families but all Nevadans. Diabetes does not discriminate, and this epidemic is not a partisan political issue. Republicans, Independents and Democrats can work together for the good of Nevadans. Thank you.

STACIE SASSO (Health Services Coalition):

The Health Services Coalition represents 21 employer and union health plans with a combined total of 380,000 covered lives. The Coalition has a primary focus of accessing quality and affordable health care for the participants of our member groups. We work to ensure the member groups pay a fair and reasonable rate for health care services in southern Nevada. That is why S.B. 265 is so important to the Coalition. Currently, there is no control in place on either a State or federal level for prescription drug costs. This allows expensive life-sustaining drugs, like insulin, to continue to increase at alarming rates. This is causing a barrier for patients diagnosed with diabetes to access medications they need to remain healthy. Unfortunately, what we are seeing is

the cost of prescription drugs is increasing faster than the cost of living. Many pharma industry representatives have stated that profit margin is needed to continue to innovate, but much more is being spent on marketing rather than innovation. That is why transparency requirements are key to helping us understand this issue. Allowing for transparency for prescription drugs in the State is the start of change in the health care arena for Nevada. The Coalition supports S.B. 265.

MATT MORRISON (Executive Director, Healthcare Operations, MGM Resorts International):

MGM Resorts International supports S.B. 265 and hopes it proceeds to ensure the affordability of diabetic drugs for our health plan members and all Nevadans. The MGM Resorts health plans provide coverage for almost 40,000 residents in Nevada and at least 2,500 of them have diabetes. While MGM Resorts has been able to shelter its diabetic health plan members from double-digit annual price increases and insulin price increases, those increases now threaten MGM's ability to offer the same level of coverage for these as well as other life-saving drugs. The effects of the recent massive increase in the prices of insulin are only compounded by the ever increasing number of diabetics that are seen every year. MGM Resorts supports efforts by the State to bring the pricing of these medications to the light of day and support the concept that competition should work to lower drug costs, not increase them. MGM Resorts supports efforts to ensure sustainable pricing on all critical medications where possible.

RUBEN R. MURILLO (Nevada State Education Association):

The Nevada State Education Association supports S.B. 265. I have provided a letter of support ([Exhibit L](#)) to the Committee.

On a personal note, I am a diabetic and most members of my family are diabetics. I will show you two bottles of medication, they are gold. One bottle is Janumet and it costs me \$93 a month in co-pay. The other bottle is Jardiance and it costs me \$100 a month in co-pay. The prices have been increasing dramatically especially in the last year. I have provided my written testimony ([Exhibit M](#)) to the Committee. The Teachers Health Trust that represents the teachers in Clark County has been struggling to reduce the costs of medications, especially for diabetics. The change in companies from Merck-Medco to Caremark to WellDyneRX does nothing to reassure people that the costs of medications are not going to go up. In late 2016, I started to notice an increase in my co-pays. The pharmacist would ask me if I knew how much

the co-pays were. I said do I have a choice? My pharmacist suggested I go to the Internet and look for coupons to bring down the price. I thought to myself, coupons on the Internet? I did look on the Internet and found a coupon for Jardiance. It brought it down to \$25 but after a year, it will go back up. A person should not depend on coupons on the Internet to offset the cost of diabetic medications. A person should not have to make a decision of choosing to pay for medications or providing for his or her family. I feel like I am in a supermarket for prescriptions. Unfortunately, there are many members who cannot afford their medications. I support S.B. 265.

SENATOR HAMMOND:

Do you feel that the passage of S.B. 265 will guarantee the lowering of the prices of diabetes medications?

MR. MURILLO:

There are no guarantees in life. We are hoping S.B. 265 will start a discussion and maybe some actions that will address the cost of diabetes medications overall.

RYAN BEAMAN (Clark County Firefighters Union Local 1908):

The Clark County Firefighters Union Local 1908 supports S.B. 265. My other job is chairman for the Las Vegas Firefighters Health & Welfare Trust, which is a nonprofit, self-funded insurance trust. The members are the insurers for the group. As chairman, I do see the costs associated with medications and see how important it is to keep the prices down regarding the co-pays and deductibles for the members. Not taking medications creates other problems. The Trust tries to make sure the members are taking their medications but the members do not see the other side of the costs of the medications. I hope, with some type of legislation, discussions about what the costs of medications are and why they are so high take place.

TODD INGALSBEE (Professional Firefighters of Nevada):

The Professional Firefighters of Nevada supports S.B. 265. Firefighters of Nevada run on hundreds of thousands of calls every year and many of those calls are on diabetic patients. I can tell you from personal experience that most of those calls are because the patient could not afford his or her medication. We hope S.B. 265 will spark a discussion about medication rates.

PRISCILLA MALONEY (AFSCME – Retirees):

The AFSCME – Retirees supports S.B. 265. Most of the AFSCME – Retirees members are insured through the Public Employees' Benefits Program (PEBP) and they have filed a fiscal note on S.B. 265. It is my understanding that the sponsor of the bill is working with PEBP on how to word the fiscal note.

MR. SASSER:

Washoe Legal Services and the Legal Aid Center of Southern Nevada are concerned for the low-income clients that come to them about the high cost of drugs, especially those who are on Medicare, and have the drug cost follow them. We are hoping S.B. 265 will put forth conversation and the examination may shed some light on lowering the costs of medications.

RUSSELL ROWE (Boyd Gaming Corp.):

The Boyd Gaming Corp. understands there is some work to be done on S.B. 265, but stands in support of its intent.

MIKE ALONSO (Caesars Entertainment):

Caesars Entertainment supports S.B. 265. Caesars Entertainment employs more than 30,000 team members in Nevada and more than 70,000 team members on a company-wide basis. Caesars Entertainment supports the efforts of additional transparency and cost controls on prescription drugs on behalf of our team members.

RACHEL GUMPERT (AFSCME International):

The AFSCME International has 1.6 million members nationally and represents State workers. You heard testimony from a State worker and member of ours that she has a friend that would be here today but she is literally dying because of the cost of her diabetes medication. State workers do not receive social security, they have poverty wages and they fall through the Part D donut hole. They cannot afford the medications as they stand today. Each of the Legislators before me have members in their districts who are dying because they cannot afford their medications. Please support S.B. 265.

RANDY SOLTERO (International Alliance of Theatrical Stage Employees):

The International Alliance of Theatrical Stage Employees supports S.B. 265.

MARLENE LOCKARD (Service Employees International Union Local 1107 Nevada):

Service Employees International Union Local 1107 Nevada supports S.B. 265.

FRAN ALMARAZ (Teamster Local 986; Teamster Local 631):  
The Teamster Local 986 and the Teamster Local 631 support S.B. 265.

JEANETTA WILLIAMS (President, NAACP Tri-State Conference Idaho-Nevada-Utah):  
The NAACP stands neutral on S.B. 265. While there are some provisions in S.B. 265 that are beneficial to patients, the NAACP is concerned with some aspects of the bill and the effect it may have on those that suffer from chronic conditions. Ideally, the NAACP would like to see a legislative solution that improves access to quality care, creates a fully transparent system and focuses on “patients first” mentality. Unfortunately, this bill provides an incomplete solution to our overall goal of improving care for patients.

First, in reviewing S.B. 265 and its stipulations on advance notice of a price increase by a pharmaceutical company, a patient’s access to needed treatment may be unintentionally affected. The advance notice of a price change may lead to stockpiling by purchasers. This can reduce access to life-saving treatments in some areas for patients living with chronic conditions. Secondly, by ignoring the role of other important stakeholders in this process, we will have an incomplete picture of what medicines truly cost. Are we accurately capturing the cost of treatments in this system when we ignore the role that other stakeholders play such as insurers and the pharmacy benefits managers? The NAACP supports transparency. Transparency should be considered for all areas of health care, not just on patient advocates and manufacturers. Therefore, we should find a solution by evaluating the total cost of care, not just the cost of medicines. Lastly, a piece of legislation like this should be created with the patient in mind. Focus on patient-centered solutions should be continued. In S.B. 265, there is no mention of ensuring affordable co-pays or preventing discrimination based on a medical condition. Solutions such as S.B. 436, A.B. 352 and A.B. 381 should be considered as an avenue to increase access that is affordable.

**SENATE BILL 436**: Prohibits certain discriminatory designs for prescription drug benefits in health benefits plans. (BDR 57-996)

**ASSEMBLY BILL 352**: Provides for continued coverage for health care for certain chronic health conditions. (BDR 57-592)

**ASSEMBLY BILL 381**: Revises provisions governing prescription drugs covered by certain policies of health insurance. (BDR 57-698)

BETH HANDLER (Chief, Bureau of Child, Family and Community Wellness, Division of Public and Behavioral Health, Department of Health and Human Services):

The Division of Public and Behavioral Health stands neutral on S.B. 265. Looking at Medicaid data and SNAP data we see trends where people 50 years old or older are typically diagnosed with diabetes. We see in our younger participants disproportionate amounts are indicated as being overweight or obese, therefore they are considered at risk of diabetes or future diabetes. We also see a disproportionate amount of minority groups affected by diabetes in the Medicaid and SNAP populations. For 2012, Nevada's total estimated medical cost for diabetes was \$2.5 billion with prediabetes representing \$194 million of this cost. Absenteeism associated with diabetes can range from 2 percent to 10 percent higher of total work days lost. Oftentimes, we like to look at health outcomes and how we can improve them for people with diabetes. That means people in better control of their diabetes, or a person with prediabetes being no longer deemed so, or an overweight or obese client losing weight with the help of his or her physician. Improved outcomes can be achieved through applying interventions to prevent diabetes among Nevadans. This can include health care and payer systems collaborating to identify and direct resources towards those diagnosed as prediabetic, overweight or obese. We can look at accessing A1C levels. Right now we can see billing claims data, but we cannot see the A1C levels, which are an indicator of how people are doing and monitoring their diabetes. We can look at ways to access this through standardized reporting and electronic health records. Another intervention is community health workers or the Promotora de Salud model, which is an imbedded person in the community that works with clients to assist with medication compliance, health care appointments and adhering to healthy behaviors as well as a transition to diabetes self-management education and diabetes prevention programs.

DUANE YOUNG (Chief, Behavioral Health and Pharmacy Services, Division of Health Care Financing and Policy, Department of Health and Human Services):

The Division of Health Care Financing and Policy (DHCFP) is taking a neutral position on S.B. 265. Currently, there are 5,454 fee-for-service Medicaid recipients and 5,537 managed care enrollees on insulin. Over 11,000 managed care and fee-for-service clients are prescribed antidiabetic medications, which are the top 25 medications that have been prescribed as of fiscal year 2015-2016. Medicaid reimburses for individual and group diabetes self-

management. Ten hours of this services is offered without previous authorizations. Additional hours for remedial and repeat training may be requested. In addition to maintenance, glucometers, test strips, prevention efforts through house screening and referral services are covered by Medicaid. The WAC is proprietary information to Medspan. The DHCFP would require permission to utilize outside claims of adjudication. No current procedure exists for this. The National Average Drug Acquisition Cost (NADAC) is public information and requires no special permission to utilize. Innovator drugs, like insulin, are priced at the greater of 21.3 percent of the average manufacturer price per unit or the difference between the average manufacturer price and best unit price adjusted by the CPI for all urban customers. This limits our total rebate amount for the innovator drug at 100 percent of the manufacturer price. Fee-for-service utilizes a pharmacy benefits manager to negotiate these rates on our behalf, while network contract offices have their own purchasing mechanisms. The DHCFP has requested a friendly amendment to exempt the recipients of Medicaid and the Children's Health Insurance Program. The DHCFP receives supplemental rebate monies that are negotiated directly with each drug manufacturer for these prescription drugs. Senate Bill 265 would jeopardize the rebate monies if not amended. The amendment will remove the fiscal note.

SENATOR HAMMOND:

Are you offering an amendment because S.B. 265 is complicated and does not do all that is needed?

MR. YOUNG:

Yes, that is correct. We have asked Senator Cancela for an amendment to exclude the recipients of Medicaid and the Children's Health Insurance Program.

SENATOR HAMMOND:

How does a patient know he or she needs a rebate and how do they ask for the rebate? Do we need to worry about the Health Insurance Portability and Accountability Act of 1996 (HIPAA) laws and is that another part of S.B. 265 that needs to be worked on?

MR. YOUNG:

Yes, as I mentioned earlier NADAC is open information. The WAC information is proprietary. Because the DHCFP does not have a mechanism set up to purchase the WAC information, it would have to use the NADAC information.

Senate Committee on Health and Human Services  
March 29, 2017  
Page 50

CHAIR SPEARMAN:

The Committee received a letter from Immunize Nevada ([Exhibit N](#)) taking a neutral stand on S.B. 265.

KIPP SNIDER (Pharmaceutical Research and Manufacturers of America):

The Pharmaceutical Research and Manufacturers of America (PhRMA) is in opposition to S.B. 265. I have provided a written statement of opposition ([Exhibit O](#)) to the Committee. We appreciate the drug pricing system in the U.S. is not perfect. We have had some bad actors and are bothered when we see people like Martin Shkreli, the self-described PhRMA brother and hoodie, and others who do not represent the values of the research-based pharmaceutical industry. It is an industry that has turned HIV/AIDS from a death sentence into a manageable chronic illness. It has essentially cured hepatitis C, drastically reduced the mortality rates in cancer in the past 20 years and the list goes on. Ninety percent of all the prescriptions filled in the U.S. are generics. We have had major products that have gone off patent with billions of dollars of savings as a result. That is what keeps drug spending in the big picture steady. It is about 10 percent retail drug spending and 10 percent of overall U.S. health care spending. Retail prescription drug spending has stayed on track at about 10 percent over the years. The government actuaries expect it will stay in the same place. The 10 percent piece that retail prescription drugs comprise is the piece of the pie that is by far best positioned to make the entire pie smaller to reduce those larger pieces such as hospitalization expense and physician office expense.

The list prices are almost never what is actually paid in the real marketplace. There are PBM companies that control the overwhelming bulk of lives. They negotiate heavy discounts in the marketplace. Senate Bill 265 is premised on the concept of WAC when that is not the price in play. To base the entire piece of legislation of price control structure on WAC is really misguided. Paying WAC is like paying the hotel rate listed on the back of a hotel door. It is a competitive system, and yes, it is complicated. The principal problem we have is that it is not the pharmaceutical manufacturer that determines what patients pay, it is the PBMs and health insurers. The cost sharing burden that is being placed on patients has gone way up for drugs relative to other pieces of the health care marketplace.

SENATOR HAMMOND:

Can you explain what PBMs are and what they do?

MR. SNIDER:

Pharmaceutical benefit management companies or PBMs negotiate with drug manufacturers for discounts on pharmaceuticals. There are three PBMs in the U.S. that control about 80 percent of the market. They have a huge amount of leverage and purchasing power. They negotiate very large discounts off the WAC price. The insulin market is one of the most competitive markets. The discounts for them are particularly large compared to other sectors. The discounts are negotiated, and that is a good thing because lower net prices are good, but the problem is that the way benefit design works is the discounts are not finding their way to the patients. There are co-pays where a person would pay \$10 or \$25, a set amount of money for prescriptions. There is coinsurance, which is much more prevalent, where a person might pay 25 percent or 50 percent of the cost of a prescription. Those prices are almost always based on the WAC number, so the discounts the manufacturers are paying back through the complex supply chain are oftentimes not making their way to patients. That is a problem.

SENATOR HARDY:

Since the manufacturer does not have control over its prices and the PBM inflates the prices, who is the bad guy? Who is making money on the insulin? Where is the egregious cost to the patient coming from?

MR. SNIDER:

It is a really complicated system as there are a lot of moving parts. There is a report that is put out by the Berkeley Research Group that tries to sort through all this. The report shows that the overall health care spent in terms of the gross health care expenditure that about 37 cents on the dollar goes to the brand manufacturer. The rest of the dollar is scattered through the system of complicated middlemen. Rebates start with the manufacturers then go to the wholesalers, who take their bite out, then to the PBMs. The PBMs only partially share, if at all, with the patient.

SENATOR HARDY:

How much of the research and development costs go into the costs of the new insulins?

MR. SNIDER:

I cannot give you a specific number on research and development for insulin. Diabetes is a major chronic condition that comprises a huge amount of health

care expenditures in this Country. Research and development spent for the industry is about \$58 billion for last year. You hear about the older medications going off patent and there should be a generic competitor coming in right away, but it does not always happen like that. There are problems with backlogs of generic medications at the Federal Drug Administration (FDA) and other factors that go into it. Overall, if you look at prescription drug spending, it is a steady state in terms of the overall spent in the health care dollar. In fact, the growth in prescription drug spending is dropping compared to the other components of the health care sector.

SENATOR HARDY:

Do you foresee a type of insulin coming off patent? What is the hope for the person who has to pay \$440 a month to buy his or her insulin?

MR. SNIDER:

Insulin is particularly complicated because it is a biological product and there are different regulatory pathways for getting products approved by the FDA and commercialized. Right now in the insulin marketplace, there is significant brand-on-brand competition. There has been a recent market entrant for a follow-on insulin product. Under the biosimilar pathway, which was approved as part of the ACA, there is a conversion that takes place with respect to insulin and other products that will allow for direct biosimilar competition for those products beginning in 2020. The marketplace is going to change and is already changing in competitive brand-on-brand with significant discounts, but we expect it to become more competitive as the landscape evolves.

SENATOR HARDY:

What happened to the neutral protamine hagedorn insulins and the regular types our grandmothers used? Can we go back to the old insulins?

MR. SNIDER:

Many of the original insulin designs are outdated, and in fact, no longer produced. There has been an evolution of the technology so that newer, more predictable molecules can be engineered that have supplanted the insulins of years ago.

SENATOR HARDY:

Do you anticipate the biosimilar insulin prices will come down just like the prices of the hepatitis drugs did?

MR. SNIDER:

Yes, that is correct.

SENATOR RATTI:

Did you say the percentage of pharmaceutical spending as an overall percentage of the entire spend on health care is staying steady?

MR. SNIDER:

Yes, that is correct.

SENATOR RATTI:

Is it also correct that the entire spend on health care is escalating dramatically?

MR. SNIDER:

Yes, the entire spend is rising. I will read a small snippet from *Health Affairs* published this month which looked at national health care expenditure data and it said, "Among the major goods and services sectors, the category with the largest projected slowdown in 2016 is prescription drug spending."

We are seeing a change. There was a blip that is undeniable in prescription drug spending in 2014 in particular, based on new product introductions. The curve has flattened and it is pretty steady as it goes in terms of the role and spend on drugs.

SENATOR RATTI:

It is steady as a percentage of overall health care spending but overall health care spending has been escalating dramatically. Therefore, pharmaceutical spending has also been escalating dramatically. It is just staying within the same ratio to all the other spend.

MR. SNIDER:

I do not know what dramatically means. I believe some of the net prescription drug spending growth is 5 percent or lower year on year.

SENATOR RATTI:

You stated earlier that PBMs are part of the problem. What S.B. 265 does is shine a light on the manufacturer portion of the process. The premise of this bill is that transparency will at least help to pinpoint the problem. If there was a companion bill that asked for transparency for PBMs, then that would help us

see another part of the issue, and where we can put a finger on what exactly is causing the escalation of prices because people cannot get basic health care. What is specifically in S.B. 265 that PhRMA opposes? There is nothing in the bill that says you cannot charge what you want to charge. There are no price caps. There is nothing that stops PhRMA from making a profit.

MR. SNIDER:

There are multiple provisions that PhRMA opposes and the most fundamental are the price controls that are in S.B. 265. The direct price controls, forcing manufacturers to pay rebates to claimants based on prices outside the U.S. or based on a differential from the CPI medical care component as compared to WAC. Yes, on multiple levels we have a problem with price controls as PhRMA believes it stifles innovation and is simply bad policy. PhRMA believes S.B. 265 is unworkable with respect to many of the details such as references to the prices that are paid in foreign countries. It is not that simple in the real world. Paid by whom? The distribution systems in those countries are also very complex. There are multiple channels and prices within those places. It is not as simple as people may think.

Other provisions in S.B. 265 that we find problematic are the idea of having to give 90-day advance notice of price increases. PhRMA believes it will be highly disruptive to the marketplace, potentially inducing harmful behavior by suppliers with hoarding, potential antitrust violations and requiring the reporting of all the data, research and development profit data and financial data. It is really difficult for manufacturers to report on the true research and development costs for an individual product because the true cost includes the cost of all the failures. Many of the products that go into testing in humans never make it to the market.

SENATOR RATTI:

Do you agree there is a problem that people cannot afford their diabetes medications?

MR. SNIDER:

I agree the system creates challenges for some people and we should work on ways to minimize or eliminate those challenges.

SENATOR RATTI:

Apparently, in your point of view, there is nothing in S.B. 265 that helps the challenges. If not this, then what? What is the solution?

MR. SNIDER:

There are several solutions. One is understanding rebates and how they are passed down or not through the system. Explore ways that if people are paying coinsurance, it is based on a price that is more reflective of the reality of the marketplace. Examination of different pricing models that are based on the value that products bring and advancement at the State level biosimilar substitution legislation which will help to facilitate the new category of drugs that are approved by the FDA. Focusing on consumers' understanding of how their drug benefit works is another solution. We hear time and time again that consumers are running out to select a plan on the exchange, and then immediately gravitate to the plan with the lowest premium even though that plan may not cover their medications. They do not understand what deductibles and co-payments are in many instances and that ends up hurting people.

SENATOR RATTI:

I believe in data-driven decision-making because it is the only way to get to a place of understanding. Is there any data you are willing to share?

MR. SNIDER:

Yes. The industry already shares all sorts of data on overall research and development spend with respect to basic financial information that many of the publicly traded companies are required to file with the U.S. Securities and Exchange Commission. We have seen a movement across the industry where many of our companies are taking steps to provide more information about, for example, aggregate rebates. Doing that will produce a better understanding of how the marketplace actually works.

SENATOR HARDY:

People pick the prescription drug coverage based on a monthly price for the coverage, then the people are told that the insurance will not cover any or only cover a certain price for their prescriptions. The people then have to pay for a prescription that they have to have in order to live. Does this make sense?

MR. SNIDER:

There is no doubt that the burden is on people. What people are actually paying in cost sharing for pharmaceuticals is disproportionate to other pieces of the health care system. It is about 20 percent on average that people are shelling out for cost sharing on medications, about 4 percent for hospitalization and about 10 percent for physician office visits. That number has gone up significantly.

CHAIR SPEARMAN:

If the cost of health care has risen dramatically and the percentage has remained the same, is it fair to deduce that the cost of prescription drugs has gone up dramatically?

MR. SNIDER:

I do not know what dramatically means as I cannot quantify it, but yes, health expenditures are going up. The population is rising, there is inflation that factors into health care costs, and then there is the older segment of the baby boomers who are higher utilizers. If you look back historically at the role of prescription drugs and the overall health care spend, it has been stable and is expected to stay stable.

CHAIR SPEARMAN:

I am talking about stable as connected to health care costs. If health care costs 10 years ago were \$100 and that is 10 percent, and now the health care costs go up to \$200, but the percentage of prescription drugs now comes down to 5 percent because it has not followed the escalation in price. If prescription drug costs are tied to the escalation of health care costs and health care costs have gone up, then the prescription drug costs have gone up. There is a difference between 15 percent of \$1 and 15 percent of \$300.

MR. SNIDER:

We can provide data to you on overall health care spending in the U.S. and the different pieces like prescription drugs.

CHAIR SPEARMAN:

Yes, I would like the information. In the testimony heard earlier today, someone showed us a bottle of medicine that cost \$93 a month in co-pay and another bottle that cost \$100 a month in co-pay, and then the letter I received which addressed other medicines that have to be taken along with the diabetes

medicine. I just want to understand how we get to the place where we are actually looking at health as a human service. How do we bridge the disconnect? Maybe it is just perception, but I do not know that. I would like to get to the heart of the matter. The heart of the matter is there is a drug that will help people who are diabetics. I looked at the information for my district and it is off the charts in terms of the number of people who are either diabetic or prediabetic. I will tell you a personal story. My mother, who is now deceased, could not afford her medicine. She had renal failure as a result of untreated diabetes. I did not tell her, but I was buying her medicine monthly and it was \$250 a month. I let her think it was the hospital paying for it. I was doing that because she needed the medicine to keep up her quality of life. I need data to tell the people of my district why I voted yes or no on S.B. 265. People tell me they have insurance now and they want to keep it. They ask me what am I going to do about it. People tell me they have \$280 a month in prescription co-pays. They ask me, "What are you doing to help get that co-pay down?" They do not want to hear how the system works or how PBMs work. They want to know what I am doing to get the health care and prescription costs down.

MR. SNIDER:

You can tell your constituents that if they have commercial health insurance, many manufacturers do offer important assistance with cost sharing like rebates or coupons. That can make a real difference in terms of the out-of-pocket burden for people.

BRIAN WARREN (Biotechnology Innovation Organization):

Biotechnology Innovation Organization (BIO) is in opposition to S.B. 265. I have submitted a written statement of opposition ([Exhibit P](#)) to the Committee. Biotechnology Innovation Organization's members consist of the companies that research, develop and manufacture biological medications, many of which are injectable medications. Some of our members are names you would recognize but most of them are small academic research institutes and start-up companies. Seventy percent of innovative therapies are coming from small companies and they rely heavily on outside investors to fund their research and development costs. Sometimes funds are from angel investors or it is venture capital funds or partnering with a larger pharmaceutical manufacturer. It takes 10 to 12 years and on average \$2.6 billion to bring a new therapy to market. Of the thousands of potential therapies that start out, there are only a handful that make it to clinical trial stage. From those that do make it to the clinical trial

stage, 90 percent of those fail. This is a high cost industry with a high failure rate.

Investing in this industry entails a significant amount of risk. For this to be sustainable and the return on investment to be successful, therapies must make up for the losses on those that are unsuccessful. This is part of the price we pay for the extremely valuable innovation that this industry has brought to patients, the new cures that did not previously exist, and the new therapies that are having a significant benefit to patients. Investors look at risk versus reward. Price caps cap the reward part of the equation. It is an economic law that if one is impacted, the other will go out of whack. If the reward is capped that an investor can make when investing in a small company, the risk will be put out of balance and it will be extremely difficult and have a very detrimental effect on small companies' ability to secure funding. Senate Bill 265 could end up stifling innovation and, in some cases, make it more expensive for small companies to actually obtain the financing they need to move forward with their research and development. The price caps are BIO's significant concerns but we do have other concerns with S.B. 265 and they are noted in [Exhibit P](#).

SENATOR RATTI:

If I understood the testimony in support of S.B. 265, it did not sound like there had been any new innovation in the field of insulin in quite some time. It sounds like the drug has not changed significantly since the early 2000s. How does what you are saying specifically relate to insulin drugs?

MR. WARREN:

I am not familiar with what is currently in the pipeline specifically for insulin. I do know it is still an area where there are innovative companies bringing new products to market to provide better and more efficient treatment for patients with diabetes.

SENATOR RATTI:

Are you familiar specifically with any new innovations?

MR. WARREN:

No, I cannot name specific products in the pipeline right now.

SENATOR RATTI:

Forget about the pipeline, what has been innovative in the last ten years?

MR. WARREN:

I would have to get back to you with a list. Our members do manufacture medications for a number of diseases, not just diabetes, so I would need to get back to you with a list.

CHAIR SPEARMAN:

What is the average amount of time that a patent on a drug is renewed so the drug never reaches the generic stage?

MR. WARREN:

I will have to get back to you with that information. I know that patents granted by the FDA are initially granted for a 20-year timeframe and starts at the beginning of when the patent was filed prior to all the clinical trial stages. I will need to get back to you on the individual therapies and how many times the patent has changed.

MR. SNIDER:

Patents do not get renewed, they expire. When patents expire, that is the end. There are other types of exclusivity under federal law for manufacturers, but once the exclusivity is gone, the marketplace is free for competition to come in. That is what we have talked about. The story that very often does not get told is the big blockbuster medications that go off patent and a patient now pays \$6 where he or she used to pay \$75. It is important that we look at the entire story. Yes, the U.S. does pay more than its fair share, but the innovations do come from this Country. The innovations do not come from those other countries that are referenced in S.B. 265 nearly to the extent they do here. That is a result of the system that we have established.

CHAIR SPEARMAN:

When people are investing in the research of new drugs is there any understanding with respect to the timeline and the return on investment (ROI)? How do you explain to an investor that the patent will probably expire before the investor gets any money back?

MR. WARREN:

The timeline for the approval process once you get to the clinical trial stage on average is 10 to 12 years. That has increased in recent years and depending on different categories of medications it does vary. The risks and potential of the ROI for individual therapies that investors look at it depends on a significant

number of factors. Those factors range from the overall population of patients that a therapy could potentially treat, the medical benefits the patients receive, and whether some medications provide smaller benefits, but significant above and beyond previous therapies as some are leaps and bounds beyond where previous therapies were. Lot of things are factors that investors might take into account. It is an extremely complicated question and one that is always going to have risks because even the investors that do the most due diligence are still going to fail or invest in failures 90 percent of the time.

SENATOR HAMMOND:

How does insulin affect your direct opposition to S.B. 265, as it is only dealing with insulin and not necessarily other drugs?

MR. WARREN:

Senate Bill 265 does not just impact insulin. It impacts State-designated essential diabetes drugs yet undefined. The total number of therapies and the total number of diagnoses that fall under that category is up to the discretion of that department that is given the authority under S.B. 265. That could be comorbidities that are commonly associated with diabetes. It could be other non-insulin diabetes treatments. It is very difficult to say. Yes, there are innovations in insulin and I will do my due diligence to provide the Committee more information in regard to that specific question.

SENATOR RATTI:

Would you still oppose this bill if S.B. 265 was redrafted to be very specific to insulin and very specific to diabetes medication?

MR. WARREN:

Yes, BIO would still oppose S.B. 265 because it has members who provide research and development to bring new therapies to market in the insulin space and we would not want to deter future innovation in that area.

CHAIR SPEARMAN:

Could you please show me where it says in S.B. 265 that it is not just limited to insulin, but it covers all diabetes medication?

ERIC ROBBINS (Counsel):

Senate Bill 265 requires the DHHS to compile and annually update a list of essential diabetes drugs. The list must include, without limitation, all forms of

insulin and biguanides marketed for sale in this State. It has to include the insulin and biguanides, but because it says without limitation it is not limited to those things. If the Department decides that something else is an essential diabetes drug under this bill, it can put it on the list.

SENATOR RATTI:

Can you acknowledge that the pharmaceutical companies set the first base price, and that price plays a part in what the price is to the consumer?

MR. WARREN:

Yes.

JEFF BUEL (Johnson & Johnson Services, Inc.):

Johnson & Johnson is in opposition to S.B. 265. I have submitted a statement of opposition ([Exhibit Q](#)) to the Committee. Senate Bill 265 does not address the important issues of maintaining access to new medicines. This bill may actually result in unintended consequences without really addressing what the public is seeking. Johnson & Johnson believes the solution lies in changing the way we pay for and reimburse for care; paying for how well medical treatments and interventions work as opposed to the volume of procedures or medicines. So everyone involved is held accountable for the value they deliver. Johnson & Johnson and Janssen recently released the North America Transparency report which provides important information about our transparency commitments and responsible business practices. This is available on the Janssen Website. I have committed to speak to the sponsor of S.B. 265 about this report.

Johnson & Johnson wants its current and future business partners to know that it is committed to responsible pricing and embracing transparency. Diabetes is a very complex disease and is among the top ten causes of death in the U.S. and while death rates have declined, the number of Americans diagnosed with diabetes has more than tripled since 1980, making the needs for innovative medicines greater than ever before. Over 29 million people have diabetes, and another 86 million are considered to have prediabetes. It is imperative to address this disease.

Senate Bill 265 fails to take into consideration the individual treatment effect of medicines that will potentially limit access to a number of treatments. The diabetes patients need an armament of treatments that will provide a maximum

clinical benefit to the specific patient's needs. Innovation is necessary and very important. Senate Bill 265 underestimates or undermines those efforts for these new types of clinical therapies. As drafted, S.B. 265 does not meaningfully provide consumer cost savings given that insurers may collect refunds and are not required to pass them on to consumers. Under the scope of S.B. 265, the manufacturer would pay additional rebates based on foreign prices that do not reflect the U.S. marketplace or the economic system. Johnson & Johnson wants its current and future business partners to know it is committed to responsible pricing and embracing transparency and welcomes the opportunity to be a part of the discussion. As stated before regarding prior notice, S.B. 265 requires prescription drug manufacturers to provide a 90-day advance notice of a planned price increase to the WAC unit, which is very problematic. As a matter of principle, health plans set their premiums on an annual basis, so it is unclear how advance notice of impending price increases will help reduce health plan costs and help patients access their products. Advance notice would create inefficiencies in the market and introduce greater unpredictability for manufacturers, suppliers, payers, patients and providers, and potentially increase the cost of medications.

CHRIS FERRARI (Pfizer, Inc.):

Pfizer, Inc. is in opposition to S.B. 265. I have provided a letter of opposition ([Exhibit R](#)) to the Committee. There is no one in this room who is not sympathetic to health care cost and specifically to the stories mentioned previously. Every one of us in this room has been touched by someone who had a challenge with diabetes. We all agree that health care costs are too expensive and there has to be something done about it. Pfizer simply believes this is not the bill or the vehicle to do so. Pfizer has significant concerns regarding drug pricing reimbursement as outlined in section 6, disclosure mandates in section 7 and price increase prenotification in section 8 of S.B. 265. Additionally, Pfizer wants to put on record that it supports the comments made by PhRMA.

Senate Bill 265 mandates a process, regarding drug price reimbursement, in which claims can be submitted to a drug manufacturer, and the manufacturer must directly reimburse a patient or third party purchaser. Pfizer would be happy to work with the sponsor to discuss how that system would work. There is an insurance layer and trying to figure out what is due back to the consumers is a relatively confusing process. A prenotification mandate on pricing can lead to stockpiling of drugs and advance purchasing can lead to shortages and result in

medicines sold by unauthorized distributors or on the gray market, disrupting a manufacturer's processes to maintain high quality assurance of its products.

Requiring any industry to report proprietary information such as pricing, research and development, manufacturing costs related to administration, marketing, etc. is a concerning precedence. Some of those items are currently listed in public filings, especially with public companies. Disclosure mandates gather only a narrow slice of information.

If better health care and lower costs are our goals, everyone has to come together and participate to look at all aspects of the system rather than just picking on one to try to find a broader solution.

CHAIR SPEARMAN:  
Can you tell more about the gray market?

MR. FERRARI:  
I will provide the Committee additional information on the gray market. When price increases are announced in advance, different entities will purchase larger quantities of prescription drugs resulting in oversupply of those prescription drugs and then being filtered into the gray market.

CHAIR SPEARMAN:  
Can you explain unauthorized distributors?

MR. FERRARI:  
I will also provide to you an explanation of unauthorized distributors.

SENATOR HAMMOND:  
Are you referencing section 8 of S.B. 265 when speaking about price increase prenotifications?

MR. FERRARI:  
Yes, that is correct.

CHAIR SPEARMAN:  
If unauthorized distributors are selling prescription drugs on the gray market, do we have statutes that would address the criminality of that act?

MR. ROBBINS:

Nevada has statutes that deal with controlled substances and dangerous drugs and the unauthorized sale of those substances. There are federal statutes that address the issue to a certain degree. For example, if there was a patented drug coming into the Country, courts have held that there is not patent exhaustion in that case. There is also the general principle of patent exhaustion where if something is sold in this Country, the patent holder can lose his or her rights to it. I can look into that and get back to you.

CHAIR SPEARMAN:

This is a question that you can get back to me with the answer. If there is a federal law that exists that addresses the unauthorized distributors selling prescription drugs on the gray market, how can it be appropriated into the *Nevada Revised Statutes* so they are prosecuted to the fullest extent of the law? If they are unauthorized distributors that means they are putting the people's lives at risk who they are selling to.

The Committee received letters of opposition to S.B. 265 from the following companies: National Taxpayers Union ([Exhibit S](#)), Americans for Prosperity Nevada ([Exhibit T](#)), Americans for Tax Reform ([Exhibit U](#)), Council for Citizens Against Government Waste ([Exhibit V](#)), Bristol-Myers Squibb ([Exhibit W](#)), Novo Nordisk ([Exhibit X](#)), AbbVie Pharmaceuticals ([Exhibit Y](#)), Boehringer Ingelheim ([Exhibit Z](#)), UCB, Inc. ([Exhibit AA](#)), Sanofi ([Exhibit BB](#)), Astellas Pharma US, Inc. ([Exhibit CC](#)).

SENATOR CANCELA:

I am certainly willing to work with all the people who testified on S.B. 265 and I am open to include them in the working group. It is very easy to look at what is happening with diabetes in this Country, in Nevada and as a business and see it is a growing opportunity. The fact that Nevada is at 12 percent and 38 percent prediabetic means more and more people are going to be relying on insulin in the near future. If we do not take action and look at this as what it is, a public health crisis, then we end up in a situation where we literally put lives at risk. What we heard from the opposition tonight, in very few instances specific to insulin, I ask the Committee to give weight to arguments we heard and the evidence we heard that are specific to price increases on insulin. If it is true that overall pharmaceutical costs are steady, then S.B. 265 would never get enacted in that it is only designed to create equity and reimbursement in the situation when price gouging happens. There are specific measures for what that should

look like. If pricing stays steady, then there would never be a reimbursement enacted. The people who testified in support of S.B. 265 are either groups who represent big health plans or represent a lot of employees. All of these groups would not be testifying in support if it were not for the fact that they too are suffering from the increases in insulin cost, and it is a testament to the fact that action is needed. I am looking forward to working with people who are here tonight and with others to get to a place where we get through the details that were brought up tonight and hopefully end the Session with something that could have a tremendous impact.

Remainder of page intentionally left blank; signature page to follow.

Senate Committee on Health and Human Services  
March 29, 2017  
Page 66

CHAIR SPEARMAN:

This question does not have to be answered right now, but I would like someone to get back to me with an answer. Instead of coupons, is it conceivable that a price reduction could be commensurate with what a coupon does?

I close the hearing on S.B. 265. Seeing no further business, I adjourn the meeting at 8:22 p.m.

RESPECTFULLY SUBMITTED:

---

Debbie Carmichael,  
Committee Secretary

APPROVED BY:

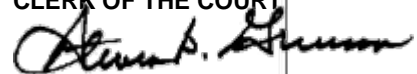
---

Senator Pat Spearman, Chair

DATE: \_\_\_\_\_

<b>EXHIBIT SUMMARY</b>				
<b>Bill</b>	<b>Exhibit / # of pages</b>		<b>Witness / Entity</b>	<b>Description</b>
	A	2		Agenda
	B	27		Attendance Roster
S.B. 323	C	15	Jodi Tyson / Three Square	Presentation
S.B. 323	D	2	Jodi Tyson / Three Square	Proposed Friendly Amendment
S.B. 305	E	1	Senator Julia Ratti	Proposed Amendment
S.B. 265	F	1	Kevin Hooks	Rising Insulin Prices Graphs
S.B. 265	G	5	Senator Yvanna D. Cancela	Section by Section Summary
S.B. 265	H	2	Tanya George	Written Testimony in Support
S.B. 265	I	2	Rita Neanover	Written Testimony in Support
S.B. 265	J	2	Bonnie Jean Sedich	Written Testimony in Support
S.B. 265	K	3	Keith Lee	America's Health Insurance Plans Letter
S.B. 265	L	1	Ruben Murillo / NSEA	Letter of Support
S.B. 265	M	1	Ruben Murillo	Written Testimony
S.B. 265	N	2	Heidi Parker / Immunize Nevada	Neutral Letter
S.B. 265	O	4	Kipp Snider / Pharmaceutical Research and Manufacturers of America	Written Statement of Opposition
S.B. 265	P	2	Brian Warren / Biotechnology Innovation Organization	Letter of Opposition
S.B. 265	Q	2	Jeff Buel / Johnson & Johnson Services, Inc.	Statement of Opposition
S.B. 265	R	3	Chris Ferarri / Pfizer, Inc.	Letter of Opposition
S.B. 265	S	1	Pete Sepp / National Taxpayers Union	Letter of Opposition

S.B. 265	T	2	Elliot Malin / Americans for Prosperity Nevada	Letter of Opposition
S.B. 265	U	1	Grover Norquist / Americans for Tax Reform	Letter of Opposition
S.B. 265	V	2	Thomas A. Schatz / Council for Citizens Against Government Waste	Letter of Opposition
S.B. 265	W	3	Tamar Thompson / Bristol-Myers Squibb	Letter of Opposition
S.B. 265	X	2	Tricia Brooks / Novo Nordisk	Letter of Opposition
S.B. 265	Y	2	Floreine R. Kahn / AbbVie Pharmaceuticals	Letter of Opposition
S.B. 265	Z	3	Cheyenne K. Cook / Boehringer Ingelheim	Letter of Opposition
S.B. 265	AA	3	Patricia A. Fritz / UCB, Inc.	Letter of Opposition
S.B. 265	BB	1	Adam Gluck / Sanofi	Letter of Opposition
S.B. 265	CC	2	Joseph F. Devaney / Astellas Pharma US, Inc.	Letter of Opposition



1 **ORD**

2 **DISTRICT COURT**  
3 **CLARK COUNTY, NEVADA**

4 **THE NEVADA INDEPENDENT,**

Case No.: A-19-799939-W  
Department 14

5  
6 **Petitioner,**

7 **vs.**

8 **RICHARD WHITLEY, in his official capacity as**  
9 **the Director of the Nevada Department of**  
10 **Health and Human Services; and the STATE**  
11 **OF NEVADA, ex rel. the NEVADA**  
12 **DEPARTMENT OF HEALTH AND HUMAN**  
13 **SERVICES,**

14 **Respondent(s).**

15 **ORDER SETTING HEARING RE PETITION FOR WRIT OF MANDAMUS**

16 Good cause appearing, it is hereby **ORDERED** that this matter is set for  
17 hearing on **Tuesday, October 22, 2019, at the hour of 9:30 a.m.,** in the District  
18 Court Department 14 in the Regional Justice Center, 200 Lewis Avenue, 14<sup>th</sup> Floor  
19 in Courtroom 14C, Las Vegas, Nevada, for further proceedings. Please provide  
20 Briefs, if filed as provided for in NRCP and NRS Chapter 34, to Chambers at least  
21 five (5) days prior to hearing. Your presence is required.

22 Failure to appear may result in dismissal of the case.

23 DATED this 19<sup>th</sup> day of August 2019.

24   
25 **ADRIANA ESCOBAR**  
26 **DISTRICT JUDGE**  
27

**CERTIFICATE OF SERVICE**

I hereby certify that on or about the date signed, a copy of this Order was electronically served to all registered parties in the Eighth Judicial District Court Electronic Filing Program and/or placed in the attorney's folder maintained by the Clerk of the Court and/or transmitted via facsimile and/or mailed, postage prepaid, by United States mail to the proper parties as follows:

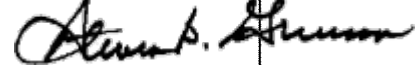
Matthew J. Rashbrook, Esq.  
Robert L. Langford, Esq.  
ROBERT L LANGFORD & ASSOCIATES  
Email: [matt@robertlangford.com](mailto:matt@robertlangford.com)  
[Robert@robertlangford.com](mailto:Robert@robertlangford.com)  
*Attorneys for Petitioner The Nevada Independent*

Scott Jones  
Manager, Primary Care and Health Workforce Development Office  
Nevada Department of Health and Human Services  
Division of Public and Behavioral Health  
4150 Technology Way  
Suite 300  
Carson City, Nevada 89706

Office of the Attorney General  
Health and Human Services Division  
555 East Washington Avenue  
Suite 3900  
Las Vegas, Nevada 89101

Office of the Attorney General  
Health and Human Services Division  
100 North Carson Street  
Carson City, Nevada 89701

  
\_\_\_\_\_  
Diana D. Powell, Judicial Assistant



1 **SB**

2 MATTHEW J. RASHBROOK  
3 Nevada State Bar No. 12477  
4 ROBERT L. LANGFORD, ESQ.  
5 Nevada State Bar No. 3988  
6 ROBERT L. LANGFORD & ASSOCIATES  
7 616 S. Eighth Street  
8 Las Vegas, NV 89101  
9 (702) 471-6565  
10 matt@robertlangford.com  
11 robert@robertlangford.com  
12 *Attorneys for Petitioner*  
13 *The Nevada Independent*

9 **EIGHTH JUDICIAL DISTRICT COURT**  
10 **LAS VEGAS, NEVADA**

11 THE NEVADA INDEPENDENT,

Case No.: A-19-799939-W

12  
13 Petitioner,

Dept. No.: 14

14 vs.

**SUPPLEMENTAL BRIEF IN SUPPORT OF  
PETITION FOR WRIT OF MANDAMUS**

15 RICHARD WHITLEY, in his official  
16 capacity as the Director of the Nevada  
17 Department of Health and Human Services,  
18 and THE STATE OF NEVADA, ex rel. the  
19 NEVADA DEPARTMENT OF HEALTH  
AND HUMAN SERVICES;

20 Respondents.

21  
22 COMES NOW Petitioner, The Nevada Independent, and submits this  
23 Supplemental Brief in support of its Petition for a Writ of Mandamus. This Brief is

24 ///

25 ///

26 ///

27 ///

28 ///

1 composed of the Memorandum of Points and Authorities and further based on the papers  
2 and pleadings already on file in this matter.

3 All of which is respectfully submitted, this 15th day of October, 2019.

4  
5 /s/

6 MATTHEW J. RASHBROOK  
7 Nevada State Bar No. 12477  
8 ROBERT L. LANGFORD, ESQ.  
9 Nevada State Bar No. 3988  
10 ROBERT L. LANGFORD &  
11 ASSOCIATES  
12 616 S. Eighth Street  
13 Las Vegas, NV 89101  
14 (702) 471-6565  
15 matt@robertlangford.com  
16 robert@robertlangford.com  
17 *Attorneys for Petitioner*  
18 *The Nevada Independent*  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

1 Points and Authorities

2 Diabetes is a scourge to Nevada and Nevadans. Presently, about 291,000  
3 Nevadans have diabetes, and another 787,000 are estimated to be prediabetic. Diabetes  
4 tends to disproportionately affect low-income earners, African Americans, American  
5 Indians, Hispanics, Latinos, Asian-Americans, and Pacific-Islanders, and is the seventh  
6 leading cause of death in the United States.

7 Between direct and indirect expenses, diabetes is estimated to cost Nevada nearly  
8 three billion dollars (\$3,000,000,000.00) per year. A significant portion of that spending is  
9 directly attributable to the rising cost of insulin, which from 2012 to 2016 approximately  
10 doubled.<sup>1</sup> The average American with diabetes has annual diabetes-related medical  
11 expenses of about \$8-9,000. Many attribute the quickly escalating costs to a lack of  
12 transparency in the industry, where pharmaceutical manufacturers and pharmacy benefit  
13 managers (“PBM”) frequently blame each other for the rising costs, and where gag orders  
14 and non-disclosure agreements are the norm.

15 In an effort to help Nevadans better understand why the price of insulin is rising  
16 so dramatically and to combat that escalation, during the 2017 Legislative Session, the  
17 Nevada Legislature passed Senate Bill (“S.B.”) 539, which, in pertinent part, established a  
18 requirement for pharmaceutical manufacturers and PBMs to disclose to Respondents the  
19 reasons for increased prices of certain diabetes medications, where those medications saw  
20 price increases greater than the same-year overall CPI for healthcare.

21 Throughout the many hearings and debate on S.B. 539, and a related bill, S.B.  
22 265, legislators made clear that their goal in the enactment of this legislation was to  
23 increase transparency within the marketplace, specifically because the current condition of  
24 opacity is killing Nevadans and driving to bankruptcy those who survive. *See, generally,*  
25 *Petition*, at 4 – 7. To that end, the information collected from pharmaceutical manufacturers  
26 and PBMs was exempted from trade secret status by S.B. 539. NRS § 600A.030(5)(b).

27 \_\_\_\_\_  
28 <sup>1</sup> In fact, the rising price of insulin is seen as a primary driver in the skyrocketing overall  
costs of healthcare in the United States.

1 On January 17 and June 11, 2019, Petitioner, by its reporter Megan Messerly,  
2 requested of Respondents certain public records in the possession of Respondents related to  
3 S.B. 539 – roughly, the reports filed by pharmaceutical manufacturers and PBMs related to  
4 S.B. 539. *See*, Petition at ¶¶49 – 52. Petitioner is entitled to access these public records  
5 under Nevada law. Respondents have refused access to the records in every meaningful  
6 respect, producing only that portion of the records which is already publicly available, and  
7 refusing to produce the remainder due to their fear of liability under the federal Defend  
8 Trade Secrets Act (“DTSA”). *See*, Petition at ¶¶53 – 57.

9 The Nevada Public Records Act (“NPRA”), Nev. Rev. Stat. § 239.001 et seq., is  
10 intended to “foster democratic principles by providing members of the public with access  
11 to inspect and copy public books and records[.]” To that end, the Nevada Legislature has  
12 frequently broadened and strengthened the NPRA with frequent amendments, including as  
13 recently as during the 2019 Legislative Session, by enacting S.B. 287, which, among other  
14 things, requires governmental entities to pay civil penalties – in addition to the attorney’s  
15 fees and costs provisions the prior version of the NPRA already required – for improperly  
16 refusing or delaying access to public records.<sup>2</sup>

17 Respondents have indicated that they believe the records at issue herein are made  
18 confidential by the DTSA, and presumably fear that if they provide access to the records,  
19 they could face liability for that decision. Respondents’ position represents a fundamental  
20 misunderstanding of the DTSA. The DTSA merely provides a federal cause of action for  
21 misappropriation of trade secrets. It does not render any particular thing confidential, and  
22 critically, does not provide a cause of action against states. In fact, the DTSA specifically  
23 by its terms does not preempt state law and does not preclude “otherwise lawful activity  
24 conducted by a governmental entity of . . . a State.” 18 U.S.C. § 1833(a)(1). Further, and in  
25 any event, the Eleventh Amendment, which Nevada, In Nev. Rev. Stat. § 41.031(3) has  
26 specifically not waived, further entitles Respondents not to face such a suit.

---

27  
28 <sup>2</sup> NB: these changes are effective for cases filed on or after October 1, 2019, and therefore  
are not applicable to this matter.

1           The Nevada Legislature has determined that diabetes and the escalating price of  
2 diabetes medications represent such a threat to the public that they enacted a law  
3 specifically to try to create transparency in the market, in the hope that fewer Nevadans  
4 would die or be subjected to financial ruin because of a disease that became manageable  
5 nearly 100 years ago. The Nevada Independent has requested the records, and under the  
6 NPRA, is entitled to them.

7                           The DTSA has no Application to This Case

8           The public records at issue in this case are not made confidential by the DTSA.  
9 The DTSA does not provide anyone a cause of action against Respondents, and even if it  
10 did, they would still be entitled to immunity from suit under the Eleventh Amendment. In  
11 short, the DTSA provides no shelter to Respondents for their unreasonable refusal to  
12 disclose the public records requested herein.

13           “In 2016, Congress passed the DTSA, providing that ‘[a]n owner of a trade secret  
14 that is misappropriated may bring a civil action . . . if the trade secret is related to a product  
15 or service used in, or intended for use in, interstate or foreign commerce.’ 18 U.S.C. §  
16 1836(b)(1); See P.L. 114-153 (May 11, 2016). In enacting the law, Congress provided  
17 some limitation to the applicability of the law by expressing that the DTSA ‘does not  
18 prohibit or create a private right of action’ with regard to ‘any otherwise lawful activity  
19 conducted by a governmental entity . . . of a State.’ 18 U.S.C. § 1833(a)(1).” *Medsense,*  
20 *LLC v. Univ. Sys. of Md.*, U.S. Dist. LEXIS 166730, 16 – 17 (D. Md. Sep. 27, 2019).

21           But, the DTSA does not in and of itself make any particular thing confidential, or  
22 place them outside the reach of a state public records law: “In this context, the DTSA is  
23 comparable to the Copyright Act, 17 U.S.C. §§ 101 – 1332, in that neither federal statute  
24 exempts records from disclosure.” *Baron v. Dep’t of Human Servs.*, 169 A.3d 1268, 1276  
25 n.6 (Pa. Cmwlth. 2017), citing *Ali v. Phila. Planning Comm’n*, 125 A.3d 92 (Pa. Cmwlth.  
26 2015)<sup>3</sup>. “The DTSA does not expressly provide the rates are confidential or trade secrets;

27                           <sup>3</sup> “Based on our review of the Copyright Act and our precedent, we conclude that  
28 Copyright Act is not a federal law that exempts materials from disclosure . . . It neither  
expressly makes copyrighted material private or confidential, nor does it expressly preclude

1 rather, the statute creates a private right of action to prosecute the improper use of trade  
2 secrets.” *Id.*

3 Although the DTSA is a relatively new law with a limited application, numerous  
4 Federal District Courts have already had the chance to and have held that States have no  
5 liability under the DTSA. *See, e.g., Fast enterprises, LLC v. Pollack*, 2018 U.S. Dist.  
6 LEXIS 161518, 2018 WL 4539685, U.S. Dist. Mass. 16-cv-12149, Sept. 21, 2018,  
7 *Medsense, LLC v. Univ. Sys. of Md.*, U.S. Dist. LEXIS 166730, 2019 WL 4735430, D. Md.  
8 GLS-18-3262, Sep. 27, 2019, *and, see also, Baron v. Dep’t of Human Servs.*, 169 A.3d  
9 1268 (Pa. Cmwlth. 2017).

10 In *Fast Enterprises, LLC v. Pollack*, under a virtually identical set of facts, the  
11 District of Massachusetts found that the DTSA does not even provide a cause of action  
12 against a state governmental entity, and that, in fact, “it appears that Congress specifically  
13 intended to circumscribe the DTSA so it would not interfere with the policy choices made  
14 by state governments in regard to their own operations.” *Fast Enterprises, LLC v. Pollack*,  
15 2018 U.S. Dist. LEXIS 161518, 5.

16 In *Fast Enterprises*, the CEO of the Massachusetts Department of Transportation,  
17 Stephanie Pollack, was sued by a software designer, Fast Enterprises, LLC, in order to  
18 prevent Pollack from disclosing certain information Fast considered trade secrets. *Id.*, at 1.  
19 Massachusetts had solicited bids for certain software related to the administration of its  
20 Department of Transportation, and Fast Enterprises made a bid. *Id.*, at 2. Fast indicated in  
21 the bid package that it believed some of the information contained was trade secret. *Id.*, at 2  
22 – 3. Pollack moved to have the case dismissed on the basis that the DTSA does not grant a  
23 federal court jurisdiction over such a suit, because it “‘does not prohibit or create a private  
24 right of action’ in regard to ‘any otherwise lawful activity conducted by a governmental  
25 entity of . . . a State.’” *Id.*, at 5, quoting 18 U.S.C. § 1836(c). Pollack’s motion was granted,  
26 and the case was dismissed: “based on the plain text of the DTSA . . . the Court must

27 a government agency, lawfully in possession of the copyrighted material, from disclosing  
28 that material to the public.” *Ali v. Phila Planning Comm’n*, 125 A.3d 92, 101 – 102 (Pa.  
Cmwlth. 2015).

1 conclude that FAST seeks to enjoin the ‘otherwise lawful’ activity of the state of  
2 Massachusetts, and because the DTSA does not create a cause of action in such  
3 circumstances, the case is dismissed.” *Id.*, at 9 – 10.

4 In *Medsense*, “[MedSense] allege[d] that: (a) the University System of Maryland .  
5 . . breached an exclusive licensing agreement related to certain intellectual property . . .  
6 and (b) Defendants Yu and Bae, the authors of those publications, disclosed trade secrets  
7 and confidential information.” *Medsense*, 2019 U.S. Dist. LEXIS 166730, 1. Following a  
8 lengthy inquiry and discussion, the District of Maryland determined that the Eleventh  
9 Amendment protected the State defendants from suit, and that the DTSA did not abrogate  
10 that protection. *Id.*

11 Under Nev. Rev. Stat. § 41.031(3), “The State of Nevada does not waive its  
12 immunity from suit conferred by Amendment XI of the Constitution of the United States.”  
13 Thus, even if the DTSA did provide a cause of action – and as discussed above, it doesn’t –  
14 Respondents would nonetheless be immune from suit, let alone from liability or damages.

15 These decisions comport with the Congressional intent in creating the DTSA:  
16 “Congress went out of tis way to make clear that the DTSA does not preempt state trade  
17 secret laws. *Id.* Rather, the DTSA merely provides ‘a complementary Federal remedy if the  
18 jurisdictional threshold for Federal jurisdiction is satisfied.’ *Id.*” *Brand Energy &*  
19 *Infrastructure Servs. v. Irex Contracting Grp.*, 2017 U.S. Dist. LEXIS 43497, 17 n.17, E.D.  
20 Pa. 16-2499, Mar. 23, 2017, citing H.R. REP. NO. 114-529, at 5.

21 In sum, the DTSA is totally inapplicable in this case: it does not render the public  
22 records at issue confidential, it does not prevent Respondents from carrying out their  
23 otherwise lawful activity of complying with the NPRA, it does not provide a cause of  
24 action against Respondents for complying with the NPRA, and, in any event, the Eleventh  
25 Amendment, which Nevada has specifically statutorily invoked, further protects  
26 Respondents from any potential suit.

27 ///

28 ///

1                   Nevada Law Specifies the Public Records at Issue Must be Produced

2                   Respondents have based their refusal to produce the requested public records  
3 entirely in the mistaken belief that the DTSA renders them confidential. As discussed  
4 throughout, the DTSA does not render anything confidential, and certainly does not  
5 preclude Respondents from carrying on otherwise lawful activities, like complying with the  
6 NPRA.

7                   The public records at issue herein are inarguably subject to disclosure under  
8 Nevada law. As discussed throughout the Petition and herein, the stated intent of the  
9 Nevada Legislature in enacting S.B. 539 was to create some transparency in an otherwise  
10 opaque market, because that opacity was killing Nevadans. To that end, under Nev. Rev.  
11 Stat. § 600A.030(5)(b), the public records sought herein are not trade secrets. Further, they  
12 are not made confidential by any other Nevada law, and therefore are exactly the kind of  
13 information the Nevada Legislature has expressly sought to make public under the NPRA.

14                  In 2007 the Nevada Legislature amended the NPRA, and the amendment meant  
15 “that all statutory provisions related to the Act must be construed liberally in favor of the  
16 Act’s purpose . . . In contrast, any exemption, exception, or a balancing of interests that  
17 restricts the public’s right to access a governmental entity’s records must be construed  
18 narrowly.” *Reno Newspapers, Inc. v. Haley*, 126 Nev. Adv. Rep. 23, 6, 234 P.3d 922, 924  
19 (2010) (internal citations omitted).

20                  Recognizing the Legislature’s intention, the Nevada Supreme Court held in *Haley*  
21 that access to public records is of paramount importance, and therefore any governmental  
22 entity seeking to withhold records must show that their interest in concealing public records  
23 from the public “*clearly outweighs* the public’s interest in access[.]” *Id.*, at 16, at 927  
24 (emphasis added). This standard must be applied, when, as is the case here, “the requested  
25 record is not explicitly made confidential by a statute.” *Reno Newspapers, Inc. v. Gibbons*,  
26 127 Nev. 873, 879, 266 P.3d 623, 627 (2011), citing *DR Partners v. Board of County*  
27 *Comm’rs*, 116 Nev. 616, 622, 6 P.3d 465, 468 (2000).

1 Further, no governmental entity may satisfy their obligation by offering “non-  
2 particularized hypothetical concerns,” as ““it is insufficient [for the governmental entity] to  
3 hypothesize cases where secrecy might prevail and then contend that the hypothetical  
4 controls all cases[.]”” *DR Partners v. Board of County Comm’rs*, 116 Nev. 616, 628, 6 P.3d  
5 465, 472 – 73 (2000), quoting *Star Pub. Co. v. Parks*, 875 P.2d 837, 838 (Ariz. Ct. App.  
6 1993). Similarly, “A private party cannot render public records exempt from disclosure  
7 merely by designating information it furnishes a governmental agency confidential. Neither  
8 the desire for nor the expectation of non-disclosure is determinative.” *Seapro Corp. v. Fla.*  
9 *Dep’t of Envtl. Prot.*, 839 So. 2d 781, 784 (Fla. 2003).

10 The Nevada Supreme Court has previously examined numerous NPRA cases in  
11 which privilege or confidentiality were claimed: *Donrey v. Bradshaw*, 106 Nev. 630, 798  
12 P.2d 144 (1990) (in which the Court considered whether certain police reports were  
13 confidential, and ordered production of the records), *DR Partners v. Board of County*  
14 *Comm’rs*, 116 Nev. 616, 4 P.3d 465 (2000) (in which the Clark County Commissioners  
15 claimed the deliberative process privilege protected their phone records, and the Court  
16 ordered production), *Reno Newspapers, Inc. v. Haley*, 126 Nev. Adv. Rep. 23, 234 P.3d  
17 922 (2010) (in which the Sheriff of Reno claimed all applications for a concealed firearm  
18 permit were confidential under Nev. Rev. Stat. § 202.3662, and the Court ordered  
19 production of substantially all of them), *Public Employees’ Ret. Sys. v. Reno Newspapers,*  
20 *Inc.*, 129 Nev. 833, 313 P.3d 221 (in which the Court affirmed the release of certain  
21 information which was found both in a confidential personal file, and a non-confidential  
22 file), *Clark Cty. Sch. Dist. v. Las Vegas Review-Journal*, 134 Nev. Adv. Rep. 84, 429 P.3d  
23 313 (2018) (in which the Court affirmed the production of certain internal investigative  
24 records the School District claimed were made confidential or privileged either by CCSD  
25 regulations, or the deliberative process privilege, or related NAC sections). Taken together,  
26 the cases make clear that the Nevada Supreme Court understands the Legislature’s intent in  
27 enacting and expanding the NPRA: to provide Nevadans wide access to public records.  
28

1           The cases noted above stand in stark contrast to this one, wherein Respondents  
2 refusal is based in a “non-particularized hypothetical concern,” *DR Partners*, 116 Nev. at  
3 628, 6 P.3d at 472 – 73, of possible DTSA liability, which the Nevada Supreme Court has  
4 stated unequivocally is not enough to outweigh the public’s interest in open democratic  
5 government. This is especially obvious in a case such as this, where the health and welfare  
6 of so many Nevadans is at stake and the Legislature has spoken so clearly as to the policy  
7 considerations inherent in the issue.

8           To this end, the Nevada Supreme Court has indicated that public policy questions  
9 are “better left to the Legislature.” *Renown Health, Inc. v. Vanderford*, 126 Nev. Adv. Rep.  
10 24, 7, 235 P.3d 614, 616 (2010), citing *Nevada Hwy. Patrol v. State, Dep’t Mtr. Veh.*, 107  
11 Nev. 547, 550 – 51, 815 P.2d 608, 610 – 11 (1991)<sup>4</sup>. This is particularly so in areas in  
12 which “The Legislature has heavily regulated,” because courts can safely assume that the  
13 Legislature would have codified a particular result if they’d intended it. *Renown Health,*  
14 *Inc.*, 126 Nev. Adv. Rep. 24, 7, 235 P.3d at 616.

15           The result here must be that Respondents are ordered to produce the requested  
16 public records. There is no statute, state or federal, which renders the records confidential.  
17 In any consideration of the policy at issue, the Court should defer to the Legislature – the  
18 people’s branch of the government – who have clearly stated their position throughout the  
19 debate and by the very enactment of S.B. 539.

20           Nevada Administrative Codes That Conflict with the NPRA are Invalid

21           Respondents have created Administrative Codes, NAC §§ 439.730 – .740, in  
22 response to the enactment of S.B. 539 and federal litigation which ensued. In part, NAC §§  
23 439.730 – .740 obligate Respondents to provide pharmaceutical manufacturers or PBMs  
24 with notice of a request for public records which would have the result of producing  
25 information the manufacturer or PBM has produced under S.B. 539, allow 30-day waiting

---

26  
27 <sup>4</sup> And, *see also*, *Niece v. Elmview Group Home*, 131 Wn.2d 39, 929 P.2d 420, 428 (Wash.  
28 1997) (“[N]oting that the policy decision to expand the scope of an employer’s liability for  
an employee’s intentional acts against a person to whom the employer owes a duty of care  
‘should be left to the legislature.’”).

1 periods to provide manufacturers and PBMs an opportunity to enjoin the production of  
2 public records if they see fit to, and so on.

3 To whatever extent, if any, these NAC sections conflict with S.B. 539 or with the  
4 NPRA, they must be invalidated:

5 A court will not hesitate to declare a regulation invalid  
6 when the regulation violates the constitution, *conflicts with*  
7 *existing statutory provisions* or exceeds the statutory  
8 authority of the agency or is otherwise arbitrary and  
capricious.

9 *Division of Ins. v. State Farm Mutual Ins. Co.*, 116 Nev. 290, 293, 995 P.2d 482, 485  
10 (2000) (emphasis added), citing NRS § 233B.110, *Clark Co. Social Service Dep't v.*  
11 *Newkirk*, 106 Nev. 177, 179, 789 P.2d 227, 228 (1990); *Roberts v. State*, 104 Nev. 33, 37,  
12 752 P.2d 221, 223 (1988).

13 The Nevada Supreme Court dispensed with a similar claim in *Clark Cty. Sch.*  
14 *Dist. v. Las Vegas Review-Journal*, 134 Nev. Adv. Rep. 84, 9 – 10, 429 P.3d 313, 317 – 18  
15 (2018): “CCSD argues that its regulations are laws with legal effect under NRS 386.350  
16 and, under those regulations, the documents that the district court ordered it to disclose are  
17 confidential by law . . . However, we have already indicated that such internal regulations  
18 do not limit the NPRA.” The Court further explained that, “Ascribing a force to such  
19 regulations that limits the NPRA would create an opportunity for government organizations  
20 to make an end-run around the NPRA by drafting internal regulations that render  
21 documents confidential by law.” *Id.*

22 Similarly, in *Comstock Residents Ass’n v. Lyon Cty. Bd. of Comm’rs*, the Nevada  
23 Supreme Court explained: “Administrative regulations do not limit the reach of the NPRA .  
24 . . The best practices for local government record management and what constitutes a  
25 public record for purposes of the NPRA are distinct[.]” 134 Nev. Adv. Rep. 19, 10, 414  
26 P.3d 318, 322 (2018).

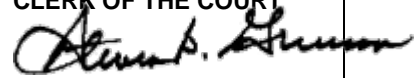
These cases make clear that to any extent that administrative codes or regulations established by Respondents conflict with the NPRA, or limit disclosure under the NPRA, they are invalid.

## Conclusion

The records sought by Petitioners herein are undoubtedly public records within the scope of the NPRA. They are not protected by any privilege or made confidential by any statute. Respondents do not face any liability or even any suit under the DTSA, as none is possible. The result must be an order mandating Respondents to disclose to Petitioners the public records they seek in their entirety, together with an order for the reasonable attorney's fees and costs incurred in the prosecution of this matter.

All of which is respectfully submitted, this 15th day of October, 2019.

/s/   
MATTHEW J. RASHBROOK  
Nevada State Bar No. 12477  
ROBERT L. LANGFORD, ESQ.  
Nevada State Bar No. 3988  
ROBERT L. LANGFORD &  
ASSOCIATES  
616 S. Eighth Street  
Las Vegas, NV 89101  
(702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*



**OPPS**

AARON D. FORD (Bar No. 7704)  
Attorney General  
Steve Shevorsi (Bar No. 8256)  
Chief Litigation Counsel  
Office of Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
(702) 486-3783 (phone)  
(702) 486-3773 (facsimile)

*Attorneys for Respondents*

**DISTRICT COURT**

**CLARK COUNTY, NEVADA**

THE NEVADA INDEPENDENT,

Petitioner,

vs.

RICHARD WHITLEY, in his official capacity  
as the Director of the Nevada Department of  
Health and Human Services, and THE  
STATE OF NEVADA, ex rel. the NEVADA  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES,

Respondents.

Case No. A-19-799939-W  
Dept. No. XIV

**Hearing Date: October 22, 2019**  
**Hearing Time: 9:30 a.m.**

**OPPOSITION TO THE NEVADA INDEPENDENT'S PETITION FOR WRIT OF**  
**MANDAMUS AND MOTION TO DISMISS**

Respondent, Richard Whitley, in his official capacity as Director of the Nevada Department of Health and Human Services, and the State of Nevada ex rel. the Nevada Department of Health and Human Services, oppose Plaintiff's petition for writ of mandamus and move for dismissal.

**MEMORANDUM OF POINTS AND AUTHORITIES**

**I. Introduction**

This Court should deny Plaintiff's petition for writ of mandamus and dismiss Plaintiff's complaint. Plaintiff in its complaint does nothing to overcome the presumption that Nevada Administrative Code sections 439.730-740 are valid. They are valid because the mere fact that SB 539 removed state trade secret protection for data or information

1 does not affect the protections that Plaintiff's concede exist under the federal Defend Trade  
2 Secrets Act. That the DTSA does not preempt state law does not mean that state law  
3 controls it. The DTSA creates a separate, independent layer of federal protection for trade  
4 secrets, which are ideas, data, and information that derive independent economic value  
5 from not being generally known.

6 Nevada Administrative Code sections 439.730-740 are valid regulations. They are  
7 the rational response to an issue where (i) the Department, faced with a public records  
8 request, reviews documents that have been provided to it under SB 539 but marked as  
9 trade secrets and (ii) the obligation under the Nevada Public Records Act to withhold from  
10 disclosure documents "otherwise declared by law to be confidential." NRS §239.010(1). In  
11 areas of administrative law, like this, the Department is granted great discretion in its  
12 review and determination. As a result, the Department's decision should be granted great  
13 deference and the documents should be maintained as confidential.

## 14 **II. Background**

15 This is a novel public records case. Plaintiff seek the disclosure of records that it  
16 concedes are confidential under the federal Defend Trade Secrets Act. Plaintiff asserts that  
17 Nevada Administrative Code sections 439.730-740 conflict with Senate Bill 539. Comp. at  
18 ¶66. A review of public records law and these administrative provisions demonstrates that  
19 Plaintiff is seeing conflict where none exists. Plaintiff's request for mandamus fails where  
20 the Department has no mandatory duty to turn over material that federal law protects.

### 21 **A. Nevada's Public Records Act protects the confidentiality of records** 22 **"...declared by law to be confidential"**

23 The Nevada Public Records Act starts with the rule that "unless otherwise declared  
24 by law to be confidential, all public books and records of a governmental entity must be  
25 open at all times during office hours to inspection by any person. . . ." NRS §239.010(1).  
26 Where a statute declares information protected from disclosure that is the end of the  
27 inquiry. As explained in *Reno Newspapers, Inc. v. Gibbons*:

1           **[I]n the absence of a statutory provision that explicitly**  
2           **declares a record to be confidential**, any limitations on  
3           disclosure must be based upon a broad balancing of the interests  
4           involved, and the state entity bears the burden to prove that its  
          interest in nondisclosure clearly outweighs the public's interest  
          in access.

5   127 Nev. 873, 880, 266 P.3d 623, 628 (2011) (citations omitted) (emphasis added).  
6   Accordingly, where a statute declares a record to be confidential, a court must protect the  
7   record's confidential character by keeping fidelity with a legislative command.

8           **B.     The Federal Defend Trade Secrets Act and the Copyright Act**

9           In 2016, Congress passed the DTSA, providing that “[a]n owner of a trade secret that  
10   is misappropriated may bring a civil action...if the trade secret is related to a product or  
11   service used in, or intended for use in, interstate or foreign commerce.” 18 U.S.C. §  
12   1836(b)(1); *See* P.L. 114-153 (May 11, 2016). Here, Plaintiffs do not dispute that the  
13   information that they seek is protected as confidential by the DTSA.

14          Plaintiff writes in its brief that “[the DTSA] does not render any particular thing  
15   confidential...” Br. at 4:21. It is unclear what point Plaintiff is making, but what is clear  
16   is that Plaintiff is missing one. For protection to apply under the DTSA, the information  
17   (1) derives independent economic value, actual or potential, from not being generally  
18   known to, or readily ascertainable by other people who can obtain economic value from its  
19   disclosure or use and (2) is subject to reasonable efforts to maintain its secrecy. 18 U.S.C.  
20   § 1839(3). Confidentiality is an essential prerequisite of federal law's definition of a  
21   protectable trade secret. That a particular item of information, hypothetically, is not a  
22   trade secret is beside the point. Plaintiffs are not challenging the trade secret status under  
23   the DTSA of any particular item of information they seek.

24          Equally bizarre is Plaintiff's statement that the DTSA is like the Copyright Act. Br.  
25   at 5:21-23. Copyright owners have five exclusive rights, but secrecy is not one of them.  
26   *Jules Jordan Video, Inc. v. 144942 Canada Inc.*, 617 F.3d 1146, 1152 (9th Cir. 2010)  
27   (copyright owners have the exclusive right to do and authorize others to display, perform,  
28   reproduce or distribute copies of the work and to prepare derivative works). In fact, a

1 copyright owner cannot even bring an enforcement action without registration of the  
2 copyrighted work – exactly on the opposite spectrum from trade secrets. 17 U.S.C. §§  
3 411(a), 501(b). Moreover, Copyright Act, in an important way, encourages forms of copying  
4 by enshrining in federal law the “fair use” doctrine. 11 U.S.C. §107. The “fair use” doctrine  
5 statute actually lists six classic examples of copying that are considered fair use, “criticism,  
6 comment, news reporting, teaching, scholarship, and research.” *Id.*

7 In sum, copyrighted works receive no federal protection and derive no economic  
8 value from not being generally known – but trade secrets do.

9 **C. There is no conflict between the DTSA and SB 539**

10 The background of Senate Bill 539 is as follows. SB 539, now codified in NRS 439B,  
11 has four relevant parts. **First**, NRS 439B.630 requires the Department to compile (1) a  
12 “list of prescription drugs [including insulin and biguanides] that the Department  
13 determines to be essential for treating diabetes in this State”; and (2) a “list of prescription  
14 drugs described in subsection 1 that have been subject to [a significant price] increase in  
15 the wholesale acquisition...”<sup>1</sup> **Second**, NRS 439B.635 requires the manufacturer of a drug  
16 included on the list above to submit to the Department an annual report that contains  
17 certain information concerning the cost of the drug. **Third**, NRS 439B.640 requires the  
18 manufacturer to submit a report concerning the reasons for the cost increase, if any.  
19 **Fourth**, NRS 439B.640 requires pharmacy benefit managers to report detailed  
20 information relating to the rebates that they negotiated and provided. Upon information  
21 and belief, for many manufacturers, the types of information that must be disclosed under  
22 these sections are generally factors relevant to pricing decisions for *all* of their  
23 pharmaceutical products, not just the essential diabetes medicines they provide.<sup>2</sup>

24 SB 539 says nothing about stripping the confidentiality that pharmaceutical entities  
25 may enjoy for their trade secrets under the DTSA. Examining the relevant provision of  
26

27  
28 <sup>1</sup> See also Pet. at ¶40.

<sup>2</sup> See Case 2:17-cv-02315 at Doc. 1, p. 20.

1  
2                   **IN THE SUPREME COURT OF THE STATE OF NEVADA**

3           THE NEVADA INDEPENDENT,

4                                   Appellant,

No.: 81844

5  
6           vs.

DC No.: A-19-799939-W

7           RICHARD WHITLEY, IN HIS  
8           OFFICIAL CAPACITY AS THE  
9           DIRECTOR OF THE NEVADA  
10          DEPARTMENT OF HEALTH AND  
11          HUMAN SERVICES, THE STATE  
12          OF NEVADA, EX REL. THE  
13          NEVADA DEPARTMENT OF  
14          HEALTH AND HUMAN  
15          SERVICES, AND SANOFI-  
16          AVENTIS U.S. LLC,

17                                   Respondent.

18  
19                                   

---

  
20                                   **JOINT APPENDIX**  
21                                   **VOLUME II**  
22                                   **PGS. 251-500**  
23                                   

---

24           MATTHEW J. RASHBROOK  
25           Nevada State Bar No. 12477  
26           ROBERT L. LANGFORD, ESQ.  
27           Nevada State Bar No. 3988  
28           ROBERT L. LANGFORD & ASSOCIATES  
          616 S. Eighth St.  
          Las Vegas, NV 89101  
          (702) 471-6565  
          *Attorneys for Appellant*  
          *The Nevada Independent*

          AARON D. FORD  
          Nevada Attorney General  
          Nevada State Bar No. 7704  
          HEIDI PARRY STERN  
          Nevada State Bar No. 8873  
          STEVE SHEVORSKI  
          Nevada State Bar No. 8256  
          Office of the Nevada Attorney General  
          555 E. Washington Ave., Ste. 3900  
          Las Vegas, NV 89101

1 JOHN R. BAILEY  
 Nevada State Bar No. 137  
 2 DENNIS KENNEDY  
 Nevada State Bar No. 1462  
 3 SARAH E. HARMON  
 Nevada State Bar No. 8106  
 4 REBECCA L. CROOKER  
 Nevada State Bar No. 15202  
 5 BAILEY KENNEDY  
 8984 Spanish Ridge Avenue  
 7 Las Vegas, NV 89148-1302  
 (702) 562-8820  
 8 *Attorneys for Respondent Sanofi-Aventis U.S.*  
 9 *LLC*

(702) 486-3594  
*Attorneys for Respondents Whitley, and  
 the State of Nevada ex rel. The Nevada  
 Department of Health and Human  
 Services*

## **TABLE OF CONTENTS**

<b><u>VOL.</u></b>	<b><u>DOCUMENT</u></b>	<b><u>DATE</u></b>	<b><u>PAGE NUMBERS</u></b>
I	Petition for a Writ of Mandamus	8/8/2019	JA-000001 – JA-000014
I	Appendix to Petition for a Writ of Mandamus	8/8/2019	JA-000015 – JA-000232
I	Order Setting Hearing re Petition for Writ of Mandamus	8/27/2019	JA-000233 – JA-000234
I	Supplemental Brief in Support of Petition for a Writ of Mandamus	10/15/2019	JA-000235 – JA-000246
I	Opposition to The Nevada Independent’s Petition for Writ of Mandamus and Motion to Dismiss	10/17/2019	JA-000247 – JA-000256
II	Motion to Intervene and to Continue Hearing, on Shortened Time	10/21/2019	JA-000257 – JA-000455
II	Petitioner’s Opposition to Sanofi- Aventis U.S. LLC’s Motion to Intervene and to Continue Hearing	10/31/2019	JA-000456 – JA-000465

II	Sanofi-Aventis U.S. LLC's Reply in Support of Motion to Intervene	11/1/2019	JA-000466 – JA-000472
II	Transcript of Proceedings – Motion to Intervene and to Continue Hearing on Shortened Time	11/5/2019	JA-000473 – JA-000491
II	Errata	11/11/2019	JA-000492 – JA-000520
III	Minute Order	11/14/2019	JA-000521 – JA-000522
III	Sanofi-Aventis U.S. LLC's Supplemental Brief in Support of Motion to Intervene	11/21/2019	JA-000523 – JA-000528
III	Supplemental Brief in Opposition to Motion to Intervene and Reply to Proposed Response	12/5/2019	JA-000529 – JA-000544
III	Minute Order	12/16/2019	JA-000545 – JA-000548
III	Order Granting Sanofi-Aventis U.S. LLC's Motion to Intervene	12/23/2019	JA-000549 – JA-000553
III	Intervenor Sanofi-Aventis U.S. LLC's Response to Petitioner's Petition for a Writ of Mandamus	12/23/2019	JA-000554 – JA-000738
III	Reply to Intervenor's Response	1/3/2020	JA-000739 – JA-000758
IV	Petitioner The Nevada Independent's Witness List	1/17/2020	JA-000759 – JA-000761
IV	Sanofi-Aventis U.S. LLC's Disclosure of Witnesses	1/17/2020	JA-000762 – JA-000764
IV	Defendants' Disclosure of Witnesses	1/17/2020	JA-000765 – JA-000766
IV	Reply in Support of Motion to Dismiss	1/23/2020	JA-000767 – JA-000775
IV	Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	1/30/2020	JA-000776 – JA-000815

IV	Sanofi's Opposition to Petitioner's Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	2/3/2020	JA-000816 – JA-000841
IV	Transcript of Proceedings – Motion to Compel Testimony of James Borneman, or in the Alternative, To Strike his Declaration	2/4/2020	JA-000842 – JA-000890
IV	Motion for Leave to File Brief Amicus Curiae	2/13/2010	JA-000891 – JA-000917
IV	Notice of Non-Opposition	2/14/2020	JA-000918 – JA-000920
IV	Minute Order	2/14/2020	JA-000921 – JA-000922
IV	Notice of Non-Opposition to Culinary union's Motion for Leave to file an Amicus Brief	2/14/2010	JA-000923 – JA-000924
IV	Transcript of Proceedings – Petition for Writ of Mandamus	2/21/2020	JA-000925 – JA-000968
IV	Minute Order	4/21/20	JA-000969 – JA-000973
IV	Order Denying Petition for Writ of Mandamus	9/4/2020	JA-000974 – JA-000984
IV	Notice of Entry of Order	9/9/2020	JA-000985 – JA-000998
IV	Notice of Appeal	9/22/2020	JA-000999 – JA-001001
V	Notice of Appeal (cont.)	9/22/2020	JA-001001

1 Nevada Revised Statute 600A shows why. SB 539 amended Chapter 600A's definition of a  
2 trade secret under state law as follows:

3           5.     Trade secret

4           (b)    Does not include any information that a manufacturer is  
5                required to report pursuant to section 3.8 or 4 of this act,  
6                information that a pharmaceutical sales representative is  
7                required to report pursuant to section 4.6 of this act or  
              information that a pharmacy benefit manager is required to  
              report pursuant to section 4.2 of this act, to the extent that such  
              information is required to be disclosed by those sections.

8 NRS §600A.030(5)(a). Notably, however, SB 539 did not—and could not—alter the  
9 protection provided by the federal DTSA.

10           **D.     The Department enacted NAC 439.735, which created a regulatory**  
11                **scheme to examine whether data required to be provided to the**  
12                **Department under NRS 439B.635, 439B.640, and NRS 439B.645 were**  
13                **nonetheless “declared by law to be confidential”**

14           The Department enacted NAC 439.735, which allows manufacturers and pharmacy  
15           benefit managers to protect their trade secrets from public (or competitor) view while still  
16           turning over the information required by NRS §§439B.635, 439B.640, and NRS §439B.645.  
17           Under that regulation, “[i]n complying with NRS 439B.635, 439B.640 or 439B.645, if a  
18           manufacturer or pharmacy benefit manager reasonably believes that public disclosure of  
19           information that it submits to the Department would constitute misappropriation of a trade  
20           secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act  
21           of 2016, 18 U.S.C. § 1836, as amended, the manufacturer or pharmacy benefit manager  
22           may submit to the Department a request to keep the information confidential.” NAC  
23           §439.735(1). If the Department is then faced with a public records request, the Department  
24           then must determine if it agrees with the designations made. NAC §439.735(3). If it  
25           agrees, it must deny the public records request. NAC §439.735(4). If it does not agree,  
26           then it provides the affected entity at least 30-days’ notice and allows the affected entity to  
27           go to court to defend its alleged trade secrets. NAC §439.735(5).

1 In this case, the Department reasonably believed that the vast majority of the  
2 information sought by Plaintiffs, which were marked by manufacturers and pharmacy  
3 benefit managers, were in fact trade secrets. Relying on this determination, the  
4 Department turned over what was not a trade secret and has withheld the remaining  
5 documents pursuant to NAC §439.735.

### 6 **III. Legal standards**

#### 7 **A. Motion to Dismiss**

8 In lieu of filing an answer, NRCP 12(b)(5) permits a defendant to file a motion to  
9 dismiss for failure to state a claim upon which relief may be granted. A motion to dismiss  
10 under NRCP 12(b)(5) should be granted where it appears beyond a doubt that the plaintiff  
11 could prove no set of facts, which, if accepted by the trier of fact, would entitle him to relief.  
12 *See Buzz Stew, LLC v. City of N. Las Vegas*, 124 Nev. 224, 228, 181 P.3d 670, 672 (2008).  
13 Although a district court generally may not consider matters outside of the pleadings when  
14 reviewing a motion to dismiss, the court “may take into account matters of public record,  
15 orders, items, present in the record of the case, and any exhibits attached to the complaint.”  
16 *Breliant v. Preferred Equities Corp.*, 109 Nev. 842, 847, 858 P.2d 1258, 1261 (1993).

#### 17 **B. Writ of Mandamus**

18 Mandamus is an extraordinary remedy to compel the performance of an act that the  
19 law requires as a duty resulting from an office, trust or station. *State v. Dist. Ct.*  
20 *(Armstrong)*, 127 Nev. 927, 929, 267 P.3d 777, 779 (2011). The burden is upon the petitioner  
21 to demonstrate that a writ of mandamus is warranted. *Am. Home Assurance Co. v. Dist.*  
22 *Ct.*, 122 Nev. 1229, 1234, 147 P.3d 1120, 1124 (2006).

### 23 **IV. Legal argument**

#### 24 **A. There is no conflict between NAC §439.735 (a regulation presumed** 25 **valid) and SB 539**

26 That the DTSA protects the data or information that Plaintiff seeks is not disputed.  
27 That the Department acted according to its regulations is also not disputed. Thus, this  
28 Court is left with Plaintiff’s sole argument, a putative conflict between SB 539 and NAC

1 439.735. Plaintiff's assertion of a conflict is utterly divorced from the standard of review  
2 applicable to allegations seeking to invalidate a regulation.

3 Plaintiff's lead argument, and indeed its sole argument, is one it barely makes in  
4 passing. Plaintiff argues in paragraphs 65 and 66 of its Petition that NAC 439.735 is  
5 invalid "to whatever extent the agency-created regulations at issue conflict with ... either  
6 SB 539 ... or, with the NRPA ... and must be invalidated. Comp. at ¶¶65-66.

7 It is not for this Court to find conflict where none exists. Regulations created by the  
8 Department are presumed valid. NRS §233B.090; *see also Montage Marketing, LLC v.*  
9 *Washoe County ex rel. Washoe County Bd. of Equalization*, 134 Nev. 294, 300, 419 P.3d 129,  
10 133 (2018). Further, this Court should defer to the Department's interpretation of a statute  
11 it is charged with enforcing. *State, Div. of Insurance v. State Farm*, 116 Nev. 290, 293, 995  
12 P.2d 482, 485 (2000). Plaintiff's lawsuit can only succeed by finding a direct conflict  
13 between the unambiguous language of the statute and the agency's regulation. *Clark Co.*  
14 *Social Service Dep't v. Newkirk*, 106 Nev. 177, 179, 789 P.2d 227, 228 (1990). Here, there  
15 is no such conflict.

16 Plaintiff is trying to find a conflict where none exists. The NRPA under NRS  
17 239.010, specifically contemplates that certain documents may be withheld when they are  
18 "otherwise declared by law to be confidential." The DTSA is such a law, which declares  
19 trade secrets cannot be misappropriated. Nothing in SB 539 provides that documents  
20 cannot be withheld based upon protections under the DTSA. SB 539 wrote only that data  
21 or information no longer would be classified as confidential under state trade secret law.

22 Plaintiff in its complaint cites to the anti-preemption language in the DTSA. Comp.  
23 at ¶68. Under that section of the DTSA, Congress indicated that the DTSA does not  
24 displace state trade secret law remedies. 18 U.S.C. §1838. This provision does not help  
25 Plaintiff's theory. Section 1838 illustrates the obvious point that Plaintiff ignores, which  
26 is that state trade secret law and federal trade secret law exist independently. That  
27 Nevada chose in SB 539 to remove from the definition of a trade secret under its law does  
28 not mean that Nevada did, or could, remove the DTSA's protection granted by Congress.

1 Plaintiff's citation to several unpublished decisions, which hold that the Eleventh  
2 Amendment bars suits for damages, i.e. past harm, not prospective harm from the  
3 disclosure of trade secret information, against States in federal court is both irrelevant and  
4 beside the point. As this Court knows, the Eleventh Amendment does not prevent suits for  
5 prospective relief against a state in federal court. *Puerto Rico Aqueduct and Sewer Auth.*  
6 *v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 146 (1993) (explaining the *Ex Parte Young* doctrine).  
7 Further, this is an administrative law issue where Plaintiff is challenging the validity of  
8 an administrative regulation that this Court must presume is valid. Since Plaintiff never  
9 explains why any Nevada Administrative Code section, Plaintiff cannot hope to meet its  
10 burden of persuasion.

11 Plaintiff's citation to *Fast Enterprises v. Pollack*, Civ. Act. No. 16-cv-12149-ADB,  
12 2018 WL 4539685 (D. Mass September 21, 2018) does not assist it. That case from the  
13 public bidding context where a private company voluntarily turned over records under the  
14 auspices of a unique Massachusetts law, which expressly stripped information in bidding  
15 documents from trade secret protection that were submitted "a condition of receiving a  
16 government contract or benefit." *Id.* at \*2 n.6. This case does not arise from the public  
17 bidding context. Also, noticeably absent from Plaintiff's complaint is any allegation that  
18 the trade secret information that Plaintiff seeks was already voluntarily disgorged by the  
19 pharmaceutical companies.

20 Likewise, Plaintiff's citation to *Baron v. Dep't of Human Services*, 169 A.3d 1268,  
21 1276 (Pa. Commw. Ct. 2017) lacks merit. Like the voluntary disclosure of data in *Fast*  
22 *Enterprises*, supra, the requestor in *Baron* sought information that had been voluntarily  
23 disclosed by private entities participating in a state program, e.g. rates paid to nursing  
24 homes by managed care organizations participating in Pennsylvania's "HealthChoices." *Id.*  
25 at 1270-71. The court noted that MCO's were merely presuming that such rates were trade  
26 secrets. *Id.* at 1277 n.6. In contrast to this case, Plaintiff concedes that the DTSA protects  
27 the information that Plaintiff seeks, but argues that the Department is compelled, without  
28

1 any discretion, to ignore the DTSA (federal law) because of Plaintiff's mistaken  
2 interpretation of the Nevada Public Records Act.

3 Nothing in the NRPA supports Plaintiff's interpretation. Plaintiff cites to *Clark*  
4 *County School District v. Las Vegas Review-Journal*, 134 Nev. Adv. Op. 84, 429 P.3d 313  
5 (2018), but that case is not on point. The issue in that case, among other things, was  
6 whether CCSD regulations could render information confidential and exempt from the  
7 NPRA. *CCSD*, 134 Nev. Adv. Op. at 9-10, 429 P.3d at 317-18. In contrast to that case,  
8 Plaintiff here wants this Court to ignore independent, federal protection that it concedes  
9 applies to the information it seeks under the DTSA.

10 Finally, Plaintiff's suit is contrary to the purposes of Nevada public records law. The  
11 NPRA's purpose is to promote government transparency and accountability by facilitating  
12 public access to information regarding government activities. *Reno Newspapers, Inc. v.*  
13 *Gibbons*, 127 Nev. 873, 877, 266 P.3d 623, 626 (2011). Given that all the documents being  
14 requested relate to private entities, there is no good reason to require their disclosure.

15 **V. Conclusion**

16 SB 539 did not amend the NPRA to destroy all trade secret protection whether under  
17 federal or state law. Far from acting arbitrarily, the Department responded to an express  
18 statute, the DTSA, which creates an independent layer of trade secret protection, by  
19 creating sound regulations that recognize the Department's responsibility to protect the  
20 confidentiality of documents declared by law to be confidential. This Court should deny  
21 Plaintiff's petition for mandamus and grant the Department's motion to dismiss.

22 DATED this 17th day of October, 2019.

23 AARON D. FORD  
24 Attorney General

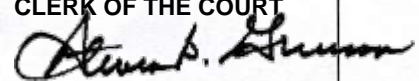
25 By: /s/ Steve Shevorski  
26 Steve Shevorski (Bar No. 8256)  
27 Chief Litigation Counsel  
28 Attorneys for Respondents

1 **CERTIFICATE OF SERVICE**

2 I certify that I am an employee of the State of Nevada, Office of the Attorney General,  
3 and that on October 17, 2019, I electronically filed the foregoing **OPPOSITION TO THE**  
4 **NEVADA INDEPENDENT'S PETITION FOR WRIT OF MANDAMUS AND**  
5 **MOTION TO DISMISS** via this Court's electronic filing system. Parties who are  
6 registered with this Court's electronic filing system will be served electronically as follows:

7 Matthew J. Rashbrook, Esq.  
8 Robert L. Langford, Esq.  
9 ROBERT L. LANGFORD & ASSOCIATES  
10 matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

11  
12 /s/ Barbara Fell  
13 Barbara Fell, an employee of the  
14 Office of the Nevada Attorney General  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28



1 **MINV**

JOHN R. BAILEY

2 Nevada Bar No. 0137

DENNIS L. KENNEDY

3 Nevada Bar No. 1462

SARAH E. HARMON

4 Nevada Bar No. 8106

**BAILEY ♦ KENNEDY**

5 8984 Spanish Ridge Avenue

Las Vegas, Nevada 89148-1302

6 Telephone: 702.562.8820

Facsimile: 702.562.8821

7 [JBailey@BaileyKennedy.com](mailto:JBailey@BaileyKennedy.com)

[DKennedy@BaileyKennedy.com](mailto:DKennedy@BaileyKennedy.com)

8 [SHarmon@BaileyKennedy.com](mailto:SHarmon@BaileyKennedy.com)

9 *Attorneys for Intervenor*

SANOFI-AVENTIS U.S. LLC

DISTRICT COURT

CLARK COUNTY, NEVADA

13 THE NEVADA INDEPENDENT,

14 Petitioner,

15 vs.

16 RICHARD WHITLEY, in his official capacity as  
17 the Director of the Nevada Department of Health  
and Human Services, and THE STATE OF  
18 NEVADA ex rel. the NEVADA DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

19 Respondents.

Case No. A-19-799939-W

Dept. No. XIV

**Date of Hearing:**

**Time of Hearing:**

**HEARING REQUESTED**

**MOTION TO INTERVENE AND TO  
CONTINUE HEARING, ON SHORTENED TIME**

23 Sanofi-Aventis U.S. LLC ("Sanofi" or "Sanofi US"<sup>1</sup>), by and through its attorneys,  
24 BAILEY ♦ KENNEDY, hereby moves to intervene in the above-captioned action pursuant to NRCP  
25 24 and NRS 12.130. Sanofi further moves to continue the October 22, 2019 hearing on the Petition  
26 of Writ of Mandamus pursuant to EDCR 2.25. This Motion is made and based upon the following

28 <sup>1</sup> "Sanofi US" is the registered trade name of Sanofi-Aventis U.S. LLC.

1 Memorandum of Points and Authorities, the exhibits attached hereto, the pleadings and papers on  
2 file in this action, the supporting declarations included herein, and any oral argument heard by this  
3 Court.

4 DATED this 17th day of October, 2019.

5 BAILEY ♦ KENNEDY

6  
7 By: 

8 JOHN R. BAILEY

9 DENNIS L. KENNEDY

10 SARAH E. HARMON


11 *Attorneys for Intervenor* SANOFI-AVENTIS  
12 U.S. LLC  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

APPLICATION FOR ORDER SHORTENING TIME

Sanofi hereby applies for an Order Shortening Time for the hearing on its Motion to Intervene and to Continue Hearing. This Application is based on the following Declaration of Sarah E. Harmon.

DATED this 17th day of October, 2019.

BAILEY ♦ KENNEDY

By:   
JOHN R. BAILEY  
DENNIS L. KENNEDY  
SARAH E. HARMON

*Attorneys for Intervenor SANOFI-AVENTIS  
U.S. LLC*

**DECLARATION OF SARAH E. HARMON IN SUPPORT OF MOTION TO INTERVENE  
AND TO CONTINUE HEARING AND APPLICATION FOR ORDER SHORTENING TIME**

I, Sarah E. Harmon, declare as follows:

1. I am a partner of the law firm of Bailey ♦ Kennedy, counsel for Sanofi. I have personal knowledge of and am competent to testify to the facts contained in this Declaration. I have made this Declaration in support of the: (i) Motion to Intervene and to Continue Hearing; and (ii) Application for Order Shortening Time.

2. On August 8, 2019, the Petitioner filed a Petition for a Writ of Mandamus pursuant to NRS 239.011.

3. Pursuant to this Court's August 27, 2019 Order Setting Hearing Re Petition for Writ of Mandamus ("Hearing Order"), the hearing on the Petition has been scheduled for October 22, 2019, at 9:30 a.m.

4. On October 15, 2019, the Petitioner filed a Supplemental Brief in Support of Petition for Writ of Mandamus.

5. The Respondents' response to the Petition is due on or before October 17, 2019.

6. The public records request at issue in this action seeks disclosure of Sanofi's trade secrets and other confidential information.

7. If this Court issues the requested Writ of Mandamus, Sanofi's interests would be adversely affected, and Sanofi would suffer irreparable harm.

8. While Sanofi anticipates that the State of Nevada can adequately represent Sanofi's interests in demonstrating the statutory and/or regulatory basis for withholding the requested information from disclosure, Sanofi possesses unique information regarding: (1) the classification of its information as a trade secret; and (2) the irreparable harm it will suffer if its trade secrets are disclosed to the Petitioner (and, ultimately, to the public at large).

9. Because the State of Nevada cannot provide a full and adequate representation of Sanofi's interests in this litigation, Sanofi seeks to intervene in this action.

10. Moreover, Sanofi requests that the October 22, 2019 hearing on the Petition be continued 30 days and that Sanofi be given leave to file a supplement to its Response to the Petition

1 for Writ of Mandamus (attached hereto as Exhibit 1), in order to address the issues raised and  
2 authorities cited in the Petitioner's new Supplemental Brief.

3 11. Because this Motion cannot be heard in the normal course before the October 22,  
4 2019 hearing on the Petition for Writ of Mandamus, Sanofi respectfully requests that this Motion be  
5 heard on shortened time.

6 I declare under penalty of perjury, under the laws of the State of Nevada, that the foregoing is  
7 true and correct.

8 EXECUTED on this 17th day of October, 2019.

9  
10   
11 SARAH E. HARMON

**ORDER SHORTENING TIME**

The Court, having considered Sanofi's Application for Order Shortening Time and the Declaration of Sarah E. Harmon in support thereof, and good cause appearing,

IT IS HEREBY ORDERED that the above MOTION TO INTERVENE AND TO CONTINUE HEARING shall be heard on the 5<sup>th</sup> day of November, 2019, at the hour of 9:30 a.m., in Department XIV, at the Regional Justice Center, located at 200 Lewis Avenue, Las Vegas, Nevada 89155.

DATED this 18<sup>th</sup> day of October, 2019.

  
ADRIANA ESCOBAR  
DISTRICT COURT JUDGE

1 **MEMORANDUM OF POINTS AND AUTHORITIES**

2 **I. INTRODUCTION**

3 Sanofi is a manufacturer of several drugs that the Nevada Department of Health and Human  
4 Services (the “Department”) has determined to be essential to the treatment of diabetes. As such,  
5 Sanofi must submit annual reports to the Department containing substantial financial and marketing  
6 information related to the cost of producing, manufacturing, marketing, and selling these drugs. The  
7 Petitioner made a public records request for these annual reports, and the Department has withheld  
8 some or all of the information requested, asserting that the information is confidential and/or a trade  
9 secret. Sanofi agrees with the Department’s determination.

10 However, the Petitioner now seeks a Writ of Mandamus instructing the Department to  
11 produce and publicly disclose Sanofi’s trade secrets and confidential information. While it is  
12 anticipated that the State of Nevada – through the Nevada Attorney General’s Office – can  
13 adequately represent Sanofi’s interest in demonstrating the statutory and/or regulatory basis for  
14 withholding confidential information in response to a public records request (although Sanofi  
15 reserves the right to supplement these arguments should the need arise), Sanofi moves to intervene  
16 because it possesses unique knowledge regarding: (1) the classification of its information as  
17 confidential and/or a trade secret; and (2) the irreparable harm that it will suffer if the Court issues  
18 the requested Writ of Mandamus and orders the public disclosure of Sanofi’s confidential business,  
19 financial, and/or economic information.

20 Because Sanofi: (i) has a substantial interest in the outcome of this litigation; (ii) will suffer  
21 irreparable harm if the Court orders the Petitioner’s requested relief; (iii) possesses unique  
22 knowledge and information outside of the State’s knowledge which is relevant to the issues raised in  
23 this action; and (iv) has timely filed this Motion, Sanofi respectfully requests that the Court grant its  
24 Motion to Intervene.

25 Further, because the Petitioner filed a Supplemental Brief in support of its Petition for Writ  
26 of Mandamus on October 15, 2017, just two days before the deadline to respond to the Petition,  
27 Sanofi respectfully requests that the hearing on the Petition be continued for 30 days and that Sanofi

28 ///

1 be granted leave to file a supplement to its Response to the Petition for Writ of Mandamus (attached  
2 hereto as Exhibit 1).

## 3 II. STATEMENT OF FACTS<sup>2</sup>

4 On January 17, 2019, The Nevada Independent (“Petitioner”), a news and opinion website  
5 founded by Jon Ralston, submitted a request for government records pursuant to the Nevada Public  
6 Records Request Act (NRS § 239.001 et seq.). (Pet. for Writ of Mandamus (“Petition”), at Ex. 1, at  
7 ¶¶ 3, 5, Ex. 2-1.) Specifically, the Petitioner sought copies of the annual reports submitted to the  
8 Department by certain pharmaceutical manufacturers pursuant to NRS 439B.635 and NRS  
9 439B.640. (*Id.* at Ex. 2-1, at 1.) These reports contain, among other things, highly sensitive  
10 confidential and trade secret information including detailed and particularized costs of producing,  
11 manufacturing, marketing, and selling each drug, along with any particularized factors impacting the  
12 wholesale acquisition cost of each drug and the impact of each factor. (*See* Decl. of James  
13 Borneman, attached as Exhibit 2, ¶¶ 8-9.) Sanofi was one of the pharmaceutical manufacturers  
14 included in the Petitioner’s public records request. (Pet. at Ex. 2-1, at 2.) On April 3, 2019, the  
15 Department informed the Petitioner that it intended to disclose only a limited amount of non-  
16 confidential information in response to the Petitioner’s Request. (*Id.* at Ex. 2-2.)

17 On June 11, 2019, the Petitioner re-submitted its public records request for the annual reports  
18 submitted to the Department by pharmaceutical manufacturers pursuant to NRS 439B.635 and NRS  
19 439B.640. (*Id.* at Ex. 2-3.) On June 24, 2019, the Department again informed the Petitioner that it  
20 would disclose certain non-confidential information in response to the records request, but that all  
21 other information in the annual reports would be withheld pursuant to the federal Defend Trade  
22 Secrets Act of 2016 (“DTSA”) and NAC 439.735. (*Id.* at Ex. 2-4.)

23 Therefore, on August 8, 2019, the Petitioner filed a Petition for Writ of Mandamus. (*See*  
24 *generally* Pet.) The Petitioner now requests that the Court issue a writ instructing the Department to  
25 disclose unredacted copies of the pharmaceutical manufacturers’ annual reports. (*Id.* at ¶ 78(a).)

26 ///

27 \_\_\_\_\_  
28 <sup>2</sup> In the interest of judicial economy and efficiency, a more detailed recitation of the relevant facts is set forth in Sanofi’s Response to the Petition for Writ of Mandamus, attached hereto as Exhibit 1.

### III. ARGUMENT

Pursuant to NRS 12.130, any person may, before trial, intervene in an action if he or she “has an interest in the matter in litigation [or] in the success of either of the parties.” NRS 12.130(1)(a). Specifically, Nevada law permits a person to intervene in order to “unit[e] with the defendant in resisting the claims of the plaintiff.” NRS 12.130(1)(b).

A person seeking to intervene in an action must comply with Nevada Rule of Civil Procedure 24. NRS 12.130(1)(c). NRCP 24 provides that the Court *must* permit a person to intervene in an action if the person files a timely motion to intervene, and the person “claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant’s ability to protect its interest, unless existing parties adequately represent that interest.” NRCP 24(a)(2). Similarly, NRCP 24 states that the Court *may* permit a person to intervene in an action if the person files a timely motion to intervene, and the person “has a claim or defense that shares with the main action a common question of law or fact.” NRCP 24(b)(1)(B). Sanofi’s interest in this action satisfies both NRCP 24(a)(2) and NRCP 24(b)(1)(B).

#### A. Intervention Pursuant to NRCP 24(a)(2).

The Nevada Supreme Court has held that the moving party must meet four requirements to intervene pursuant to NRCP 24(a)(2):

- (1) It must have a “sufficient interest in the litigation’s subject matter”;
- (2) It must demonstrate that it “could suffer an impairment of its ability to protect that interest if it does not intervene”;
- (3) It must demonstrate that “its interest is not adequately represented by existing parties;” and
- (4) Its application must be timely.

*Am. Home Assurance Co. v. Eighth Jud. Dist. Ct. ex rel. Cty. of Clark*, 122 Nev. 1229, 1238, 147 P.3d 1120, 1126 (2006).

Each of these requirements is satisfied here.

1                   **1.       Sanofi has a sufficient interest in this action.**

2           While most federal courts have recognized that there is no “bright-line” test for assessing  
3 whether a person has a “sufficient interest” to intervene in an action, the Ninth Circuit has  
4 determined that a “sufficient interest” is a “significantly protectable interest” or “one that is  
5 protected under the law and bears a relationship to the plaintiff’s claims.” *Id.* at 1238-39, 147 P.3d  
6 at 1126-27 (citing *S. Cal. Edison Co. v. Lynch*, 307 F.3d 794, 803 (9th Cir. 2002)). With regard to  
7 the “relationship” component of this test, the Ninth Circuit has held that this requirement is met “if  
8 the resolution of the plaintiff’s claims actually will affect the applicant.” *S. Cal. Edison Co.*, 307  
9 F.3d at 803 (quoting *Donnelly v. Glickman*, 159 F.3d 405, 410 (9th Cir. 1998)).<sup>3</sup> Here, Sanofi has a  
10 legally protected interest that will be affected by the Petitioner’s claims.

11           The Petitioner seeks a writ instructing the Department to disclose Sanofi’s annual reports  
12 submitted pursuant to NRS 439B.635 and NRS 439B.640. (Pet. at ¶ 78(a).) As set forth more fully  
13 in the Response to Petition for Writ of Mandamus, attached hereto as Exhibit 1, NRS 439B.635  
14 requires pharmaceutical manufacturers to disclose, *to the Department*, information which includes,  
15 but is not limited to, their production costs, marketing costs, and profits. NRS 439B.640 requires  
16 pharmaceutical manufacturers to disclose, *to the Department*, the factors considered in setting and  
17 adjusting the price of drugs, among other things. While pharmaceutical manufacturers cannot assert  
18 trade secret protection to avoid reporting this information *to the Department*, NRS 600A.030(5)(b),  
19 such information is still legally protected from public disclosure to third parties. *See generally* 18  
20 U.S.C. § 1839(3) (defining trade secrets as financial, business, and economic information); NAC  
21 439.735 (permitting manufacturers to submit requests for the Department to keep such information  
22 confidential where public disclosure would constitute misappropriation of trade secrets under the  
23 Defense of Trade Secrets Act of 2016, 18 U.S.C. § 1836).

24           Sanofi considers the information it discloses to the Department pursuant to NRS 439B.635  
25 and NRS 439B.640 to be confidential and/or trade secrets, and, it expressly sets forth the basis for

26 \_\_\_\_\_  
27 <sup>3</sup> Because the Nevada Rules of Civil Procedure are closely based upon the Federal Rules of Civil Procedure,  
28 Nevada courts consider federal cases interpreting the rules as strong persuasive authority. *Exec. Mgmt., Ltd. v. Ticor Title Ins. Co.*, 118 Nev. 46, 53, 38 P.2d 872, 876 (2002); *Las Vegas Novelty, Inc. v. Fernandez*, 106 Nev. 113, 119, 787 P.2d 772, 776 (1990).

1 such designations at the time its information is submitted to the Department. As will be more fully  
2 detailed in the Response to the Petition for Writ of Mandamus (Exhibit 1), Sanofi's costs, profits,  
3 and pricing inputs and rationale are so confidential that such information is restricted even internally  
4 and is shared on only a need-to-know basis within the company. (Ex. 2, at ¶¶ 12-13.) Further, such  
5 information is subject to express non-disclosure provisions within Sanofi's employment and  
6 business agreements. (*Id.*) In fact, Sanofi's employees are subject to termination for the  
7 unauthorized disclosure of this information. (*Id.*)

8 Nonetheless, the Petitioner seeks a writ instructing the Department to publicly disclose  
9 Sanofi's confidential information and trade secrets. Therefore, Sanofi should be permitted to  
10 intervene in this action because it has a legally protected interest that will be substantially affected  
11 by the resolution of the Petitioner's claims.

12 **2. Sanofi Will Suffer An Impairment of Its Ability to Protect Its Interests**  
13 **Without Intervention.**

14 As will be more fully detailed in the attached Response to the Petition for Writ of Mandamus  
15 (Ex. 1), Sanofi will suffer irreparable harm if its confidential information and trade secrets are  
16 publicly disclosed as a result of the requested Writ of Mandamus. Specifically, Sanofi's competitors  
17 would gain an unfair competitive advantage by learning how Sanofi allocates its resources and sets  
18 its prices. (Ex. 2, at ¶¶ 16-17.) Even Sanofi's competitors who produce pharmaceuticals used to  
19 treat other diseases and conditions can gain a competitive advantage over Sanofi based on the public  
20 disclosure of the information requested by the Petitioner. Such competitors can apply information  
21 about Sanofi's resource allocation and price setting processes for diabetes drugs to determine how  
22 Sanofi may perform these processes with respect to other pharmaceuticals it produces. (*Id.* at ¶ 17.)

23 Similarly, consumers will also gain an unfair advantage over Sanofi as a result of the public  
24 disclosure of this information. Consumers can use the information requested by the Petitioner  
25 against Sanofi in negotiations with insurers and other intermediaries in the healthcare system. (*Id.* at  
26 ¶ 16.)

27 Finally, the irreparable harm to Sanofi will not occur in just Nevada. The methods that  
28 Sanofi uses to set its drug prices are substantially the same from state-to-state. (*Id.* at ¶ 18.)

Therefore, public disclosure of Sanofi's confidential information and trade secrets will impact its negotiations with consumers and its competitive positioning nationwide.

**3. Sanofi's Interests Cannot Be Adequately Represented by the State.**

Sanofi anticipates that the State will adequately demonstrate a statutory and/or regulatory basis for maintaining the confidentiality of the information included within the manufacturer's annual reports; however, Sanofi reserves its right to seek leave to supplement its Response to the Petition for Writ of Mandamus if the need arises.

Regardless of the State's anticipated arguments, Sanofi still seeks the right to intervene in this action because the State cannot fully detail the steps Sanofi takes to maintain and protect its trade secrets and confidential information. Moreover, the State cannot fully and adequately describe the irreparable harm and prejudice that Sanofi will suffer if the court issues the Petitioner's requested writ. Such information is solely within Sanofi's knowledge, possession, and control.

Because the State lacks information necessary and relevant to responding to the Petition and to protecting Sanofi from irreparable harm resulting from the requested writ, Sanofi must be permitted to intervene in this action.

**4. Sanofi's Motion Is Timely.**

"Determining whether an application is timely under NRCP 24 involves examining the extent of prejudice to the rights of existing parties resulting from the delay and then weighing that prejudice against any prejudice resulting to the applicant if intervention is denied." *Am. Home Assurance Co. v. Eighth Jud. Dist. Ct. ex rel. Cty. of Clark*, 122 Nev. 1229, 1244, 147 P.3d 1120, 1130 (2006) (internal quotations and citations omitted). Here, the Petition for Writ of Mandamus was filed on August 8, 2019. On August 27, 2019, the Court scheduled the hearing on this Petition for October 22, 2019, and ordered that briefs in response to the Petition be filed by October 17, 2019. This Motion was filed within the time period for briefs in response to the Petition, and Sanofi has applied for this Motion to be heard on shortened time. Therefore, this motion is timely filed, and Sanofi's intervention will not prejudice the Petitioner. However, as set forth above, if Sanofi is denied the right to intervene, it will suffer severe prejudice and potentially irreparable harm based on the State's inability to fully and adequately represent Sanofi's interests in this action.

1 Because Sanofi has a sufficient interest in the subject matter of this action, will suffer  
2 irreparable harm if it is not permitted to intervene, cannot be fully and adequately represented by the  
3 State, and has timely filed its Motion to Intervene, Sanofi respectfully requests that the Court grant it  
4 the right to intervene pursuant to NRCP 24(a)(2).

5 **B. Intervention Pursuant to NRCP 24(b)(1)(B).**

6 If this Court determines that Sanofi does not possess the right to intervene pursuant to NRCP  
7 24(a)(2), then Sanofi also seeks permission to intervene pursuant to NRCP 24(b)(1)(B). As set forth  
8 in detail above, Sanofi has a defense that shares with the main action a common question of law or  
9 fact. Specifically, Sanofi asserts that the information included within the annual reports submitted to  
10 the Department pursuant to NRS 439B.635 and NRS 439B.640 constitutes confidential information  
11 and/or trade secrets that must be protected from public disclosure. While to date, the Department  
12 has (correctly) refused to disclose any confidential information or trade secrets included within the  
13 annual reports in response to public records requests, the Petition challenges the Department's  
14 decision based on questions of law and fact. Thus, Sanofi's defense to the Petition shares common  
15 questions of law and fact with the State's defense.

16 **C. Sanofi Requests that the Hearing on the Petition Be Continued Thirty Days and**  
17 **That It Be Granted Leave to Supplement Its Response to the Petition.**

18 The Petitioner filed its Petition for Writ of Mandamus on August 8, 2019. Despite no recent  
19 change in the facts or the law, the Petitioner waited until two days before the deadline to respond to  
20 the Petition to file a supplemental brief in support of its Petition. The Supplemental Brief contains  
21 additional arguments and authorities. Therefore, in order to fully and adequately respond to the  
22 Supplemental Brief, Sanofi respectfully requests that the Court continue the October 22, 2019  
23 hearing for 30 days and grant Sanofi leave to file a supplement to its Response to the Petition for  
24 Writ of Mandamus (attached hereto as Exhibit 1).

25 ///

26 ///

27 ///

28 ///

IV. CONCLUSION

For the foregoing reasons, Sanofi respectfully requests that the Court grant its Motion to Intervene and to Continue Hearing.

DATED this 17th day of October, 2019.

BAILEY ♦ KENNEDY

By: 

JOHN R. BAILEY

DENNIS L. KENNEDY

SARAH E. HARMON

*Attorneys for Intervenor* SANOFI-AVENTIS  
U.S. LLC

**CERTIFICATE OF SERVICE**

I certify that I am an employee of BAILEY❖KENNEDY and that on the 21st day of October, 2019, service of the foregoing **MOTION TO INTERVENE AND TO CONTINUE HEARING, ON SHORTENED TIME** was made by mandatory electronic service through the Eighth Judicial District Court’s electronic filing system and/or by depositing a true and correct copy in the U.S. Mail, first class postage prepaid, and addressed to the following at their last known addresses:

MATTHEW J. RASHBROOK ROBERT L. LANGFORD <b>ROBERT L. LANGFORD &amp; ASSOCIATES</b> 616 South Eighth Street Las Vegas, Nevada 89101	Email: matt@robertlangford.com robert@robertlangford.com  <i>Attorneys for Petitioner</i> <b>THE NEVADA INDEPENDENT</b>
--	---

AARON D. FORD ATTORNEY GENERAL STEVE SHEVORSKI CHIEF LITIGATION COUNSEL <b>OFFICE OF NEVADA ATTORNEY GENERAL</b> 555 East Washington Avenue, Suite 3900 Las Vegas, Nevada 89101	Email: sshevorski@ag.nv.gov  <i>Attorneys for Respondents</i> RICHARD WHITLEY, in his official capacity as the Director of the Nevada Department of Health and Human Services, and THE STATE OF NEVADA, ex rel. the NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES
---	---

/s/ Josephine Baltazar  
Employee of BAILEY❖KENNEDY

# EXHIBIT 1

# EXHIBIT 1

**RSPN**

JOHN R. BAILEY

Nevada Bar No. 0137

DENNIS L. KENNEDY

Nevada Bar No. 1462

SARAH E. HARMON

Nevada Bar No. 8106

**BAILEY ♦ KENNEDY**

8984 Spanish Ridge Avenue

Las Vegas, Nevada 89148-1302

Telephone: 702.562.8820

Facsimile: 702.562.8821

[JBailey@BaileyKennedy.com](mailto:JBailey@BaileyKennedy.com)

[DKennedy@BaileyKennedy.com](mailto:DKennedy@BaileyKennedy.com)

[SHarmon@BaileyKennedy.com](mailto:SHarmon@BaileyKennedy.com)

*Attorneys for Intervenor*

SANOFI-AVENTIS U.S. LLC

DISTRICT COURT

CLARK COUNTY, NEVADA

THE NEVADA INDEPENDENT,

Petitioner,

vs.

RICHARD WHITLEY, in his official capacity as  
the Director of the Nevada Department of Health  
and Human Services, and THE STATE OF  
NEVADA ex rel. the NEVADA DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

Respondents,

and

SANOFI-AVENTIS U.S. LLC,

Intervenor.

Case No. A-19-799939-W  
Dept. No. XIV

**Date of Hearing: October 22, 2019**

**Time of Hearing: 9:30 a.m.**

**INTERVENOR SANOFI-AVENTIS U.S. LLC'S RESPONSE TO PETITIONER'S  
PETITION FOR A WRIT OF MANDAMUS**

Intervenor Sanofi-Aventis U.S. LLC ("Sanofi" or "Sanofi US"<sup>1</sup>) hereby submits its Response  
to The Nevada Independent's ("Petitioner") Petition for a Writ of Mandamus ("Petition"). This

<sup>1</sup> "Sanofi US" is the registered trade name of Sanofi-Aventis U.S. LLC.

1 Response is based upon the following Memorandum of Points and Authorities, the exhibits attached  
2 hereto, the pleadings and papers on file in this action, and any oral argument heard by this Court.

3 DATED this 17th day of October, 2019.

4 BAILEY ♦ KENNEDY

5  
6 By: 

7 JOHN R. BAILEY  
8 DENNIS L. KENNEDY  
9 SARAH E. HARMON

10 *Attorneys for Intervenor* SANOFI-AVENTIS  
11 U.S. LLC  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

1 **MEMORANDUM OF POINTS AND AUTHORITIES**

2 **I. INTRODUCTION**

3 Sanofi is a manufacturer of several drugs that the Nevada Department of Health and Human  
4 Services (the “Department”) has determined to be essential to the treatment of diabetes. As such,  
5 Sanofi must submit annual reports to the Department regarding the cost of these drugs. The annual  
6 reports include information about Sanofi’s production costs, marketing costs, profits, resource  
7 allocation, and price setting, among other things. Such information is confidential and/or a trade  
8 secret and is vigorously protected from public disclosure by Sanofi. The public disclosure of this  
9 information would irreparably harm Sanofi by providing a competitive advantage to other  
10 pharmaceutical manufacturers and undermining Sanofi’s negotiations with insurers and other  
11 intermediaries in the healthcare industry.

12 In recognition of the harm that would be caused by the public disclosure of such information,  
13 the Department adopted a regulation allowing pharmaceutical manufacturers (like Sanofi) to submit  
14 requests for confidentiality. Specifically, manufacturers may request that the Department maintain  
15 the confidentiality of certain information included within the annual reports that are submitted to the  
16 Department. Moreover, when the Department receives public records requests for the annual  
17 reports, or information included within the annual reports, the regulation expressly permits the  
18 Department to: (i) conduct a review to determine if public disclosure of the requested information  
19 would constitute a misappropriation of a trade secret; and (ii) deny the request for public records on  
20 the basis that the requested information is confidential pursuant to the federal Defend Trade Secrets  
21 Act of 2016 (18 U.S.C. § 1836) (“DTSA”). For the information sought by the Petitioner, Sanofi  
22 expressly submitted to the Department a request for confidentiality pursuant to this regulation.

23 The Petitioner, a news and opinion website, submitted two public records requests to the  
24 Department for all annual reports received from pharmaceutical manufacturers since 2017. In  
25 response to these requests, the Department released certain limited information and withheld all  
26 confidential information and trade secrets. The Petitioner now seeks a Writ of Mandamus from the  
27 Court instructing the Department to produce and publicly disclose the withheld confidential  
28 information and trade secrets.

Sanofi respectfully requests that the Court deny the Petition. Disclosure of the annual reports, and/or certain categories of information included in the reports, will cause Sanofi irreparable harm in its dealings with competitors, consumers, insurers, and others in the health care industry. The Nevada Public Records Act (NRS Ch. 239 et seq.) ("NPRA") does not allow the public to have unfettered access to all information in the possession, custody, or control of a governmental agency. All information "declared by law to be confidential" is expressly excluded from the NPRA. NRS 239.010; NRS 239.030. The information sought by the Petitioner has been declared confidential by NAC 439.735, the DTSA, and NRS 600A.030. Therefore, the Department has properly denied the Petitioner's public records request (as it pertains to the confidential information and trade secrets), and the Petition should be denied.

## II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

### A. Enactment of Senate Bill 539.

In or around 2017, Nevada passed Senate Bill 539, which was designed to address the increasing costs of diabetes health care. Specifically, NRS 439B.630 was enacted to require the Department, on February 1<sup>st</sup> of each year, to compile a list of all prescription drugs deemed essential to treating diabetes. Then, on April 1<sup>st</sup> of each year, the manufacturers of any prescription drugs on this list must submit a report to the Department that includes, but is not limited to, the following information:

- The costs of producing the drug;
- The total administrative expenditures relating to the drug, including marketing and advertising costs;
- The profit that the manufacturer has earned from the drug and the percentage of the manufacturer's total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug;
- The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;
- The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs;

\* \* \*

- The aggregate amount of all rebates that the manufacturer has provided to pharmacy benefit managers for sales of the drug within this State; and
- Any additional information prescribed by regulation of the Department for the purpose of analyzing the cost of prescription drugs . . . , trends in those costs and rebates available for such drugs.

NRS 439B.635. Moreover, for all prescription diabetes drugs which experienced an increase in the wholesale acquisition cost of the drug, manufacturers must also disclose the reasons for the increase in this cost, including:

- A list of each factor that has contributed to the increase;
- The percentage of the total increase that is attributable to each factor;
- An explanation of the role of each factor in the increase; and
- Any other information prescribed by regulation by the Department.

NRS 439B.640.

In addition, the Nevada Legislature amended the definition of a “trade secret” in NRS 600A.030, and stated that the term “[d]oes not include any information that a manufacturer is required to report pursuant to NRS 439B.635 or 439B.640, . . . to the extent that such information is required to be disclosed by those sections.” NRS 600A.030(5)(b).

**B. The *PhRMA* Action and New Department Regulations.**

Approximately 1 month before these regulations were scheduled to take effect, Pharmaceutical Research and Manufacturers of America (“PhRMA”) and Biotechnology Innovation Organization (“BIO”) filed a federal action against the Governor of Nevada and the Director of the Department (the “*PhRMA Action*”) alleging that the statutes were unconstitutional and were preempted by the DTSA. (*See generally* Ex. 3.<sup>2</sup>) Sanofi is a member of both PhRMA and BIO. (Ex. 4,<sup>3</sup> at ¶ 2.) On October 3, 2017, the Nevada Legislature was granted the right to intervene in the *PhRMA Action*. (Ex. 5.<sup>4</sup>)

///

<sup>2</sup> Compl. for Declaratory & Injunctive Relief (Sept. 1, 2017) [ECF No. 1], filed in *Pharm. Research & Mfrs. of Am. v. Sandoval*, 2:17-cv-02315-JCM-CWH, U.S. Dist. Ct., Dist. of Nev. (“*PhRMA Action*”), attached as Exhibit 3.

<sup>3</sup> Decl. of James Borneman (Sept. 13, 2017) [ECF No. 26-6], filed in *PhRMA Action*, attached as Exhibit 4.

<sup>4</sup> Order (Oct. 3, 2017) [ECF No. 43], filed in *PhRMA Action*, attached as Exhibit 5.

1 In sum, the plaintiffs in the *PhRMA Action* asserted that Senate Bill 539 was unconstitutional  
2 and violated trade secret law because it required manufacturers to submit confidential information  
3 and trade secrets to the Department, placed no limitations upon the Department's use or  
4 dissemination of the information, and directed the Department to publicly disclose reports regarding  
5 such information. (Ex. 6,<sup>5</sup> at 16:4-17.) The plaintiffs contended that Senate Bill 539 would  
6 essentially strip pharmaceutical manufacturers of any trade secret protections nationwide, because  
7 once the information was publicly disclosed in Nevada, it could no longer qualify as a trade secret in  
8 any other state. (*Id.* at 16:18-17:2 (citing *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir.  
9 2002) (holding that it is "paradigmatic" that compelled disclosure to a party not required to keep the  
10 secret extinguishes the property right).)

11 In May 2018, in recognition of the problems posed by Senate Bill 539, the Department  
12 adopted and implemented new regulations which provided pharmaceutical manufacturers with  
13 procedures to safeguard the confidentiality of the information included in the required annual  
14 reports. Specifically, NAC 439.735 provides that if a manufacturer reasonably believes that public  
15 disclosure of information provided pursuant to NRS 439B.635 or NRS 439B.640 would constitute  
16 the misappropriation of a trade secret pursuant to the DTSA, the manufacturer can request that the  
17 Department maintain the confidentiality of the information. NAC 439.735(1). The request for  
18 confidentiality requires the manufacturer to "describe, with particularity, the information sought to  
19 be protected from public disclosure" and to explain "the reasons why public disclosure of the  
20 information would constitute misappropriation of a trade secret." NAC 439.735(2).

21 Further, under the regulation, if the Department receives a request for public records pursuant  
22 to NRS 239.010, seeking information from the manufacturer's annual reports, the Department must  
23 inform the manufacturer of the request and conduct an "initial review to determine whether the  
24 Department reasonably believes that public disclosure of the information would constitute  
25 misappropriation of a trade secret" pursuant to the DTSA.<sup>6</sup> NAC 439.735(3). If the Department  
26

<sup>5</sup> Pls.' Mot. for TRO & Prelim. Inj., & Supporting Mem. of Points & Auth. (Sept. 13, 2017) [ECF No. 26], filed in *PhRMA Action*, attached as Exhibit 6.

<sup>6</sup> The DTSA explicitly defines a "trade secret" as any all "forms and types of financial, business, scientific, technical, economic, or engineering information," including plans, methods, techniques, processes, and procedures. 18

determines that public disclosure of the information would constitute the misappropriation of a trade secret pursuant to the DTSA, the Department must deny the public records request on that ground. NAC 439.735(4).

The Department's regulations also provided manufacturers with some additional protections with regard to the Department's reporting requirements; specifically, NRS 439B.650 requires the Department to compile an annual report on the price of the prescription diabetes drugs based on the information submitted by the manufacturers pursuant to NRS 439B.635 and NRS 439B.640. However, the Department's regulations provide that this report will only include "aggregated data that does not disclose the identity of any drug [or] manufacturer" and a "description of trends concerning the prices of [the] prescription drugs" along with an explanation of how such prices and trends may affect the "prevalence and severity of diabetes" in Nevada and the "system of health care" in Nevada. NAC 439.740.

On June 28, 2018, shortly after the adoption of the Department's regulations, the plaintiffs in the *PhRMA Action*, *along with the Department and the Nevada Legislature*, informed the court that they had resolved their dispute. (Ex. 7,<sup>7</sup> at 2:23-3:5.) The parties informed the court that they *agreed and acknowledged* that:

- (1) *"under SB 539, the Department may acquire manufacturer trade secrets, such as a manufacturer's costs or production and other internal costs, 'under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret'"; and*
- (2) *"that so long as such trade secrets continue to satisfy the definition of 'trade secret' in 18 U.S.C. § 1839, if the Department were to disclose such trade secrets to any third party or use such trade secrets, such disclosure or use would constitute 'misappropriation' for which a court may award relief pursuant to the DTSA."*

(*Id.* at 3:6-21 (emphasis added).)

U.S.C. 1839(3); *see also* *Mastronardi Int'l Ltd. v. SunSelect Produce (Cal.), Inc.*, Civ. No. 1:18-cv-00737-AWI-JLT, 2019 WL 3996608 (E.D. Cal. Aug. 23, 2019) (finding that plaintiff sufficiently alleged that its pricing information and other financial information constituted a protectable trade secret and did not dismiss DTSA claims for failure to state a claim); *H.Q. Milton, Inc. v. Webster*, Civ. No. 17-cv-06598-PJH, 2017 WL 5625929 (N.D. Cal. Nov. 22, 2017) (granting temporary restraining order under the DTSA where plaintiff alleged misappropriation of "customer list and contact information, sales leads, customer interests, and H.Q. Milton's proprietary pricing (e.g., final sales price and profit margins)" where that "information constitutes protectable trade secrets under the DTSA).

<sup>7</sup> Joint Status Report (June 28, 2018) [ECF No. 95], filed in *PhRMA Action*, attached as Exhibit 7.

As a result of this regulatory resolution, the plaintiffs agreed to dismiss the action and their challenge to the constitutionality of NRS 439B.600 to NRS 439B.695. Thus, the court granted the plaintiffs' unopposed motion for voluntary dismissal of the action without prejudice. (Ex. 8.<sup>8</sup>)

C. **Sanofi Submitted a Request for Confidentiality for Certain Information Included in Its Annual Report to the Department.**

Sanofi US is the United States affiliate of Sanofi, a global life sciences company committed to improving access to healthcare and supporting the people it serves throughout the continuum of care. (Ex. 2,<sup>9</sup> at ¶ 2.) Specifically, Sanofi transforms scientific innovation into healthcare solutions in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious disease, diabetes and cardiovascular, consumer healthcare, established prescription products, and generics. (*Id.*) Some of the drugs that Sanofi manufactures include Adlyxin, Admelog, Amaryl, Apidra, DiaBeta, Lantus, Soliqua, and Toujeo, which are all FDA-approved for the treatment of diabetes. (*Id.* at ¶ 6.)

On October 31, 2017, the Department's list of essential diabetes drugs included the following Sanofi products: DiaBeta, Amaryl Glimepiride, Basaglar, Lantus, Toujeo, Soliqua, and Apidra. (Ex. 9.<sup>10</sup>) Similarly, the Department's February 1, 2019 list included Adlyxin, Admelog, Amaryl, Apidra, Lantus, Soliqua, and Toujeo. (Ex. 10.<sup>11</sup>) Therefore, Sanofi was required to submit the necessary annual reports to the Department pursuant to NRS 439B.635 and NRS 439B.640.

On January 15, 2019, and again on April 1, 2019, *in reliance upon the Department's new regulations*, Sanofi submitted requests for confidentiality to the Department along with its January, April, and subsequent August 2019 supplemental submissions pursuant to NRS 439B.635 and NRS

<sup>8</sup> Pls.' Unopposed Mot. for Voluntary Dismissal Without Prejudice (June 28, 2018) [ECF No. 97], filed in *PhRMA Action*, attached as Exhibit 8.

<sup>9</sup> Decl. of John Borneman, attached as Exhibit 2.

<sup>10</sup> 2017 List of Essential Diabetes Drugs v02.13.2018, [dhhs.nv.gov/HCPWD/Drug\\_Transparency\\_Essential\\_Lists\\_Reports\\_Resources/](http://dhhs.nv.gov/HCPWD/Drug_Transparency_Essential_Lists_Reports_Resources/) (Oct. 31, 2017), attached as Exhibit 9.

<sup>11</sup> 2019 Essential Diabetes Drug List v02.01.2019, [dhhs.nv.gov/HCPWD/Drug\\_Transparency\\_Essential\\_Lists\\_Reports\\_Resources/](http://dhhs.nv.gov/HCPWD/Drug_Transparency_Essential_Lists_Reports_Resources/) (Feb. 1, 2019), attached as Exhibit 10.

1 439B.640. (Ex. 11;<sup>12</sup> Ex. 12.<sup>13</sup>) Sanofi requested that the Department keep the following  
2 information confidential:

- 3 • The costs of producing the drug;
- 4 • The total administrative expenditures relating to the drug, including marketing and  
5 advertising costs;
- 6 • The profit that Sanofi has earned from the drug and the percentage of Sanofi's total  
7 profit that is attributable to the drug;
- 8 • The total amount of financial assistance that the manufacturer has provided through  
9 any patient prescription assistance program;
- 10 • The cost associated with coupons provided directly to consumers and for programs to  
11 assist consumers in paying copayments, and the cost to the manufacturer attributable  
12 to the redemption of those coupons and the use of those programs; and
- 13 • The aggregate amount of all rebates that Sanofi has provided to pharmacy benefit  
14 managers for sales of the drug within the State of Nevada.<sup>14</sup>

15 (collectively, the "Sanofi Confidential Information") (Ex. 11, at 1-2; Ex. 12, at 1-2.)

16 In order for information to qualify as a trade secret under the DTSA or NRS 600A.030, the  
17 federal and state laws require that the owners of trade secrets take reasonable steps to keep the trade  
18 secrets and/or confidential information secret. 18 U.S.C. § 1839(3)(A); NRS 600A.030(5)(a)(2).

19 Therefore, Sanofi's requests for confidentiality to the Department detailed the steps it has taken to  
20 protect and maintain the confidentiality of the Sanofi Confidential Information; namely:

21 [T]he Sanofi Confidential Information is not shared publicly, and  
22 access to it is restricted internally and only shared internally on a need-  
23 to-know basis. It is subject to non-disclosure requirements in  
24 [Sanofi's] employment and other business agreements. Employees of  
25 [Sanofi] are required to maintain the secrecy of the Sanofi Confidential  
26 Information, and are subject to discipline — up to and including  
27 termination — by [Sanofi] for its unauthorized disclosure.

28 (Ex. 11, at 2; Ex. 12, at 2; *see also* Ex. 2, at ¶¶ 12-13.)

///

<sup>12</sup> A true and correct copy of Sanofi's Letter to the Department (Jan. 15, 2019) is attached as Exhibit 11. *See* Ex. 2, at ¶ 11.

<sup>13</sup> A true and correct copy of Sanofi's Letter to the Department (Apr. 1, 2019) is attached as Exhibit 12. *See* Ex. 2, at ¶ 11.

<sup>14</sup> To the extent that any of Sanofi's Confidential Information might be disclosed by publication of another party's report, Sanofi opposes such disclosure.

1 The DTSA also defines a trade secret as “information [which] derives independent economic  
2 value, actual or potential, from not being generally known to, and not being readily ascertainable  
3 through proper means by, another person who can obtain economic value from the disclosure or use  
4 of the information.” 18 U.S.C. 1839(3)(B). NRS 600A.030 includes a substantially similar  
5 requirement. NRS 600A.030(5)(a)(1). Thus, in Sanofi’s requests for confidentiality, Sanofi  
6 explained:

7 The customers and competitors of [Sanofi] would gain an unfair  
8 competitive advantage if they were to obtain the Sanofi Confidential  
9 Information through a public records request pursuant to NRS  
10 239.010. In particular, [Sanofi’s] competitors and customers would  
11 receive the details of our cost structure, marketing and advertising  
12 costs, rebate strategies and profit information, which in turn provides  
13 insight into our pricing. This information could be used against us in  
14 negotiations with insurers and other intermediaries in the healthcare  
15 system. This could put [Sanofi] at a significant disadvantage,  
16 especially if our competitors do not make a diabetes drug and thus are  
17 not subject to [NRS 439B.635’s and NRS 439B.640’s] disclosure  
18 requirements. Disclosure of the Sanofi Confidential Information could  
19 prejudice [Sanofi] in competition involving non-diabetes products as  
20 well, given that [Sanofi] considers the same or similar factors when  
21 establishing pricing, advertising and rebate strategies for its other  
22 therapeutic products.

23 (Ex. 11, at 2; Ex. 12, at 2; *see also* Ex. 2, at ¶¶ 16-17.)

24 **D. The Petitioner’s Public Records Request to the Department.**

25 Just two days after Sanofi submitted its request for confidentiality to the Department, the  
26 Petitioner sent the Department a public records request for the annual reports submitted by any  
27 pharmaceutical manufacturer pursuant to NRS 439B.635 and/or NRS 439B.640. (Pet. at Ex. 2-1, at  
28 1.) The Petitioner’s request specifically named Sanofi as one of the manufacturers subject to the  
records request. (*Id.* at 2.)

On April 3, 2019, the Department responded to the Petitioner’s records request and informed  
the Petitioner that the “source reports” it sought were subject to Requests for Confidentiality made  
by the manufacturers. (*Id.* at Ex. 2-2, at 1.) Thus, the Department would only provide the Petitioner  
with the following (non-confidential) information:

//

///

- From the manufacturers reports pursuant to NRS 439B.635:
  - Drug manufacturer name;
  - Nonproprietary prescription drug name;
  - Proprietary prescription drug name;
  - National Drug Code (NDC);
  - Wholesale Acquisition Cost (WAC) price history;
  - Increase in WAC unit price; and
  - Date of increase in WAC price.
- From the manufacturers reports pursuant to NRS 439B.640:
  - Drug manufacturer name;
  - Non-proprietary drug name;
  - Proprietary drug name; and
  - NDC.

(*Id.* at 4.) The Department denied the public records request as to all other information in the annual reports, deeming such information confidential pursuant to the DTSA. (*Id.* at 1.)

On June 11, 2019, the Petitioner submitted a second public records request to the Department, seeking all annual reports submitted by pharmaceutical manufacturers pursuant to NRS 439B.635 and NRS 439B.640. (*Id.* at Ex. 2-3.) Again, Sanofi was included in the list of manufacturers subject to the public records request. (*Id.* at 2.)

On June 24, 2019, the Department responded to the Petitioner's records request and again informed the Petitioner that the source reports sought in the request were subject to Requests for Confidentiality submitted by the manufacturers. (*Id.* at Ex. 2-4, at 1.) The Department further reiterated that it would only disclose the information detailed in its April 3, 2019 response letter, and that the Petitioner's request was denied as to all other information in the annual reports, as such information was confidential pursuant to the DTSA. (*Id.* at 2, 4.)

In response, the Petitioner filed its Petition for Writ of Mandamus.

///

///

### III. ARGUMENT

#### A. The Nevada Legislature Never Intended for Pharmaceutical Manufacturers' Trade Secrets to Be Publicly Disclosed.

In an effort to ensure that Nevadans have access to affordable diabetes medications and treatments, the Nevada Legislature passed Senate Bill 539. The goal of this legislation was to increase transparency as it relates to the price of diabetes drugs. Thus, NRS 439B.635 and NRS 439B.640 were enacted to require pharmaceutical manufacturers to disclose cost, profit, and pricing information to the *Department*. The Nevada Legislature did not require such information to be disclosed to the *general public*. (See generally NRS 439B.600 to NRS 439B.695; see also Pet. at 6 n.4.) Rather, the Nevada Legislature intended that pharmaceutical manufacturers would provide cost, profit, and pricing information to the Department, and the Department would then produce its own reports on prescription drug prices for public disclosure. NRS 439B.650; NRS 439B.670.

This legislative intent is confirmed by the Legislature's amendment to NRS 600A.030. The statute provides that a trade secret "[d]oes not include any information that a manufacturer is *required to report* pursuant to NRS 439B.635 or 439B.640 . . . *to the extent that such information is required to be disclosed by those sections.*" NRS 600A.030(5)(b) (emphasis added). By use of both the words "report" and "disclosed," it is clear that the Legislature intended to remove the trade secret protection only for the specific information which the manufacturers report to the Department *and* which the Department subsequently reports to the public pursuant to NRS 439B.650 and NRS 439B.670. Therefore, any other information which the manufacturers report to the Department pursuant to NRS 439B.635 or NRS 438B.640, still qualifies as a trade secret pursuant to NRS 600A.030.

To clarify any confusion created by NRS 600A.030(5)(b), the Department adopted NAC 439A.735 and 439A.740. NAC 439A.735 allows manufacturers to maintain the confidentiality of their proprietary, financial, business, and/or economic information by submitting a request for confidentiality to the Department. If the Department receives a public records request for information covered by a request for confidentiality, the Department must: (i) conduct a review of the information to determine if it reasonably believes that public disclosure of the information would

1 constitute a misappropriation of a trade secret under the DTSA; and (ii) if so, deny the public records  
2 request. NAC 439.735(3), (4).

3 NAC 439.740 limits the type of information that the Department can publicly disclose  
4 pursuant to NRS 439B.650. It states that the Department's report required by NRS 439B.650 can  
5 only include **aggregated data that does not disclose the identity of any drug or manufacturer**, along  
6 with pricing trends and an explanation of how prices and trends affect the prevalence and severity of  
7 diabetes in Nevada and the healthcare system in Nevada. NAC 439.740. The Department is not  
8 required to disclose any of the manufacturers' production costs, marketing costs, profits, price  
9 setting decisions, rebate information, or financial assistance information. Similarly, the information  
10 included on the Department's website can only include the **wholesale acquisition cost of each**  
11 **prescription drug**, as reported by the manufacturers in their reports submitted pursuant to NRS  
12 439B.635. NRS 439B.670(1)(a)(4). No other categories of information from the manufacturers'  
13 annual reports is included in NRS 439B.670 for disclosure on the Department's website.

14 Neither of these administrative regulations conflict with Senate Bill 539 or NRS 439B.600 to  
15 NRS 439B.695. In fact, NRS 439B.685 empowers the Department to "adopt such regulations as it  
16 determines to be necessary or advisable to carry out the provisions of NRS 439B.600 to NRS  
17 439B.695, inclusive." The statute further provides that "[s]uch regulations **must** provide for,  
18 **without limitation . . . the form and manner in which manufacturers are to provide to the**  
19 **Department the information described in NRS 439B.635, 439B.640 and 439B.660.**" NRS  
20 439B.685(6) (emphasis added).

21 The Nevada Supreme Court has determined that such regulations are valid and can be used to  
22 supplement legislation where appropriate. Specifically, in *Banegas v. State Indus. Ins. Sys.*, 117  
23 Nev. 222, 19 P.3d 245 (2001), the Supreme Court held that "the Legislature may authorize  
24 administrative agencies to make rules and regulations supplementing legislation if the power given is  
25 prescribed in terms sufficiently definite to serve as a guide in exercising that power." *Id.* at 227, 19  
26 P.3d at 248. Here, NAC 439.740 was needed to clarify the types of information from the  
27 manufacturers' annual reports which would be publicly disclosed by the Department. Similarly,  
28 NAC 439.735 was needed to clarify that disclosure of trade secrets to the Department to effectuate

1 the purpose and intent of Senate Bill 539 did not eliminate or waive trade secret protection for such  
2 information for any other purpose.

3 Finally, the Department's adoption of NAC 439.735 and NAC 439.740 not only clarified any  
4 confusion created by NRS 600A.030(5)(b), but it also resolved the *PhRMA Action* and challenges to  
5 the constitutionality of NRS 439B.600 to NRS 439B.695. The Nevada Legislature was a party to the  
6 *PhRMA Action*, and it confirmed to the Court that under Senate Bill 539, the Department has a duty  
7 to maintain the secrecy of the manufacturers' trade secrets and/or to limit the use of such trade  
8 secrets. (Ex. 7, at 3:6-14.) The Nevada Legislature also represented to the federal district court that  
9 if the Department were to disclose the manufacturers' trade secrets to a third party, such disclosure  
10 would constitute a misappropriation under the DTSA. (*Id.* at 14-21.) These statements  
11 unequivocally demonstrate the legislative intent for Senate Bill 539. The Legislature never intended  
12 for the pharmaceutical manufacturers' trade secrets to be publicly disclosed — they merely intended  
13 for the information to be reported to the Department for analysis and oversight. The Legislature  
14 recognized the importance of maintaining the secrecy of the manufacturers' cost, profit, and pricing  
15 information and agreed that NAC 439.735 and NAC 439.740 were necessary to provide  
16 manufacturers with sufficient protection for their trade secrets.

17 Sanofi relied upon the Department's and Legislature's representations in the resolution of the  
18 *PhRMA Action* in submitting its trade secret information to the Department. Sanofi vigorously  
19 protects its Confidential Information from public disclosure. It also takes great steps to internally  
20 restrict access to this information, by only sharing the information internally on a need-to-know  
21 basis, utilizing non-disclosure provisions in its employment and business agreements, and  
22 disciplining employees (up to and including termination) for any unauthorized disclosure of the  
23 Sanofi Confidential Information. (Ex. 2, at ¶¶12-13.)

24 Sanofi takes these steps to maintain the secrecy of its Confidential Information because it  
25 will suffer irreparable harm if the information is publicly disclosed. Sanofi's competitors and  
26 consumers would gain an unfair competitive advantage if they were to obtain the Sanofi Confidential  
27 Information. (*Id.* at ¶ 16.) Specifically, Sanofi's consumers could use the information against it in  
28 negotiations with insurers and others in the healthcare system. (*Id.*) Similarly, Sanofi's competitors

1 will learn how it allocates its resources and sets its prices, not only for diabetes drugs, but for all of  
2 its products (as Sanofi considers the same or similar factors when setting prices for all of its  
3 products). (*Id.* at ¶ 17.) The impact of this would be felt nationwide, as the prices Sanofi sets and  
4 the methods it uses to set them are substantially the same from state-to-state. (*Id.* at ¶ 18.)

5 **B. NAC 439.735 Does Not Conflict With the NPRA.**

6 The Petitioner contends that the Department cannot adopt any regulations which conflict with  
7 the NPRA. (Pet. at 65.) However, in *City of Sparks v. Reno Newspapers, Inc.*, 133 Nev. 398, 399  
8 P.3d 352 (2017), the Reno-Gazette Journal requested that the City disclose copies of the business  
9 licenses of persons operating medical marijuana establishments (“MME”) in Reno *Id.* at 398-99,  
10 399 P.3d at 354. The City produced the business licenses, but redacted the licensees’ identities  
11 pursuant to NAC 453A.714, which specifically exempts the identities of MME business license  
12 holders from disclosure under the NPRA. *Id.* The Court found that NRS 453A.370 specifically  
13 authorized the Department’s Division of Public and Behavioral Health to make rules and regulations  
14 supplementing NRS Ch. 453A, and, therefore, NAC 453A.714 was valid. *Id.* at 402, 399 P.3d at  
15 356. The Reno-Gazette Journal argued that NRS 453A.370(5) did not authorize the Division to  
16 create a regulation exempting information from the NPRA “because any exceptions to the NPRA  
17 can only exist when explicitly provided for under NRS 239.010.” *Id.* However, the Court held that  
18 “*in addition to* the specific exemptions listed in NRS 239.010, the NPRA also *does not apply* to  
19 records ‘*otherwise declared by law to be confidential.*’” *Id.* (quoting NRS 239.010(1)). Thus, the  
20 creation of an exception to the NPRA is not a “conflict” that would render an administrative  
21 regulation invalid.

22 As set forth above, NAC 439.735 sets forth procedures pursuant to which the Department can  
23 deny public records requests for information submitted to the Department pursuant to NRS  
24 439B.635 or NRS 439B.640. The Legislature gave the Department the authority to adopt this  
25 regulation and approved of the Department’s regulation as a means to avoid any challenges to the  
26 constitutionality of NRS 439B.600 to NRS 439B.695.

27 Sanofi complied with all of the requirements of NAC 439.735. Sanofi submitted a request  
28 for confidentiality for the Sanofi Confidential Information. (Ex. 11, at 1-2; Ex. 12, at 1-2.) Sanofi

1 set forth detailed information about the steps it takes to protect the secrecy of this information. (Ex/  
2 11, at 2; Ex. 12, at 2.) Sanofi also set forth detailed information about the value of such information  
3 to its competitors and the irreparable harm it would suffer if these trade secrets were publicly  
4 disclosed. (*Id.*) Thus, the trade secrets required to be disclosed in Sanofi's annual reports to the  
5 Department have been "declared confidential under the law" and are exempt from the NPRA.

6 In addition to the confidentiality provided by NAC 439.735, the information included in  
7 Sanofi's annual reports also qualifies as a trade secret under the DTSA. Specifically, the DTSA  
8 defines a "trade secret" as "all forms and types of *financial, business*, scientific, technical, *economic*  
9 or engineering information, including patterns, plans, compilations, program devices, formulas,  
10 designs, prototypes, methods, techniques, processes, procedures, programs, or codes . . . if — (A) the  
11 owner thereof has taken reasonable measures to keep such information secret; and (B) the  
12 information derives independent economic value, actual or potential, from not being generally  
13 known to, and not being readily ascertainable through proper means by, another person who can  
14 obtain economic value from the disclosure or use of the information." 18 U.S.C. § 1839(3).  
15 Sanofi's production costs, advertising costs, marketing costs, profits, the amount of financial  
16 assistance it provides to patient prescription assistance programs, costs associated with coupons  
17 provided to consumers, and the amount of rebates provided to pharmacy benefit managers constitute  
18 financial and/or economic information protected by the DTSA. Similarly, Sanofi's methods,  
19 techniques, processes, and/or procedures for setting prices qualifies as business information  
20 protected by the DTSA. As such, this information is "declared confidential by law" and is not  
21 subject to disclosure pursuant to the NPRA.

22 The Petitioner asserts that the Department cannot withhold the manufacturers' annual reports  
23 on the basis of confidentiality unless it can demonstrate that its interest in nondisclosure clearly  
24 outweighs the public's interest in access. (Pet. at ¶ 62.) Here, the interest in protecting the  
25 manufacturers' trade secrets clearly outweighs the public's interest in having access to the annual  
26 reports. The information that the Legislature deemed necessary for assessing the reasonableness of  
27 prescription drug prices is already included in the Department's reports and in the Department's  
28 disclosures on its website. The transparency objective of NRS 439B.600 to NRS 439B.695 is

1 satisfied by the manufacturers' disclosures to the Department. The underlying data assessed by the  
2 Department need not be publicly disclosed, particularly when such disclosure would only serve to  
3 irreparably harm manufacturers in their dealings with competitors and consumers, not just in  
4 Nevada, but nationwide.

5 Finally, as noted by the Petitioner, "[t]he Supreme Court of Nevada has repeatedly held that a  
6 court considering a claim of confidentiality in response to a public records request[] 'begin[s] with  
7 the presumption that all *government-generated records* are open to disclosure.'" (*Id.* at ¶ 61  
8 (quoting *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 266 P.3d 623, 628 (2011)).)  
9 However, the annual reports that pharmaceutical manufacturers are required to submit to the  
10 Department pursuant to NRS 439B.635 and NRS 439B.640 *are not government-generated records*.  
11 Rather, the relevant government-generated records for the purposes of the NPRA are the reports the  
12 Department prepares pursuant to NRS 439B.650/NAC 439.740 and NRS 439B.670. Therefore, the  
13 Sanofi Confidential Information included in its annual reports to the Department is not subject to  
14 disclosure under the NPRA. *See e.g., Donrey of Nev., Inc. v. Bradshaw*, 106 Nev. 630, 631-32, 798  
15 P.2d 144, 145 (1990) (concerning a request for a police investigative report); *DR Partners v. Bd. of*  
16 *Cty. Comm'rs of Clark Cty.*, 116 Nev. 616, 619, 6 P.3d 465, 467 (2000) (concerning a request for  
17 Clark County's phone records); *Reno Newspapers, Inc. v. Haley*, 126 Nev. 211, 213, 234 P.3d 922,  
18 923-24 (2010) (concerning firearms permits); *Pub. Employees' Ret. Sys. of Nev. v. Reno*  
19 *Newspapers, Inc.*, 129 Nev. 833, 834-35, 313 P.3d 221, 222-23 (2013) (concerning government  
20 employee personnel files); *Clark Cty. Sch. Dist. v. Las Vegas Review-Journal*, 134 Nev. Adv. Op.  
21 84, 429 P.3d 313, 315-16 (2018) (concerning Clark County School District's internal investigative  
22 records). The Petitioner has failed to cite to any authority demonstrating that the NPRA is a tool that  
23 allows the public to obtain access to confidential information and/or trade secrets in reports prepared  
24 by private business entities and submitted to administrative agencies as required by law, as opposed  
25 to voluntary submissions in bid proposals and license applications.

26 ///

27 ///

28 ///

IV. CONCLUSION

For the foregoing reasons, Sanofi respectfully requests that the Court deny the Petition for Writ of Mandamus.

DATED this 17th day of October, 2019.

BAILEY ♦ KENNEDY

By: 

JOHN R. BAILEY  
DENNIS L. KENNEDY  
SARAH E. HARMON

*Attorneys for Intervenor* SANOFI-AVENTIS  
U.S. LLC

# EXHIBIT 2

# EXHIBIT 2

**DECLARATION OF JAMES BORNEMAN**

I, James Borneman, declare as follows:

1. I am currently the Vice President and Head, Diabetes and Primary Care Sales, for Sanofi US. From July 2014 — May 2017, I was Vice President, Strategic Pricing and Contract Management, and from June 2017 — July 2018, I was the Head, Customer Engagement & Insights, both for Sanofi US. In these capacities, I was responsible for and am knowledgeable about the establishment of all gross and net pricing strategies for all Sanofi US pharmaceutical products to include oversight of the organization's gross-to-net investments. I am knowledgeable about Sanofi US's pricing and contracting for its prescription drugs, including its diabetes therapies.

2. Sanofi US is the U.S. affiliate of Sanofi, a global life sciences company committed to improving access to healthcare and supporting the people we serve throughout the continuum of care. From prevention to treatment, Sanofi transforms scientific innovation into healthcare solutions in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes and cardiovascular, consumer healthcare, established prescription products and generics. More than 100,000 people at Sanofi are dedicated to making a difference in patients' daily lives, wherever they live, and enabling them to enjoy a healthier life.

3. Headquartered in Bridgewater, New Jersey, Sanofi US employs approximately 12,500 professionals throughout the country, including at a distribution center in Reno, Nevada. In addition to Diabetes & Cardiovascular and General Medicines, our other businesses operating in the United States include Sanofi Genzyme (specialty care), Sanofi Pasteur (vaccines), Winthrop (generics) and Chattem (consumer healthcare).

4. Sanofi has a rich history of innovation dating back more than 100 years. We are tremendously proud of our heritage, which over the years has combined steady growth and expansion with an exceptional commitment to research and development.

5. For example, since the launch of Lantus (insulin glargine injection) 100 units/ml, Sanofi has continued investing to better support clinical decision making for patients with diabetes through comprehensive research including over 2200 full-text publications from results of

///

1 approximately 500 randomized controlled clinical trials, over 220 real-life patient studies and over  
2 50 meta-analyses.

3 6. Sanofi holds or has had rights to patents protecting prescription drugs marketed and  
4 sold by Sanofi US, including patents protecting Adlyxin, Admelog, Amaryl, Apidra, DiaBeta,  
5 Lantus, Soliqua and Toujeo which are FDA-approved for the treatment of diabetes. I understand  
6 that Sanofi is required to provide certain information to the Nevada Department of Health and  
7 Human Services (“Department”) pursuant to Nevada Senate Bill No. 539 (“SB 539” or “the Act”)  
8 for drugs that are “essential” to the treatment of diabetes, which includes the above products.

9 7. I understand that on at least January 15, 2019, April 1, 2019 and August 7, 2019,  
10 pursuant to the requirements of the Act, Sanofi US confidentially reported substantial financial and  
11 marketing information related to Adlyxin, Admelog, Amaryl, Apidra, DiaBeta, Lantus, Soliqua and  
12 Toujeo to the Department (“Sanofi Reports”).

13 8. Pursuant to Section 3.8 of the Act, the Sanofi Reports included confidential  
14 information regarding the above products in response to the following categories of information:

- 15 • The total cost of producing the drug;
- 16 • Total administrative expenditures relating to the drug;
- 17 • Profit manufacturer earned from the drug;
- 18 • Percentage of manufacturer’s total profit attributed to drug during marketing  
19 period for drug sale;
- 20 • Total amount of financial assistance provided through patient Prescription  
Assistance Programs;
- 21 • Cost associated with consumer coupons for consumer Copayment Assistance  
22 Programs;
- 23 • Manufacturer cost attributable to redemption of consumer coupons and use of  
consumer Copayment Assistance Program; and
- 24 • Aggregate amount of all rebates manufacturer provided to Pharmacy Benefit  
25 Managers for drug sales in Nevada in dollars.

26 ///

27 ///

28 ///

1 9. Pursuant to Section 4.0 of the Act, the Reports also included confidential information  
2 regarding recent wholesale acquisition cost (“WAC”) increases for Adlyxin, Apidra, Lantus, Soliqua  
3 and Toujeo in response to the following categories of information:

- 4 • A list of factors that has contributed to the increase;
- 5 • The explanation for the percent increase attributable to each factor; and
- 6 • An explanation of the role each factor played in the increase.

7 10. As part of the Sanofi Reports, Sanofi US also included letters (re: “Sanofi US Trade  
8 Secret/Confidentiality Request Pursuant to Nevada SB 539”) pursuant to, and in reliance on, Nevada  
9 Administrative Code §§439.730-740 regarding the trade secret status of Sanofi’s confidential  
10 information. The letters, among other things, referenced the Defend Trade Secrets Act of 2016 and a  
11 litigation captioned *Pharmaceutical Research and Manufacturers of America v. Sandoval, et. al.*,  
12 United States District Court, District of Nevada, Case No. 2:17-cv-02315-JCM-CWH.

13 11. A true and correct copy of the Letter dated January 15, 2019 is attached hereto as  
14 Exhibit 11. A true and correct copy of the Letter dated April 1, 2019 is attached hereto as Exhibit  
15 12.

16 12. The Sanofi Reports comprise information that is of substantial independent economic  
17 value to Sanofi US by virtue of being confidential and non-public. Information such as pricing  
18 inputs and rationale is restricted internally, is only shared internally on a need-to-know basis, and is  
19 subject to non-disclosure provisions in Sanofi US’s employment and other business agreements.  
20 Employees are required to maintain the secrecy of this information, and are subject to discipline —  
21 up to and including termination — by Sanofi US for its unauthorized disclosure.

22 13. Information such as the factors considered in setting and adjusting the prices of our  
23 products and the percentage of our profits that derive from diabetes drugs are confidential and  
24 proprietary. This information is not shared publicly, and access to it is restricted internally and only  
25 shared internally on a need-to-know basis. It is subject to non-disclosure provisions in Sanofi US’s  
26 employment and other business agreements. Employees are required to maintain the secrecy of this  
27 information, and are subject to discipline — up to and including termination — by Sanofi US for its  
28 unauthorized disclosure.

1           14.     I understand that the Department has received, from a reporter for The Nevada  
2 Independent website, at least one request for information under the Nevada Public Records Act.  
3 (Petition for Writ of Mandamus, at Ex. 2-1.) This request seeks, among other things, a disclosure of  
4 the confidential information in the Sanofi Reports.

5           15.     Disclosure of the Sanofi Reports to The Nevada Independent would significantly  
6 harm Sanofi US. Once this information is publicly disclosed in Nevada, including to the readers of  
7 the Nevada Independent, it is permanently public everywhere.

8           16.     Our customers and competitors would gain an unfair competitive advantage over  
9 Sanofi US if they were to obtain the financial and marketing information in the Sanofi Reports,  
10 which have now been requested by The Nevada Independent. In particular, our customers would  
11 learn how we develop our pricing, which in turn could be used against us in negotiations with  
12 insurers and other intermediaries in the healthcare system — and ultimately negatively impact  
13 patients, by discouraging innovations that would benefit them.

14           17.     Likewise, our competitors would learn how we allocate our resources and set our  
15 prices. This in turn could put Sanofi US at a significant disadvantage, especially if our competitors  
16 do not make a diabetes drug and thus are not subject to SB 539's disclosure requirements. We  
17 consider the same or similar factors when setting prices for other products. Thus, the information  
18 disclosed would significantly harm Sanofi US in competition involving non-diabetes products as  
19 well.

20           18.     These impacts will not just be felt in Nevada, but will be felt nationally. The prices  
21 Sanofi US sets and the methods that it uses to set them are substantially the same from state-to-state.  
22 Thus, the information disclosed under SB 539 would have implications on our negotiations with  
23 customers and our competitive positioning nationwide.

24           19.     For example, many of the other healthcare supply chain stakeholders are national  
25 companies that negotiate national contracts. Healthcare purchasers such as the Culinary Union  
26 #226, which was a major public proponent of SB 539, are affiliated with Unite Here, a national  
27 union with affiliates in 37 states.

28     ///

20. Sanofi US has a longstanding commitment to research in the diabetes space and there is much remaining to be done in the diabetes space to ensure better outcomes for patients. Sanofi invested significant capital in developing Adlyxin Admelog, Amaryl, Apidra, DiaBeta, Lantus, Soliqua and Toujeo, despite the substantial risk that this investment would not bear fruit. Sanofi obtained patents on these products, which gives Sanofi US the exclusive legal right to market these drugs for the term of those patents. Such patent exclusivity enables Sanofi US to price Adlyxin Admelog, Amaryl, Apidra, DiaBeta, Lantus, Soliqua and Toujeo at a level that helps to recoup the investment in this research and development, given that many experimental products do not even make it to the submission or approval stages. Now, however, if the Sanofi Reports were to be subject to public disclosure, Sanofi faces the unenviable choice of either forgoing its right under the patent laws to price the products at this level, or suffering the substantial penalty of disclosure of trade secret information. The risks of competitive harm will lower the value of existing and future patents on diabetes products, diminishing the incentive, or creating a disincentive, to invest in developing and enhancing those drugs. Ultimately, this could slow or blunt the process of providing better treatments for patients.

21. Disclosure of the Sanofi Reports also could have severe unintended consequences. Given the significant investment required to fund research and development, such a focus could have a chilling effect on Sanofi's efforts in the diabetes space. For example, the lack of reporting thresholds in Section 3.8 of the Act (other than the requirement that the drug be "essential" to diabetes treatment) and a very low threshold for reporting price increases in Section 4 of the Act (any price greater than the CPI for medical products) could result in lower return on the patent rights and other innovations in the diabetes space than in other disease spaces. Further, Sanofi could be placed at a competitive disadvantage relative to companies who do NOT manufacture diabetes medicines, who reap an unexpected benefit by virtue of the publication of the Sanofi Reports. Given that Sanofi US considers the same or similar factors when setting the prices for other products, the information disclosed could disadvantage Sanofi US in competition involving non-diabetes products as well.

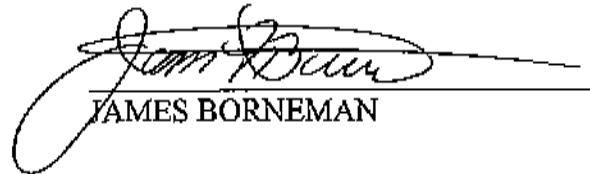
///

1           22. Disclosure of the Sanofi Reports would defeat Sanofi's legitimate investment  
2 expectations regarding its current products, and will necessitate review of our research and  
3 development priorities for diabetes products going forward. Indeed Sanofi may be forced to  
4 consider the costs and risks imposed by SB 539 in deciding what resources to allocate to enhancing  
5 its products and/or to research and development of new diabetes treatments.

6           23. Given Sanofi's confidence in our researchers and our mission to continue finding  
7 solutions for patients with diabetes — and balancing that with our duties towards those who invest in  
8 Sanofi's lifesaving and life improving treatments and patients awaiting cures and treatments in other  
9 areas — Sanofi may be forced to weigh the difficult decision of whether to reduce its efforts in  
10 continuing to pursue promising medical advances in the area of diabetes because of these  
11 disincentives.

12           I declare under penalty of perjury, under the laws of the State of Nevada, and the State of  
13 New Jersey, that the foregoing is true and correct.

14           EXECUTED on this 17<sup>th</sup> day of October, 2019.

15   
16 JAMES BORNEMAN  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 3

# EXHIBIT 3

Pat Lundvall  
Nevada Bar No. 3761  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
plundvall@mcdonaldcarano.com

Robert N. Weiner  
Pending Admission *Pro Hac Vice*  
Jeffrey L. Handwerker  
Pending Admission *Pro Hac Vice*  
R. Stanton Jones  
Pending Admission *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA, and  
  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity  
as Governor of the State of Nevada, and

RICHARD WHITLEY, in his official capacity  
as Director of the Nevada Department for  
Health and Human Services,

Defendants.

Case No.:

**COMPLAINT FOR DECLARATORY  
AND INJUNCTIVE RELIEF**

1 Plaintiffs Pharmaceutical Research and Manufacturers of America (“PhRMA”) and  
2 Biotechnology Innovation Organization (“BIO”) (together, “Plaintiffs”), on behalf of themselves  
3 and their members, for their Complaint against Brian Sandoval, in his official capacity as Governor  
4 of the State of Nevada (the “State”), and Richard Whitley, in his official capacity as Director of the  
5 Nevada Department of Health and Human Services (together, “Defendants”), allege as follows:

## 6 INTRODUCTION

7 1. Plaintiffs bring this action to block an unprecedented and unconstitutional Nevada  
8 law that interferes with the federal patent and trade-secret laws, deprives manufacturers of their  
9 property interest in their trade secrets, and improperly overrides the regulatory choices of every  
10 other state. Because the new Nevada statute violates multiple provisions of the United States  
11 Constitution, this Court has subject matter jurisdiction under 28 U.S.C. § 1331.

12 2. Nevada recently enacted Senate Bill No. 539 (“SB 539” or the “Act,” attached as  
13 Exhibit A), a statute novel in its scope, ambition, and nationwide effect. As a penalty for exercising  
14 rights protected under the U.S. patent laws, SB 539 strips pharmaceutical manufacturers of trade-  
15 secret protection for confidential, competitively sensitive, proprietary information regarding the  
16 advertising, cost, marketing, pricing, and production of their patented diabetes medicines. The Act  
17 then compels manufacturers to disclose this information to the Nevada Department of Health and  
18 Human Services (the “Department”), which must publish at least some of the information on its  
19 website and may disseminate the rest as it pleases.

20 3. By extinguishing trade-secret protection for manufacturers’ confidential, proprietary  
21 information, burdening the lawful exercise of longstanding federal patent rights, and interfering  
22 with the national market for diabetes medicines, the Act violates the U.S. Constitution in at least  
23 four ways.

24 4. *First*, SB 539 violates the Supremacy Clause because it conflicts with federal patent  
25 law, including the Drug Price Competition and Patent Term Restoration Act of 1984, known as the  
26 Hatch-Waxman Act. The federal patent laws allow a patent holder to exclude others from making,  
27 using, or selling new inventions. The Hatch-Waxman Act adapts this system to pharmaceuticals  
28 through a comprehensive federal scheme to provide broad access to affordable medicines while

1 offering economic incentives sufficiently potent to motivate innovators to shoulder the enormous  
2 costs and risks to develop pioneering new treatments. SB 539 upsets this legislative balance by  
3 burdening a patent holder's right to price its product in a manner reflecting the economic incentives  
4 the federal patent laws are intended to ensure.

5         5.       *Second*, SB 539 also conflicts with, and is therefore preempted by, federal trade-  
6 secret law. Recognizing that protection of trade secrets is critical to the success of U.S. businesses,  
7 Congress enhanced existing state-law safeguards by enacting the Defend Trade Secrets Act of 2016  
8 ("DTSA"). The DTSA sets a federal baseline for trade-secret protection. SB 539 does not merely  
9 fall below this baseline. It effectively nullifies federal protection for valuable trade secrets,  
10 undermining innovation and competition in the American pharmaceutical industry.

11         6.       *Third*, SB 539 violates the Takings Clause of the Fifth Amendment by depriving  
12 affected manufacturers of trade-secret protection for their confidential information, forcing them to  
13 disclose it to the State, and ensuring that much of it is disseminated on the Internet, including to  
14 third-party payers and competitors. Before SB 539, these materials qualified as trade secrets under  
15 the laws of every state, including Nevada. Trade secrets are property. SB 539 destroys the value of  
16 that property without recompense. It thus deprives manufacturers of their property "without just  
17 compensation," in violation of the Takings Clause.

18         7.       *Fourth*, SB 539 violates the dormant Commerce Clause because the penalty it  
19 imposes in Nevada impedes commerce in other states. By tying penalties to the national list price  
20 for a drug, SB 539 affects drug prices throughout the country, even for drugs bought and sold  
21 entirely outside of Nevada. The Act also eviscerates trade-secret protection not only in Nevada, but  
22 in every other state as well. Requiring disclosures, rescinding trade-secret protection for the  
23 information disclosed, and mandating its publication on the Internet destroys its confidentiality.  
24 Such disclosures cannot be undone—information cannot be undisclosed. SB 539 overrides the  
25 protections of other states that treat the information as trade secrets, including states where the  
26 affected manufacturers reside, pay taxes, and employ thousands of workers. Whatever purported  
27 local benefit SB 539 might seek for Nevada purchasers of diabetes medicines is far less substantial  
28 than the displacement of the laws of every other state in the Union. Only Congress has the authority

1 to override state trade-secret law or to impose national economic policies. Nevada cannot do so  
2 unilaterally.

3 8. SB 539's constitutional infirmities led Governor Brian Sandoval to veto a  
4 substantially similar bill—Senate Bill 265 (“SB 265”)—just three months ago. Governor Sandoval  
5 warned that provisions of the earlier bill “could be challenged under theories of federal preemption,  
6 the Fifth Amendment’s prohibition on uncompensated takings, and the Dormant Commerce  
7 Clause.” Veto Letter from Gov. Brian Sandoval to Sen. Maj. Leader Aaron Ford 3 (June 2, 2017)  
8 (“Veto Letter,” attached as Exhibit B). The Governor was right, but SB 539 did not alleviate the  
9 defects he identified.

10 9. Governor Sandoval further recognized that, beyond these constitutional defects, SB  
11 265 could seriously harm Nevada residents suffering from diabetes. The bill, in the Governor’s  
12 view, posed “serious risks of unintended and potentially detrimental consequences for Nevada’s  
13 consumer patients, not the least of which is the possibility that access to critical care will become  
14 more expensive, more restricted, and less equitable.” *Id.* at 2. He cautioned that the bill “could  
15 cause more harm than good for Nevada’s families.” *Id.* “Before I support a bill [this] uncertain,”  
16 he wrote, “which deals so directly and extensively with the health and well-being of countless  
17 Nevadans, there must be compelling evidence that the benefits are worth the risks.” *Id.* at 3. There  
18 was no such evidence, and the Legislature did not remedy that deficit in adopting SB 539.

19 10. Accordingly, Plaintiffs seek a declaration that the challenged provisions of SB 539  
20 are preempted by federal law and also violate the Takings Clause and the dormant Commerce  
21 Clause. Plaintiffs also seek an injunction prohibiting the defendants from implementing or  
22 enforcing those provisions.

### 23 **PARTIES**

24 11. PhRMA is a non-profit corporation organized under Delaware law, with its  
25 headquarters in Washington, D.C. PhRMA serves as the pharmaceutical industry’s principal public  
26 policy advocate, representing the interests of its members before Congress, the Executive Branch,  
27 state regulatory agencies and legislatures, and the courts. Among other objectives, PhRMA seeks to  
28 advance public policies that foster continued medical innovation and to educate the public about the

1 process for discovering and developing new drugs. PhRMA members are the leading research-  
2 based pharmaceutical and biotechnology companies in America, devoted to discovering and  
3 developing new medications that allow people to live longer, healthier, and more productive lives.<sup>1</sup>

4 12. BIO is the world's largest trade association representing more than 1,000  
5 biotechnology companies, academic institutions, state biotechnology centers and related  
6 organizations across the United States and in more than 30 other nations. BIO members are  
7 involved in the research and development of innovative healthcare, agricultural, industrial and  
8 environmental biotechnology products.<sup>2</sup>

9 13. Defendant Brian Sandoval is the Governor of the State of Nevada and is sued in his  
10 official capacity only. As Governor, Defendant Sandoval is responsible for the execution of SB  
11 539.

12 14. Defendant Richard Whitley is the Director of the Department and is sued in his  
13 official capacity only. As Director of the Department, Defendant Whitley is responsible for the  
14 implementation and execution of SB 539, including the promulgation of rules and the assessment of  
15 administrative penalties authorized by the Act. *See* SB 539, 2017 Leg., 79th Sess. §§ 7–8 (Nev.  
16 2017).

## 17 JURISDICTION AND VENUE

18 15. Plaintiffs' causes of action arise under 42 U.S.C. § 1983 and the United States  
19 Constitution. The Court thus has jurisdiction under 28 U.S.C. § 1331.

20 16. Venue is proper in this district under 28 U.S.C. § 1391(b) because Plaintiffs' claims  
21 arise in this judicial district and because Defendants reside and perform their official duties in this  
22 district.

23 17. An actual controversy exists between the parties within the meaning of 28 U.S.C.  
24 § 2201, and this Court has the authority to grant declaratory and injunctive relief pursuant to 28  
25 U.S.C. §§ 2201 and 2202.

---

26 <sup>1</sup> A list of PhRMA members is available at *Members*, <http://www.phrma.org/about/members>.

27 <sup>2</sup> A list of BIO members is available at *BIO Member Directory*, [http://www.bio.org/bio-member-](http://www.bio.org/bio-member-directory)  
28 [directory](http://www.bio.org/bio-member-directory).

## BACKGROUND

### ***Plaintiffs' Members Devote Billions of Dollars Each Year to Developing Innovative Diabetes Medicines in Reliance on Patent and Trade-Secret Law***

18. Diabetes is an epidemic in the United States, with more than 30 million Americans diagnosed with either Type 1 or Type 2 diabetes. Type 1 diabetes is an autoimmune disease in which the immune system attacks the insulin-producing cells of the pancreas, and the body as a result produces too little insulin, the principal hormone regulating the body's absorption of glucose (sugar) from the blood. In Type 2 diabetes, the body resists the effects of insulin and, although the pancreas produces abnormally high levels of insulin to overcome this resistance, blood glucose rises to higher levels than normal. About 5 to 10% of diabetes diagnoses are Type 1, and 90 to 95% are Type 2. *See What Is Diabetes?*, Nat'l Inst. of Diabetes & Digestive & Kidney Diseases, Nat'l Insts. of Health, <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes>. High levels of glucose in the blood can result in a number of complications, including vision loss, kidney disease, and cardiovascular disease. *Id.*

19. Diabetes is the seventh leading cause of death in the United States. In addition to the 30 million Americans diagnosed with the disease itself, another 84 million have pre-diabetes—abnormally high blood sugar levels that increase the risk of developing diabetes in the future. All told, over half the adults in the United States have either diabetes or pre-diabetes. *See A. Menke et al., Prevalence of and Trends in Diabetes Among Adults in the United States, 1988-2012*, 314 JAMA 1021 (2015), [www.jamanetwork.com/journals/jama/fullarticle/2434682](http://www.jamanetwork.com/journals/jama/fullarticle/2434682).

20. For a century, Plaintiffs' members have been at the forefront of the fight against diabetes, starting with the mass production of early animal-based insulins by Eli Lilly in 1922. Before the discovery of insulin as a diabetes treatment, a diagnosis of diabetes was a swift death sentence. Even with a strict diet, a patient typically survived “no more than three or four years.” *Diabetes Que., Treating Diabetes: 1921 to the Present Day* (Nov. 2016), <http://www.diabete.qc.ca/en/understand-diabetes/all-about-diabetes/history-of-diabetes/treating-diabetes-1921-to-the-present-day>. In 1897, the average life expectancy of a 10-year-old child diagnosed with diabetes was just one year and, for a 30-year-old, only four years. *See Dawn*

Swidorski, *Diabetes History*, Defeat Diabetes Found. (Jan. 22, 2014), <https://www.defeatdiabetes.org/diabetes-history>. Their quality of life was also poor. Blood vessel or nerve damage resulted in dizziness and fainting, frequent urination, blindness, kidney failure, and infections leading to amputation.

21. While the disease “is still associated with a reduced life expectancy, the outlook for patients with th[e] disease has improved dramatically,” Kenneth S. Polonsky, *The Past 200 Years in Diabetes*, 367 New Eng. J. Med. 1332, 1332 (2012), <http://www.nejm.org/doi/full/10.1056/NEJMra1110560>, owing significantly to the enormous investments by Plaintiffs’ members in research and development of innovative diabetes treatments. Many innovative treatments have broken new scientific ground and significantly improved patients’ life expectancy and quality of life.

22. In 1921, a pair of scientists discovered that they could reverse diabetes in dogs by injecting them with an extract—insulin—from the pancreatic islets of healthy dogs. See Brian Wu, *History of Diabetes: Past Treatments and New Discoveries*, Med. News Today (May 2017), <http://www.medicalnewstoday.com/articles/317484.php>. The following year, Eli Lilly began mass producing animal-based insulin and, in 1925, Novo Nordisk gained the rights to produce insulin outside North America, allowing diabetes patients across the world to better manage their condition. *Id.*; Novo Nordisk, *The Founders*, [www.novonordisk.com/about-novo-nordisk/novo-nordisk-history/the-founders.html](http://www.novonordisk.com/about-novo-nordisk/novo-nordisk-history/the-founders.html).

23. Since then, pharmaceutical manufacturers have devoted very substantial resources to improving insulin treatment and otherwise controlling diabetes. For example:

- In 1936, a scientist discovered that adding protamine prolonged the effects of injected insulin.
- In 1950, Novo Nordisk introduced Neutral Protamine Hagedorn (“NPH”) Insulin, a drug so important in treating diabetes that it is on the World Health Organization model list of essential medicines. See WHO Model List of Essential Medicines, World Health Org. (20th ed.) (Mar. 2017), [http://www.who.int/medicines/publications/essentialmedicines/20th\\_EML2017.pdf](http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017.pdf).
- In 1964, the Ames Company, a subsidiary of the Dr. Miles Medical Company that later merged into Bayer AG, introduced the first strips for testing blood

glucose, which allowed diabetes patients to monitor and regulate their glucose levels frequently and conveniently. *See* Am. Diabetes Ass'n, *75th Anniversary Timeline*, <http://www.diabetes.org/about-us/75th-anniversary/timeline.html> ("75th Anniversary Timeline"). By 1981, the Ames Company introduced home glucose meters, allowing patients to accurately check their own blood glucose levels without having to visit a doctor's office. S.F. Clarke & J.R. Foster, *A History of Blood Glucose Meters and Their Role in Self-Monitoring of Diabetes Mellitus*, 69 *Brit. J. of Biomed. Sci.* 83, 86 (2012).

- In 1982, FDA approved Eli Lilly's Humulin, the first human insulin product, freeing the world's supply of insulin from its supply using animal sources. *See* Lawrence K. Altman, *A New Insulin Given Approval for Use In U.S.*, N.Y. Times, Oct. 30, 1982, <http://www.nytimes.com/1982/10/30/us/a-new-insulin-given-approval-for-use-in-us.html?mcubz=0>.
- In 1985, Novo Nordisk developed, introduced, and marketed the first insulin pen, which allows patients to vary the injected dose and to administer insulin discreetly. Since 1985, innovators have made significant investments into designing insulin pens that improve patient satisfaction and safety.
- In 1994, Bristol Myers Squibb became the first company to secure FDA approval for the drug metformin, an oral biguanide that prevents glucose production in the liver. Press Release, U.S. Food & Drug Admin., FDA Approves New Diabetes Drug (Dec. 30, 1994), <https://web.archive.org/web/20070929152824/http://www.fda.gov/bbs/topics/ANSWERS/ANS00627.html>. Metformin is the recommended first line of treatment for Type 2 diabetes after diet and exercise. *See* Randy Dotinga, *Metformin Still Best as First Type 2 Diabetes Treatment*, WebMD (Jan. 2, 2017), <http://www.webmd.com/diabetes/news/20170102/metformin-still-best-choice-for-first-type-2-diabetes-treatment>.
- In 2000, Aventis Pharmaceuticals, a predecessor company of Sanofi U.S., received FDA approval for Lantus, the first FDA approved long-acting (basal) recombinant human insulin analog with a once-daily administration. *See* 75th Anniversary Timeline. With Lantus, the reduced risk of nighttime hypoglycemia and the flexibility of once-daily dosing made insulin a more acceptable option for patients to start insulin earlier and intensify their insulin sooner, leading to long-term improvements and reducing complications in diabetes.
- In 2005, FDA approved the first patient-use continuous glucose monitoring system, which automatically reads blood sugar levels every 5 to 15 minutes and can detect trends and patterns. *See id.*
- Also in 2005, Eli Lilly and Amylin Pharmaceuticals received FDA approval for Byetta, a first-in-class glucagon-like peptide-1 (GLP-1) receptor agonist that improves glycemic control and delays or reduces the need for insulin in patients with Type 2 diabetes. *Id.* Significant innovation in the GLP-1 space has continued since, including, for example, the development of once-weekly agents that can significantly increase patient adherence.
- In 2006, Merck & Co. received FDA approval for Januvia, a first-in-class dipeptidyl peptidase 4 (DPP-4) inhibitor that enhances the body's ability to lower

elevated blood sugar by increasing incretin levels, thereby inhibiting glucagon release and decreasing blood glucose levels. *Id.*

- In 2013, Janssen, a Johnson & Johnson subsidiary, secured FDA approval for Invokana, a first-in-class sodium/glucose cotransporter 2 (SGLT-2) inhibitor that prevents the kidneys from reabsorbing glucose back into the blood, allowing them to lower blood glucose levels and remove excess blood glucose through urination. *Id.*
- Also in 2013, Takeda Pharmaceuticals obtained FDA approval for Nesina, a new “DPP-4 inhibitor” that allows the pancreas to secrete insulin and better manage blood glucose levels. *See* Press Release, Takeda Receives FDA Approval for Three New Type 2 Diabetes Therapies, Takeda (Jan. 26, 2013), [http://www.takeda.us/newsroom/press\\_release\\_detail.aspx?year=2013&id=269](http://www.takeda.us/newsroom/press_release_detail.aspx?year=2013&id=269).
- In 2015, Novo Nordisk and Sanofi U.S. received FDA approval for Tresiba and Toujeo, respectively, which are ultra-long-acting insulins. These latest advances offer a more stable delivery of insulin and afford patients more flexibility in dosing. *See* Press Release, Novo Nordisk Receives FDA Approval for Tresiba® (insulin degludec injection) for Adults with Type 1 and Type 2 Diabetes, Novo Nordisk (Sept. 25, 2015), <http://press.novonordisk-us.com/2015-09-25-Novonordisk-Receives-FDA-Approval-for-Tresiba-insulin-degludec-injection-for-Adults-with-Type-1-and-Type-2-Diabetes>; Press Release, Sanofi Receives FDA Approval of Once-Daily Basal Insulin Toujeo®, Sanofi (Feb. 25, 2015), <http://www.news.sanofi.us/2015-02-25-Sanofi-Receives-FDA-Approval-of-Once-Daily-Basal-Insulin-Toujeo>.

24. All told, FDA has approved 39 diabetes medicines since 2000. These 39 medicines are the product of decades of investment in research and development, including both successes and failures. As shown in the chart below, Plaintiffs’ members were responsible for developing the vast majority of these medicines.

Drug name	Type of drug	Manufacturer	Approval year
Adlyxin	Glucagon-like peptide	Sanofi U.S.	2016
Soliqua	Injectable combination therapy	Sanofi U.S.	2016
Xultophy	Injectable combination therapy	Novo Nordisk	2016
Basaglar	Long-acting insulin	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2015
Tresiba	Long-acting insulin	Novo Nordisk	2015

1	Ryzodeg	Combination insulin	Novo Nordisk	2015
2	Toujeo	Long-acting insulin	Sanofi U.S.	2015
3	Glyxambi	Combination SGLT-2	Eli Lilly and Boehringer	2015
4		inhibitor and DPP-4	Ingelheim	
5		inhibitor	Pharmaceuticals	
6	Trulicity	Glucagon-like peptide	Eli Lilly	2014
7	Invokamet	Combination SGLT-2	Janssen Pharmaceuticals	2014
8		inhibitor and biguanide		
9	Jardiance	SGLT-2 inhibitor	Boehringer Ingelheim	2014
10			Pharmaceuticals	
11	Afrezza Inhalation	Inhaled insulin	Sanofi U.S. and	2014
12	Powder		MannKind	
13	Tanzeum	Glucagon-like peptide	GlaxoSmithKline	2014
14	Xigduo XR	Combination	AstraZeneca	2014
15		Dapagliflozin and		
16		Metformin		
17	Farxiga	SGLT-2 inhibitor	AstraZeneca and Bristol-	2014
18			Myers Squibb	
19	Invokana	SGLT-2 inhibitor	Janssen Pharmaceuticals	2013
20	Nesina	DPP-4 inhibitor	Takeda Pharmaceuticals	2013
21	Janumet XR	DPP-4 inhibitor	Merck	2012
22	Jentadueto	Combination DPP-4	Eli Lilly and Boehringer	2012
23		inhibitor and biguanide	Ingelheim	
24			Pharmaceuticals	
25	Bydureon	Glucagon-like peptide	Amylin Pharmaceuticals	2012
26			and Alkermes PLC	
27	Juvisync	Combination statin and	Merck	2011
28				

	DPP-4 inhibitor		
Tradjenta	DPP-4 inhibitor	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2011
Kombiglyze XR	Combination DPP-4 inhibitor and biguanide	AstraZeneca and Bristol- Myers Squibb	2010
Victoza	Glucagon-like peptide	Novo Nordisk	2010
Onglyza	DPP-4 inhibitor	AstraZeneca and Bristol- Myers Squibb	2009
PrandiMet	Combination repaglinide and biguanide	Sciele Pharma and Novo Nordisk	2008
Janumet	DPP-4 inhibitor and Biguanide	Merck	2007
Januvia	DPP-4 inhibitor	Merck	2006
Duetact	Combination pioglitazone (directly targets insulin resistance) and sulfonylurea (increases amount of insulin produced by pancreas)	Takeda Pharmaceuticals	2006
ACTOplus met	Combination pioglitazone and biguanide	Takeda Pharmaceuticals	2005
Levemir	Long-acting insulin	Novo Nordisk	2005
Byetta	Glucagon-like peptide	Amylin Pharmaceuticals and Eli Lilly	2005

1	Symlin	Antihyperglycemic drug	Amylin Pharmaceuticals	2005
2	Apidra	Rapid-acting insulin	Aventis Pharmaceuticals	2004
3	Metaglip	Combination glipizide	Bristol-Myers Squibb	2002
4		and biguanide		
5	Avandamet	Combination	GlaxoSmithKline	2002
6		rosiglitazone and		
7		biguanide		
8	Novolog 70/30	Combination insulin	Novo Nordisk	2001
9	Lantus	Long-acting insulin	Aventis Pharmaceuticals	2000
10	Novolog	Rapid-acting insulin	Novo Nordisk	2000

11 See U.S. Food & Drug Admin., *FDA-Approved Diabetes Medicines*,  
 12 <https://www.fda.gov/forpatients/illness/diabetes/ucm408682.htm>.

13 25. Although there have been substantial advances in diabetes treatments, 1.7 million  
 14 people are newly diagnosed with diabetes in the United States every year. Developing innovative  
 15 new diabetes treatments and improving existing treatments requires continuing research. To that  
 16 end, Plaintiffs' members invest billions each year. See, e.g., *2016 Biopharmaceutical Research*  
 17 *Industry Profile*, PhRMA (April 2016), [phrma-](http://docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf)  
 18 [docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf](http://docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf); David Thomas &  
 19 Chad Wessel, *Emerging Therapeutic Company Investment and Deal Trends*, BIO (June 2017),  
 20 [https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report](https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf)  
 21 [%202007-2016.pdf](https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf). In 2016 alone, more than 170 medicines for diabetes and related conditions  
 22 were in development. See *Medicines in Development for Diabetes: A Report on Diabetes and*  
 23 *Related Conditions*, PhRMA (2016), [phrma-docs.phrma.org/files/dmfile/medicines-in-](http://phrma-docs.phrma.org/files/dmfile/medicines-in-development-report-diabetes.pdf)  
 24 [development-report-diabetes.pdf](http://phrma-docs.phrma.org/files/dmfile/medicines-in-development-report-diabetes.pdf). The vast majority of drugs in development are potentially “first-  
 25 in-class medicines” that offer a new approach to fighting the disease. See, e.g., Genia Long,  
 26 *Analysis Grp., The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development*  
 27 (July 2017),  
 28 [http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the\\_biopharmaceutical\\_pi](http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the_biopharmaceutical_pi)

1 pipeline\_report\_2017.pdf (noting that 69% of diabetes drugs in development were potential first-in-  
2 class medicines).

3       26. Among the approximately 170 medicines in the development pipeline, innovations  
4 include a potential first-in-class oral medicine that provides a new way for addressing Type 1 and  
5 Type 2 diabetes; a fully recombinant monoclonal antibody that treats patients with newly diagnosed  
6 Type 1 diabetes; and a medicine for diabetic nephropathy, damage to the kidneys from Type 1 or 2  
7 diabetes. Many new innovations improve the convenience of dosing and thus increase adherence,  
8 which helps patients with diabetes avoid emergency room visits and hospitalizations, and could  
9 save the healthcare system as much as \$8.3 billion annually. Ashish Jha et al., *Greater Adherence*  
10 *to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually*, 31  
11 Health Aff. 1836, 1836 (2012). For instance, oral versions of both insulin and GLP-1 agents are  
12 included in the development pipeline of several manufacturers, and these have the potential to  
13 significantly increase adherence to these much needed diabetes therapies for millions of patients in  
14 the U.S. New diabetes therapies have also had beneficial secondary effects, including weight loss, a  
15 reduction in cardiovascular disease, and improved renal function. See A. Kuhn et al., *Intensifying*  
16 *Treatment Beyond Monotherapy in Type 2 Diabetes Mellitus: Where Do Newer Therapies Fit?*,  
17 Current Cardiology Reports (March 2017).

18       27. Another emphasis in diabetes research and development is prevention: researchers at  
19 top universities, hospitals, and pharmaceutical companies devote significant time and resources to  
20 developing a vaccine that could teach the immune system not to react to and attack beta cells (the  
21 cells in the pancreas that produce insulin), thus preventing the onset of Type 1 diabetes. In fact, a  
22 trial at a Massachusetts General Hospital lab is aimed not only at preventing Type 1 diabetes, but  
23 also reversing it in patients who have had the disease for under 5 years. See Andrew Curry,  
24 *Pathways to a Type 1 Vaccine*, Diabetes Forecast (July 2016),  
25 <http://www.diabetesforecast.org/2016/jul-aug/vaccines.html>. Congress recognized the importance  
26 of prevention and adherence in the Affordable Care Act by establishing Diabetes Prevention  
27 Programs that offer lifestyle interventions for individuals at risk for diabetes, providing grants to  
28 states for prevention activity initiatives, and requiring the U.S. Department of Health and Human

Services to prepare a biannual diabetes report card that assesses quality of care indicators, including adherence, in each state.<sup>3</sup>

28. Many potentially first-in-class medicines may reach the market in the next few years. Sanofi and Lexicon are developing sotagliflozin, a SGLT-1/SGLT-2 dual inhibitor, which has shown promising Phase 2 and 3 results in Type 1 diabetes. The drug advanced into Phase 3 trials for Type 2 diabetes in March 2017. Merck and Pfizer are developing ertugliflozin, an SGLT-2 inhibitor. Novo Nordisk is developing semaglutide, a GLP-1 receptor agonist, in a once-weekly, injected formulation and a once-daily oral formulation that are both active in lowering glucose and improving weight loss for Type 2 diabetes patients. And researchers at the University of North Carolina are working on developing glucose-responsive “smart” insulin, which is an injection that releases insulin only when glucose levels are too high. *See* John B. Buse & Mark Harmel, *New Diabetes Drugs in Development*, Medscape (Mar. 10, 2017), [www.medscape.com/viewarticle/876853](http://www.medscape.com/viewarticle/876853).

29. Meanwhile, costly and labor-intensive research continues to lay the groundwork for the next generation of treatments. Researchers at the Harvard Stem Cell Institute discovered a hormone that can stimulate insulin-secreting pancreatic cells to reproduce at up to 30 times the normal rate in mice. *See* Harvard Stem Cell Inst., *From Stem Cells to Billions of Human Insulin-Producing Cells* (Oct. 9, 2014), <https://hsci.harvard.edu/news/stem-cells-billions-human-insulin-producing-cells>. Recreating this effect in diabetes patients could lead to the body’s natural regulation of insulin as the new cells produce insulin only as needed. *Id.*

30. The cost of developing these innovative diabetes medicines is staggering. On average, a manufacturer spends between 10 and 15 years—and \$2.6 billion—developing a new medicine. Developing diabetes medicines is particularly costly, as all new medicines must comply

---

<sup>3</sup> *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 4108, 4202, 10407, 10501, 124 Stat. 119 (2010); Nat’l Conference of State Legislatures, *Federal Health Reform Provisions Related to Diabetes* (May 2011), <http://www.ncsl.org/portals/1/documents/health/DiabetesinHR511.pdf>; Ctr. for Disease Control & Prevention, *Diabetes 2014 Report Card* (2014), <https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2014.pdf>.

1 with FDA's 2008 guidance requiring new diabetes medicines to undergo costly testing on  
2 cardiovascular risk that other new medicines need not undergo. These costs are all the more  
3 daunting given the very small success rate. Between 1988 and 2014, on average only 12% of drug  
4 candidates that entered clinical testing were approved for use. From May 27 to December 29, 2016,  
5 ten different advanced drug candidates for FDA approval in different drug product areas  
6 experienced setbacks ranging from manufacturing issues, FDA requirements to conduct new trials,  
7 failing Phase II or Phase III trials altogether, and patient deaths during trial. *See* Lisa M. Jarvis, *The*  
8 *Year in New Drugs*, Chem. & Eng'g News (Jan. 30, 2017),  
9 <http://cen.acs.org/content/cen/articles/95/i5/year-new-drugs.html>.

10 31. Even when a product reaches the market, there is no guarantee that the manufacturer  
11 will earn back the cost of research and development. In 2015, for example, FDA approved Afrezza,  
12 the only available inhalable insulin, manufactured by Sanofi in partnership with another  
13 pharmaceutical company. Press Release, Sanofi and MannKind Announce Afrezza®, the Only  
14 Inhaled Insulin, Now Available in the U.S., Sanofi (Feb. 3, 2015),  
15 [en.sanofi.com/images/38264\\_20150203\\_Afrezza\\_en.pdf](http://en.sanofi.com/images/38264_20150203_Afrezza_en.pdf). However, Afrezza appealed only to a  
16 small segment of the market and suffered from lackluster sales. Ed Silverman, *Breathe Deeply:*  
17 *Sanofi Will No Longer Market Afrezza Inhaled Insulin*, Stat (Jan. 6, 2016),  
18 <https://www.statnews.com/pharmalot/2016/01/05/insulin-sanofi-diabetes/>. It is unlikely that  
19 Afrezza will ever generate enough revenue to cover the cost of its development.

20 32. Pharmaceutical manufacturers can invest these billions of dollars each year in  
21 research and development only if they have an appropriate opportunity to recoup that investment  
22 through the sales of the small fraction of products that ultimately make it to market. Patents are  
23 especially important to the biotechnology industry, as they are often the sole or the most valuable  
24 asset of a start-up venture. *See* Charles W. Wessner, *Capitalizing on New Needs and New*  
25 *Opportunities: Government-Industry Partnerships in Biotechnology and Information Technologies*  
26 40 (2001), [https://www.ncbi.nlm.nih.gov/books/NBK208686/pdf/Bookshelf\\_NBK208686.pdf](https://www.ncbi.nlm.nih.gov/books/NBK208686/pdf/Bookshelf_NBK208686.pdf).

1           ***Overview of Nevada Senate Bill 539***

2           33.     Like all states, Nevada over the past 20 years has seen a marked increase in the  
3     number of adults living with diabetes. In 1995, the estimated diabetes rate in Nevada was 4.7%.  
4     Today, an estimated 12.4% of Nevada’s adult population—281,355 people—have diabetes. An  
5     additional 787,000 people in Nevada, 38.5% of Nevada’s adult population, have pre-diabetes, with  
6     abnormally high blood glucose levels, but not at a level warranting a diabetes diagnosis.

7           34.     SB 265, introduced in the Nevada Senate in February 2017, “sought to lower the cost  
8     of certain essential diabetes drugs, such as insulin, by requiring companies that manufacture them  
9     [to] report the costs of producing and marketing the drug along with any rebates that they provide  
10    for the drugs.” Megan Messerly, *Sandoval Vetoes Major Pharmaceutical Transparency Legislation*  
11   *Citing Concerns Over “Nascent, Unproven and Disruptive” Changes*, Nev. Indep., (June 2, 2017,  
12    10:12 PM), [https://thenevadaindependent.com/article/sandoval-vetoes-major-pharmaceutical-](https://thenevadaindependent.com/article/sandoval-vetoes-major-pharmaceutical-transparency-legislation-citing-concerns-over-nascent-unproven-and-disruptive-changes)  
13    [transparency-legislation-citing-concerns-over-nascent-unproven-and-disruptive-changes](https://thenevadaindependent.com/article/sandoval-vetoes-major-pharmaceutical-transparency-legislation-citing-concerns-over-nascent-unproven-and-disruptive-changes). SB 539  
14    later incorporated many of SB 265’s provisions.

15          35.     As the legislative history of SB 265 shows, the State’s primary focus was on  
16    controlling the list prices of insulin and other patented diabetes medicines. At the very outset of the  
17    first Senate hearing on SB 265, its author cited a putative class action lawsuit charging insulin  
18    manufacturers with antitrust violations. *Hearing on S.B. 265 Before the Sen. Comm. on Health &*  
19    *Human Servs.*, 2017 Leg., 79th Sess. 33 (Nev. Mar. 29, 2017) (“Mar. 29 Mins.”) (statement of Sen.  
20    Yvanna D. Cancela). Proponents repeatedly criticized the prices of patented diabetes drugs as the  
21    main target of the bill, complaining that “competition has not led to lower [insulin] prices” and  
22    asserting that manufacturers would simply “tweak” insulin “to keep it under patent status, so the  
23    patent does not expire and become eligible for generic versions.” *Id.* at 36 (statement of Bobette  
24    Bond, Exec. Dir., Nev. Healthcare Policy, Unite Here Health); *see also id.* at 58–60 (discussion of  
25    patent protection). In reference to the patented diabetes medicines Janumet and Jardiance, one  
26    proponent argued that he “should not [have to] depend on [manufacturer] coupons on the Internet to  
27    offset the cost of diabetic medications.” *Id.* at 45 (statement of Ruben R. Murillo, Nev. State Educ.  
28    Ass’n). As another explained, the bill was designed to “hit directly to the root of the problem” of

1 high diabetes drug prices because “pharma will react accordingly with rebate dollars and trying to  
2 unwind what has been done” in order to “meet the terms of what [SB 265] puts out.” *Id.* at 37  
3 (testimony of Kevin Hooks, a managed care clinical pharmacist).

4         36. SB 265 sought to achieve these goals in several ways. First, SB 265 directed the  
5 Department to compile a list of prescription drugs “essential” for treating diabetes. SB 265, 2017  
6 Leg., 79th Sess. § 6 (Nev. 2017). It then compelled the manufacturers of those drugs to submit to  
7 the Department a report disclosing certain cost and pricing information for each of their essential  
8 diabetes drugs. *Id.* § 7(1). SB 265 excluded this cost and pricing information from the definition of  
9 “trade secret” under Nevada law, *id.* § 27.5(5), and it required the Department to compile and  
10 publish on its website a report concerning the prices of essential diabetes drugs and the effect of  
11 those prices on overall spending on health care in Nevada, *id.* § 7(2). SB 265 also required  
12 manufacturers to provide the Department with 90 days’ notice of any planned increase in the  
13 national list price, also known as the wholesale acquisition cost or “WAC,” of any essential diabetes  
14 drug. *Id.* § 8.

15         37. On May 16, 2017, a second bill targeting list price increases for diabetes drugs was  
16 introduced, SB 539. Originally a “complement” to SB 265, *see Hearing on S.B. 265 Before the Sen.*  
17 *Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 3 (Nev. May 26, 2017) (“May 26 Mins.”),  
18 SB 539 added requirements that “Pharmacy Benefit Managers” (PBMs)—intermediaries between  
19 manufacturers and payers—disclose, among other things, the amount of rebates received from  
20 manufacturers during the preceding calendar year. *See id.* at 5. The author of SB 539 justified the  
21 legislation on the ground that the “retail price [of prescription diabetes medicine] paid by patients is  
22 unpredictable and can escalate to unaffordable levels over short periods.” *Id.* at 3.

23         38. On May 19, 2017, the Nevada State Senate passed the first bill, SB 265. On May 25,  
24 2017, the Nevada State Assembly passed SB 265 and sent the bill to the Governor for approval.

25         39. On June 2, 2017, Nevada Governor Brian Sandoval vetoed SB 265. His explanation  
26 acknowledged that SB 265 was “well-intentioned,” but concluded that the bill “poses serious risks  
27 of unintended and potentially detrimental consequences for Nevada’s consumer patients, not the  
28 least of which is the possibility that access to critical care will become more expensive, more

restricted, and less equitable.” Veto Letter at 2. The bill, he wrote, “could cause more harm than good for Nevada’s families.” *Id.*

40. Governor Sandoval also concluded that “constitutional and other legal concerns” rendered the bill “problematic.” *Id.* at 3. He found the bill vulnerable to “challenge[s] under theories of federal preemption, the Fifth Amendment’s prohibition on uncompensated takings, and the Dormant Commerce Clause.” *Id.* at 2.

41. On June 5, 2017, just three days after Governor Sandoval vetoed SB 265, both the Nevada Senate and the Nevada State Assembly passed SB 539, which, as amended, included almost all the same provisions as SB 265. With respect to the drug pricing and reporting provisions, the primary exception was the 90-day notice period for increasing the WAC of an essential diabetes drug, to which Governor Sandoval had objected on the ground that it could lead to purchasers stockpiling drugs that they knew would have price increases in 90 days. *See id.*

42. Aside from the lack of the 90-day notice period, SB 539 essentially replicated SB 265. Even though SB 539 did not remedy the constitutional problems that Governor Sandoval had identified, he signed the bill on June 15, 2017.

43. Like SB 265, SB 539 directs the Department to compile, by February 1 of each year, “[a] list of prescription drugs . . . essential for treating diabetes.” SB 539 § 3.6(1). The Act does not define “essential,” but the list “must include, without limitation, all forms of insulin and biguanides marketed for sale in this State.” *Id.*<sup>4</sup>

44. In August 2017, the Nevada State Primary Care Office distributed a draft list of “essential diabetes drugs” with 46 major drug products, including Afrezza, Byetta, Duetact, Farxiga, Humulin, Invokana, Janumet, Januvia, Jardiance, Lantus, Nesina, Novolog, PrandiMet, Trulicity, and others. *See Exhibit C, Draft List of Essential Diabetes Drugs.*

---

<sup>4</sup> Both insulin and biguanides seek to lower blood glucose levels. Insulin injections replace the insulin that the body would produce naturally in patients with diabetes who do not produce enough insulin. Biguanides, such as metformin, lower blood sugar by decreasing the amount of sugar produced by the liver, increasing the amount of sugar absorbed by muscle cells, and decreasing the body’s need for insulin. *See Biguanides (Metformin) for Prediabetes and Type 2 Diabetes*, WebMD, <http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes>.

45. Once the Department releases its final list of “essential” diabetes drugs, Section 3.8 of the Act requires manufacturers of those drugs to “prepare and submit to the Department,” by April 1 of each year, a “report which must include”:

- “[t]he costs of producing the drug”;
- “marketing and advertising costs” associated with the drug;
- profit “earned from the drug” and “the percentage of the manufacturer’s total profit . . . attributable to the drug”;
- the amount spent on “patient prescription assistance program[s]”;
- “[t]he cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs”;
- the “wholesale acquisition cost of the drug,” defined as “the manufacturer’s list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing date”;
- “[a] history of any increases in the wholesale acquisition cost of the drug over the 5 years immediately preceding the date on which the report is submitted, including the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective any explanation for the increase”;
- “[t]he aggregate amount of all rebates” in Nevada; and
- “[a]ny additional information prescribed by regulation . . . for the purpose of analyzing the cost of prescription drugs . . . on the list.”

*Id.* § 3.8.

46. Beyond these disclosures, any manufacturer that increases the WAC of an “essential” diabetes drug by more than the “Consumer Price Index, Medical Care Component” (“CPI”) during the preceding year, or by double the percentage increase in the CPI for Medical Care over the previous two years, must make additional disclosures pursuant to Section 4 of the Act.

These disclosures include:

- “[a] list of each factor that has contributed to the increase”;
- “[t]he percentage of the total increase that is attributable to each factor”;
- “[a]n explanation of the role of each factor”; and
- “[a]ny other information prescribed by regulation.”

1 *Id.* §§ 3.6(2), 4.

2 47. For many manufacturers, the types of information that must be disclosed under  
3 Sections 3.8 and 4 are generally factors relevant to pricing decisions for *all* of their pharmaceutical  
4 products, not just the essential diabetes medicines they produce.

5 48. By tying these disclosures to the CPI for Medical Care, the Act penalizes those  
6 manufacturers whose diabetes drug prices exceed the index. This penalty is especially harsh, as the  
7 CPI for Medical Care includes the list prices of not only pharmaceutical products, but also  
8 professional and hospital services. Successful diabetes therapies improve the convenience and  
9 efficacy of treatment, which reduces doctor and hospital visits, which, in turn, lowers the costs  
10 factored into the CPI for Medical Care. Thus, the more successful a product is at reducing or  
11 preventing medical costs, the lower the prices the manufacturer can charge and still avoid the  
12 penalty of disclosing its confidential information. While the CPI for Medical Care is a useful  
13 benchmark for certain purposes relating to overall health care spending, it is not an appropriate  
14 measuring stick for imposing penalties on manufacturers for price increases on drug products.

15 49. Once manufacturers have submitted the disclosures required by Sections 3.8 and 4,  
16 the Department must, by June 1 of each year, “analyze the information submitted . . . and compile a  
17 report on the price of the prescription drugs that appear on the most current lists . . . , the reasons for  
18 any increases in those prices and the effect of those prices on overall spending on prescription drugs  
19 in this State.” *Id.* § 4.3.

20 50. The Department must post the report on its website, *id.* § 6(a)(5), “organized so that  
21 each individual . . . manufacturer . . . has its own separate entry,” *id.* § 6(b).

22 51. Critically, SB 539 does not prevent the Department from publishing the information,  
23 sharing it with other entities, or using it for other purposes such as the Department’s own rebate  
24 negotiations with manufacturers.

25 52. What is more, SB 539 expressly eliminates trade-secret protection for all information  
26 manufacturers must disclose concerning “essential” diabetes drugs. *Id.* § 4.3. Specifically, the Act  
27 alters the definition of “trade secret” in NRS 600A.030 to exclude “any information that a  
28

1 manufacturer is required to report pursuant to section 3.8 or 4 of [the Act], . . . to the extent that  
 2 such information is required to be disclosed by [that] section[.]” *Id.* § 9(5)(b).<sup>5</sup>

3 53. Any manufacturer that fails to disclose the required information is subject to “an  
 4 administrative penalty of not more than \$5,000 for each day of such failure.” *Id.* § 8(2).

5 54. The provisions of SB 539 relevant to this lawsuit “become effective upon passage  
 6 and approval for the purpose of adopting regulations and performing any other administrative tasks  
 7 that are necessary to carry out the provisions of this act and on October 1, 2017, for all other  
 8 purposes.” *Id.* § 28(3). Thus, while the Department has until February 1, 2018 to publish its first  
 9 list of “essential” diabetes drugs, it could publish the list as early as October 1, 2017, and, in fact,  
 10 the Department has represented that it intends to publish the list on October 15, 2017.

11 ***SB 539’s Harm to Plaintiffs’ Members and Innovation of Diabetes Treatments***

12 55. SB 539, if implemented, will seriously harm Plaintiffs’ members, including the  
 13 largest U.S. manufacturers of insulin and other diabetes medicines. Several of Plaintiffs’ members  
 14 produce drugs that appear on the Department’s draft list of “essential” diabetes drugs. None of  
 15 these companies is headquartered in Nevada.

16 56. For example, Eli Lilly and Company manufactures the diabetes drugs Basaglar (a  
 17 long-acting insulin), Glyxambi (a combination drug of SGLT-2 inhibitor and DPP-4 inhibitor),  
 18 Humalog, Humulin, Jardiance (a SGLT-2 inhibitor), Jentadueto (a combination DPP-4 inhibitor  
 19 with metformin), Synjardy, Tradjenta (a DPP-4 inhibitor), and Trulicity (a glucagon-like peptide).  
 20 The drugs Glyxambi, Jardiance, Jentadueto, Synjardy, Tradjenta, and Trulicity are patented.  
 21 Patients administer Humalog and Humalin using a patented device. And the clinical testing for  
 22 Basalgar and Trulicity is protected by test data exclusivity—*i.e.*, because this information is costly  
 23 to produce, FDA maintains its confidentiality for a number of years to prevent competitors from  
 24 benefitting at Lilly’s expense. Eli Lilly is headquartered in Indianapolis, Indiana and employs  
 25

---

26 <sup>5</sup> By contrast, every other state to legislate on pharmaceutical price transparency has acknowledged  
 27 the trade-secret status of the information to be disclosed, erecting safeguards to prevent its  
 28 dissemination. *See, e.g.*, Vt. Stat. Ann., tit. 18, § 4635(e); H.B. 631, Gen. Assemb., 437th Sess. § 1,  
 2-803(F) (Md. 2017).

1 approximately 12,600 people in Indiana. Indiana law confers trade-secret protection for the  
2 confidential information concerning advertising, cost, marketing, pricing, and production that SB  
3 539 requires Eli Lilly to disclose. *See Hydraulic Exch. & Repair, Inc. v. KM Specialty Pumps, Inc.*,  
4 690 N.E.2d 782, 786 (Ind. Ct. App. 1998) (holding that customer and pricing information, including  
5 compilations of profits and sales, were trade secrets under Indiana Uniform Trade Secrets Act);  
6 *Ackerman v. Kimball Int'l, Inc.*, 634 N.E.2d 778, 783 (Ind. Ct. App. 1994) (affirming trial court  
7 conclusion that pricing information was a trade secret).

8         57. Johnson & Johnson manufactures the diabetes drugs Invokamet (a combination  
9 SGLT-2 inhibitor with metformin), Invokamet XR (extended release), and Invokana (an SGLT-2  
10 inhibitor). The drugs Invokamet, Invokamet XR, and Invokana are patented. Johnson & Johnson is  
11 headquartered in New Brunswick, New Jersey and employs approximately 9,300 people in New  
12 Jersey. New Jersey law confers trade-secret protection for the confidential information that SB 539  
13 requires Johnson & Johnson to disclose. *See Commc'ns Workers of Am. v. Rousseau*, 9 A.3d 1064,  
14 1076 (N.J. Super. Ct. App. Div. 2010) (“A trade secret may also include pricing and marketing  
15 techniques.”); *Lamorte Burns & Co. v. Walters*, 770 A.2d 1158, 1166 (N.J. 2001) (citing with  
16 approval treatise stating that “information relating to customers, merchandising, costs, and pricing  
17 may be considered trade secrets” (citing 1 Roger M. Milgrim, *Milgrim on Trade Secrets* § 2.09  
18 (1995))).

19         58. Merck Sharp & Dohme Corp. manufactures the diabetes drugs Januvia (sitagliptin)  
20 (a dipeptidyl peptidase 4 (DPP-4) inhibitor), Janumet (sitagliptin and metformin HCl) and Janumet  
21 XR (sitagliptin and metformin HCl extended release). The drugs Januvia, Janumet, and Janumet  
22 XR are patented. Merck is headquartered in Kenilworth, New Jersey and employs approximately  
23 5,200 people in New Jersey. As noted, New Jersey law confers trade-secret protection for the  
24 confidential information that SB 539 requires Merck to disclose.

25         59. Novo Nordisk Inc. markets, sells, and distributes the diabetes drugs Levemir (insulin  
26 detemir, a long-acting recombinant human insulin analog), Victoza (liraglutide, a long-acting,  
27 acylated glucagon-like peptide-1 (GLP-1) analog), Tresiba (insulin degludec, an ultralong-acting  
28 basal human insulin analog), Ryzodeg 70/30 (insulin degludec and insulin aspart injection, a

1 combination of a long-acting basal human insulin analog and a fast-acting human insulin analog),  
2 and Xultophy 100/3.6 (insulin degludec and liraglutide injection, a combination of an ultralong-  
3 acting basal human insulin analog and a long-acting, acylated glucagon-like peptide-1 (GLP-1)  
4 analog). The drugs Levemir, Victoza, Tresiba, Ryzodeg 70/30 and Xultophy 100/3.6 have U.S.  
5 patent protection. Novo Nordisk Inc. is headquartered in Plainsboro, New Jersey. As noted, New  
6 Jersey law confers trade-secret protection for the confidential information that SB 539 requires  
7 Novo Nordisk to disclose.

8         60. Sanofi U.S. markets, sells, and distributes the diabetes drugs Lantus (insulin  
9 glargine, a long acting human insulin analog), Apidra (insulin glulisine, a fast acting, mealtime  
10 insulin), Toujeo (insulin glargine, a long acting human insulin analog), Adlyxin (lixisenatide, a  
11 GLP-1 receptor agonist) and Soliqua 100/33 (insulin glargine and lixisenatide injection, a  
12 combination of long acting insulin and GLP-1). The drugs Lantus, Apidra, Toujeo, Adlyxin and  
13 Soliqua 100/33 are patented. Sanofi U.S. is headquartered in Bridgewater, New Jersey and employs  
14 approximately 2,500 people in New Jersey. As noted, New Jersey law confers trade-secret  
15 protection for the confidential information that SB 539 requires Sanofi to disclose.

16         61. Section 3.8 of SB 539 requires these manufacturers and other PhRMA and BIO  
17 members that manufacture “essential” diabetes medicines to report advertising, cost, marketing,  
18 pricing, and production information related to those drugs to the Department. The required  
19 disclosures include information that qualifies as trade secret under federal law and the law of every  
20 state—including Nevada until SB 539 takes effect.

21         62. These companies face additional reporting requirements under Section 4 of SB 539 if  
22 the list prices for the diabetes drugs they manufacture increased during the prior year by a  
23 percentage greater than the CPI for Medical Care, or increased over the last two years by a  
24 percentage more than twice the two-year increase for that index. The additional disclosures  
25 required under Section 4 of the Act include information that qualifies as a trade secret under federal  
26 law and the law of every state—including Nevada until SB 539 takes effect.

27         63. Plaintiffs’ members zealously guard the secrecy and confidentiality of the trade-  
28 secret information that SB 539 requires them to disclose. Among other things, Plaintiffs’ members

1 require their employees to sign confidentiality agreements and nondisclosure agreements requiring  
2 them to hold this information in confidence. These companies also use a variety of security  
3 measures to ensure that such information is kept secret, including video camera monitoring,  
4 restricting access to their facilities, limiting computer system access, marking documents that reflect  
5 such information as confidential or proprietary, training their employees on the importance of not  
6 disclosing such information, adopting policies that prohibit employees from removing such  
7 information from company property, and imposing other internal controls.

8         64. Plaintiffs' members expend significant resources determining how to allocate their  
9 resources and set prices for their products. This information would be extremely valuable to  
10 competitors, who could use the information to allocate their own resources and set their own prices  
11 without expending the same level of resources. As a consequence, the companies that lost trade-  
12 secret protection would suffer serious competitive harm. This harm would undermine competition  
13 involving non-diabetes products as well, because manufacturers consider similar factors  
14 manufacturers in setting prices for non-diabetes products.

15         65. Similarly, third-party payers who learn how a manufacturer prices its diabetes drugs  
16 would gain an advantage over the manufacturer in purchase or rebate negotiations for all of the  
17 manufacturer's products.

18         66. The economic harm from SB 539 will spread to the entire Nation. Because the  
19 WAC is a national list price, SB 539's effective cap on a drug's WAC will apply throughout the  
20 country. And because drug prices and the way manufacturers set them generally apply nationally,  
21 the information disclosed under SB 539 will affect a company's negotiations and competitive  
22 positioning nationwide. Similarly, because trade-secret protection is moot in every state once the  
23 information becomes public in Nevada, the impact of SB 539 will extend across the Nation.

24         67. The competitive harm arising from SB 539's punitive and coercive effects will  
25 undermine the incentives that trade secret and patent law provides for Plaintiffs' members to invest  
26 in developing innovative diabetes medicines. Absent judicial intervention, SB 539 could force  
27 innovators into the unfortunate position of having to review and revise their research and  
28 development priorities for diabetes products, including projects underway.

## SB 539'S CONSTITUTIONAL DEFECTS

### *The Constitution Vests Congress With Sole Authority To Establish Patent Policy*

68. The Framers of the Constitution understood Congress's paramount role in setting national patent policy. Article I vests Congress with the power to "secur[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. The stated objective of this clause is to "promote the Progress of Science and useful Arts." *Id.* As James Madison observed in *The Federalist*:

The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals. The States cannot separately make effectual provisions for either of the cases, and most of them have anticipated the decision of this point, by laws passed at the instance of Congress.

*The Federalist* No. 43 (James Madison).

69. "From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). The patent laws achieve this balance first by granting an inventor the exclusive right to make, use, and sell its patented invention for a limited period of time. 35 U.S.C. § 154. Then, once the exclusivity period expires, others may enter the market and compete with the patent holder, driving down the cost of the patented product and, in turn, stimulating further innovation in the search for greater returns. Critically here, Congress has long recognized that "the right to exclude others from making, using, or selling an invention . . . enable[s] innovators to obtain greater profits than could have been obtained if direct competition existed," and that "[t]hese profits act as incentives for innovative activities." H.R. Rep. No. 98-857(I), at 17 (June 21, 1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 (Committee on Energy and Commerce).

70. During the exclusivity period, a patent holder may set the price for its product in a manner that takes into account the patent holder's ability to preclude others from marketing an infringing product. The United States Court of Appeals for the Federal Circuit has described the

1 increased return on innovation investment due to the patent holder's legal monopoly as the "carrot"  
2 that incentivizes would-be inventors to expend the substantial resources and to take the significant  
3 research and development risks required to invent a new product. *King Instruments Corp. v.*  
4 *Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). As the Federal Circuit has noted, "the only limitation on  
5 the size of the carrot should be the dictates of the marketplace." *Id.*

6 71. Patent protection is particularly necessary to promote the research and development  
7 of pharmaceutical products because it is extraordinarily difficult, costly, and rare to discover a  
8 successful new drug. By one estimate focusing on the most prolific developers of new drugs, "95%  
9 of the experimental medicines that are studied in humans fail to be both effective and safe. . . .  
10 [B]ecause so many drugs fail, large pharmaceutical companies . . . spend \$5 billion per new  
11 medicine." Matthew Herper, *The Cost of Creating A New Drug Now \$5 Billion, Pushing Big*  
12 *Pharma To Change*, Forbes.com (Aug. 11, 2013, 11:10 AM),  
13 [http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-](http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine)  
14 [drugs-is-shaping-the-future-of-medicine](http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine). Even drugs that are ultimately approved cost billions of  
15 dollars to research and develop. See Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug*  
16 *Development*, Chem. & Eng'g News (Nov. 20, 2014),  
17 <http://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html> (study found that  
18 "developing a prescription drug that gains market approval [costs] \$2.6 billion, a 145% increase"  
19 from 2003).

20 72. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration  
21 Act of 1984, commonly known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585  
22 (1984). In light of the unique economic challenges to pharmaceutical research and development,  
23 the Hatch-Waxman Act extended the patent term for pharmaceuticals to "create a significant, new  
24 incentive which would result in increased expenditures for research and development, and  
25 ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18; see also *Biotech. Indus. Org.*  
26 *v. District of Columbia* ("BIO"), 496 F.3d 1362, 1373 (Fed. Cir. 2007). President Reagan reiterated  
27 this goal when he signed the bill into law: "The bill will promote medical breakthroughs and drug  
28 innovation by granting drug companies up to 5 more years of patent protection for new drugs. And

1 this extension will help compensate for the years of patent life lost due to the time-consuming, but  
2 essential, testing required by the Food and Drug Administration.” Presidential Statement on  
3 Signing S. 1538 Into Law, 20 Weekly Comp. Pres. Doc. 1359 (Sept. 24, 1984).

4 73. Balancing consumer access to affordable medication against the critical need for  
5 sufficient economic incentives to invest in innovation, the Hatch-Waxman Act allows other  
6 manufacturers to sell generic versions of an innovator’s drug after the period of patent exclusivity  
7 expires. This carefully crafted framework provides substantial incentives for innovators to invest in  
8 research and development of new life-saving and life-enhancing treatments that will benefit patients  
9 while also “get[ting] generic drugs into the hands of patients at reasonable prices—fast.” *Andrx*  
10 *Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Lab.,*  
11 *Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

12 74. Congress, moreover, has bestowed patent protection on “[w]hoever invents or  
13 discovers any new and useful process, machine, manufacture, or composition of matter, or any new  
14 and useful improvement thereof.” 35 U.S.C. § 101. Thus, the federal patent system, including the  
15 Hatch-Waxman Act, encourages not only the discovery of new pharmacological compounds, but  
16 also new methods of manufacturing or improving the effectiveness of existing drugs.

17 75. Under the Supremacy Clause of the United States Constitution, federal statutes are  
18 “the supreme Law of the Land.” U.S. Const. art. IV, cl. 2. And under settled principles of federal  
19 “conflict” preemption, no state law may “stand[] as an obstacle to the accomplishment and  
20 execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U.S. 52, 67  
21 (1941).

22 76. State laws penalizing patent holders for exercising the right to set prices that the  
23 patent affords and coercing them to forgo those rights “stand as an obstacle to the federal patent  
24 law’s balance of objectives as established by Congress” and thus are invalid under the Supremacy  
25 Clause. *BIO*, 496 F.3d at 1374. In *BIO*, the Federal Circuit struck down a District of Columbia  
26 statute that prohibited pharmaceutical manufacturers from selling or supplying a “patented  
27 prescription drug that results in the prescription drug being sold in the District for an excessive  
28 price.” *Id.* at 1365. The court held that the statute was a “clear attempt to restrain . . . excessive

1 [drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to  
2 District drug consumers.” *Id.* at 1374. Because Congress—and Congress alone—is the  
3 “promulgator of patent policy,” federal law preempted the District’s attempt to “re-balance the  
4 statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* at  
5 1373–74.

6 77. Just like the District of Columbia statute invalidated in *BIO*, SB 539 “attempt[s] to  
7 restrain . . . excessive [essential diabetes drug] prices, in effect diminishing the reward to patentees  
8 in order to provide greater benefit to [Nevada] drug consumers.” *Id.* at 1374. In purpose and effect,  
9 the Act punishes manufacturers for the price of their “essential” diabetes drugs as well as for list  
10 price increases by more than the “percentage increase in the Consumer Price Index, Medical Care  
11 Component during the immediately preceding calendar year; or . . . [t]wice the percentage increase  
12 in the Consumer Price Index, Medical Care Component during the immediately preceding 2  
13 calendar years.” SB 539 §§ 3.6(2), 4. If an essential diabetes drug’s list price increases by more  
14 than these benchmarks, then the Act compels the manufacturer to report to the Department  
15 additional confidential, competitively sensitive, proprietary information about that price increase,  
16 including a list of “factors” that contributed to the increase and an “explanation” of the role of each  
17 factor. *Id.* § 4. The Act also strips trade-secret protection for that information. *Id.* § 9. The only  
18 way a manufacturer can avoid forfeiting trade-secret protection for the “factors” of a price increase  
19 is by limiting its list prices to the Act’s effective cap. SB 539 thus restrains patent holders from  
20 setting list prices in a manner that the federal patent laws secure in order to incentivize innovation.

21 78. Further, the Act impermissibly burdens the federal patent rights of diabetes drug  
22 manufacturers by requiring disclosure of trade secrets associated with these patented products—and  
23 hence it eliminates trade-secret protection in retaliation for pricing diabetes drugs as the patent laws  
24 specifically allow. *See BIO*, 496 F.3d at 1374 (holding invalid District of Columbia law that had  
25 the effect of “diminishing the reward” federal law grants to patentees). The mandatory disclosures  
26 chill the exercise of patent rights by penalizing past exercises and forcing manufacturers either to  
27 charge less than the patent laws permit or to furnish their proprietary information to third-party  
28 payers and competitors and thereby suffer significant economic loss.

79. As a result of SB 539, innovators cannot raise list prices without being stripped of valuable trade-secret protection for their confidential, proprietary information. SB 539 thus interferes with the objectives of the patent laws by undermining, if not defeating altogether, affected manufacturers' ability to recover the enormous up-front costs to research and develop diabetes medicines.

80. The Act's burdens on federal patent rights will discourage research and development of new diabetes drugs—a chilling of innovation itself. *See, e.g., Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1351–53 (Fed. Cir. 2014) (Newman, J., dissenting) (quoting *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757 (2014)) (burdening patentees who file infringement claims with threat of antitrust liability chills innovation); *In re Microsoft Corp. Antitrust Litig.*, 274 F. Supp. 2d 743, 745 (D. Md. 2003) (finding that “to require one company to provide its intellectual property to a competitor would significantly chill innovation”).

81. The Nevada Legislature jettisoned concerns that “transparency in prescription drug pricing will stifle innovation.” Mar. 29 Mins. at 34. They chose to elevate other, insular considerations over the law's interference with federal innovation incentives. But whether the Nevada Legislature's judgment is right or wrong is beside the point. The policy choice of whether the benefits of innovation in the treatment of diabetes justify the prices of existing drugs is reserved exclusively to the United States Congress, not to the State of Nevada. *See BIO*, 496 F.3d at 1374; H.R. Rep. 98-857(I), at 17–18. Congress exercised that choice through the patent laws. Nevada cannot unilaterally displace it.

#### ***SB 539 Conflicts with Federal Trade-Secret Law***

82. Federal and state trade-secret laws play a similarly important role in fueling the American economy. Legal protection for trade secrets “encourage[s] invention in areas where patent law does not reach, and . . . prompt[s] the independent innovator to proceed with the discovery and exploitation of his invention.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 485 (1974). “Competition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention.” *Id.*

1           83. Every state in the nation protects trade secrets. Initially, the common law provided  
2 safeguards “for the advantage of the public, to encourage and protect invention and commercial  
3 enterprise.” *Peabody v. Norfolk*, 98 Mass. 452, 457 (1868). “Traditionally defined as relating to  
4 technical matters in the production of goods, trade secrets now encompass non-technical aspects of  
5 a business including, customer lists, price codes economic studies, costs reports, customer tracking  
6 and marketing strategies.” *First Mfg. Co. v. Young*, 3 N.Y.S.3d 284, at \*3 (Sup. Ct. 2014).

7           84. In evaluating whether information is a trade secret under the common law, courts  
8 consider, among other things, “[1] the extent of measures taken by the employer to guard the  
9 secrecy of the information; [2] the value of the information to the employer and to his competitors;  
10 [3] the amount of effort or money expended by the employer in developing the information; and [4]  
11 the ease or difficulty with which the information could be properly acquired or duplicated by  
12 others.” *Jet Spray Cooler, Inc. v. Crampton*, 385 N.E.2d 1349, 1355 n.9 (Mass. 1979) (citation  
13 omitted); *Frantz v. Johnson*, 999 P.2d 351, 358–59 (Nev. 2000) (“Factors to be considered include:  
14 (1) the extent to which the information is known outside of the business and the ease or difficulty  
15 with which the acquired information could be properly acquired by others; (2) whether the  
16 information was confidential or secret; (3) the extent and manner in which the [company] guarded  
17 the secrecy of the information; and (4) . . . whether this information is known by the [company’s]  
18 competitors.”).

19           85. Forty-eight states, including Nevada, have adopted, with slight variations in some  
20 states, the Uniform Trade Secrets Act (“UTSA”), which “codifie[d] the common law elements of  
21 misappropriation of confidential information.” *Frantz*, 999 P.2d at 357–58. The UTSA defines a  
22 “trade secret” as:

23           [I]nformation, including a formula, pattern, compilation, program, device, method,  
24 technique, or process, that: (i) derives independent economic value, actual or  
25 potential, from not being generally known to, and not being readily ascertainable by  
26 proper means by, other persons who can obtain economic value from its disclosure  
or use, and (ii) is the subject of efforts that are reasonable under the circumstances to  
maintain its secrecy.”

27           UTSA, § 1(4).

86. Courts in UTSA jurisdictions routinely hold that confidential information concerning advertising, cost, marketing, pricing, and production constitutes a trade secret. *See, e.g., Finkel v. Cashman Profl, Inc.*, 270 P.3d 1259, 1263 (Nev. 2012) (holding that “confidential pricing structures and marketing plans” were trade secrets); *Frantz*, 999 P.2d at 359 (holding pricing information was trade secret because “its secrecy was guarded, and it was not readily available to others because the plastic gaming card industry is highly specialized”); *Aerodynamics Inc. v. Ceasars Entm’t Operating Co.*, No. 2:15-CV-01344, 2015 WL 5679843, at \*8 (D. Nev. Sept. 24, 2015) (a company’s “confidential pricing information, . . . marketing strategies, . . . exact pricing for [certain] bid[s], payment terms, and credits and discounts provided” are trade secrets); *accord In re Dana Corp.*, 574 F.3d 129, 152 (2d Cir. 2009) (recognizing that under New York law, “[c]onfidential proprietary data relating to pricing, costs, systems, and methods are protected by trade secret law”); *S.I. Handling Sys., Inc. v. Heisley*, 753 F.2d 1244, 1260 (3d Cir.1985) (same under Pennsylvania law); *Burbank Grease Servs., LLC v. Sokolowski*, 693 N.W.2d 89, 96 (Wis. App. 2005) (“Generally, it appears that when prices are based on complicated or unique formulas that the customers do not know about, courts conclude the information meets the standard embodied in [the UTSA].”), *aff’d in part, rev’d in part*, 717 N.W.2d 781 (Wis. 2006); *Whyte v. Schlage Lock Co.*, 101 Cal. App. 4th 1443, 1455 (2002) (“[P]ricing, profit margins, costs of production, pricing concessions, promotional discounts, advertising allowances, volume rebates, marketing concessions, payment terms and rebate incentives” have independent economic value as trade secrets).

87. In 2016, Congress enacted the Defend Trade Secrets Act (“DTSA”), creating for the first time a federal private right of action for misappropriation of trade secrets “related to a product or service used in, or intended for use in, interstate or foreign commerce.” Pub. L. No. 114-153, 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)).

88. Congress enacted the DTSA because “trade secrets are increasingly becoming the foundation of businesses across the country, with one estimate placing the value of trade secrets in the United States at \$5 trillion. . . . With so much at stake, it is absolutely vital . . . [to] include strong protections against theft of trade secrets.” 162 Cong. Rec. H2028-01, H2033 (Apr. 27, 2016)

(comments of Rep. Nadler). “By improving trade secret protection,” Congress intended the DTSA to “incentivize future innovation while protecting and encouraging the creation of American jobs.” S. Rep. No. 114-220, at 3 (2016).

89. Although every state protects confidential and proprietary advertising, cost, marketing, pricing, and production information, Congress intended the DTSA to provide businesses engaged in interstate commerce with a uniform remedy for misappropriation. Congress expressed concerns that “state laws vary in a number of ways and contain built-in limitations that make them not wholly effective in a national and global economy.” H.R. Rep. No. 114-529, at 4 (Apr. 26, 2016) (Committee on the Judiciary). Congress acknowledged that “trade secret cases often require swift action by courts across state lines to preserve evidence.” *Id.* “[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist.” 162 Cong. Rec. H2034 (comments of Rep. Jackson Lee). Thus, the DTSA allows businesses “to move quickly to Federal court . . . to stop trade secrets from winding up being disseminated and losing their value.” H.R. Rep. No. 114-529, at 6; *accord* S. Rep. No. 114-220, at 3. The primary goal was to create “remedies that, first, halt the misappropriator’s use and dissemination of the . . . trade secret.” H.R. Rep. No. 114-529, at 13.

90. Congress likewise modeled the DTSA definition of “trade secret” on the UTSA, as did Nevada—that is, until SB 539. *Compare* UTSA § 1, *with* 18 U.S.C. § 1839(4), *and* Nev. Rev. Stat. § 600A.030(5) (1999); *see also* H.R. Rep. 114-529, at 14 (“[T]he Committee does not intend for the definition of a trade secret to be meaningfully different from the scope of that definition as understood by courts in States that have adopted the UTSA.”). Reflecting Congress’s intention to provide a uniform remedy, the DTSA makes information related to advertising, cost, marketing, pricing, and production a protectable trade secret, just as it is in UTSA jurisdictions. *See supra*, ¶ 86.

91. SB 539 compels manufacturers to disclose to the Department confidential and proprietary advertising, cost, marketing, pricing, and production information that derives independent value from not being generally known to third parties and competitors. This valuable

1 information constitutes a trade secret under the DTSA—and also under Nevada law until SB 539  
2 takes effect.

3 92. Further, the Act amends Nevada’s trade-secret statute expressly to eliminate trade-  
4 secret protection for all information “that a manufacturer is required to report” to the Department.  
5 SB 539 § 9. Thus, the manufacturer loses trade-secret protection the moment the Department issues  
6 its annual list of “essential” diabetes drugs, even before the manufacturer actually turns the  
7 information over to the State.

8 93. Furthermore, the Act places no restriction on how the Department may use or  
9 disseminate the information disclosed. To the contrary, SB 539 affirmatively requires the  
10 Department to publish a report on its website that identifies the information belonging to each  
11 manufacturer. *Id.* § 6(a)(5), (b). Once published on the Internet or otherwise publicly disseminated  
12 under the authority of SB 539, the information no longer constitutes a trade secret under either the  
13 UTSA or the DTSA. *See, e.g.*, 18 U.S.C. § 1839. As a practical matter, even if there were some  
14 residual trade-secret protection from the laws of other states, it would be ineffective once the  
15 previously protected information is in the public domain for all to see.

16 94. The destruction of trade-secret protection in Nevada will thwart the ability of  
17 manufacturers subject to the Act’s disclosure requirements to sue for misappropriation in any  
18 jurisdiction, including in federal court under the DTSA.

19 95. In effect, SB 539 alters the operation of the DTSA—and the laws of every other  
20 jurisdiction in the nation—to eliminate trade-secret protection for confidential advertising, cost,  
21 marketing, pricing, and production information associated with diabetes drugs. This, in turn,  
22 undercuts both of Congress’s goals in enacting the DTSA—to “incentivize future innovation while  
23 protecting and encouraging the creation of American jobs.” S. Rep. No. 114-220, at 3.

24 96. Thus, SB 539 “stands as an obstacle to the accomplishment and execution of the full  
25 purposes and objectives of Congress.” *Hines*, 312 U.S. at 67. Indeed, the Act jeopardizes the \$5  
26 trillion worth of trade secrets that Congress enacted the DTSA to protect.

***SB 539's Uncompensated Elimination of Trade-Secret Protection for Valuable Information Violates the Fifth Amendment Takings Clause***

97. The Fifth Amendment provides that “private property [shall not] be taken for public use, without just compensation.” U.S. Const. amend. V. This proscription applies to the states through the Fourteenth Amendment.

98. Government regulation of private property can constitute a taking. *See Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992). “Private property” includes not only tangible property, but also intangible property, such as trade secrets. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984). A state’s “failure to provide adequate protection to assure [a trade secret’s] confidentiality, when disclosure is compelled . . . , can amount to an unconstitutional taking of property by destroying [the trade secret], or by exposing it to the risk of destruction by public disclosure or by disclosure to competitors.” *St. Michael’s Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981) (alteration omitted) (quoting *Wearly v. FTC*, 462 F. Supp. 589, 598 (D.N.J. 1978)).

99. There are two kinds of regulatory takings: (1) categorical and (2) noncategorical. *See Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005). A categorical taking occurs where a state statute “denies all economically beneficial or productive use” of property. *Lucas*, 505 U.S. at 1015. By contrast, a noncategorical taking may occur where a regulation “fall[s] short of eliminating *all* economically beneficial use,” *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001), yet still goes “too far” for purposes of the Fifth Amendment, *Lucas*, 505 U.S. at 1014–15 (quoting *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)). To determine whether a noncategorical regulatory taking goes “too far,” courts apply the three-part test articulated in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978), and its progeny. That test assesses: “[1] the character of the governmental action, [2] its economic impact, and [3] its interference with reasonable investment-backed expectations.” *Ruckelshaus*, 467 U.S. at 1005.

100. SB 539 works as a categorical taking of property rights. “With respect to a trade secret, the right to exclude others is central to the very definition of the property interest.” *Id.* at 1011. SB 539 does not merely “expos[e] [manufacturers’ trade secrets] to the *risk* of destruction by

1 public disclosure or by disclosure to competitors.” *St. Michael’s*, 643 F.2d at 1374 (emphasis  
2 added). Rather, the Act strips trade-secret protection and *mandates* public disclosure of  
3 manufacturers’ confidential advertising, cost, marketing, pricing, and production information on the  
4 Department’s website, *see* SB 539 §§ 6(a)(5), 9, thus destroying for all time any trade-secret  
5 protection for the information disclosed. The normal operation of the Act ensures that  
6 manufacturers lose any claim of confidentiality, the *sine qua non* of what makes a trade secret  
7 valuable. *See Ruckelshaus*, 467 U.S. at 1011–12; *see also* 162 Cong. Rec. H2034 (“[U]nlike  
8 patents, once this information is disclosed it instantly loses its value and the property right itself  
9 ceases to exist.” (comments of Rep. Jackson Lee in support of DTSA)).

10 101. In the alternative, even if SB 539 did not work a categorical taking by destroying  
11 manufacturers’ property interests in their trade secrets, the Act would still constitute an  
12 impermissible regulatory taking under the three-part test articulated in *Penn Central*.

13 102. First, the “character” of Nevada’s legislative action weighs heavily against sustaining  
14 the Act. It prevents pharmaceutical manufacturers from “exclud[ing] others from their trade  
15 secrets,” causing the trade secrets to “lose all value.” *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41  
16 (1st Cir. 2002) (en banc) (citing this aspect of state disclosure statute’s “character” to show a  
17 regulatory taking). “Therefore, if the [pharmaceutical manufacturers] comply with the requirements  
18 of [SB 539], their property right will be extinguished.” *Id.* at 42. “[T]his is precisely what the  
19 Takings Clause is designed to prevent.” *Id.* at 43.

20 103. Second, eliminating trade-secret protection for confidential advertising, cost,  
21 marketing, pricing, and production information relating to diabetes drugs will have a devastating  
22 “economic impact” not only on manufacturers subject to the disclosure requirements, but also on  
23 the market for diabetes drugs. *See Penn Cent.*, 438 U.S. at 124. Manufacturers forced to disclose  
24 such information will be at a severe disadvantage against competing diabetes-drug manufacturers  
25 not subject to the Act. These competitors will be able to obtain the information that Sections 3.8  
26 and 4 of the Act require to be disclosed, and will gain a competitive advantage by knowing how the  
27 manufacturer allocates its resources and sets its prices. Because manufacturers consider similar  
28 factors in setting prices for non-diabetes products, disclosure of pricing information under SB 539

1 will also impair the ability of the affected manufacturers to compete with regard to non-diabetes  
2 products. Similarly, the Act disadvantages affected manufacturers in their dealings with third-party  
3 payers, who will be able to use the manufacturer's pricing information against it in negotiations.

4 104. These adverse effects are not confined to Nevada, but rather will be nationwide. A  
5 trade secret published in Nevada may be used in New York, Ohio, Florida, or any other state, as a  
6 trade secret must in fact be "secret" to be protected. *See, e.g.*, UTSA § 1(4) (restricting definition of  
7 "trade secret" to information "not . . . generally known" or "readily ascertainable by proper  
8 means"); 18 U.S.C. § 1839(3) (same). Thus, losing trade-secret protection anywhere means losing  
9 it everywhere. This substantial competitive harm increases the penalty for Plaintiffs' members who  
10 exercise their patent rights to set prices on their diabetes products, thereby diminishing the incentive  
11 to invest in the development of diabetes drugs. *See supra* ¶¶ 77–81.

12 105. Third, manufacturers investing in diabetes treatments had the reasonable  
13 "investment-backed expectation" that their confidential and proprietary information would remain  
14 secret. *See Penn Cent.*, 438 U.S. at 124. For many years Nevada has treated confidential  
15 advertising, cost, marketing, pricing, and production information as entitled to trade-secret  
16 protection without any exception for manufacturers of diabetes drugs, as has virtually every other  
17 state. *See, e.g.*, Nev. Rev. Stat § 600A.030 (1987); *Finkel*, 270 P.3d at 1263; *Frantz*, 999 P.2d at  
18 359. Manufacturers thus had reasonable investment-backed expectations in the secrecy of this  
19 information, because of longstanding trade-secret protection and because no state has ever required  
20 such intrusive disclosures. *See Reilly*, 312 F.3d at 40. Manufacturers did not expect and could not  
21 reasonably have expected the economic impact detailed above, or the erosion of the anticipated  
22 returns on their investments in researching, developing, and marketing their diabetes drugs, in  
23 reliance on the protection of their valuable trade secrets.

24 106. Thus, under any Takings analysis, SB 539's disclosure requirements destroy  
25 valuable trade secrets related to diabetes drugs without any compensation, let alone just  
26 compensation, in violation of the Takings Clause. U.S. Const. amends. V, XIV.

***SB 539 Violates the Commerce Clause by Overriding the Laws of Every Other State***

107. The Constitution grants Congress the power “[t]o regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. The Commerce Clause “reflect[s] a central concern of the Framers . . . : the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.” *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979).

108. Thus, the Supreme Court has “long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute.” *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This is the “so-called ‘dormant’ aspect of the Commerce Clause.” *Id.*

109. When a state “directly regulates” interstate commerce, the Supreme Court has “generally struck down the statute without further inquiry.” *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see also Edgar v. MITE Corp.*, 457 U.S. 624, 640 (1982) (“The Commerce Clause, however, permits only *incidental* regulation of interstate commerce by the States; direct regulation is prohibited.”). By contrast, when a state law directly regulates only *intrastate* commerce, the regulation will not survive scrutiny if “the burden imposed on [*interstate*] commerce is clearly excessive in relation to the putative local benefits” of the statute. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

110. SB 539 imposes a burden on interstate commerce that “is clearly excessive in relation to [its] putative local benefits.” *Id.* The Act strips trade-secret protection for broad categories of proprietary information belonging to “essential” diabetes drug manufacturers, *none* of whom is headquartered in Nevada. By doing so, the Act directly negates the trade-secret laws of every other state and the federal government. The extraterritorial effects of SB 539 are substantial and unavoidable because the market for diabetes drugs—especially “essential” diabetes drugs—is inherently national. *See Nat’l Ass’n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir. 2012) (“[S]ignificant burdens on interstate commerce generally result from inconsistent regulation of activities that are inherently national or require a uniform system of regulation.”). SB

1 539 will prevent manufacturers from protecting and enforcing their trade secrets in every state.  
2 This in turn will impose significant burdens on other states that host a substantial part of these  
3 manufacturers' operations. Those jurisdictions have a legitimate interest in promoting the economic  
4 success of these manufacturers by protecting their trade secrets. *See Healy v. Beer Inst., Inc.*, 491  
5 U.S. 324, 336–37 (1989); *Rocky Mtn. Farmers Union v. Corey*, 730 F.3d 1070, 1101 (9th Cir.  
6 2013).

7 111. Take, for example, Eli Lilly—one of the major manufacturers of diabetes drugs. Eli  
8 Lilly is headquartered in Indianapolis, Indiana. It has *no* offices or operations in Nevada. The State  
9 of Indiana and the other states where Eli Lilly has operations protect Eli Lilly's trade secrets—  
10 including its pricing and cost information for essential diabetes drugs. *See, e.g., Hydraulic Exch. &*  
11 *Repair*, 690 N.E.2d at 786. These states have an interest in protecting Eli Lilly's trade secrets in  
12 order to promote the company's growth, which creates local jobs and fuels the local economy. SB  
13 539, however, overthrows the protection these other states provide by compelling Eli Lilly to  
14 disclose the information that the other states protect as trade secrets. By enacting SB 539, Nevada  
15 legislators have told legislators in every other state that Nevada knows best, and its decision  
16 controls, when balancing the interest in protecting trade secrets against the interest in price  
17 transparency. The dormant Commerce Clause does not tolerate such efforts by one state to impose  
18 its preferred regulation on every other state.

19 112. Furthermore, because WAC is a national list price, SB 539's effective cap on a  
20 drug's WAC will apply throughout the country, including to drugs that are bought and sold outside  
21 of Nevada. A manufacturer of essential diabetes drugs based in New York selling to a purchaser in  
22 California will not be able to raise list prices without having the state of *Nevada* stripping the New  
23 York manufacturer of its valuable trade secrets.

24 113. These substantial effects on interstate commerce will clearly exceed any putative  
25 local benefit to the residents of Nevada. While the purpose of the Act is apparently to control prices  
26 for diabetes drugs, neither the Act nor its legislative history explain how transparency will lower  
27 prices apart from impermissibly burdening manufacturers' lawful exercise of federal patent rights.  
28 The Act is precisely the kind of attempt by a state to "extend [its] police power beyond its

jurisdictional bounds” that offends the dormant Commerce Clause. *C & A Carbone*, 511 U.S. at 393.

114. In fact, SB 539’s publication of competitively sensitive price and cost information may lead to unintended anticompetitive effects that prevent drug prices from falling as quickly as they would have without the Act. “Too much transparency can harm competition in any market, including in health care markets. . . . [W]hen information disclosures allow competitors to figure out what their rivals are charging, [it] dampens each competitor’s incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices.” Tara Isa Koslov & Elizabeth Jex, *Price Transparency or TMI?*, Fed. Trade Comm’n (July 2, 2015, 2:31 PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi>. The Congressional Budget Office has found that compelled disclosure of drug pricing information, specifically rebates, “could set in place conditions for tacit collusion, as manufacturers would find it more difficult to set prices below their competitors’ without detection.” Cong. Budget Office, *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals* 6 (June 5, 2008), <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf>.

115. The Federal Trade Commission has also explained, “If, for example, pharmaceutical manufacturers know the precise details of rebate arrangements offered by their competitors, then tacit collusion among them may be more feasible. Absent such knowledge, manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment may yield increased sales. Unprotected disclosures thus may raise the price that . . . consumers pay for pharmaceutical coverage by undermining competition among pharmaceutical companies for preferred formulary treatment.” Letter from James Cooper, Pauline M. Ippolito, & David P. Wales of the Fed. Trade Comm’n to Hon. James L. Seward (Mar. 31, 2009), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf).

116. In sum, the Act excessively burdens interstate commerce without a commensurate local benefit. The Constitution entrusts national economic policy to Congress precisely to avoid such outcomes. U.S. Const. art. I, § 8, cl. 3.

## CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF

#### **(Declaratory/Injunctive Relief – SB 539 Is Preempted By Federal Patent Law In Violation Of The Supremacy Clause Of The U.S. Constitution)**

117. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

118. Under the Supremacy Clause of the United States Constitution, federal statutes are “the supreme Law of the Land.” U.S. Const. art. IV, cl. 2. No state law may “stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Hines*, 312 U.S. at 67.

119. The federal patent laws embody “a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.” *Bonito Boats*, 489 U.S. at 146. Federal patent laws, including the Hatch-Waxman Act, grant an inventor the exclusive right to make, use, and sell his patented invention for a limited period of time. During this exclusivity period, a patent holder may set the price for its product in a manner that takes into account the patent holder’s ability to preclude others from marketing an infringing product. *See BIO*, 496 F.3d at 1373–74. This protection extends to “[whom]ever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101. By this means, the federal patent system, including the Hatch-Waxman Act, encourages not only the discovery of new pharmacological compounds, but also new methods of manufacturing or improving the effectiveness of drugs already discovered.

120. Federal patent law preempts SB 539 because the Act stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the federal law. The Act impermissibly burdens the federal patent rights of diabetes drug manufacturers by requiring the

disclosure of trade secrets associated with these patented products if manufacturers raise the list prices of those patented drugs.

121. Accordingly, the Act constitutes an impermissible and “clear attempt to restrain . . . excessive [drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to [Nevada] drug consumers.” *BIO*, 496 F.3d at 1374.

## SECOND CLAIM FOR RELIEF

### **(Declaratory/Injunctive Relief – SB 539 Is Preempted By Federal Trade-Secret Law In Violation Of The Supremacy Clause Of The U.S. Constitution)**

122. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

123. SB 539 violates the Supremacy Clause for the independent reason that eliminating trade-secret protection for the information disclosed by manufacturers stands as an obstacle to the accomplishment and execution of the full purposes and objectives of, and is therefore preempted by, the federal Defend Trade Secrets Act of 2016.

124. SB 539 compels manufacturers to disclose to the Department confidential and proprietary advertising, cost, marketing, pricing, and production information that derives independent value from not being generally known to third-party payers and competitors. These categories of information are “trade secrets” under the DTSA. SB 539, however, removes trade-secret protection from these categories of information by requiring their disclosure and by amending Nevada’s trade-secret statute expressly to eliminate trade-secret protection for all information “that a manufacturer is required to report.” SB 539 § 9. These provisions stand as an obstacle to the purposes and objectives of the DTSA.

125. Although the DTSA provides that it “shall not be construed to preempt or displace any other remedies . . . provided by . . . [s]tate . . . law for the misappropriation of a trade secret,” 18 U.S.C. § 1838, that provision has no applicability here. SB 539 does not merely provide a *different* remedy for the misappropriation that must be disclosed. Rather, SB 539 *eliminates all remedies*, not only in Nevada, but throughout the Nation. Thus, the rule of construction set forth in Section 1838 does not save SB 539 from federal preemption.

### THIRD CLAIM FOR RELIEF

#### **(Declaratory/Injunctive Relief – The Act Works A Taking Without Just Compensation In Violation Of The Fifth And Fourteenth Amendments To The U.S. Constitution)**

126. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

127. The Fifth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, provides that “private property [shall not] be taken for public use, without just compensation.”

128. SB 539 constitutes a categorical taking of Plaintiffs’ members’ intellectual property rights because it guarantees public disclosure of their trade secrets, which in turn negates the value of those trade secrets.

129. Alternatively, the Act works a regulatory taking under the three-part test set out in *Penn Central*. First, SB 539 has the “character” of a total interference with manufacturers’ property rights in their trade secrets. *Penn Cent.*, 438 U.S. at 124–25. Second, eliminating all trade-secret protection for the confidential advertising, cost, marketing, pricing, and production information for diabetes drugs will have a devastating “economic impact” not only on manufacturers subject to the disclosure requirements, but also on the market for diabetes drugs. *Id.* at 124. Third, manufacturers invest in diabetes treatments with the reasonable “investment-backed expectation” that their confidential and proprietary information will remain a secret. *Id.* at 124, 127.

130. Thus, SB 539’s disclosure requirements destroy valuable trade secrets related to diabetes drugs without any compensation, let alone just compensation, in violation of the Takings Clause. U.S. Const. amends. V, XIV.

### FOURTH CLAIM FOR RELIEF

#### **(Declaratory/Injunctive Relief – The Act Imposes An Excessive Burden On Interstate Commerce In Violation Of The Commerce Clause Of The U.S. Constitution)**

131. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

132. The Constitution grants Congress the power “[t]o regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. The Commerce Clause places an implicit restraint, known as the dormant Commerce Clause, on state laws that are inimical to national commerce.

133. SB 539 violates the dormant Commerce Clause because the burden it imposes on interstate commerce is clearly excessive in relation to any putative local benefits. Because WAC is a national list price, SB 539's effects will be felt throughout the country. SB 539 also will prevent manufacturers from protecting and enforcing their trade secrets in every state. These other jurisdictions, especially those in which manufacturers reside, have a legitimate interest in promoting the economic success of manufacturers. These substantial effects on interstate commerce clearly exceed any putative local benefit to the residents of Nevada. While the purpose of the Act is to control prices for diabetes drugs, neither the Act nor its legislative history explain how transparency will lower prices apart from impermissibly burdening manufacturers' lawful exercise of federal patent rights. The Constitution entrusts national economic policy to Congress precisely to avoid such outcomes. U.S. Const. art. I, § 8, cl. 3.

#### PRAYER FOR RELIEF

**NOW, THEREFORE**, Plaintiffs request a judgment in their favor against Defendants as follows:

1. A declaration that Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of SB 539 are unconstitutional and void;
2. A preliminary and permanent injunction preventing Defendants from implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of SB 539;
3. That Plaintiffs be awarded attorneys' fees and costs, plus interest accruing thereon, in their favor at the maximum rate allowed by law; and

///

///

///

///

///

///

4. That the Court award such other and further relief as it may deem appropriate.

DATED this 1st day of September, 2017.

Respectfully submitted,

/s/ Pat Lundvall

Pat Lundvall

Nevada Bar No. 3761

MCDONALD CARANO LLP

2300 West Sahara Avenue, Suite 1200

Las Vegas, NV 89102

Telephone: (702) 873-4100

plundvall@mcdonaldcarano.com

Robert N. Weiner

Pending Admission *Pro Hac Vice*

Jeffrey L. Handwerker

Pending Admission *Pro Hac Vice*

R. Stanton Jones

Pending Admission *Pro Hac Vice*

ARNOLD & PORTER KAY SCHOLER LLP

601 Massachusetts Avenue, NW

Washington, DC 20001

Telephone: (202) 942-5000

robert.weiner@apks.com

jeffrey.handwerker@apks.com

stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical Research  
and Manufacturers of America and Biotechnology  
Innovation Organization*

# EXHIBIT 4

# EXHIBIT 4

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA, and

BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official  
capacity  
as Governor of the State of Nevada, and

RICHARD WHITLEY, in his official  
capacity as Director of the Nevada  
Department for Health and Human  
Services,

Defendants.

Case No.: 2:17-cv-02315

**DECLARATION OF JAMES  
BORNEMAN**

1 I, James Borneman, declare pursuant to 28 U.S.C. § 1746 as follows:

2  
3 1. I am the Head, Customer Engagement & Insights for Sanofi US. From  
4 July 2014 – May 2017, I was Vice President, Strategic Pricing and Contract  
5 Management for Sanofi US. In that capacity, I was responsible for the establishment  
6 of all gross and net pricing strategies for all Sanofi US pharmaceutical products to  
7 include oversight of the organization's gross-to-net investments. I am knowledgeable  
8 about Sanofi US's pricing and contracting for its prescription drugs, including its  
9 diabetes therapies.  
10  
11

12  
13 2. Sanofi US is a member of the Pharmaceutical Research and  
14 Manufacturers of America ("PhRMA"), a plaintiff in this action. Sanofi US is the  
15 U.S. affiliate of Sanofi, a global life sciences company committed to improving  
16 access to healthcare and supporting the people we serve throughout the continuum of  
17 care. Sanofi is a member of PhRMA as well as the Biotechnology Innovation  
18 Organization ("BIO"), also a plaintiff in this action. From prevention to treatment,  
19 Sanofi transforms scientific innovation into healthcare solutions in human vaccines,  
20 rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes  
21 and cardiovascular, consumer healthcare, established prescription products and  
22 generics. More than 100,000 people at Sanofi are dedicated to making a difference in  
23 patients' daily lives, wherever they live, and enabling them to enjoy a healthier life.  
24  
25  
26  
27  
28

1           3.     Headquartered in Bridgewater, New Jersey, Sanofi US employs more  
2     than 15,000 professionals throughout the country including over 35 at a distribution  
3     center in Reno, Nevada. In addition to Diabetes & Cardiovascular and General  
4     Medicines, our other businesses operating in the United States include Sanofi  
5     Genzyme (specialty care), Sanofi Pasteur (vaccines), Winthrop (generics) and  
6     Chattem (consumer healthcare).  
7

8  
9           4.     Sanofi has a rich history of innovation dating back more than 100 years.  
10    We are tremendously proud of our heritage, which over the years has combined  
11    steady growth and expansion with an exceptional commitment to research and  
12    development.  
13

14           5.     For example, since the launch of Lantus (insulin glargine injection) 100  
15    units/ml, Sanofi has continued investing to better support clinical decision making for  
16    patients with diabetes through comprehensive research including over 2200 full-text  
17    publications from results of approximately 500 randomized controlled clinical trials,  
18    over 220 real-life patient studies and over 50 meta-analyses.  
19  
20

21           6.     Sanofi holds or has rights to patents protecting prescription drugs  
22    marketed and sold by Sanofi US, including patents protecting Lantus, Apidra,  
23    Toujeo, Soliqua and Adlyxin, which are FDA-approved for the treatment of diabetes.  
24    Lantus, Apidra, Toujeo, Soliqua and Adlyxin are thus likely to be subjected to  
25    Nevada Senate Bill No. 539 ("SB 539" or "the Act") as "essential" to the treatment of  
26    diabetes.  
27  
28

1           7.     Simply because Lantus, Apidra, Toujeo, Soliqua and Adlyxin are  
2 “essential” to the treatment of diabetes, I understand that section 3.8 of the Act  
3 requires Sanofi US to report substantial financial and marketing information related  
4 to Lantus, Apidra, Toujeo, Soliqua and Adlyxin to the Nevada Department of Health  
5 and Human Services (“Department”):  
6

- 7
- 8     •     “[t]he costs of producing the drug”;
  - 9
  - 10    •     “marketing and advertising costs” associated with the drug;
  - 11
  - 12    •     profit “earned from the drug” as a “percentage of . . . total profit”;
  - 13
  - 14    •     the amount spent on “patient prescription assistance programs”;
  - 15
  - 16    •     “[t]he aggregate amount of all rebates” in Nevada; and

17

18    “[a]ny additional information prescribed by regulation . . . for the purpose of  
19 analyzing the cost of prescription drugs . . . on the list.” *Id.* § 3.8.  
20

21           8.     The information that Sanofi US must disclose under Section 3.8 is  
22 confidential. Moreover, this information is of substantial independent economic  
23 value to Sanofi US by virtue of being confidential and non-public. Information such  
24 as pricing inputs and rationale is restricted internally, is only shared internally on a  
25 need-to-know basis, and is subject to non-disclosure provisions in Sanofi US’s  
26 employment and other business agreements. Employees are required to maintain the  
27  
28

1 secrecy of this information, and are subject to discipline – up to and including  
2 termination – by Sanofi US for its unauthorized disclosure.

3  
4 9. The Department, however, has no obligation to treat this information as  
5 confidential. The Department may publish it, share it with other public or private  
6 entities, or use it for other purposes, such as negotiating rebates with manufacturers.  
7 In fact, SB 539 expressly eliminates trade secret protection for all information  
8 required to be disclosed to the Department. *Id.* § 9.

10 10. Moreover, I understand that SB 539 imposes additional reporting  
11 requirements if manufacturers raise the price of diabetes drugs more than a specified  
12 benchmark linked to the CPI for Medical Services. For the period from July 2016 to  
13 July 2017, this CPI benchmark was 2.6 percent. Our price changes for Apidra for  
14 that period exceed this threshold.<sup>1</sup> For products that exceed the threshold, Section 4  
15 of SB 539 requires companies to disclose:  
16

- 17 • “[a] list of each factor that has contributed to the increase”;
- 18 • “[t]he percentage of the total increase that is attributable to each factor”;
- 19 • “[a]n explanation of the role of each factor”; and
- 20 • “[a]ny other information prescribed by regulation.” *Id.* § 4.

21 11. Information such as the factors considered in setting and adjusting the  
22 prices of our products and the percentage of our profits that derive from diabetes  
23 drugs are confidential and proprietary. This information is not shared publicly, and  
24

25  
26  
27  
28 <sup>1</sup> We have not taken a price increase on Lantus, Toujeo, Soliqua or Adlyxin during this timeframe.

1 access to it is restricted internally and only shared internally on a need-to-know basis.  
2 It is subject to non-disclosure provisions in Company's employment and other  
3 business agreements. Employees are required to maintain the secrecy of this  
4 information, and are subject to discipline – up to and including termination – by  
5 Sanofi US for its unauthorized disclosure.  
6

7  
8 12. The Department is required to prepare a report analyzing the information  
9 and post it on the Internet, and the Department has no limitations on how it may  
10 disclose or otherwise use this information. In fact, SB 539 expressly revokes the  
11 trade secret protection covering this information.  
12

13 13. Once this information is publicly disclosed in Nevada, it is public  
14 everywhere.  
15

16 14. Our customers and competitors would gain an unfair competitive  
17 advantage over Sanofi US if they were to obtain the financial and marketing  
18 information that Section 3.8 and 4 of the Act require Sanofi US to disclose to the  
19 Department. In particular, our customers would learn how we develop our pricing,  
20 which in turn could be used against us in negotiations with insurers and other  
21 intermediaries in the healthcare system – and ultimately negatively impact patients,  
22 by discouraging innovations that would benefit them.  
23  
24

25 15. Likewise, our competitors would learn how we allocate our resources  
26 and set our prices. This in turn could put Sanofi US at a significant disadvantage,  
27 especially if our competitors do not make a diabetes drug and thus are not subject to  
28

1 SB 539's disclosure requirements. We consider the same or similar factors when  
2 setting prices for other products. Thus, the information disclosed could prejudice  
3 Sanofi US in competition involving non-diabetes products as well.  
4

5 16. These impacts will not just be felt in Nevada, but will be felt nationally.  
6 The prices Sanofi US sets and the methods that it uses to set them are substantially  
7 the same from state-to-state. Thus, the information disclosed under SB 539 would  
8 have implications on our negotiations with customers and our competitive positioning  
9 nationwide.  
10

11 17. For example, many of the other healthcare supply chain stakeholders are  
12 national companies that negotiate national contracts. Healthcare purchasers such as  
13 the Culinary Union #226, which was a major public proponent of SB 539, are  
14 affiliated with Unite Here, a national union with affiliates in 37 states.  
15  
16

17 18. In fact, I understand that if the costs of other medical care (such as  
18 hospitalization) decline, then the CPI could decrease, such that unless Sanofi US  
19 lowers the price of Lantus, Apidra, Toujeo, Soliqua and Adlyxin it will be subject to  
20 SB 539's reporting requirements.  
21

22 19. Sanofi US has a longstanding commitment to research in the diabetes  
23 space and there is much remaining to be done in the diabetes space to ensure better  
24 outcomes for patients. Sanofi invested significant capital in developing Lantus,  
25 Apidra, Toujeo, Soliqua and Adlyxin, despite the substantial risk that this investment  
26 would not bear fruit. Sanofi obtained patents on these products, which gives Sanofi  
27  
28

1 US the exclusive legal right to market Lantus, Apidra, Toujeo, Soliqua and Adlyxin  
2 for the term of those patents. Such patent exclusivity enables Sanofi US to price  
3 Lantus, Apidra, Toujeo, Soliqua and Adlyxin at a level that helps to recoup the  
4 investment in this research and development, given that many experimental products  
5 do not even make it to the submission or approval stages. Now, however, Sanofi  
6 faces the unenviable choice of either forgoing its right under the patent laws to price  
7 the products at this level, or suffering the substantial penalty of disclosure of trade  
8 secret information. The risks of competitive harm will lower the value of existing  
9 and future patents on diabetes products, diminishing the incentive, or creating a  
10 disincentive, to invest in developing and enhancing those drugs. Ultimately, this  
11 could slow or blunt the process of providing better treatments for patients.  
12

13  
14  
15 20. SB 539's focus on diabetes medicines also could have severe unintended  
16 consequences. Given the significant investment required to fund research and  
17 development, such a focus could have a chilling effect on Sanofi's efforts in the  
18 diabetes space. For example, the lack of reporting thresholds in Section 3.8 (other  
19 than the requirement that the drug be "essential" to diabetes treatment) and a very low  
20 threshold for reporting price increases in Section 4 (any price greater than the CPI for  
21 medical products) could result in lower return on the patent rights and other  
22 innovations in the diabetes space than in other disease spaces. Further, Sanofi could  
23 be placed at a competitive disadvantage relative to companies who do NOT  
24 manufacture diabetes medicines, who reap an unexpected benefit by virtue of the SB  
25  
26  
27  
28

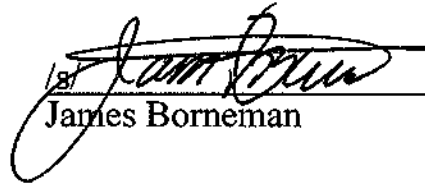
1 539 disclosure requirements. Given that Sanofi US considers the same or similar  
2 factors when setting the prices for other products, the information disclosed could  
3 disadvantage Sanofi US in competition involving non-diabetes products as well.  
4

5 21. Because of these consequences of SB 539's disclosure requirements and  
6 the direct implications they have on products that treat diabetes, SB 539 defeats  
7 Sanofi's legitimate investment expectations regarding its current products, and will  
8 necessitate review of our research and development priorities for diabetes products  
9 going forward. Indeed Sanofi may be forced to consider the costs and risks imposed  
10 by SB 539 in deciding what resources to allocate to enhancing Lantus, Apidra,  
11 Toujeo, Soliqua and Adlyxin and/or to research and development of new diabetes  
12 treatments.  
13  
14  
15

16 22. Given Sanofi's confidence in our researchers and our mission to  
17 continue finding solutions for patients with diabetes – and balancing that with our  
18 duties towards those who invest in Sanofi's lifesaving and life improving treatments  
19 and patients awaiting cures and treatments in other areas – Sanofi may be forced to  
20 weigh the difficult decision of whether to reduce its efforts in continuing to pursue  
21 promising medical advances in the area of diabetes because of these disincentives.  
22  
23  
24  
25  
26  
27  
28

1 I declare under penalty of perjury that the foregoing is true and correct.

2 Executed on September 7, 2017.

3  
4   
James Borneman

# EXHIBIT 5

# EXHIBIT 5

UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA, et al.,

Plaintiffs,

v.

BRIAN SANDOVAL, et al.,

Defendants.

Case No. 2:17-cv-02315-JCM-CWH

**ORDER**

Presently before the Court is proposed Intervenor-Defendant Nevada Legislature's motion to intervene (ECF No. 39), filed on September 26, 2017. Plaintiffs filed a response (ECF No. 41) on September 29, 2017, in which they informed the Court that they do not oppose the Nevada Legislature's motion.

Under Local Rule 7-2(d), the "failure of an opposing party to file points and authorities in response to any motion, except a motion under Fed. R. Civ. P. 56 or a motion for attorney's fees, constitutes a consent to the granting of the motion." The Court will therefore grant the Nevada Legislature's motion to intervene.

IT IS THEREFORE ORDERED that proposed Intervenor-Defendant Nevada Legislature's motion to intervene (ECF No. 39) is GRANTED.

DATED: October 3, 2017

  
C.W. Hoffman, Jr.  
United States Magistrate Judge

# EXHIBIT 6

# EXHIBIT 6

Pat Lundvall  
Nevada Bar No. 3761  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
plundvall@mcdonaldcarano.com

Robert N. Weiner  
Pending Admission *Pro Hac Vice*  
Jeffrey L. Handwerker  
Pending Admission *Pro Hac Vice*  
R. Stanton Jones  
Pending Admission *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA and

BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity  
as Governor of the State of Nevada, and

RICHARD WHITLEY, in his official capacity  
as Director of the Nevada Department for  
Health and Human Services,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

**PLAINTIFFS' MOTION FOR  
TEMPORARY RESTRAINING ORDER  
AND PRELIMINARY INJUNCTION, AND  
SUPPORTING MEMORANDUM OF  
POINTS AND AUTHORITIES**

**EXPEDITED TREATMENT REQUESTED  
(RELIEF NEEDED BY OCTOBER 1, 2017)**

**ORAL ARGUMENT REQUESTED**

**MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY  
INJUNCTION**

Plaintiffs Pharmaceutical Research and Manufacturers of America (“PhRMA”) and Biotechnology Innovation Organization (“BIO”) hereby move pursuant to Federal Rule of Civil Procedure 65 for a temporary restraining order requiring Defendants Brian Sandoval, in his official capacity as Governor of the State of Nevada, and Richard Whitley, in his official capacity as Director of the Nevada Department of Health and Human Services (together, “Defendants”), to immediately cease and desist all action implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of Nevada Senate Bill No. 539 (“SB 539” or the “Act”), which will impose irreparable injury on Plaintiffs beginning on October 1, 2017—the date that the challenged provisions of SB 539 go into effect. Such a temporary restraining order will preserve the status quo until the Court can rule on Plaintiffs’ motion for a preliminary injunction. Pursuant to Rule 65(b), sufficient grounds exist to issue a temporary restraining order. Plaintiffs further move for a preliminary injunction barring implementation or enforcement of the Sections of the Act identified above. Should this Court not enter a temporary restraining order, Plaintiffs ask the Court to set a briefing schedule on the motion for a preliminary injunction allowing sufficient time for a ruling before October 1, 2017. Defendants were notified of Plaintiffs’ intent to seek preliminary injunctive relief on August 25, 2017. Through the meet and confer process since then, the parties’ counsel discussed a potential resolution to avoid this motion, but on September 12, 2017, Defendants’ counsel advised that Defendant Sandoval would prefer that Plaintiffs proceed with the filing of a motion.

1 In support of this motion, Plaintiffs respectfully submit the accompanying memorandum of  
2 points and authorities, affidavits, and exhibits detailing the grounds entitling them to relief.

3 Dated this 13th day of September, 2017.

4 McDONALD CARANO LLP

5  
6 By: /s/ *Pat Lundvall*

7 Pat Lundvall  
8 2300 West Sahara Avenue, Suite 1200  
9 Las Vegas, NV 89102  
10 Telephone: (702) 873-4100  
11 Facsimile: (702) 873-9966

12 Robert N. Weiner  
13 Jeffrey L. Handwerker  
14 R. Stanton Jones  
15 ARNOLD & PORTER KAYE SCHOLER LLP  
16 601 Massachusetts Avenue, NW  
17 Washington, DC 20001  
18 Telephone: (202) 942-5000  
19 Facsimile: (202) 942-5999

20 *Attorneys for Plaintiffs Pharmaceutical Research*  
21 *and Manufacturers of America and Biotechnology*  
22 *Innovation Organization*  
23  
24  
25  
26  
27  
28

# TABLE OF CONTENTS

	Page
INTRODUCTION .....	1
BACKGROUND .....	3
A.    Plaintiffs’ Members Spend Billions Each Year Developing Innovative Diabetes Medicines in Reliance on Patent and Trade-Secret Protections.....	3
B.    History and Overview of Nevada Senate Bill 539 .....	4
C.    SB 539’s Harm to Plaintiffs’ Members and Innovation of Diabetes Treatments.....	8
ARGUMENT .....	9
I.    PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS .....	10
A.    SB 539 Is Preempted By Federal Patent and Trade-Secret Law.....	10
1.    SB 539 Conflicts with Federal Patent Law .....	11
2.    SB 539 Conflicts with Federal Trade-Secret Law .....	15
B.    SB 539’s Uncompensated Abolition of Trade-Secret Protection for Valuable Information Violates the Fifth Amendment Takings Clause.....	17
C.    SB 539 Violates the Commerce Clause by Overriding Every Other State’s Laws .....	19
II.    PLAINTIFFS’ MEMBERS WILL SUFFER IRREPARABLE HARM ABSENT A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTIVE RELIEF .....	22
III.    THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST SUPPORT A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION .....	22
CONCLUSION .....	23

## TABLE OF AUTHORITIES

	Page(s)
<b>CASES</b>	
<i>Aerodynamics Inc. v. Caesars Entm't Operating Co.</i> , No. 2:15-CV-01344, 2015 WL 5679843 (D. Nev. Sept. 24, 2015).....	16, 22
<i>All. for the Wild Rockies v. Cottrell</i> , 632 F.3d 1127 (9th Cir. 2011).....	9, 20
<i>Amoco Prod. Co. v. Vill. of Gambell</i> , 480 U.S. 531 (1987).....	9
<i>Andrx Pharms., Inc. v. Biovail Corp. Int'l</i> , 256 F.3d 799 (D.C. Cir. 2001).....	12
<i>Ariz. Dream Act Coal. v. Brewer</i> , 757 F.3d 1053 (9th Cir. 2014).....	21
<i>Ashland Mgmt. Inc. v. Janien</i> , 624 N.E.2d 1007 (N.Y. 1993).....	15
<i>Bonito Boats, Inc. v. Thunder Craft Boats, Inc.</i> , 489 U.S. 141 (1989).....	11
<i>Broadcom Corp. v. Qualcomm Inc.</i> , No. SACV 05-468, 2005 WL 5925584 (C.D. Cal. Oct. 19, 2005).....	9
<i>C &amp; A Carbone v. Town of Clarkstown</i> , 511 U.S. 383 (1994).....	21
<i>Excellence Cmty. Mgmt., LLC v. Gilmore</i> , 351 P.3d 720 (Nev. 2015).....	21
<i>Finkel v. Cashman Prof'l, Inc.</i> , 270 P.3d 1259 (Nev. 2012).....	16, 18, 21
<i>Flex-Foot, Inc. v. CRP, Inc.</i> , 238 F.3d 1362 (Fed. Cir. 2001).....	9
<i>Frantz v. Johnson</i> , 999 P.2d 351 (Nev. 2000).....	14, 18
<i>FTC v. Actavis, Inc.</i> , 133 S. Ct. 2223 (2013).....	10
<i>Gade v. Nat'l Solid Wastes Mgmt. Ass'n</i> , 505 U.S. 88 (1992).....	10

1	<i>Healy v. Beer Inst.</i> ,	
2	491 U.S. 324 (1989).....	19, 20, 21
3	<i>Hines v. Davidowitz</i> ,	
4	312 U.S. 52 (1941).....	10, 14, 16
5	<i>Hughes v. Oklahoma</i> ,	
6	441 U.S. 322 (1979).....	19
7	<i>Hydraulic Exch. &amp; Repair, Inc. v. KM Specialty Pumps, Inc.</i> ,	
8	690 N.E.2d 782 (Ind. Ct. App. 1998).....	21
9	<i>Johnson v. Nguyen</i> ,	
10	No. 3:12-CV-00538, 2015 WL 105826 (D. Nev. Jan. 7, 2015).....	9
11	<i>Kewanee Oil Co. v. Bicron Corp.</i> ,	
12	416 U.S. 470 (1974).....	10, 14
13	<i>King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.</i> ,	
14	791 F.3d 388 (3d Cir. 2015).....	10
15	<i>King Instruments Corp. v. Perego</i> ,	
16	65 F.3d 941 (Fed. Cir. 1995).....	11
17	<i>Kuryakyn Holdings, LLC v. Ciro, LLC</i> ,	
18	No. 15-CV-703-JDP, 2017 WL 1026025 (W.D. Wis. Mar. 15, 2017).....	16
19	<i>Lucas v. S.C. Coastal Council</i> ,	
20	505 U.S. 1003 (1992).....	18
21	<i>Mikohn Gaming Corp. v. Acres Gaming, Inc.</i> ,	
22	165 F.3d 891 (Fed. Cir. 1998).....	9
23	<i>of Nashville, Inc. v. Metro. Gov't of Nashville &amp; Davidson Cty.</i> ,	
24	274 F.3d 377 (6th Cir. 2001).....	22
25	<i>Nelson v. NASA</i> ,	
26	530 F.3d 865 (9th Cir. 2008), <i>rev'd on other grounds</i> , 562 U.S. 134 (2011).....	22
27	<i>Peabody v. Norfolk</i> ,	
28	98 Mass. 452 (1868).....	15
	<i>Penn Cent. Transp. Co. v. City of New York</i> ,	
	438 U.S. 104 (1978).....	18
	<i>Perez v. Campbell</i> ,	
	402 U.S. 637 (1971).....	13
	<i>Pharm. Research &amp; Mfrs. of Am. v. District of Columbia (PhRMA)</i> ,	
	406 F. Supp. 2d 56 (D.D.C. 2005), <i>aff'd sub nom. Biotech. Indus. Org. v. District</i> <i>of Columbia (BIO)</i> , 496 F.3d 1362 (Fed. Cir. 2007) .....	10, 19, 20

1	<i>Philip Morris, Inc. v. Reilly</i> ,	
2	312 F.3d 24 (1st Cir. 2002) (en banc) .....	16, 17, 18
3	<i>Pike v. Bruce Church, Inc.</i> ,	
4	397 U.S. 137 (1970) .....	19
5	<i>Preminger v. Principi</i> ,	
6	422 F.3d 815 (9th Cir. 2005) .....	23
7	<i>Prot. Techs., Inc. v. Ribler</i> ,	
8	2017 WL 923912 (D. Nev. Mar. 8, 2017) .....	23
9	<i>Ruckelshaus v. Monsanto Co.</i> ,	
10	467 U.S. 986 (1984) .....	16, 17, 18
11	<i>Saini v. Int'l Game Tech.</i> ,	
12	434 F. Supp. 2d 913 (D. Nev. 2006) .....	21, 22
13	<i>Sears, Roebuck &amp; Co. v. Stiffel Co.</i> ,	
14	376 U.S. 225 (1964) .....	11
15	<i>Sorrell v. IMS Health Inc.</i> ,	
16	564 U.S. 552 (2011) .....	13
17	<i>St. Michael's Convalescent Hosp. v. California</i> ,	
18	643 F.2d 1369 (9th Cir. 1981) .....	17
19	<i>Sw. Voter Registration Educ. Project v. Shelley</i> ,	
20	344 F.3d 882 (9th Cir.), rev'd on other grounds, 344 F.3d 914 (9th Cir. 2003) .....	23
21	<i>United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.</i> ,	
22	550 U.S. 330 (2007) .....	19
23	<i>Wearly v. FTC</i> ,	
24	462 F. Supp. 589 (D.N.J. 1978) .....	17
25	<i>Winter v. Nat. Res. Def. Council, Inc.</i> ,	
26	555 U.S. 7 (2008) .....	9
27	<b>STATUTES</b>	
28	Defend Trade Secrets Act, Pub. L. No. 114-153, 130 Stat. 376 (2016)	
	(codified at 18 U.S.C. § 1836(b)) .....	1, 15, 16, 23
	Drug Price Competition and Patent Term Restoration Act of 1984 .....	1, 11
	Nev. Rev. Stat § 600A.030 (1987) .....	7, 18
	Uniform Trade Secrets Act .....	14, 16, 23

## OTHER AUTHORITIES

1	162 Cong. Rec. H2028-01 (Apr. 27, 2016).....	15, 18
2	Andrew Curry, <i>Pathways to a Type 1 Vaccine</i> , Diabetes Forecast (July 2016),	
3	<a href="http://www.diabetesforecast.org/2016/jul-aug/vaccines.html">http://www.diabetesforecast.org/2016/jul-aug/vaccines.html</a> .....	4
4	Ashish Jha et al., <i>Greater Adherence to Diabetes Drugs Is Linked to Less Hospital</i>	
5	<i>Use and Could Save Nearly \$5 Billion Annually</i> , 31 Health Aff. 1836 (2012) .....	3
6	<i>Diabetes: Past Treatments and New Discoveries</i> , Med. News Today (May 2017),	
7	<a href="http://www.medicalnewstoday.com/articles/317484.php">http://www.medicalnewstoday.com/articles/317484.php</a> .....	3
8	Diabetes Que., <i>Treating Diabetes: 1921 to the Present Day</i> (Nov. 2016),	
9	<a href="https://tinyurl.com/yaqsq7s">https://tinyurl.com/yaqsq7s</a> .....	3
10	<i>Diabetes</i> , WebMD, <a href="http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes">http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes</a> .....	6
11	Genia Long, Analysis Grp., <i>The Biopharmaceutical Pipeline: Innovative Therapies</i>	
12	<i>in Clinical Development</i> (July 2017) .....	3
13	H.R. Rep. No. 114-529 (2016).....	14, 15, 16
14	H.R. Rep. No. 98-857(I) (1984).....	11
15	<i>Hearing on S.B. 265 Before the Sen. Comm. on Health &amp; Human Servs.</i> , 2017 Leg.,	
16	79th Sess. (Nev. May 26, 2017).....	5
17	<i>Hearing on S.B. 265 Before the Sen. Comm. on Health &amp; Human Servs.</i> , 2017 Leg.,	
18	79th Sess. (Nev. Mar. 29, 2017) .....	4
19	<i>Hearing on S.B. 265 Before the Sen. Comm. on Health &amp; Human Servs.</i> , 2017 Leg.,	
20	79th Sess. (Nev. May 3, 2017).....	4
21	Matthew Herper, <i>The Cost of Creating A New Drug Now \$5 Billion, Pushing Big</i>	
22	<i>Pharma To Change</i> , Forbes.com (Aug. 11, 2013).....	11
23	<i>Medicines in Development for Diabetes: A Report on Diabetes and Related</i>	
24	<i>Conditions</i> , PhRMA (2016), <a href="https://tinyurl.com/ydfnrqx7">https://tinyurl.com/ydfnrqx7</a> .....	3
25	Nevada Senate Bill No. 539 .....	1, 2
26	Presidential Statement on Signing S. 1538 Into Law, 20 Weekly Comp. Pres. Doc.	
27	1359 (Sept. 24, 1984).....	12, 13
28	<i>Recent Developments Which May Impact Consumer Access to, and Demand for,</i>	
	<i>Pharmaceuticals: Hearing Before the Subcomm. on Health of the House Comm.</i>	
	<i>on Energy and Commerce</i> , 107th Cong. (June 13, 2001) (statement of Rep.	
	Barbara Cubin).....	12

**MCDONALD CARANO LLP**  
 2300 WEST SAHARA AVENUE, SUITE 1200 • LAS VEGAS, NEVADA 89102 PHONE  
 (702) 873-4100 • FAX (702) 873-9966

Rick Mullin, <i>Tufts Study Finds Big Rise In Cost Of Drug Development</i> , Chem. & Eng’g News (Nov. 20, 2014) .....	11
S. Rep. No. 114-220 (2016) .....	15, 16
Senate Bill No. 265 .....	4
U.S. Const., amend. V .....	17
U.S. Const., amend. XIV .....	17
U.S. Const. art. I, § 8, cl. 3 .....	19
U.S. Const. art. I, § 8, cl. 8 .....	10
U.S. Const. art. VI, § 1, cl. 2 .....	10

**MEMORANDUM OF POINTS AND AUTHORITIES****INTRODUCTION**

Plaintiffs bring this action to prevent Nevada Senate Bill No. 539 (“SB 539” or the “Act,” attached as Ex. A) from inflicting serious, nationwide injuries. This unprecedented, overreaching, and unconstitutional statute undermines federal law, devalues intellectual property, and dictates patent and trade secret protection to the entire nation. The challenged provisions of SB 539 will irreparably harm Plaintiffs’ members who invent and manufacture diabetes drugs. Plaintiffs therefore seek a temporary restraining order and preliminary injunction barring implementation or enforcement of those provisions.

SB 539, signed on June 15, 2017, is novel in scope, ambition, and nationwide effect. As a penalty for exercising rights protected under the U.S. patent laws, SB 539 strips pharmaceutical manufacturers of trade secret protection for confidential, competitively sensitive, proprietary information regarding the production, cost, pricing, marketing, and advertising of their patented diabetes medicines. The Act then requires manufacturers to disclose this information to the Nevada Department of Health and Human Services (the “Department”), which must publish some of the information on its website and can disseminate the rest as it sees fit.

SB 539 violates the Constitution in at least four ways. *First*, SB 539 conflicts with federal patent law, including the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”) and is thus invalid under the Supremacy Clause. Federal law allows a patent holder to exclude others from making, using, or selling new inventions. For pharmaceuticals, the Hatch-Waxman Act adapts this system to ensure broad access to affordable medicines while offering innovators economic incentives sufficiently potent to surmount the enormous costs and risks of developing new treatments. SB 539 upsets this legislative balance by burdening a patent holder’s right to set prices reflecting the incentives the federal patent laws provide.

*Second*, SB 539 is also preempted by federal trade-secret law. Recognizing that trade secrets are critical to U.S. businesses, Congress enhanced existing state-law safeguards by enacting the Defend Trade Secrets Act of 2016 (“DTSA”). The DTSA sets a federal baseline for trade-secret

1 protection. SB 539 not only falls below this baseline; it effectively nullifies federal protection for  
2 trade secrets, undermining innovation and competition in the American pharmaceutical industry.

3 *Third*, SB 539 violates the Takings Clause of the Fifth Amendment by depriving affected  
4 manufacturers of trade-secret protection, forcing them to disclose confidential information to the  
5 State, and mandating its dissemination on the Internet. Before SB 539, every state, including  
6 Nevada, treated these materials as trade secrets. They are property, and SB 539 destroys their value  
7 without recompense. It thus takes manufacturers' property "without just compensation."

8 *Fourth*, SB 539 violates the dormant Commerce Clause because the penalty it imposes in  
9 Nevada impairs interstate commerce. By tying penalties to the national benchmark price for a drug,  
10 SB 539 affects drug prices nationwide, even for transactions entirely outside Nevada. The  
11 abrogation of trade-secret protection likewise extends to every state. Rescinding trade-secret  
12 protection, mandating disclosures, and requiring online publication of information destroys its  
13 confidentiality—everywhere. Such disclosures cannot be undone—information cannot be  
14 undisclosed. SB 539 overrides the laws of other states protecting the information as trade secrets,  
15 including states where the affected manufacturers reside, pay taxes, and employ thousands. Only  
16 Congress can override state trade-secret law or impose national economic policies. Nevada cannot.

17 These issues are not only ripe, but urgent. The Department plans to publish its list of  
18 "essential" diabetes drugs on October 15, 2017, stripping away trade-secret protection and raising  
19 the risk of misappropriation. The Act also compels disclosures that will undermine manufacturers'  
20 ability to compete. *See* Veto Letter from Gov. Sandoval to Sen. Maj. Leader Ford (June 2, 2017), at  
21 2-3 ("Veto Letter," attached as Ex. B). The harm to Plaintiffs' members and the public far  
22 outweighs any inconvenience to Defendants from delayed implementation of SB 539. And  
23 maintaining the status quo while this Court considers the constitutional issues is in the public  
24 interest. Plaintiffs therefore ask the Court to temporarily restrain Defendants from implementing or  
25 enforcing the challenged provisions of SB 539 pending resolution of Plaintiffs' motion for a  
26 preliminary injunction, and that the Court enjoin such implementation or enforcement pending  
27 resolution of this action.  
28

## BACKGROUND

### A. Plaintiffs' Members Spend Billions Each Year Developing Innovative Diabetes Medicines in Reliance on Patent and Trade-Secret Protections

More than 30 million Americans live with diabetes. An additional 84 million have pre-diabetes, with blood sugar levels higher than normal, increasing the risk they will develop diabetes. The disease is the seventh leading cause of death in the United States. It is, in short, an epidemic.<sup>1</sup>

Before 1922, a diagnosis of diabetes was a swift death sentence. Even with a strict diet, a patient typically survived “no more than three or four years,” with miserable quality of life.<sup>2</sup> Blood vessel and nerve damage resulted in dizziness and fainting, sexual issues, frequent urination, blindness, kidney failure, and infections leading to amputation. In 1921, two scientists were able to reverse diabetes in dogs by injecting them with insulin from the pancreatic islets of healthy dogs.<sup>3</sup> The following year, Eli Lilly began mass producing early animal-based insulins, which allowed many patients to manage their diabetes.<sup>4</sup>

Since then, pharmaceutical manufacturers have devoted enormous resources to improving insulin treatment and controlling diabetes. They have produced human insulin and developed other ways to treat diabetes and to reduce its risks. They have made diabetes medication easier to use, increasing patients' adherence to their prescribed dosing, thereby reducing emergency room visits and hospitalizations, saving \$8.3 billion a year.<sup>5</sup> Since 2000, FDA has approved 39 diabetes medicines. *See* Ex. C, Chart of FDA-Approved Diabetes Medicines; Compl. ¶ 24.

Despite these advances, 1.7 million Americans a year receive a new diagnosis of diabetes. Developing innovative new diabetes treatments and improving existing ones requires continuing

<sup>1</sup> *See Medicines in Development for Diabetes: A Report on Diabetes and Related Conditions*, PhRMA (2016) (“PhRMA 2016 Report”), <https://tinyurl.com/ydfnrqx7>.

<sup>2</sup> Diabetes Que., *Treating Diabetes: 1921 to the Present Day* (Nov. 2016), <https://tinyurl.com/yaqsq7s>.

<sup>3</sup> *See* Brian Wu, *History of Diabetes: Past Treatments and New Discoveries*, Med. News Today (May 2017), <http://www.medicalnewstoday.com/articles/317484.php>.

<sup>4</sup> *Id.*

<sup>5</sup> Ashish Jha et al., *Greater Adherence to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually*, 31 Health Aff. 1836, 1836 (2012).

research. In 2016 alone, more than 170 medicines for diabetes and related conditions were in development. *See* PhRMA 2016 Report. Most reflect a potential new approach to fighting the disease.<sup>6</sup> The development pipeline includes a potential “first-in-class” oral medicine for Types 1 and 2 diabetes, a fully recombinant monoclonal antibody to treat patients with newly diagnosed Type 1 diabetes, and a medicine for nephropathy (kidney damage) from Type 1 or 2 diabetes.

Diabetes research and development also focuses on prevention: top universities, hospitals, and pharmaceutical companies devote significant time and resources to developing a vaccine that could teach the immune system not to attack pancreatic beta cells (which produce insulin), thus preventing Type 1 diabetes. In fact, a trial at Massachusetts General Hospital aims not only to prevent Type 1 diabetes, but to reverse it in patients who have had the disease under 5 years.<sup>7</sup>

The cost of such innovation is staggering. It takes on average 10-15 years and \$2.6 billion to develop a new medicine, with low odds of success. From 1988-2014, only 12% of drugs that entered clinical trials were approved for use. Manufacturers can invest billions of dollars each year in research and development only if they have an appropriate opportunity to recoup that investment through sales of the small fraction of products that make it to market.

#### **B. History and Overview of Nevada Senate Bill 539**

As in all states, the number of adults in Nevada with diabetes has skyrocketed over the last 20 years. In 1995, the diabetes rate for adults in Nevada was about 4.7%. Today, it is near 12.4%. An additional 787,000 people, 38.5% of Nevada’s adult population, have pre-diabetes. Senate Bill No. 265 (“SB 265”), introduced in the Nevada Senate in February 2017, was “intended to address the rapidly increasing cost of diabetes care in Nevada.” *Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 33 (Nev. Mar. 29, 2017) (“Mar. 29 Mins.”). The bill’s author “sincerely believe[d] increased transparency leads to decreased costs.” *Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 5 (Nev. May 3,

<sup>6</sup> *See, e.g.,* Genia Long, Analysis Grp., *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development* (July 2017) (69% of diabetes drugs in development were potential first-in-class medicines).

<sup>7</sup> *See* Andrew Curry, *Pathways to a Type 1 Vaccine*, Diabetes Forecast (July 2016), <http://www.diabetesforecast.org/2016/jul-aug/vaccines.html>.

2017). SB 539 incorporated much of SB 265. As the legislative history of SB 265 shows, the State focused primarily on controlling the list prices of insulin and other patented diabetes medicines. Proponents of the bill complained that “competition has not led to lower [insulin] prices” and asserted that manufacturers would simply “tweak” insulin “to keep it under patent status, so the patent does not expire and become eligible for generic versions.” Mar. 29 Mins. at 36; *see also, e.g., id.* at 33 (noting antitrust allegations against insulin manufacturers); *id.* at 58–60 (discussion of patent protection). Referring to the patented medicines Janumet and Jardiance, one proponent argued that he “should not [have to] depend on [manufacturer] coupons on the Internet to offset the cost of diabetic medications.” *Id.* at 45. Another explained that the bill was designed to “hit directly to the root of the problem” of high diabetes drug prices because “pharma will react accordingly with rebate dollars and trying to unwind what has been done” to “meet the terms of what [SB 265] puts out.” *Id.* at 37 (testimony of managed care pharmacist).

SB 265 sought to control prices by, first, directing the Department to compile a list of prescription drugs “essential” for treating diabetes. SB 265 § 6. Second, it compelled the manufacturer to report to the Department specific cost and pricing information for each essential diabetes drug. *Id.* § 7(1). Third, it excluded this cost and pricing information from Nevada’s definition of “trade secret,” *id.* § 27.5(5), and required the Department to publish a report on the prices and how they affect health care spending in Nevada, *id.* § 7(2). Fourth, it directed manufacturers to provide 90 days’ notice before increasing the national benchmark list price, known as the wholesale acquisition cost or “WAC,” of any essential diabetes drug. *Id.* § 8.

On May 16, 2017, SB 539, also targeting list price increases for diabetes drugs, was introduced. Originally a “complement” to SB 265, *see Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 3 (Nev. May 26, 2017) (“May 26 Mins.”), SB 539 also required that “Pharmacy Benefit Managers” (PBMs)—intermediaries between manufacturers and payers—disclose rebates received from manufacturers the prior calendar year. SB 539’s author justified it as an effort to control prices, as the “retail price [of diabetes drugs] paid by patients is unpredictable and can escalate to unaffordable levels over short periods.” *Id.*

On June 2, 2017, Governor Sandoval vetoed SB 265 because it “pose[d] serious risks of unintended and potentially detrimental consequences for Nevada’s consumer patients,” including the risk “that access to critical care will become more expensive, more restricted, and less equitable.” Veto Letter at 2. The bill, he wrote, “could cause more harm than good for Nevada’s families.” *Id.* Governor Sandoval concluded that “constitutional and other legal concerns” rendered the bill “problematic” and vulnerable to challenges based on “federal preemption, the Fifth Amendment’s prohibition on uncompensated takings, and the Dormant Commerce Clause.” *Id.* at 3.

On June 5, 2017, the Nevada Senate and State Assembly both passed SB 539, which, as amended, largely replicated the drug pricing and reporting provisions of SB 265 that the Governor had deemed constitutionally problematic. *See* Veto Letter at 2.<sup>8</sup> Nonetheless, on June 15, 2017, three days after his veto, the Governor signed SB 539. Like SB 265, it directs the Department to compile, by February 1 of each year, a list of prescription drugs “essential for treating diabetes.” SB 539 § 3.6(1). While not defining “essential,” the Act requires the list to include “all forms of insulin and biguanides” sold in the State. *Id.*<sup>9</sup> In August 2017, the Nevada State Primary Care Office distributed a draft list of “essential diabetes drugs” with 46 major drugs, including Afrezza, Byetta, Duetact, Farxiga, Humulin, Invokana, Janumet, Januvia, Jardiance, Lantus, Nesina, Novolog, PrandiMet, and Trulicity. *See* Ex. D, Draft List of Essential Diabetes Drugs.

Upon release of the final list, the Act requires drug manufacturers, by April 1 of each year, to submit to the Department a report that includes:

- “[t]he costs of producing the drug”;
- “marketing and advertising costs” associated with the drug;
- profit “earned from the drug” and the amount of “total profit” attributable to it;
- the amount spent on “patient prescription assistance program[s]”;

<sup>8</sup> The key exception was dropping the 90-day notice provision for increases in the WAC.

<sup>9</sup> Insulin and biguanides each lower blood glucose through different physiological mechanisms. *See Biguanides (Metformin) for Prediabetes and Type 2 Diabetes*, WebMD, <http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes>.

- the cost of “coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs”;
- the “wholesale acquisition cost of the drug,” defined as “the manufacturer’s list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing date”;
- “[a] history of any increases in the wholesale acquisition cost of the drug” for the prior five years, “including the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective and any explanation for the increase”;
- “[t]he aggregate amount of all rebates” in Nevada; and
- other “information prescribed by regulation . . . for the purpose of analyzing the cost of prescription drugs . . . on the list.”

SB 539 § 3.8.

Any manufacturer that increases the WAC of an “essential” diabetes drug by more than the “Consumer Price Index, Medical Care Component” (“CPI”) during the preceding year, or by double the percentage increase in the CPI for Medical Care over the previous two years, also must disclose:

- “[a] list of each factor that has contributed to the increase”;
- “[t]he percentage of the total increase that is attributable to each factor”;
- “[a]n explanation of the role of each factor”; and
- “[a]ny other information prescribed by regulation.”

*Id.* §§ 3.6(2), 4.

By tying these disclosures to the CPI for Medical Care, the Act penalizes manufacturers whose diabetes drug prices exceed the index. But the CPI for Medical Care is not based only on drug prices. It also reflects prices for professional and hospital services. Effective diabetes drugs reduce doctor and hospital visits and thereby lower the CPI for Medical Care. Thus, on this measure, the more effective the product, the tighter the constraint on its price.

Once manufacturers have submitted the disclosures required by Sections 3.8 and 4, the Department, by June 1 of each year, must analyze them and “report on the price of the prescription drugs that appear on the most current lists . . . , the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State.” *Id.* § 4.3. The Department must post the report on its website, *id.* § 6(a)(5), organized to provide each

1 manufacturer “its own separate entry,” *id.* § 6(b). SB 539 allows the Department to publish the  
2 information, share it widely, or use it for such purposes as negotiating rebates with manufacturers.

3 What is more, SB 539 expressly eliminates trade-secret protection for all the information  
4 manufacturers must disclose. *Id.* § 4.3. Specifically, the Act narrows the definition of “trade secret”  
5 in NRS 600A.030 to exclude “any information that a manufacturer is required to report pursuant to  
6 section 3.8 or 4 of [the Act], . . . to the extent that such information is required to be disclosed by  
7 [that] section[.]” *Id.* § 9(5)(b). Failure to disclose the required information subjects the manufacturer  
8 to an administrative penalty of up to \$5,000 per day. *Id.* § 8(2).

9 The provisions of SB 539 relevant to this lawsuit are effective immediately “for the purpose  
10 of adopting regulations and performing any other [necessary] administrative tasks . . . and on  
11 October 1, 2017, for all other purposes.” *Id.* § 28(3). The Department intends to publish the first list  
12 of “essential” diabetes drugs on October 15, 2017.

### 13 **C. SB 539’s Harm to Plaintiffs’ Members and Innovation of Diabetes Treatments**

14 SB 539 would seriously harm Plaintiffs’ members, including the largest U.S. manufacturers  
15 of diabetes medicines. Several members produce drugs on the Department’s draft list of “essential”  
16 diabetes drugs. *Compare* Ex. D, *with* Ex. E, Decl. of Vanessa Broadhurst, at ¶ 4; Ex. F, Decl. of  
17 James Borneman, at ¶ 6; Ex. G, Decl. of Derek L. Asay, ¶ 4; Ex. H, Decl. of Patrick T. Davish, at  
18 ¶ 4; Ex. I, Decl. of Steve Albers, at ¶ 4; Ex. J, Decl. of Christine Marsh, at ¶ 4. None resides in  
19 Nevada. *See, e.g.*, Ex. F ¶ 3; Ex. I ¶ 3; Ex. J ¶ 3.

20 Eliminating trade secret protection allows competitors of affected manufacturers to freely  
21 use the confidential data the Act requires be disclosed showing a manufacturer’s cost structure,  
22 resource allocation, and pricing practices. Such access by competitors could handicap that  
23 manufacturer in the marketplace. Ex. E ¶ 13; Ex. F ¶¶ 15, 20; Ex. G ¶ 13; Ex. H ¶ 13; Ex. I ¶ 13; Ex.  
24 J ¶ 13. Worse, the factors manufacturers consider and the methodologies they deploy in setting  
25 prices are similar from product to product. Thus, this prejudice could spread to competition  
26 involving non-diabetes products. Similarly, information on a manufacturer’s costs and pricing  
27 formulas can prejudice the company’s ability to negotiate with third-party payers, including Nevada  
28

1 itself, regarding purchases and rebates for all the manufacturer's products. Ex. E ¶ 12; Ex. F ¶¶ 14,  
2 17; Ex. G ¶ 12; Ex. H ¶ 12; Ex. I ¶ 12; Ex. J ¶ 12.

3 The economic harm from SB 539 will be nationwide. Because the WAC is a national  
4 benchmark, SB 539's effective cap on a drug's WAC will apply nationwide. Similarly, the  
5 economic value of trade secrets withers in every state—including those where affected  
6 manufacturers reside—once Nevada makes the information public. The competitive harm from SB  
7 539 will undermine the incentives that patents provide for Plaintiffs' members to invest in  
8 developing innovative diabetes medicines. Ex. E ¶¶ 16–18; Ex. F ¶¶ 19–22; Ex. G ¶¶ 16–18; Ex. H  
9 ¶¶ 16–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 16–18. Absent judicial intervention, SB 539 could force  
10 innovators to revise their current and future priorities for diabetes research and development.

### 11 ARGUMENT

12 “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on  
13 the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the  
14 balance of equities tips in his favor, and that an injunction is in the public interest.” *Winter v. Nat.*  
15 *Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also DiTech Financial LLC v. Am. West Vill. II*  
16 *Owners Ass’n*, No. 2:17-CV-2164, 2017 WL 3610559, at \*1 (D. Nev. Aug. 22, 2017) (applying  
17 same standard for temporary restraining order). Under this Circuit's “serious questions” test, a  
18 temporary restraining order and preliminary injunction are also “appropriate when a plaintiff  
19 demonstrates that serious questions going to the merits were raised and the balance of hardships tips  
20 sharply in the plaintiff's favor.” *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134–35 (9th  
21 Cir. 2011); *accord Johnson v. Nguyen*, No. 3:12-CV-00538, 2015 WL 105826, at \*9 (D. Nev. Jan.  
22 7, 2015).<sup>10</sup> The court must balance “competing claims of injury” and “consider the effect on each

23  
24  
25 <sup>10</sup> Although the Federal Circuit would hear any appeal in this case as a result of Plaintiffs' patent  
26 preemption argument, *see, e.g., Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1365 (Fed. Cir. 2001),  
27 Ninth Circuit law governs whether this Court should grant a temporary restraining order and  
28 preliminary injunction. *See Broadcom Corp. v. Qualcomm Inc.*, No. SACV 05-468, 2005 WL  
5925584, at \*2 (C.D. Cal. Oct. 19, 2005); *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d  
891, 894 (Fed. Cir. 1998).

party” of granting or withholding the requested relief. *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 542 (1987).

Plaintiffs’ constitutional challenges to SB 539 will likely succeed on the merits. In stripping trade-secret protection from manufacturers of patented diabetes medicines, the Act conflicts with federal patent and trade-secret law, destroys valuable intellectual property without compensation, and imposes Nevada’s economic policy on every other state. The loss of trade secrets is irreversible and will not only harm the affected manufacturers, but also weaken national competition and undermine incentives to develop diabetes medicines. This harm outweighs any possible inconvenience to Defendants from postponing the Act’s implementation and enforcement.

## **I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS**

### **A. SB 539 Is Preempted By Federal Patent and Trade-Secret Law**

The Supremacy Clause makes “the Laws of the United States . . . the supreme Law of the Land.” U.S. Const. art. VI, § 1, cl. 2. “Thus, where Congress legislates within the scope of its constitutionally granted powers, that legislation may displace state law.” *Pharm. Research & Mfrs. of Am. v. District of Columbia (PhRMA)*, 406 F. Supp. 2d 56, 64 (D.D.C. 2005), *aff’d sub nom. Biotech. Indus. Org. v. District of Columbia (BIO)*, 496 F.3d 1362 (Fed. Cir. 2007). Even where federal legislation does not explicitly preempt state law, “federal courts [must] inquire whether a[n] implied preemption exists.” *Id.* And implied preemption exists, in the form of “conflict preemption,” where compliance with both state and federal regulation is either a “physical impossibility,” *id.* at 65, or “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

To determine whether a state statute poses such an obstacle, courts scrutinize both the legislature’s purpose and the “law’s actual effect.” *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 105 (1992); *accord BIO*, 496 F.3d at 1372 (“Our conflict inquiry is a searching one that ranges beyond the literal text of the statute.”). In purpose and effect, SB 539 obstructs federal patent and trade-secret laws from achieving their goals. It is therefore preempted.

1                   **1.       SB 539 Conflicts with Federal Patent Law**

2           The Constitution delineates Congress’s paramount role in setting national patent policy,  
3 vesting Congress with the power to “secur[e] for limited Times to Authors and Inventors the  
4 exclusive Right to their respective Writings and Discoveries.” U.S. Const. art. I, § 8, cl. 8. The  
5 stated objective of this clause is to “promote the Progress of Science and useful Arts.” *Id.*

6           Federal patent laws “promote . . . progress by offering a right of exclusion for a limited  
7 period as an incentive to inventors to risk the often enormous costs in terms of time, research, and  
8 development.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). Thus, a patent holder  
9 may “‘exclude all from the use of the protected process or product’ and charge prices of its  
10 choosing, including supracompetitive prices.” *King Drug Co. of Florence, Inc. v. SmithKline*  
11 *Beecham Corp.*, 791 F.3d 388, 400–01 (3d Cir. 2015) (quoting *FTC v. Actavis, Inc.*, 133 S. Ct.  
12 2223, 2231 (2013)); *see also Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) (“The  
13 grant of a patent is the grant of a statutory monopoly . . .”). Patent laws “suppl[y] a carrot in the  
14 form of economic rewards resulting from the right to exclude,” and “the only limitation on the size  
15 of the carrot [of exclusivity] should be the dictates of the marketplace.” *King Instruments Corp. v.*  
16 *Perego*, 65 F.3d 941, 950, 960 (Fed. Cir. 1995).

17           The federal patent system thus “embodies a carefully crafted bargain for encouraging the  
18 creation and disclosure of new, useful, and nonobvious advances in technology and design in return  
19 for the exclusive right to practice the invention for a period of years.” *Bonito Boats, Inc. v. Thunder*  
20 *Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). “Congress, as the promulgator of patent policy, is  
21 charged with balancing these disparate goals. The present patent system reflects the result of  
22 Congress’s deliberations. Congress has decided that patentees’ present amount of exclusionary  
23 power, the present length of patent terms, and the present conditions for patentability represent the  
24 best balance between exclusion and free use.” *BIO*, 496 F.3d at 1373.

25           Patent protection is critical to promote pharmaceutical research and development because  
26 discovering a successful new drug is exceedingly difficult, costly, and rare. By one estimate, “95%  
27 of the experimental medicines that are studied in humans fail to be both effective and safe. . . .  
28 [B]ecause so many drugs fail, large pharmaceutical companies . . . spend \$5 billion per new

1 medicine.”<sup>11</sup> Research and development costs of just the drugs that are ultimately approved are, on  
 2 average, \$2.6 billion, “a 145% increase” over the past decade.<sup>12</sup>

3 To deal with the unique economic challenges of pharmaceutical research and development,  
 4 Congress in the Hatch-Waxman Act, extended the patent term for pharmaceuticals to “create a  
 5 significant, new incentive which would result in increased expenditures for research and  
 6 development, and ultimately in more innovative drugs.” H.R. Rep. No. 98-857(I), at 18 (1984), *as*  
 7 *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 (Committee on Energy and Commerce); *see also BIO*,  
 8 496 F.3d at 1373. Balanced against the need for these incentives to innovate was the goal of  
 9 increasing consumer access to affordable medication. *Andrx Pharms., Inc. v. Biovail Corp. Int’l*,  
 10 256 F.3d 799, 809 (D.C. Cir. 2001). To that end, the Hatch-Waxman Act permits generic versions  
 11 of an innovator’s drug after the patent exclusivity expires. Signing the bill, President Reagan  
 12 reiterated that it “will promote medical breakthroughs and drug innovation by granting drug  
 13 companies up to 5 more years of patent protection for new drugs. And this extension will help  
 14 compensate for the years of patent life lost due to the time-consuming, but essential, testing required  
 15 by the Food and Drug Administration.” Presidential Statement on Signing S. 1538 Into Law, 20  
 16 Weekly Comp. Pres. Doc. 1359 (Sept. 24, 1984).

17 Relying on the incentives in the Hatch-Waxman Act, innovators boosted research and  
 18 development spending from \$3.6 billion in 1984 to more than \$30 billion in 2001.<sup>13</sup> In 2016 alone,  
 19 PhRMA members invested roughly \$65.5 billion in discovering and developing new medicines.<sup>14</sup>  
 20 For example, Novo Nordisk developed NovoLog, a rapid-acting insulin product and one of the most  
 21 widely used diabetes drugs in the United States. Since launching NovoLog, Novo Nordisk has  
 22

23 <sup>11</sup> Matthew Herper, *The Cost of Creating A New Drug Now \$5 Billion, Pushing Big Pharma To*  
*Change*, Forbes.com (Aug. 11, 2013).

24 <sup>12</sup> Rick Mullin, *Tufts Study Finds Big Rise In Cost Of Drug Development*, Chem. & Eng’g News  
 25 (Nov. 20, 2014).

26 <sup>13</sup> *See Recent Developments Which May Impact Consumer Access to, and Demand for,*  
*Pharmaceuticals: Hearing Before the Subcomm. on Health of the House Comm. on Energy and*  
 27 *Commerce*, 107th Cong. (June 13, 2001) (statement of Rep. Barbara Cubin).

28 <sup>14</sup> Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey  
 (Washington, DC: PhRMA, 2017, forthcoming).

continued to invest in improving delivery of the treatment, with patented devices such as a special injection syringe, an injection button, and a dose-setting limiter. By enhancing the convenience and efficacy of treatment, such innovations reduce nonadherence and help patients control blood sugar. The balance struck in the Hatch-Waxman Act has spurred many other innovations in treating diabetes. *See* Compl. ¶¶ 23–28 (innovative diabetes products developed by Plaintiffs’ members).

In *BIO*, the Federal Circuit found that federal patent law preempted legislation at odds with this careful balance. Plaintiffs there challenged a District of Columbia statute prohibiting pharmaceutical manufacturers from selling or supplying a “patented prescription drug that results in the prescription drug being sold in the District for an excessive price.” *BIO*, 496 F.3d at 1365. The court held that the statute was a “clear attempt to restrain . . . excessive [drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers.” *Id.* at 1374. Because Congress—and Congress alone—is the “promulgator of patent policy,” federal patent law preempted the District’s attempt to “re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* at 1373–74.

Like the D.C. law invalidated in *BIO*, SB 539 “attempt[s] to restrain . . . excessive [essential diabetes drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to [Nevada] drug consumers.” *Id.* at 1374. The Act punishes manufacturers if “essential” diabetes drug prices increase more than the “percentage increase in the [CPI for Medical Services] during” the prior year or “[t]wice the percentage increase [in that index]” over the prior two years. SB 539 §§ 3.6(2), 4. The punishment is compelled disclosure of additional confidential pricing information and loss of trade-secret protection for that information. *See supra*, p. 5. The only way a manufacturer can preserve trade-secret protection is by limiting its list price to the *de facto* cap. SB 539 thus restrains patent holders from exercising their right under federal patent law to set prices.

This is precisely why the Federal Circuit in *BIO* struck down the D.C. law, because it “shift[ed] the benefits of a patented invention from inventors to consumers.” 496 F.3d at 1374. The D.C. law did so by prohibiting manufacturers from selling patented prescription drugs at “excessive prices.” Nevada seeks to do so by penalizing manufacturers who, on its measure, excessively raise the price of essential diabetes drugs. Both methods of curtailing federal patent rights are

1 unconstitutional. The preemption analysis is the same whether a local law bans excessive prices and  
 2 then imposes penalties for violating the ban, as the D.C. law did, or imposes penalties for ostensibly  
 3 excessive prices without expressly banning them first. *See Perez v. Campbell*, 402 U.S. 637, 652  
 4 (1971) (states may not “nullify . . . unwanted federal legislation by simply . . . articulating some  
 5 state interest or policy—other than frustration of the federal objective—that would be tangentially  
 6 furthered by the proposed state law”); *cf. Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565–66 (2011)  
 7 (“[T]he Government’s content-based burdens [on speech] must satisfy the same rigorous scrutiny as  
 8 its content-based bans.”). The dispositive question is whether the law “stands as an obstacle to the  
 9 accomplishment and execution of the full purposes and objectives of Congress.” *BIO*, 496 F.3d at  
 10 1372 (quoting *Hines*, 312 U.S. at 67). In this respect, the laws in *BIO* and SB 539 are  
 11 indistinguishable: both “stand[] as an obstacle to the federal patent law’s balance of objectives as  
 12 established by Congress” by “penalizing high prices . . . and thus limiting the full exercise of the  
 13 exclusionary power that derives from a patent.” *BIO*, 496 F.3d at 1374.

14 In many ways, SB 539 is even less compatible with Congress’s comprehensive federal  
 15 patent scheme than was the law in *BIO*. That law only curbed *future* price increases, barring sales of  
 16 patented drugs at “excessive” prices. SB 539 does that *and* punishes manufacturers for *past* price  
 17 increases. It singles out a class of private companies—makers of essential diabetes drugs—because  
 18 Nevada deems their past prices excessive. *See, e.g.*, Mar. 29 Mins at 33, 36–37, 58–60; May 26  
 19 Mins. at 3. The Act requires these companies alone to disclose confidential, competitively critical,  
 20 proprietary information detailing costs, pricing factors, advertising plans, and marketing strategies  
 21 for their patented diabetes medicines. *See* SB 539 § 3.8. The Act also wipes out trade-secret  
 22 protection for this information. *Id.* § 9. Like many retrospective penalties, SB 539 also has a  
 23 prospective effect. It deters the enormous investment needed to develop new diabetes medicines,  
 24 because when manufacturers seek to recoup their investments by setting prices as federal patent law  
 25 contemplates, the State will punish them for doing so. Thus, both retroactively and prospectively,  
 26 SB 539 burdens pharmaceutical innovators’ exercise of the right the federal patent laws confer.

## 2. SB 539 Conflicts with Federal Trade-Secret Law

Federal and state trade-secret laws also play an important role in sustaining the American economy. Legal protection for trade secrets “encourage[s] invention in areas where patent law does not reach, and . . . prompt[s] the independent innovator to proceed with the discovery and exploitation of his invention.” *Kewanee Oil*, 416 U.S. at 485. In the end, “[c]ompetition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention.” *Id.*

Every U.S. state protects trade secrets. Forty-eight states, including Nevada, have adopted some form of the Uniform Trade Secrets Act (“UTSA”). *See* H.R. Rep. No. 114-529, at 4 (2016) (Committee on the Judiciary); *Frantz v. Johnson*, 999 P.2d 351, 357–58 (Nev. 2000). The remaining two states—New York and Massachusetts—protect trade secrets under the longstanding common-law tort of misappropriation. *See Ashland Mgmt. Inc. v. Janien*, 624 N.E.2d 1007, 1012 (N.Y. 1993); *Peabody v. Norfolk*, 98 Mass. 452, 457 (1868).

Against this backdrop, Congress passed the Defend Trade Secrets Act (“DTSA”) of 2016, creating a federal private right of action for misappropriation of trade secrets “related to a product or service used in, or intended for use in, interstate or foreign commerce.” Pub. L. No. 114-153, 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)). Congress enacted the DTSA because “trade secrets are increasingly becoming the foundation of businesses across the country, with one estimate placing the value of trade secrets in the United States at \$5 trillion. . . . With so much at stake, it is absolutely vital . . . [to] include strong protections against the theft of trade secrets.” 162 Cong. Rec. H2028-01, H2033 (Apr. 27, 2016) (comments of Rep. Nadler). “By improving trade secret protection,” Congress sought “to incentivize future innovation while protecting and encouraging the creation of American jobs.” S. Rep. No. 114-220, at 3 (2016).

Even though all states protected trade secrets, Congress worried that state trade-secret “laws vary in a number of ways and contain built-in limitations that make them not wholly effective in a national and global economy.” H.R. Rep. No. 114-529, at 4. The DTSA therefore provides U.S. businesses a uniform remedy for misappropriation because “trade secret cases often require swift action by courts across state lines to preserve evidence.” *Id.* “[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist.” 162 Cong. Rec.

H2034 (comments of Rep. Jackson Lee). Thus, the DTSA allows businesses “to move quickly to Federal court . . . to stop trade secrets from winding up being disseminated and losing their value.” H.R. Rep. No. 114-529, at 6; *see also id.* at 13; *accord* S. Rep. No. 114-220, at 3.

SB 539 frustrates Congress’s purpose to provide an effective nationwide remedy for misappropriation of trade secrets. The Act compels manufacturers to disclose confidential information that derives independent value from not being generally known to third-party payers and competitors. Ex. E ¶¶ 6, 9; Ex. F ¶¶ 8, 11; Ex. G ¶¶ 6, 9; Ex. H ¶¶ 6, 9; Ex. I ¶¶ 6, 9; Ex. J ¶¶ 6, 9. This information is a trade secret under the DTSA as well as Nevada law—unless and until SB 539 takes effect.<sup>15</sup> *See, e.g., Aerodynamics Inc. v. Caesars Entm’t Operating Co.*, No. 2:15-CV-01344, 2015 WL 5679843, at \*8 (D. Nev. Sept. 24, 2015) (“confidential pricing information, . . . marketing strategies, . . . exact pricing for [certain] bid[s], payment terms, and credits and discounts provided” held trade secrets under state law); *Finkel v. Cashman Prof’l, Inc.*, 270 P.3d 1259, 1263 (Nev. 2012) (“confidential pricing structures and marketing plans” were trade secrets); *see also* Compl. ¶ 86 (collecting additional cases). Further, as noted, the Act eliminates trade-secret protection for information that a manufacturer is required to report, SB 539 § 9, allows the Department to freely use or disseminate the disclosed information, and *directs* the Department to post a report matching the information to each manufacturer. *Id.* § 6(a)(5), (b).

Once published under the authority of SB 539, a manufacturer’s information loses its trade-secret status not just in Nevada, but nationwide. Fundamental to the definition of a trade secret is that it remains confidential. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984) (“Because of the intangible nature of a trade secret, the extent of the property right therein is defined by the extent to which the owner of the secret protects his interest from disclosure to others.”). Thus, information broadcast over the Internet has become “public knowledge” and no longer remains a trade secret.

---

<sup>15</sup> Because Congress modeled the DTSA definition of “trade secret” on the UTSA definition, “courts may look to the state UTSA when interpreting the DTSA.” *Kuryakyn Holdings, LLC v. Ciro, LLC*, No. 15-CV-703-JDP, 2017 WL 1026025, at \*5 (W.D. Wis. Mar. 15, 2017); *see also* H.R. Rep. 114-529, at 14 (“[T]he Committee does not intend for the definition of a trade secret to be meaningfully different from . . . [those] States that have adopted the UTSA.”).

1 *Id.*; *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir. 2002) (en banc) (it is “paradigmatic” that  
2 compelled disclosure to a party not required to keep the secret extinguishes the property right).

3 The difference between SB 539 and the DTSA (plus other states’ laws) is not merely a  
4 matter of nuance. SB 539 guts the trade-secret protection afforded by the federal government and  
5 every state for confidential information associated with essential diabetes drugs. This mass  
6 nullification frustrates Congress’s goal in the DTSA to enhance trade-secret protections and thereby  
7 to “incentivize future innovation while protecting and encouraging the creation of American jobs.”  
8 S. Rep. No. 114-220, at 3. SB 539 thus “stands as an obstacle to the accomplishment and execution  
9 of the full purposes and objectives of Congress.” *Hines*, 312 U.S. at 67.

10 **B. SB 539’s Uncompensated Abolition of Trade-Secret Protection for Valuable**  
11 **Information Violates the Fifth Amendment Takings Clause**

12 The Fifth and Fourteenth Amendments forbid the taking of “private property . . . for public  
13 use, without just compensation.” U.S. Const., amend. V, XIV. “Private property” includes  
14 intangible property, such as trade secrets. *Ruckelshaus*, 467 U.S. at 1002–04. A state’s “failure to  
15 provide adequate protection to assure [a trade secret’s] confidentiality, when disclosure is  
16 compelled . . . , can amount to an unconstitutional taking of property by destroying [the trade  
17 secret], or by exposing it to the risk of destruction by public disclosure or by disclosure to  
18 competitors.” *St. Michael’s Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981)  
19 (alteration omitted) (quoting *Wearly v. FTC*, 462 F. Supp. 589, 598 (D.N.J. 1978)).

20 In *Ruckelshaus*, the Supreme Court held that the Environmental Protection Agency (EPA)  
21 impermissibly took property without compensation by disclosing pesticide manufacturers’ trade  
22 secrets collected under EPA’s regulatory authority. 467 U.S. at 1016. A prior version of the statute  
23 had required EPA to keep confidential all information that manufacturers designated as trade  
24 secrets. *Id.* at 990–97. However, the revised statute authorized EPA to disclose this information to  
25 competitors for regulatory purposes so long as they agreed to pay for it and, if necessary, submit to  
26 arbitration over the price. *Id.* The Court held that this revision violated the Takings Clause because  
27 the manufacturer had disclosed the information with the expectation it would remain secret but then  
28

found that the information was available to any competitor willing to arbitrate over the price. *Id.* at 1011; *see also Reilly*, 312 F.3d at 41–42; *St. Michael’s*, 643 F.2d at 1374.

The Supreme Court explained that “[t]he right to exclude others is generally one of the most essential sticks in the bundle of [property] rights,” and for trade secrets “the right to exclude others is central to the very definition of the property interest.” *Ruckelshaus*, 467 U.S. at 1011. Under the revised statute, EPA (like Nevada) was “extinguish[ing]” trade secrets through public disclosure. *Id.* at 1002. Eliminating confidentiality, the essence of the property right, defeated manufacturers’ investment-backed expectations. *Id.* at 1011–12. The expectations were reasonable because the information had trade-secret protection when generated. *Id.* at 1013; *Reilly*, 312 F.3d at 41. Disclosure destroyed its value as a trade secret. *Ruckelshaus*, 467 U.S. at 1012. Although the Court typically considered “several factors . . . when determining whether a governmental action has gone beyond ‘regulation’ and effects a ‘taking’”—such as “the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations,” *id.* at 1005—the Court found the depredation of the manufacturers’ investment-backed expectations dispositive because “the force of this factor [was] so overwhelming,” *id.* In other words, this taking was “categorical.” *Id.* at 1012; *see also Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992) (destruction of core property interest is a categorical taking).

Like the statute at issue in *Ruckelshaus*, SB 539 extinguishes pharmaceutical manufacturers’ property interest in the confidentiality of their trade secrets and thus works a categorical taking. Manufacturers investing in diabetes treatments had reasonable “investment-backed expectations” that their confidential information would remain secret. *See Reilly*, 312 F.3d at 40. For many years Nevada—like every other state—treated this information as a trade secret, with no diabetes exception. *See, e.g., Nev. Rev. Stat § 600A.030* (1987); *Finkel*, 270 P.3d at 1263; *Frantz*, 999 P.2d at 359. SB 539, however, strips trade-secret protection and *mandates* public disclosure of confidential information, eradicating trade-secret protection in other states. *See Ruckelshaus*, 467 U.S. at 1011–12; *see also* 162 Cong. Rec. H2034 (“[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist.” (comments of Rep. Jackson Lee))). This is precisely the result that the Supreme Court held unconstitutional.

The other two factors in the takings analysis, while cumulative, *see Ruckelshaus*, 467 U.S. at 1005; *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978), reconfirm that the Act is an impermissible taking. First, the “character” of this legislative action weighs heavily against the Act. For punishment and coercion, it discloses trade secrets, causing them to “lose all value.” *Reilly*, 312 F.3d at 41 (citing this aspect of state disclosure statute’s “character” to show a regulatory taking). “Therefore, if the [pharmaceutical manufacturers] comply with the requirements of [SB 539], their property right will be extinguished.” *Id.* at 42. “[T]his is precisely what the Takings Clause is designed to prevent.” *Id.* at 43.

Second, eliminating trade-secret protection here will have a devastating “economic impact.” Manufacturers of essential diabetes drugs, if forced to disclose such information, will be at a severe disadvantage vis-à-vis competitors not subject to the Act. *See supra*, p. 8. Affected manufacturers, but not manufacturers of non-diabetes drugs, also will be disadvantaged in dealing with third-party payers, who have the manufacturer’s playbook in negotiations. *See supra*, p. 8.

These adverse effects extend beyond Nevada to the entire Nation. Ex. E ¶¶ 10–14; Ex. F ¶¶ 12–17; Ex. G ¶¶ 10–14; Ex. H ¶¶ 10–14; Ex. I ¶¶ 10–13; Ex. J ¶¶ 10–14. As noted, for trade secrets, disclosure anywhere is disclosure everywhere. *See supra*, pp. 8–9. A trade secret published in Nevada is useable in New York, Ohio, or any other state. This nationwide geographic scope amplifies the competitive harm to, and hence the penalty on, Plaintiffs’ members for exercising the right federal patent law confers to set prices for their diabetes products. Manufacturers relied on the protection that the federal government, Nevada, and every other state afforded trade secrets. These companies did not expect Nevada to overturn that protection everywhere. Nor did they expect the consequent economic impact: the nationwide erosion of anticipated returns on their investments in researching, developing, and marketing their diabetes drugs. Ex. E ¶¶ 15–18; Ex. F ¶¶ 18–21; Ex. G ¶¶ 15–18; Ex. H ¶¶ 15–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 15–18.

### C. SB 539 Violates the Commerce Clause by Overriding Every Other State’s Laws

The Constitution authorizes Congress “[t]o regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. The Commerce Clause “reflect[s] a central concern of the Framers . . . : the conviction that in order to succeed, the new Union would have to avoid the

tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.” *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979). Thus, the Supreme Court has “long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute.” *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This is the “so-called ‘dormant’ aspect of the Commerce Clause.” *Id.*

A state law oversteps these constitutional limits when it imposes a burden on interstate commerce “clearly excessive in relation to the putative local benefits.” *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). The dormant Commerce Clause “prohibits states . . . from regulating interstate commerce and enacting legislation that would ‘offend sister States and exceed the inherent limits of the State’s power.’” *PhRMA*, 406 F. Supp. 2d at 67 (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336 n.13 (1989)). SB 539 violates this principle by imposing sanctions for out-of-state conduct and nullifying rights that all other states grant.

First, SB 539 restrains PhRMA and BIO members’ commerce in other states by penalizing them in Nevada. The Act’s price cap is keyed to the WAC, a *national* benchmark. By affecting a drug’s WAC, SB 539 affects drug prices *nationally*, including for drugs bought and sold outside Nevada. A New York manufacturer of essential diabetes drugs selling to a California purchaser must lower its price to prevent Nevada from negating the company’s trade secrets. The dormant Commerce Clause bars Nevada from imposing such burdens on wholly extraterritorial commerce.

Again, *BIO* is instructive. Besides holding the D.C. law preempted by federal patent law, the district court found that the law’s “impermissible extraterritorial reach” violated the dormant Commerce Clause. *PhRMA*, 406 F. Supp. 2d at 70. The court stressed that Plaintiffs’ members “manufacture patented prescription drugs wholly outside the District of Columbia,” are neither headquartered nor operate warehouses there, and make “the overwhelming majority of [their] sales” outside D.C. to out-of-state wholesalers. *Id.* at 68. “[T]he critical inquiry” was “whether the practical effect of the [law was] to control conduct beyond the boundaries of the State.” *Id.* at 70 (quoting *Healy*, 491 U.S. at 336). It was indeed, as Plaintiffs’ members could not “conduct commerce on their own terms elsewhere, without either scrutiny or control by the District.” *Id.*

1 The same is true of SB 539. By penalizing manufacturers for increasing the WAC of  
 2 diabetes drugs above the CPI for Medical Care, SB 539 prevents them from “conduct[ing]  
 3 commerce on their own terms elsewhere, without either scrutiny or control by [Nevada].” *Id.* Such a  
 4 statute “offend[s] sister States and exceed[s] the inherent limits of [Nevada’s] power.” *Id.* at 67.

5 Second, SB 539 burdens interstate commerce by eviscerating commercial rights other states  
 6 grant, stripping a broad compass of trade-secret protection for *all* manufacturers of essential  
 7 diabetes drugs, whatever the prices they charge. *See* SB 539 §§ 3.8, 9. None of these companies is  
 8 headquartered in Nevada. SB 539 will prevent manufacturers from protecting their trade secrets in  
 9 every state. This imposition will interfere in particular with states that host these manufacturers’  
 10 headquarters or key operations. Those jurisdictions have a legitimate interest—which Nevada  
 11 overrides—in promoting the success of these manufacturers by protecting their trade secrets. *See*  
 12 *Healy*, 491 U.S. at 336–37 (“[T]he Commerce Clause protects against inconsistent legislation  
 13 arising from the projection of one state regulatory regime into the jurisdiction of another State.”).

14 For example, Eli Lilly—one of three major insulin manufacturers—is headquartered in  
 15 Indianapolis, Indiana, with *no* offices or operations in Nevada. Indiana law protects Eli Lilly’s trade  
 16 secrets—including pricing and cost information for its essential diabetes drugs. *See, e.g., Hydraulic*  
 17 *Exch. & Repair, Inc. v. KM Specialty Pumps, Inc.*, 690 N.E.2d 782, 786 (Ind. Ct. App. 1998).  
 18 Indiana has an interest in protecting that confidential information to preserve the company’s  
 19 financial strength, which affects local jobs and economic growth. In compelling the disclosure of  
 20 information that is a trade secret under Indiana law, SB 539 overturns Indiana’s protection. SB 539  
 21 bestows upon Nevada legislators supreme judgment as to the proper balance between the protection  
 22 of trade secrets and the promotion of “transparency” in pricing. The dormant Commerce Clause  
 23 does not tolerate such efforts by one state to foist its regulatory preferences on every other state.

24 These substantial effects on interstate commerce clearly exceed any putative local benefit  
 25 SB 539 may have in Nevada. While the purpose of the Act is to control prices for diabetes drugs,  
 26 neither the Act nor its legislative history explains how gutting manufacturers’ trade-secret  
 27 protection will lower prices—apart, that is, from impermissibly burdening manufacturers’ lawful  
 28 exercise of federal patent rights. *See, e.g., Mar. 29 Mins.* at 33, 36–37, 58–60; *May 26 Mins.* at 3.

1 Nevada’s attempt to “extend [its] police power beyond its jurisdictional bounds” offends the  
2 dormant Commerce Clause. *C & A Carbone v. Town of Clarkstown*, 511 U.S. 383, 393 (1994).

3 **II. PLAINTIFFS’ MEMBERS WILL SUFFER IRREPARABLE HARM ABSENT A**  
4 **TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTIVE**  
5 **RELIEF**

6 “Irreparable harm is traditionally defined as harm for which there is no adequate legal  
7 remedy, such as an award of damages.” *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th  
8 Cir. 2014). It is “presumed where a party misappropriates a trade secret.” *Excellence Cmty. Mgmt.,*  
9 *LLC v. Gilmore*, 351 P.3d 720, 724 (Nev. 2015) (presumption where use of stolen trade secret was  
10 ongoing or imminent); *see also Finkel*, 270 P.3d at 1264; *Saini v. Int’l Game Tech.*, 434 F. Supp. 2d  
11 913, 919 (D. Nev. 2006) (“[D]isclosure of confidential information or trade secrets would create  
12 irreparable injury . . .”). “[I]t is axiomatic that unprotected disclosure of a trade secret destroys the  
13 secret.” 4 Robert M. Milgrim & Eric E. Bensen, *Milgrim on Trade Secrets* § 15.02[1][c].

14 The challenged provisions of SB 539 become effective on October 1, 2017, and officially  
15 strip affected manufacturers of trade-secret protection for their confidential data as soon as the  
16 Department publishes its list of “essential” diabetes drugs, which Defendants represent will happen  
17 on October 15, 2017—just weeks from now. *See* SB 539 § 28(3). Furthermore, the Act compels  
18 disclosure no later than April 1, 2018. The Department then has free rein to disseminate the  
19 information. Faced with this forced disclosure, Plaintiffs’ members must immediately reassess the  
20 risks and returns of their investments in diabetes therapies. *See* Ex. E ¶¶ 16–18; Ex. F ¶¶ 19–22; Ex.  
21 G ¶¶ 16–18; Ex. H ¶¶ 16–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 16–18. “[Such] harms, which are not readily  
22 addressed through payment of economic damages, are sufficient to meet the irreparable injury  
23 requirement for a preliminary injunction.” *Saini*, 434 F. Supp. 2d at 919; *accord Aerodynamics*,  
24 2015 WL 5679843, at \*12. Only a temporary restraining order and preliminary injunction can  
25 prevent irreparable harm by protecting trade secrets pending resolution of this litigation.

26 **III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST SUPPORT A**  
27 **TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

28 The balance of hardships decisively favors a temporary restraining order and preliminary  
injunction. Where, as here, a “plaintiff shows a substantial likelihood that the challenged law is

1 unconstitutional, no substantial harm to others can be said to inhere in its enjoinderment.” *Déjà vu of*  
 2 *Nashville, Inc. v. Metro. Gov’t of Nashville & Davidson Cty.*, 274 F.3d 377, 400 (6th Cir. 2001);  
 3 *accord Nelson v. NASA*, 530 F.3d 865, 881–82 (9th Cir. 2008) (constitutional violation tips balance  
 4 of hardships “sharply toward” party seeking injunction), *rev’d on other grounds*, 562 U.S. 134  
 5 (2011). Because Plaintiffs have shown a likelihood of success on their constitutional claims, the  
 6 balance of hardships favors them, and the Court need not assess any potential effect on Defendants.

7 In any event, the only arguable “hardship” to Defendants is a possible delay in  
 8 implementation of the Act. Even if publication of the list of “essential” diabetes drugs were  
 9 postponed temporarily, any inconvenience resulting from the delay would pale compared to the  
 10 substantial and irreparable harm that the Act would inflict on Plaintiffs’ members.

11 Finally, the public interest strongly favors a temporary restraining order pending disposition  
 12 of Plaintiffs’ motion for a preliminary injunction, and a preliminary injunction pending resolution of  
 13 this case. “[I]t is always in the public interest to prevent the violation of a party’s constitutional  
 14 rights.” *Sw. Voter Registration Educ. Project v. Shelley*, 344 F.3d 882, 910 (9th Cir.), *rev’d on other*  
 15 *grounds*, 344 F.3d 914 (9th Cir. 2003); *see also Preminger v. Principi*, 422 F.3d 815, 826 (9th Cir.  
 16 2005) (similar). And “there is a strong public interest in protecting trade secrets, as evidenced by the  
 17 existence of the DTSA and UTSA.” *Prot. Techs., Inc. v. Ribler*, 2017 WL 923912, at \*3 (D. Nev.  
 18 Mar. 8, 2017). Allowing SB 539 to take effect could undermine public health by upending  
 19 Congress’s carefully crafted a system of incentives encouraging the development of new medicines.  
 20 It is therefore in the public interest to preserve the *status quo* while the Court considers SB 539’s  
 21 constitutional defects.

## 22 CONCLUSION

23 SB 539 interferes with federal patent and trade-secret laws, deprives manufacturers of  
 24 property rights in their trade secrets, and improperly overrides the regulatory choices of every other  
 25 state. These violations threaten irreparable harm to Plaintiffs’ members, and ultimately, diabetes  
 26 patients. Plaintiffs therefore respectfully ask the Court to temporarily restrain and preliminarily  
 27  
 28

1 enjoin Defendants from implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, and 9 of SB 539,  
2 and all related sections or subsections.

3 Dated: September 13, 2017.

4 McDONALD CARANO LLP

6 By: /s/ Pat Lundvall

7 Pat Lundvall

8 2300 West Sahara Avenue, Suite 1200

9 Las Vegas, NV 89102

Telephone: (702) 873-4100

Facsimile: (702) 873-9966

10 Robert N. Weiner

11 Jeffrey L. Handwerker

12 R. Stanton Jones

ARNOLD & PORTER KAYE SCHOLER LLP

601 Massachusetts Avenue, NW

Washington, DC 20001

Telephone: (202) 942-5000

Facsimile: (202) 942-5999

15 *Attorneys for Plaintiffs Pharmaceutical Research and*  
16 *Manufacturers of America and Biotechnology*  
17 *Innovation Organization*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that I am an employee of McDonald Carano LLP, and that on this 13th day of September, 2017, I caused a true and correct copy of the foregoing **PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION, AND SUPPORTING MEMORANDUM OF POINTS AND AUTHORITIES** to be served via HAND DELIVERY upon the following:

Linda C. Anderson  
Chief Deputy Attorney General  
555 E. Washington, #3900  
Las Vegas, NV 89101  
Phone: (702) 486-3077

*Counsel for Defendants*

/s/ Marianne Carter  
An employee of McDonald Carano LLP

**INDEX OF EXHIBITS**

<b><u>Description</u></b>	<b><u>Exhibit No.</u></b>
Nevada State Senate Bill No. 539	A
June 2, 2017 Letter from Gov. Sandoval to Sen. Majority Leader Ford	B
Chart of FDA-Approved Diabetes Medicines	C
List of Essential Diabetes Drugs	D
Declaration of Vanessa Broadhurst	E
Declaration of James Borneman	F
Declaration of Derek L. Asay	G
Declaration of Patrick T. Davish	H
Declaration of Steve Albers	I
Declaration of Christine Marsh	J

# EXHIBIT 7

# EXHIBIT 7

Pat Lundvall (NSBN 3761)  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
lundvall@mcdonaldcarano.com

Robert N. Weiner  
Admitted *Pro Hac Vice*  
Jeffrey L. Handwerker  
Admitted *Pro Hac Vice*  
R. Stanton Jones  
Admitted *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA and  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as  
Governor of the State of Nevada; RICHARD  
WHITLEY, in his official capacity as Director of  
the Nevada Department for Health and Human  
Services; and the NEVADA LEGISLATURE,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

**JOINT STATUS REPORT**

Plaintiffs Pharmaceutical Research and Manufacturers of America (“PhRMA”) and  
Biotechnology Innovation Organization (“BIO”) (together, “Plaintiffs”), and Defendants Brian

Sandoval, in his official capacity as Governor of the State of Nevada (the “State”), Richard Whitley, in his official capacity as Director of the Nevada Department of Health and Human Services (the “Department”), and the Nevada Legislature (the “Legislature”) (together, “Defendants”), by and through their respective undersigned counsel, hereby submit this joint status report to apprise the Court of their collective views regarding the implications of the now-effective regulation adopted by the Department, LCB File No. R042-18 (Joint Status Report Ex. 1), and the State’s subsequent actions on this litigation.

*First*, as the Court is aware, the Department previously issued a proposed regulation (ECF No. 86-1) designed to mitigate the constitutional concerns that Plaintiffs raised with respect to Nevada Senate Bill No. 539 (“SB 539”). Plaintiffs argued that the challenged provisions of SB 539, including the provision that excludes from the definition of “trade secret” “any information that a manufacturer is required to report pursuant to section 3.8 or 4 of [SB 539],” *see* SB 539 § 9, are preempted by the federal patent laws and the federal Defend Trade Secrets Act (“DTSA”), and also violate the Fifth Amendment Takings Clause and the dormant Commerce Clause. The Department argued that Plaintiffs’ claims were not ripe for review because “the Department is not exempt from exposure for liability under [the] DTSA if the Department were to disclose a federally defined trade secret without consent from the manufacturer who asserted that secrecy. Plaintiffs have a separate, stand-alone remedy under [the] DTSA that affords protection for their trade secrets if they need to challenge any action of the Department.” *Opp’n to Pls.’ Mot. Summ. J. 4*, ECF No. 74. Further, the Department also argued that “[t]o the extent that the state law fails to set forth a process for protecting trade secrets that could be subject to dissemination under SB 539, the void will be filled by regulations of the Department.” *Id.* at 4–5.

On May 31, 2018, the Department accelerated its anticipated timeline and adopted the proposed regulation, which became effective that same date (Joint Status Report Ex. 1 at 1). Defendants believe that, as predicted, the now-effective regulation has filled any void and obviated Plaintiffs’ alleged facial constitutional claims. Under the now-effective regulation, pharmaceutical manufacturers may request that information they submit to the Department pursuant to Sections 3.8 and 4 of SB 539 be kept confidential as trade secrets under the DTSA. *See* Regulation § 3 (Joint

Status Report Ex. 1 at 6-10). To request such confidentiality, the manufacturer must (1) “describe, with particularity, the information sought to be protected from public disclosure,” *id.* § 3(2)(a); and (2) “include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal [DTSA], as amended,” *id.* § 3(2)(b).

Under the DTSA, a court may award relief where a trade secret is “misappropriated,” which the DTSA defines to include “disclosure or use of a trade secret of another without express or implied consent by a person who . . . at the time of disclosure or use, knew or had reason to know that the knowledge of the trade secret was . . . acquired under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret.” 18 U.S.C. § 1839(5)(B)(ii)(II). The parties agree and acknowledge that, under SB 539, the Department may acquire manufacturer trade secrets, such as a manufacturer’s costs of production and other internal costs, “under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret.” *Id.* Thus, the parties agree and acknowledge that, so long as such trade secrets continue to satisfy the definition of “trade secret” in 18 U.S.C. § 1839, if the Department were to disclose such trade secrets to any third party or use such trade secrets, such disclosure or use would constitute “misappropriation” for which a court may award relief pursuant to the DTSA. These protections are intended to afford an opportunity to manufacturers that submit trade secrets to the Department to seek to safeguard their interests in the confidentiality of those trade secrets. In Defendants’ view, the now-effective regulation, as described, resolves the alleged facial constitutional issues with respect to the challenged provisions of SB 539.

*Second*, on June 7, 2018, the Department represented on its website that it would not proceed with enforcement actions for manufacturer reports submitted on or before January 15, 2019. The Department has further assured Plaintiffs through email correspondence that it will not bring any enforcement action against any manufacturer based on the submission of an incomplete report or no report during this time period, so long as the manufacturer submits a compliant report on or before January 15, 2019. On the basis of these representations, on June 8, 2018, Plaintiffs withdrew their renewed motion for a preliminary injunction without prejudice.



**McDONALD**  **CARANO**

2300 WEST SAHARA AVENUE, SUITE 1200 • LAS VEGAS, NEVADA 89102  
PHONE 702.873.4100 • FAX 702.873.9966

/s/ Kevin C. Powers

Kevin C. Powers  
Chief Litigation Counsel  
Nevada Bar No. 6781  
Nevada Legislative Counsel Bureau, Legal Division  
401 S. Carson Street  
Carson City, Nevada 89701  
Telephone: (775) 684-6830  
kpowers@lcb.state.nv.us

*Attorney for Defendant Nevada Legislature*

### **CERTIFICATE OF SERVICE**

I certify that I am an employee of McDonald Carano, and that on the 28<sup>th</sup> day of June, 2018, a true and correct copy of the foregoing JOINT STATUS REPORT was electronically filed with the Clerk of the Court by using CM/ECF service which will provide copies to all counsel of record registered to receive CM/ECF notification.

/s/ Beau Nelson

An employee of McDonald Carano LLP

# EXHIBIT 1

SECRETARY OF STATE  
FILING DATA



FILED.NV.SOS  
2018 MAY 31 PM4:42

**Form For Filing  
Administrative Regulations**

**Agency:  
Department of Health and Human  
Services**

FOR EMERGENCY  
REGULATIONS ONLY

Effective date \_\_\_\_\_

Expiration date \_\_\_\_\_

\_\_\_\_\_  
Governor's signature

**Classification:**     **PROPOSED**   **X**   **ADOPTED BY AGENCY**     **EMERGENCY**

**Brief description of action:**

The adopted regulation outlines how the Department of Health and Human Services will support submission of certain reports by manufacturers of prescription drugs, pharmacy benefit managers and pharmaceutical sales representatives by providing forms online. It describes the process by which a manufacturer or pharmacy benefit manager can submit a request for confidentiality covering certain information. Lastly, it describes procedures the Department will follow when public information requests for information are filed and for which a confidentiality request has been submitted.

**Authority citation other than 233B:**

**Notice date:**     January 30, 2018; April 30, 2018

**Date of Adoption by Agency:** May 31, 2018

**Hearing date:** February 15, 2018; May 31, 2018

**APPROVED REGULATION OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**LCB File No. R042-18**

Effective May 31, 2018

EXPLANATION – Matter in *italics* is new; matter in brackets ~~[omitted material]~~ is material to be omitted.

AUTHORITY: §§1-4, NRS 439.930.

A REGULATION relating to prescription drugs; providing that the Department of Health and Human Services will make available on an Internet website maintained by the Department certain forms that must be used by manufacturers of prescription drugs, pharmacy benefit managers and pharmaceutical sales representatives to submit certain reports to the Department; authorizing a manufacturer or pharmacy benefit manager that submits such a report to request that the Department keep certain information confidential as a trade secret under federal law; establishing procedures for the Department to follow when it receives a request for public records seeking disclosure of information for which a manufacturer or pharmacy benefit manager has submitted a request for confidentiality; prescribing certain requirements for reports compiled by the Department concerning the prices of certain prescription drugs; and providing other matters properly relating thereto.

**Legislative Counsel's Digest:**

Existing law requires the Department of Health and Human Services to compile each year: (1) a list of prescription drugs essential for treating diabetes in this State; and (2) a list of such prescription drugs which have been subject to an increase in wholesale acquisition cost that exceeds a prescribed amount. (Section 3.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4297 (NRS 439B.630)) Existing law also requires the manufacturers of drugs that appear on those lists and pharmacy benefit managers to submit to the Department annual reports containing certain information about the prices of those drugs. (Sections 3.8, 4 and 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 and 439B.645)) Existing law further requires a pharmaceutical sales representative who markets prescription drugs on behalf of a manufacturer in this State to submit to the Department an annual report concerning the provision of compensation and free samples to certain persons. (Section 4.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.660)) **Section 2** of this regulation provides that the Department will make

available on an Internet website maintained by the Department the forms that must be used by the manufacturers, pharmacy benefit managers and pharmaceutical sales representatives to submit such annual reports.

Under existing law, commonly known as the Nevada Public Records Act, when a state or local governmental entity receives a request to disclose information contained in public records within its legal custody or control, the governmental entity must disclose the information, unless the information is confidential under state or federal law. (NRS 239.010; *City of Reno v. Reno Gazette-Journal*, 119 Nev. 55, 58-61 (2003)) Upon receiving such a request for public records, the governmental entity must respond to the requester within five business days by doing one of the following: (1) if the requested information is confidential under state or federal law, the governmental entity must provide the requester with written notice of the denial of the request and a citation to the specific statute or other legal authority that makes the information confidential; (2) if the requested information is not confidential under state or federal law and the governmental entity is able to make the information available within those five business days, the governmental entity must provide the requester with the information; or (3) if the governmental entity is unable to make the information available within those five business days, the governmental entity must provide the requester with written notice of that fact and a date and time after which the information will be made available. (NRS 239.0107)

Under existing federal law, when a state or local governmental entity is exercising its powers and duties under state or local law, the governmental entity must also comply with federal law, which supersedes any conflicting state or local law, because federal law is the supreme law of the land under the Supremacy Clause of the United States Constitution. (U.S. Const. Art. VI, cl. 2; *Alden v. Maine*, 527 U.S. 706, 755 (1999)) For example, if information is provided to state governmental entities and maintained in their databases as part of state regulatory programs and the information has potential commercial value in interstate commerce, Congress may exercise its power under the Commerce Clause of the United States Constitution to prohibit the state governmental entities from disclosing the information, even if such disclosure is authorized by state law. (U.S. Const. Art. I, § 8, cl. 3; *Reno v. Condon*, 528 U.S. 141, 143-51 (2000))

In the context of trade secrets related to products or services used in interstate commerce, Congress has exercised its power under the Commerce Clause to enact the federal Defend Trade Secrets Act of 2016 (DTSA), which authorizes the owner of a trade secret to bring a civil action to prevent the improper disclosure of information that would constitute misappropriation of a trade secret under federal law and, if such information is improperly disclosed, to provide remedies for violations of the federal law. (18 U.S.C. § 1836) In such a civil action brought under the federal DTSA, a court of competent jurisdiction may award legal and equitable relief, including protective orders, injunctive relief, compensatory damages, punitive damages and attorney's fees, to the owner of a trade secret to prevent or remedy violations of the federal law. (18 U.S.C. §§ 1833-1839) In addition to the remedies established by the federal DTSA, federal

law also prohibits certain conduct that constitutes theft of a trade secret and prescribes criminal penalties for such violations. (18 U.S.C. § 1832)

Because information that constitutes a trade secret may be submitted to federal agencies, the federal Trade Secrets Act prohibits federal officers and employees from disclosing such information, unless the disclosure is specifically authorized by federal law. (18 U.S.C. § 1905; *Chrysler Corp. v. Brown*, 441 U.S. 281, 294-319 (1979)) As a result of this federal prohibition, when federal agencies receive requests for public records under the federal Freedom of Information Act (FOIA), the federal agencies cannot disclose information that constitutes a trade secret under the federal Trade Secrets Act, and such information is also exempt from disclosure under the “trade secrets” exemption in FOIA, which is commonly referred to as “Exemption 4.” (5 U.S.C. § 552(b)(4); 18 U.S.C. § 1905; *Canadian Commercial Corp. v. Dep’t of Air Force*, 514 F.3d 37, 39 (D.C. Cir. 2008); *Pac. Architects & Eng’rs v. Dep’t of State*, 906 F.2d 1345, 1346-47 (9th Cir. 1990); *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1286-90 (D.C. Cir. 1983))

To ensure that trade secrets are not improperly disclosed under the federal Trade Secrets Act and FOIA, federal agencies have a duty to adopt regulations establishing specific procedures that the federal agencies must follow when they receive requests for public records under FOIA seeking disclosure of information that may constitute a trade secret or other confidential commercial information. The purpose of such procedures is to ensure that persons who have submitted trade secrets or other confidential commercial information to federal agencies are provided with notice of the potential disclosure of the information under FOIA and an opportunity to respond and protect their interests in the confidentiality of the information before the federal agencies may disclose the information to the public. (*Predisclosure Notification Procedures for Confidential Commercial Information*, Exec. Order No. 12,600, 52 Fed. Reg. 23,781 (June 23, 1987); *OSHA Data/CIH v. Dep’t of Labor*, 220 F.3d 153, 163-64 (3d Cir. 2000); *Venetian Casino Resort v. EEOC*, 530 F.3d 925, 934-35 (D.C. Cir. 2008))

**Section 3** of this regulation establishes specific procedures that the Department will follow when it receives a request for public records under the Nevada Public Records Act seeking disclosure of information which: (1) may constitute a trade secret under the federal DTSA; and (2) is included by a manufacturer or pharmacy benefit manager in an annual report concerning the prices of prescription drugs submitted to the Department under sections 3.8, 4 or 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 or 439B.645). **Section 3** provides that a manufacturer or pharmacy benefit manager which is required to submit such a report may submit to the Department a request to keep information included in the report confidential if the manufacturer or pharmacy benefit manager reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA. If a manufacturer or pharmacy benefit manager submits a request for confidentiality, **section 3** requires the request to: (1) describe, with particularity, the information sought to be protected from public disclosure;

and (2) include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA.

If the Department receives a request for public records under the Nevada Public Records Act seeking disclosure of information for which the manufacturer or pharmacy benefit manager has submitted a request for confidentiality, **section 3** requires the Department, as soon as reasonably practicable after receiving the request, to provide the manufacturer or pharmacy benefit manager with: (1) written notice of the request for public records and the procedures set forth in **section 3**; and (2) a copy of the request for public records and the date on which the Department received the request. **Section 3** also requires the Department to undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA. When the Department undertakes its initial review, **section 3** states that the Department will consider, as persuasive authority, the interpretation and application given to the term “trade secrets” under Exemption 4 of FOIA.

If, after undertaking its initial review, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA, **section 3** provides that the Department will: (1) within the time required by the Nevada Public Records Act, provide the requester of public records with written notice that the Department must deny the request on the basis that the information is confidential under the federal DTSA; and (2) as soon as reasonably practicable after notifying the requester, provide the manufacturer or pharmacy benefit manager with written notice that the Department denied the request and a copy of the written notice provided to the requester and the date on which it was sent to the requester. Under the Nevada Public Records Act, the requester would have the right to bring an action against the Department to challenge the denial of the request for public records. (NRS 239.011; *City of Sparks v. Reno Newspapers*, 133 Nev. Adv. Op. 56, 399 P.3d 352, 354 (2017); *DR Partners v. Bd. of County Comm’rs*, 116 Nev. 616, 620-21 (2000)) If the requester were to bring such an action against the Department, the manufacturer or pharmacy benefit manager could assert a right to intervene in the action to protect its interests in the confidentiality of the information. (*Appleton v. FDA*, 310 F. Supp. 2d 194, 196-97 (D.D.C. 2004); *Yorkshire v. IRS*, 26 F.3d 942, 944-45 (9th Cir. 1994))

If, after undertaking its initial review, the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret under the federal DTSA, **section 3** requires the Department, within the time required by the Nevada Public Records Act, to provide the requester of public records with written notice that the Department intends to disclose the information. However, **section 3** also requires the Department to inform the requester that: (1) the Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and (2) if the manufacturer or pharmacy benefit manager timely commences an action within that 30-day period to enjoin disclosure of the information under the federal DTSA, the Department will not be able to disclose the information, unless the disclosure is permitted after final resolution of the

action, including any appeals. **Section 3** additionally requires the Department, as soon as reasonably practicable after notifying the requester, to provide the manufacturer or pharmacy benefit manager with: (1) written notice that the Department intends to disclose the information; and (2) a copy of the written notice sent to the requester and the date on which it was sent to the requester.

If, within the 30-day period following the date on which the Department sent the written notice to the requester, the manufacturer or pharmacy benefit manager does not commence an action to enjoin the Department from disclosing the information under the federal DTSA, **section 3** requires the Department to disclose the information. However, if such an action is timely commenced within the 30-day period, **section 3** provides that the Department will not disclose the information until final resolution of the action, including any appeals. Following commencement of the action, the requester of the public records could assert a right to intervene in the action to protect its interests in the disclosure of the information. (*Entergy Gulf States La. v. EPA*, 817 F.3d 198, 203-06 (5th Cir. 2016); *LaRouche v. FBI*, 677 F.2d 256, 257-58 (2d Cir. 1982))

After final resolution of the action, including any appeals, if the court enjoins the Department from disclosing the information as a trade secret, **section 3** provides that the Department will not disclose the information so long as the information retains its status as a trade secret. However, if the court does not enjoin the Department from disclosing the information as a trade secret, **section 3** provides that the Department will disclose the information as soon as reasonably practicable after final resolution of the action.

Finally, existing law requires the Department to: (1) analyze the information submitted by manufacturers and pharmacy benefit managers in their annual reports; and (2) compile a report on the prices of the prescription drugs that appear on the most current lists of essential diabetes drugs compiled by the Department. (Section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650)) **Section 4** of this regulation provides that the report compiled by the Department will include only aggregated data that does not disclose the identity of any drug, manufacturer or pharmacy benefit manager. **Section 4** also provides that the Department will include in the report: (1) a description of trends concerning the prices of the prescription drugs that appear on the most current lists of essential diabetes drugs compiled by the Department; and (2) an explanation of how those prices and trends may affect the prevalence and severity of diabetes in this State and the system of health care in this State.

**Section 1.** Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2, 3 and 4 of this regulation.

**Sec. 2. The Department will make available on an Internet website maintained by the Department the forms on which:**

**1. A manufacturer is required to submit the reports required by sections 3.8 and 4 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635 and 439B.640).**

**2. A pharmacy benefit manager is required to submit the report required by section 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4298 (NRS 439B.645).**

**3. A person included on a list of pharmaceutical sales representatives provided by a manufacturer to the Department pursuant to subsection 1 of section 4.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.660), is required to submit the report required by subsection 4 of that section.**

**Sec. 3. 1. In complying with section 3.8, 4 or 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 or 439B.645), if a manufacturer or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the manufacturer or pharmacy benefit manager may submit to the Department a request to keep the information confidential.**

**2. A request for confidentiality submitted pursuant to subsection 1 must be divided into the following parts, which must be severable from each other:**

**(a) The first part of the request for confidentiality must describe, with particularity, the information sought to be protected from public disclosure. Upon a request for public records**

*pursuant to NRS 239.010, the Department will not disclose the description set forth in the request for confidentiality or the information sought to be protected from public disclosure, unless the description and information are disclosed pursuant to subsections 5 and 6.*

*(b) The second part of the request for confidentiality must include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. Upon a request for public records pursuant to NRS 239.010, the Department will disclose the explanation set forth in the request for confidentiality.*

*3. If the Department receives a request for public records pursuant to NRS 239.010 seeking disclosure of any information for which a manufacturer or pharmacy benefit manager has submitted a request for confidentiality pursuant to subsection 1, the Department will:*

*(a) As soon as reasonably practicable after receiving the request for public records, provide the manufacturer or pharmacy benefit manager with:*

*(1) Written notice of the request for public records and the procedures set forth in this section; and*

*(2) A copy of the request for public records and the date on which the Department received the request.*

*(b) Undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016,*

*18 U.S.C. § 1836, as amended. In undertaking its initial review, the Department will consider, as persuasive authority, the interpretation and application given to the term “trade secrets” in Exemption 4 of the federal Freedom of Information Act, 5 U.S.C. § 552(b)(4), as amended.*

*4. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:*

*(a) Within the time prescribed by NRS 239.0107, provide the requester of the public records with written notice pursuant to paragraph (d) of subsection 1 of NRS 239.0107 that the Department must deny the request for public records on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended.*

*(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:*

*(1) Written notice that the Department denied the request for public records; and*

*(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.*

*5. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:*

*(a) Within the time prescribed by NRS 239.0107, provide the requester of the public records with written notice pursuant to paragraph (c) of subsection 1 of NRS 239.0107 that the Department intends to disclose the information, except that:*

*(1) The Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and*

*(2) If the manufacturer or pharmacy benefit manager timely commences an action within the 30-day period as provided in subsection 6, the Department will not be able to disclose the information, unless the disclosure is permitted by that subsection.*

*(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:*

*(1) Written notice that the Department intends to disclose the information; and*

*(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.*

*6. If, within the 30-day period following the date on which the Department sent the written notice to the requester of public records pursuant to subsection 5, the manufacturer or pharmacy benefit manager:*

*(a) Does not commence an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will disclose the information.*

*(b) Commences an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18*

*U.S.C. § 1836, as amended, the Department will not disclose the information until final resolution of the action, including any appeals. After final resolution of the action, if the court:*

*(1) Enjoins the Department from disclosing the information as a trade secret, the Department will not disclose the information so long as the information retains its status as a trade secret.*

*(2) Does not enjoin the Department from disclosing the information as a trade secret, the Department will disclose the information as soon as reasonably practicable after final resolution of the action.*

*Sec. 4. In the report compiled by the Department pursuant to section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650), the Department will include:*

*1. Only aggregated data that does not disclose the identity of any drug, manufacturer or pharmacy benefit manager; and*

*2. In addition to the information required by section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650), a description of trends concerning the prices of prescription drugs that appear on the most current lists compiled by the Department pursuant to section 3.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4297(NRS 439B.630), and an explanation of how those prices and trends may affect:*

*(a) The prevalence and severity of diabetes in this State; and*

*(b) The system of health care in this State.*

# EXHIBIT 8

# EXHIBIT 8

Pat Lundvall (NSBN 3761)  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
lundvall@mcdonaldcarano.com

Robert N. Weiner  
Admitted *Pro Hac Vice*  
Jeffrey L. Handwerker  
Admitted *Pro Hac Vice*  
R. Stanton Jones  
Admitted *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA and  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as  
Governor of the State of Nevada; RICHARD  
WHITLEY, in his official capacity as Director of  
the Nevada Department for Health and Human  
Services; and the NEVADA LEGISLATURE,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

**PLAINTIFFS' UNOPPOSED MOTION  
FOR VOLUNTARY DISMISSAL  
WITHOUT PREJUDICE**

Pursuant to Federal Rule of Civil Procedure 41(a)(2), Plaintiffs Pharmaceutical Research and  
Manufacturers of America and Biotechnology Innovation Organization (together, "Plaintiffs"), by

1 and through their undersigned counsel, hereby move unopposed for voluntary dismissal of this action  
2 and state as follows:

3 On September 1, 2017, Plaintiffs filed their complaint against Defendants Governor Brian  
4 Sandoval and Nevada Department of Health and Human Services Director Richard Whitley, in their  
5 official capacities, seeking injunctive relief and a declaration that Nevada Senate Bill 539 is  
6 unconstitutional on the grounds that it conflicts with federal patent law and the 2016 Defend Trade  
7 Secrets Act, constitutes an unlawful government taking of trade secrets under the Fifth and  
8 Fourteenth Amendments, and violates the Commerce Clause of Article I. ECF No. 1.

9 On October 3, 2017, the Court permitted the Nevada Legislature to intervene as a defendant  
10 (collectively with Governor Sandoval and Director Whitley, "Defendants"). ECF No. 43.

11 On October 4, 2017, Governor Sandoval and Director Whitley answered the complaint, ECF  
12 No. 44, and, on October 5, 2017, the Legislature answered, ECF No. 45.

13 Pending before the Court are the parties' cross-motions for summary judgment. *See, e.g.*,  
14 ECF Nos. 46, 66.

15 Plaintiffs have met and conferred with Defendants regarding the filing of this motion.  
16 Plaintiffs have agreed to move for voluntary dismissal without prejudice in light of the  
17 acknowledgements, assurances, changed circumstances, and reservation of rights described in the  
18 parties' June 28, 2018 joint status report. ECF No. 95. Defendants do not oppose.

19 ///

20 ///

21 ///

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

28 ///

1 Plaintiffs therefore respectfully request that the Court dismiss the complaint without  
2 prejudice pursuant to Federal Rule of Civil Procedure 41(a)(2), with each party to bear its own costs.

3 Dated: June 28, 2018.

4 /s/ Pat Lundvall

5 Pat Lundvall (NSBN 3761)  
6 McDONALD CARANO LLP  
7 2300 West Sahara Avenue, Suite 1200  
8 Las Vegas, Nevada 89102  
9 Telephone: (702) 873-4100  
10 lundvall@mcdonaldcarano.com

11 Robert N. Weiner  
12 Jeffrey L. Handwerker  
13 R. Stanton Jones  
14 ARNOLD & PORTER KAYE SCHOLER LLP  
15 601 Massachusetts Avenue, NW  
16 Washington, DC 20001  
17 Telephone: (202) 942-5000

18 *Attorneys for Plaintiffs Pharmaceutical Research  
19 and Manufacturers of America and  
20 Biotechnology Innovation Organization*

21 **CERTIFICATE OF SERVICE**

22 I certify that I am an employee of McDonald Carano, and that on the 28<sup>th</sup> day of June, 2018,  
23 a true and correct copy of the foregoing PLAINTIFFS' UNOPPOSED MOTION FOR  
24 VOLUNTARY DISMISSAL WITHOUT PREJUDICE was electronically filed with the Clerk of  
25 the Court by using CM/ECF service which will provide copies to all counsel of record registered to  
26 receive CM/ECF notification.  
27

28 /s/ Beau Nelson

An employee of McDonald Carano LLP

McDONALD CARANO

2300 WEST SAHARA AVENUE, SUITE 1200 • LAS VEGAS, NEVADA 89102  
PHONE 702.873.4100 • FAX 702.873.9966

# Proposed Order

Pat Lundvall (NSBN 3761)  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
lundvall@mcdonaldcarano.com

Robert N. Weiner  
Admitted *Pro Hac Vice*  
Jeffrey L. Handwerker  
Admitted *Pro Hac Vice*  
R. Stanton Jones  
Admitted *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA and  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as  
Governor of the State of Nevada; RICHARD  
WHITLEY, in his official capacity as Director of  
the Nevada Department for Health and Human  
Services; and the NEVADA LEGISLATURE,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

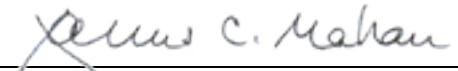
**ORDER GRANTING  
PLAINTIFFS' UNOPPOSED MOTION  
FOR VOLUNTARY DISMISSAL**

1 Having reviewed Plaintiffs Pharmaceutical Research and Manufacturers of America and  
2 Biotechnology Innovation Organization's Unopposed Motion for Voluntary Dismissal Without  
3 Prejudice, and good cause appearing therefor:

4 IT IS HEREBY ORDERED THAT:

5 Pursuant to Federal Rule of Civil Procedure 41(a)(2), the instant action, *Pharmaceutical*  
6 *Research and Manufacturers of America, et al. v. Sandoval, et al.*, Case No. 2:17-cv-02315-JCM-  
7 CWH, is hereby dismissed without prejudice, each party to bear its own costs.

8 It is SO ORDERED June 28, 2018.

9  
10   
11 \_\_\_\_\_  
12 United States District Judge  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 9

# EXHIBIT 9



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIRECTOR'S OFFICE  
4126 Technology Way, Suite 100  
Carson City, Nevada 89706  
Telephone (775) 684-4000 • Fax (775) 684-4010  
<http://dhhs.nv.gov>

October 31, 2017

SB539 required the Department of Health and Human Services (DHHS) to develop a list of essential diabetes drugs. To that end, DHHS sought public comment from prescribers in Nevada, analyzed data to determine drugs most often prescribed, and consulted with FDA resources to determine appropriate use as established by the label. Below describes the process for creation of the list:

- An initial list of frequently prescribed drugs used for the treatment of diabetes was created by pharmacists employed by the department.
- The list was then sent to prescribers in the state as a survey to solicit public comment and determine if any drugs needed to be removed/added. DHHS received over 300 responses.
- That list was compared to the Medicaid pharmacy data reported to the Centers for Medicare and Medicaid Services (CMS) and information from the Public Employees Benefit Program on prescribed drugs. This prescriber data accounted for approximately 700,000 Nevadans insured under these public plans and was used to whittle down the list to just those drugs prescribed in Nevada.
- The remaining drugs were checked against the FDA database to ensure that only drugs approved by the FDA for the treatment of diabetes were included on the list. No drugs were included if their treatment of diabetes was considered an "off-label" use.

This process was designed to include the feedback from prescriber stakeholders along with addressing the concerns expressed by industry members regarding appropriate label use. This list does not include any drugs used to treat co-morbidities often present in an individual with diabetes. The list also does not contain every single drug that may be an effective treatment for diabetes or approved for the treatment of diabetes. This list attempts to distill down the numerous treatments to those which are approved for treatment, identified by prescribers as essential, and most frequently prescribed in Nevada (as determined by the publicly available data sources).

As this is the first year DHHS has created this list, we welcome feedback on the process that can be used for the development of the list for 2018. Feedback and questions can be directed to the email: [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov).

Proprietary Name	Non_Proprietary_Name	Class	Labeler
Tanzeum	albiglutide	Glucagon-Like Peptide-1 (GLP-1) Agonists	GlaxoSmithKline, LLC
Byetta	exenatide	Glucagon-Like Peptide-1 (GLP-1) Agonists	Astrazeneca AB; Physicians Total Care, Inc.
Invokana; Invokamet	canagliflozin	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	Jansen Pharmaceuticals, Inc.
Cycloset; Parlodel; Bromocriptine mesylate	bromocriptine mesylate	Ergolines	Paddock Laboratories, LLC; Ranbaxy Pharmaceuticals, Inc.; Sandoz, Inc.; Physicians Total Care, Inc.; Santarus, Inc.; Validus Pharmaceuticals, LLC
Farxiga; Xigduo	DAPAGLIFLOZIN Propanediol	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	AstraZeneca Pharmaceuticals, LP
DiaBeta	glyburide	Sulfonylureas (SUs)	Actavis Elizabeth; Aurobindo Pharma; Dava Pharms, Inc; Epic Pharma LLC; Heritage Pharms, Inc.; Hikma; Impax Labs, Inc; Mylan; Pharmadax, Inc; Sandoz; Sanofi-Aventis U.S., LLC; Teva; Zydus Pharms USA, Inc
Trulicity	Dulaglutide	Glucagon-Like Peptide-1 (GLP-1) Agonists	Eli Lilly and Company
Jardiance Synjardy	Empagliflozin	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.; Cardinal Health
Glyxambi	Empagliflozin and linagliptin	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.
Synjardy	empagliflozin and metformin hydrochloride	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.
Bydureon Byetta	exenatide	Glucagon-Like Peptide-1 (GLP-1) Agonists	AstraZeneca Pharmaceuticals, LP; Physicians Total Care, Inc.
Fortamet	Metformin hydrochloride	Biguanide	Physicians Total Care, Inc.; Shionogi, Inc.

Proprietary Name	Non_Proprietary_Name	Class	Labeler
Amaryl Glimepiride	Glimepiride	Sulfonylureas (SUs)	<p>Accord Healthcare Inc; Aidarex Pharmaceuticals LLC; American Health Packaging; Aurobindo Pharma Limited; Avera McKennan Hospital; Bionpharma Inc. Blenheim Pharmacal, Inc.; BluePoint Laboratories; Bryant Ranch Prepack; Cardinal Health; Carlsbad Technology, Inc.; Citron Pharma LLC; Dr. Reddy's Laboratories Limited; DIRECT RX; Golden State Medical Supply, Inc.; International Laboratories, LLC; Lake Erie Medical DBA Quality Care Products LLC; Liberty Pharmaceuticals, Inc.; MedVantx, Inc.; Micro Labs Limited; Mylan Institutional Inc.; Mylan Pharmaceuticals Inc.; NCS HealthCare of KY, Inc dba Vanguard Labs; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc. PD-Rx Pharmaceuticals, Inc.;</p> <p>Prasco Laboratories; Preferred Pharmaceuticals Inc.; Physicians Total Care, Inc.; Proficient Rx LP; Qualitest Pharmaceuticals; Rebel Distributors Corp; RedPharm Drug, Inc. REMEDYREPACK INC.; St Marys Medical Park Pharmacy; Sanofi-Aventis U.S., LLC; Solco Healthcare U.S., LLC; STAT Rx USA LLC; Takeda Pharmaceuticals America, Inc.; Teva Pharmaceuticals USA, Inc.; Unit Dose Services; Virtus Pharmaceuticals</p>
Glipizide Glipizide XL Glipizide ER Glucotrol Glucotrol XL	glipizide	Sulfonylureas (SUs)	<p>Accord Healthcare Inc; Actavis Elizabeth LLC; Actavis Pharma, Inc.; Aidarex Pharmaceuticals LLC; Aphena Pharma Solutions - Tennessee, LLC; Apotex Corp.; Apotheca Inc.; Aurobindo Pharma Limited; Avera McKennan Hospital; Bionpharma Inc. Blenheim Pharmacal, Inc.; Bryant Ranch Prepack; Cardinal Health; Carlsbad Technology, Inc.; Clinical Solutions Wholesale; Contract Pharmacy Services-PA; Dr. Reddy's Laboratories Limited; DIRECT RX; Dispensing Solutions, Inc.; Golden State Medical Supply, Inc.; Greenstone LLC; International Laboratories, LLC; H.J. Harkins Company, Inc.; Lake Erie Medical DBA Quality Care Products LLC; Legacy Pharmaceutical Packaging, LLC; Major Pharmaceuticals;</p> <p>MedVantx, Inc.; Mylan Institutional Inc.; Mylan Pharmaceuticals Inc.; NCS HealthCare of KY, Inc dba Vanguard Labs; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc. PD-Rx Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Physicians Total Care, Inc.; Preferred Pharmaceuticals Inc.; Proficient Rx LP; Rebel Distributors Corp; RedPharm Drug, Inc. REMEDYREPACK INC.; Rising Pharmaceuticals, Inc.; St Marys Medical Park Pharmacy; Sandoz Inc; State of Florida DOH Central Pharmacy; STAT Rx USA LLC; Sun Pharmaceutical Industries, Inc.; TYA Pharmaceuticals; Unit Dose Services; Virtus Pharmaceuticals</p>

Proprietary Name	Non_Proprietary_Name	Class	Labeler	
Glipizide and Metformin Hydrochloride Glipizide and Metformin HCl	Glipizide and Metformin Hydrochloride	Sulfonylureas (SUs)	AvKARE, Inc.; Bryant Ranch Prepack; Cadila Healthcare Limited; Heritage Pharmaceuticals Inc.; KAISER FOUNDATION HOSPITALS; Lake Erie Medical DBA Quality Care Products LLC; Mylan Pharmaceuticals Inc.;	Physicians Total Care, Inc.; Rebel Distributors Corp; REMEDYREPACK INC.; St Marys Medical Park Pharmacy; Teva Pharmaceuticals USA, Inc.; Unit Dose Services; Zydus Pharmaceuticals (USA) Inc.
Glucophage	Metformin Hydrochloride	Biguanide	Bristol-Myers Squibb Company; PD-Rx Pharmaceuticals, Inc.	
Glumetza	Metformin Hydrochloride	Biguanide	Depomed, Inc.; Santarus, Inc.	
Glyset	Miglitol	Alpha-Glucosidase Inhibitors	Pharmaceia and Upjohn Company LLC	
Novolin	Human Insulin	Short Acting or Regular	Novo Nordisk; Physicians Total Care, Inc.; TYA Pharmaceuticals	
Novolog	insulin aspart	Rapid-Acting Insulin	Dispensing Solutions; Novo Nordisk; Physicians Total Care, Inc.; TYA Pharmaceuticals	
Tresiba	insulin degludec	insulin	Novo Nordisk	
Xultophy	insulin degludec; liraglutide	Glucagon-Like Peptide-1 (GLP-1) Agonists	Novo Nordisk	
Levemir	insulin detemir	Long-Acting Insulin	Dispensing Solutions; Novo Nordisk; Physicians Total Care, Inc.	
Basaglar Lantus Toujeo	insulin glargine	Long-Acting Insulin	Dispensing Sololutions, Inc.; Eli Lilly and Company; Physicians Total Care, Inc.; Sanofi-Aventis U.S. LLC	
Soliqua	insulin glargine; Lixisenatide	Insulin	Sanofi-Aventis U.S. LLC	
Apidra	insulin glulisine	Rapid-Acting Insulin	Sanofi-Aventis U.S. LLC	
Afrezza Humalog 70/30 Humulin Humulin N Humulin R	Insulin human	Intermediate Insulin or Baseline, Basal	Eli Lilly and Company; Mankind Corporation; Physicians Total Care, Inc.	
Humalog	Insulin lispro	Rapid-Acting Insulin	Dispensing Solutions, Inc.; Eli Lilly and Company; Physicians Total Care, Inc.	
Tradjenta	linagliptin	Dipeptidyl Peptidase 4 Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.; Cardinal Health	
Jentadueto Jentadueto XR	linagliptin and metformin hydrochloride	Dipeptidyl Peptidase 4 Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc; Bryant Ranch Prepack; Physicians Total Care, Inc.	

Proprietary Name	Non_Proprietary_Name	Class	Labeler
Victoza	liraglutide	Glucagon-Like Peptide-1 (GLP-1) Agonists	Novo Nordisk
Metformin HCL	Metformin HCL	Biguanide	Ascend Laboratories, Inc.; Cambridge Therapeutics Technologies, LLC; Time Cap Laboratories, Inc.
Nesina	Alogliptin	Dipeptidyl Peptidase 4 Inhibitors	Takeda Pharmaceuticals America, Inc.
Pioglitazone Actos	Pioglitazone	Thiazolidinediones (TZDs)	Avera McKennan Hospital; Cadila Healthcare Limited; Cardinal Health; Carilion Materials Management; Citron Pharma LLC; Dispensing Solutions, Inc.; International Laboratories, LLC; Lake Erie Medical & Surgical Supply dba Quality Care Products LLC; Macleods Pharmaceuticals Limited; MedVantx, Inc.; Mylan Institutional Inc.; Mylan Pharmaceuticals Inc.; NuCare Pharmaceuticals, Inc.; Physicians Total Care, Inc.; Ranbaxy Pharmaceuticals, Inc.; Rebel Distributors Corp.; Sandoz, Inc.; Takeda Pharmaceuticals America, Inc.; Teva Pharmaceuticals USA, Inc.; Wockhardt Limited; Zydus Pharmaceuticals (USA) Inc.
Prandin	Repaglinide	Meglitinides	Cardinal Health; Carilion Materials Management; Gemini Laboratories, LLC; Lake Erie Medical dba Quality Care Products LLC; Novo Nordisk; Physicians Total Care
Precose	Acarbose	Alpha-Glucosidase Inhibitors	Aphena Pharma Solutions - Tennessee, LLC; Bayer Healthcare Pharmaceuticals, Inc.; Physicians Total Care, Inc.
Riomet	Metformin Hydrochloride	Biguanide	Ranbaxy Laboratories, Inc.
Onglyza	SAXAGLIPTIN	Dipeptidyl Peptidase 4 Inhibitors	AstraZeneca Pharmaceuticals LP; Cardinal Health; Physicians Total Care, Inc.
Kombiglyze	SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE	Metformin +	AstraZeneca Pharmaceuticals LP
Januvia	sitagliptin	Dipeptidyl Peptidase 4 Inhibitors	Avera McKennan Hospital; Cardinal Health; Lake Erie Medical & Surgical Supply dba Quality Care Products LLC; Merck Sharp & Dohme Corp.; Physicians Total Care, Inc.
Janumet	sitagliptin and metformin hydrochloride	Metformin +	Lake Erie Medical & Surgical Supply dba Quality Care Products LLC; Merck Sharp & Dohme Corp
Starlix	Nateglinide	Meglitinides	Novartis Pharmaceuticals Corporation
SymlinPen 60 & 120	Pramlintide	Amylin Agonist	AstraZeneca Pharmaceuticals LP

Proprietary Name	Non_Proprietary_Name	Class	Labeler
Welchol	Colesevelam Hydrochloride	Bile Acid Binding Resins	Avera McKennan Hospital; Carillion Materials Management; Daiichi Sankyo, Inc.; Physicians Total Care Inc.; Rebel Distributors

# EXHIBIT 10

# EXHIBIT 10



**Steve Sisolak**  
**Governor**



**Richard Whitley, MS**  
**Director**

**Julie Kotchevar, PhD**  
**DPBH Administrator**

# **2019 Essential Diabetes Drug List**

*Report Date:*

**February 1, 2019**



**Nevada Department of  
Health and Human Services**

*Prepared by:*

Primary Care and Health Workforce Development Office, State of Nevada  
Division of Public and Behavioral Health (DPBH)  
4150 Technology Way, Suite 300, Carson City, NV 89706  
Office: (775) 684-4255 Email: [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov)  
[drugtransparency.nv.gov](http://drugtransparency.nv.gov)

Helping People. It's who we are and what we do.



## Introduction

During the 79th legislative session, Senate Bill (SB) 539, which supports prescription drug transparency, was approved. SB 539 was codified in Nevada Revised Statutes (NRS) 439B. The law requires in NRS 439B.630 that the Department of Health and Human Services (DHHS) compile a list of prescription drugs essential for treating diabetes in Nevada:

**NRS 439B.630 Department to annually compile lists of certain prescription drugs essential for treating diabetes.** On or before February 1 of each year, the Department shall compile:

1. A list of prescription drugs that the Department determines to be essential for treating diabetes in this State and the wholesale acquisition cost of each such drug on the list. The list must include, without limitation, all forms of insulin and biguanides marketed for sale in this State.
2. A list of prescription drugs described in subsection 1 that have been subject to an increase in the wholesale acquisition cost of a percentage equal to or greater than:
  - a.) The percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year; or
  - b.) Twice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years.

(Added to NRS by [2017, 4297](#))

The first essential diabetes drug list was published on October 31, 2017. The 2019 Essential Diabetes Drug List identifies Nevada's essential diabetes drugs as of the publication date and also indicates if these drugs underwent a significant price increase as defined by NRS 439B.630 (2). To produce the current list, DHHS posted a draft version of the essential diabetes drug list online on January 14, 2019 and received public and other stakeholder comments. All requests were carefully reviewed before finalization of this publication. Manufacturers that produce drugs found on this list are required to submit reports by April 1, 2019 that include information about these drugs as outlined in NRS 439B.635 and NRS 439B.640. Additionally, Pharmacy Benefit Managers (PBMs) are required to provide information to DHHS by April 1, 2019 regarding these drugs as outlined in NRS 439B.645. Data from these reports will be aggregated and published in the DHHS report required by NRS 439B.650 by June 1, 2019.

## Report Methodology

To compile the 2019 DHHS Essential Diabetes Drug list, DHHS utilized a methodology that met the requirements of NRS 439B.630. Two versions of the list are published: (1) a summary of the nonproprietary and brand or proprietary drug names found on the essential list [Appendix 1], and (2) a detailed list of all the National Drug Codes (NDCs) indicated by DHHS as essential diabetes drugs and if each drug NDC experienced a significant price increase [Appendix 2]. The summary list [Appendix 1] provides a concise outline of the essential drugs, while the NDC list [Appendix 2] identifies the specific drug NDCs that will be monitored by DHHS and included in the yearly report.



To generate the final list, DHHS compiled an initial list of diabetes drug NDCs that included varying drug packing formulations based on prior and current stakeholder input of essential diabetes drugs. These NDC codes were filtered down to include the drugs for which Nevada Medicaid expended funds in 2017 and/or 2018. Additional NDCs that were of interest to the public and stakeholders were added to this list.

This essential list does not include any drugs used to treat co-morbidities often present in individuals with diabetes. The list does not contain every single drug that may be an effective treatment for diabetes or approved for the treatment of diabetes. This list attempts to refine the numerous treatments to those approved for treatment, identified by prescribers as essential, and most frequently prescribed in Nevada (as determined by publicly available data sources). For this reason, some brand names are excluded while generics or alternative brands are included.

DHHS welcomes feedback regarding this report. DHHS strives to ensure that consumers receive accurate information. Any identified errors, omissions, or feedback can be submitted to the department via email at [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov).

DHHS invites you to view the Drug Transparency website at [drugtransparency.nv.gov](http://drugtransparency.nv.gov). If you are interested in receiving email notifications for Nevada Drug Transparency information and updates, please subscribe online at <http://drugtransparency.nv.gov> to the DHHS Drug Transparency LISTSERV.



# **Appendix 1:** **2019 DHHS Essential Diabetes Drug** **Summary List**

Essential Non-Proprietary Drug Name	Included Essential Drug Brand Names (Note: some brand names are excluded from this list)
Acarbose	
Albiglutide	Tanzeum
Alogliptin	Nesina
Alogliptin and Metformin HCL	Kazano
Alogliptin and Pioglitazone	Oseni
Bromocriptine Mesylate	Cycloset
Canagliflozin	Invokana
Canagliflozin and Metformin HCL	Invokamet; Invokamet XR
Colesevelam HCL	Welchol
Dapagliflozin	Farxiga
Dapagliflozin and Metformin HCL	Xigduo XR
Dulaglutide	Trulicity
Empagliflozin	Jardiance
Empagliflozin and Linagliptin	Glyxambi
Empagliflozin and Metformin HCL	Synjardy; Synjardy XR
Ertugliflozin	Steglatro
Ertugliflozin and Metformin HCL	Segluromet
Ertugliflozin and Sitagliptin	Steglujan
Exenatide	Bydureon; Bydureon BCise; Byetta
Glimepiride	Amaryl
Glipizide	Glucotrol; Glucotrol XL; Glipizide XL; Glipizide ER
Glipizide and Metformin HCL	
Glucagon	GlucaGen
Glyburide	Glynase
Glyburide and Metformin HCL	
Insulin Aspart	Fiasp; Novolog; Novolog 70/30
Insulin Degludec	Tresiba
Insulin Degludec and Liraglutide	Xultophy 100/3.6
Insulin Detemir	Levemir
Insulin Glargine	Basaglar; Lantus; Toujeo
Insulin Glargine and Lixisenatide	Soliqua 100/33
Insulin Glulisine	Apidra
Insulin Human	Afrezza; Humulin N; Humulin R; Humulin R500; Humulin 70/30; Novolin R; Novolin N; Novolin 70/30
Insulin Lispro	Admelog; Humalog; Humalog 50-50; Humalog 75-25; Humalog Jr
Linagliptin	Tradjenta
Linagliptin and Metformin HCL	Jentaduetto; Jentaduetto XR
Liraglutide	Victoza
Lixisenatide	Adlyxin
Metformin HCL	Fortamet ER; Glumetza ER; Glucophage; Glucophage XR; Riomet; Metformin ER
Miglitol	Glyset

Essential Non-Proprietary Drug Name	Included Essential Drug Brand Names (Note: some brand names are excluded from this list)
Nateglinide	Starlix
Pioglitazone	Actos
Pioglitazone and Glimepiride	
Pioglitazone and Metformin HCL	Actoplus Met; Actoplus Met XR
Pramlintide Acetate	SymlinPen
Repaglinide	Prandin
Rosiglitazone	Avandia
Saxagliptin	Onglyza
Saxagliptin and Metformin HCL	Kombiglyze XR
Semaglutide	Ozempic
Sitagliptin	Januvia
Sitagliptin and Metformin HCL	Janumet; Janumet XR



**Appendix 2:**  
**2019 Essential Diabetes Drug**  
**NDC List**

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
16252-0523-01	Acarbose	Actavis Pharma, Inc.	
47781-0340-01	Acarbose	Alvogen, Inc.	
47781-0341-01	Acarbose	Alvogen, Inc.	
47781-0342-01	Acarbose	Alvogen, Inc.	
00115-1152-02	Acarbose	Global Pharmaceuticals	
23155-0149-01	Acarbose	Heritage Pharmaceuticals Inc.	
00378-2821-77	Acarbose	Mylan	
64380-0758-06	Acarbose	Strides Shasun Limited	
64380-0759-06	Acarbose	Strides Shasun Limited	
64380-0760-06	Acarbose	Strides Shasun Limited	
69543-0120-10	Acarbose	Virtus Pharmaceuticals LLC	
69543-0121-10	Acarbose	Virtus Pharmaceuticals LLC	
69543-0122-10	Acarbose	Virtus Pharmaceuticals LLC	
00054-0140-25	Acarbose	West-Ward Pharmaceuticals Corp	
00054-0141-25	Acarbose	West-Ward Pharmaceuticals Corp	
00054-0142-25	Acarbose	West-Ward Pharmaceuticals Corp	
64764-0158-60	Actoplus Met	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0310-30	Actoplus Met XR	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0510-30	Actoplus Met XR	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0151-04	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0151-05	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0301-14	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0301-15	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0451-24	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0451-25	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
00024-5745-02	Adlyxin	Sanofi-Aventis U.S. LLC	Yes
00024-5747-02	Adlyxin	Sanofi-Aventis U.S. LLC	Yes
00024-5924-10	Admelog	Sanofi-Aventis U.S. LLC	
47918-0874-90	Afrezza	Mannkind Corporation	Yes
47918-0878-90	Afrezza	Mannkind Corporation	Yes
47918-0880-18	Afrezza	Mannkind Corporation	Yes
47918-0882-36	Afrezza	Mannkind Corporation	Yes
47918-0884-63	Afrezza	MannKind Corporation	Yes
47918-0891-90	Afrezza	Mannkind Corporation	Yes
47918-0894-63	Afrezza	Mannkind Corporation	Yes
47918-0902-18	Afrezza	Mannkind Corporation	Yes
45802-0169-72	Alogliptin-Metformin	Perrigo New York Inc	
45802-0211-72	Alogliptin-Metformin	Perrigo New York Inc	
00039-0221-10	Amaryl	Sanofi-Aventis U.S. LLC	
00088-2500-33	Apidra	Sanofi-Aventis U.S. LLC	Yes
00088-2502-05	Apidra	Sanofi-Aventis U.S. LLC	Yes
00173-0861-18	Avandia	GlaxoSmithKline LLC	
00002-7715-01	Basaglar	Eli Lilly and Company	
00002-7715-59	Basaglar	Eli Lilly and Company	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
60687-0286-21	Bromocriptine	American Health Packaging	
00378-2042-01	Bromocriptine	Mylan	
00378-7096-01	Bromocriptine	Mylan	
00378-7096-93	Bromocriptine	Mylan	
00574-0106-01	Bromocriptine	Paddock Laboratories, LLC	
00574-0106-03	Bromocriptine	Paddock Laboratories, LLC	
00781-5325-01	Bromocriptine	Sandoz Inc	
00781-5325-31	Bromocriptine	Sandoz Inc	
63304-0962-30	Bromocriptine	Sun Pharmaceutical Industries, Inc.	
68382-0110-06	Bromocriptine	Zydus Pharmaceuticals (USA) Inc.	
00310-6520-04	Bydureon	AstraZeneca Pharmaceuticals LP	
00310-6530-04	Bydureon	AstraZeneca Pharmaceuticals LP	
00310-6540-04	Bydureon BCise	AstraZeneca Pharmaceuticals LP	
00310-6512-01	Byetta	AstraZeneca Pharmaceuticals LP	
00310-6524-01	Byetta	AstraZeneca Pharmaceuticals LP	
51660-0996-28	Colesevelam	Ohm Laboratories, Inc.	
68012-0258-20	Cycloset	Santarus, Inc.	Yes
00003-1428-11	Farxiga	AstraZeneca Pharmaceuticals LP	
00310-6205-30	Farxiga	AstraZeneca Pharmaceuticals LP	Yes
00310-6210-30	Farxiga	AstraZeneca Pharmaceuticals LP	Yes
00169-3201-11	Fiasp	Novo Nordisk	Yes
00169-3204-15	Fiasp	Novo Nordisk	Yes
59630-0574-60	Fortamet ER	Shionogi Inc.	
59630-0575-60	Fortamet ER	Shionogi Inc.	
16729-0001-01	Glimepiride	Accord Healthcare Inc	Yes
16729-0001-16	Glimepiride	Accord Healthcare Inc	Yes
16729-0002-01	Glimepiride	Accord Healthcare Inc	Yes
16729-0002-16	Glimepiride	Accord Healthcare Inc	Yes
16729-0003-01	Glimepiride	Accord Healthcare Inc	Yes
16729-0003-16	Glimepiride	Accord Healthcare Inc	Yes
69452-0128-20	Glimepiride	Bionpharma Inc.	
69452-0128-30	Glimepiride	Bionpharma Inc.	
69452-0129-20	Glimepiride	Bionpharma Inc.	
69452-0130-20	Glimepiride	Bionpharma Inc.	
69452-0130-30	Glimepiride	Bionpharma Inc.	
68001-0177-00	Glimepiride	BluePoint Laboratories	
68001-0178-00	Glimepiride	BluePoint Laboratories	
68001-0178-03	Glimepiride	BluePoint Laboratories	
68001-0179-00	Glimepiride	BluePoint Laboratories	
68001-0179-03	Glimepiride	BluePoint Laboratories	
61442-0115-01	Glimepiride	Carlsbad Technology, Inc.	
61442-0116-01	Glimepiride	Carlsbad Technology, Inc.	
61442-0116-05	Glimepiride	Carlsbad Technology, Inc.	
61442-0117-01	Glimepiride	Carlsbad Technology, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
61442-0117-05	Glimepiride	Carlsbad Technology, Inc.	
55111-0320-01	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0320-05	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0321-01	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0321-05	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0322-01	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0322-05	Glimepiride	Dr. Reddy's Laboratories Limited	
54458-0966-10	Glimepiride	International Laboratories, LLC	
54458-0966-16	Glimepiride	International Laboratories, LLC	
54458-0967-10	Glimepiride	International Laboratories, LLC	
54458-0967-16	Glimepiride	International Laboratories, LLC	
54458-0968-10	Glimepiride	International Laboratories, LLC	
68645-0572-90	Glimepiride	Legacy Pharmaceutical Packaging, LLC	
68645-0573-90	Glimepiride	Legacy Pharmaceutical Packaging, LLC	
51079-0426-20	Glimepiride	Mylan	
00378-4012-01	Glimepiride	Mylan	
00378-4013-01	Glimepiride	Mylan	
00093-7254-01	Glimepiride	Teva Pharmaceuticals USA, Inc.	
00093-7255-01	Glimepiride	Teva Pharmaceuticals USA, Inc.	
00093-7256-01	Glimepiride	Teva Pharmaceuticals USA, Inc.	
00093-7256-52	Glimepiride	Teva Pharmaceuticals USA, Inc.	
69543-0123-10	Glimepiride	Virtus Pharmaceuticals	
69543-0123-50	Glimepiride	Virtus Pharmaceuticals	
69543-0124-10	Glimepiride	Virtus Pharmaceuticals	
69543-0124-50	Glimepiride	Virtus Pharmaceuticals	
69543-0125-10	Glimepiride	Virtus Pharmaceuticals	
69543-0125-50	Glimepiride	Virtus Pharmaceuticals	
16729-0139-00	Glipizide	Accord Healthcare Inc.	
16729-0139-16	Glipizide	Accord Healthcare Inc.	
16729-0140-00	Glipizide	Accord Healthcare Inc.	
16729-0140-16	Glipizide	Accord Healthcare Inc.	
00591-0460-01	Glipizide	Actavis Pharma, Inc.	
00591-0460-05	Glipizide	Actavis Pharma, Inc.	
00591-0460-10	Glipizide	Actavis Pharma, Inc.	
00591-0461-01	Glipizide	Actavis Pharma, Inc.	
00591-0461-05	Glipizide	Actavis Pharma, Inc.	
00591-0461-10	Glipizide	Actavis Pharma, Inc.	
60505-0141-00	Glipizide	Apotex Corp.	
60505-0141-01	Glipizide	Apotex Corp.	
60505-0141-02	Glipizide	Apotex Corp.	
60505-0142-00	Glipizide	Apotex Corp.	
60505-0142-01	Glipizide	Apotex Corp.	
60505-0142-02	Glipizide	Apotex Corp.	
60505-0142-04	Glipizide	Apotex Corp.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
68645-0150-54	Glipizide	Legacy Pharmaceutical Packaging, LLC	
68645-0151-59	Glipizide	Legacy Pharmaceutical Packaging, LLC	
51079-0810-20	Glipizide	Mylan	
51079-0811-20	Glipizide	Mylan	
00378-1105-01	Glipizide	Mylan	
00378-1105-05	Glipizide	Mylan	
00378-1110-01	Glipizide	Mylan	
00378-1110-05	Glipizide	Mylan	
00781-1452-01	Glipizide	Sandoz Inc	
00781-1452-10	Glipizide	Sandoz Inc	
00781-1453-01	Glipizide	Sandoz Inc	
00781-1453-10	Glipizide	Sandoz Inc	
57664-0398-13	Glipizide	Sun Pharmaceutical Industries, Inc.	
00591-0844-01	Glipizide ER	Actavis Pharma, Inc.	
00591-0844-10	Glipizide ER	Actavis Pharma, Inc.	
00591-0844-15	Glipizide ER	Actavis Pharma, Inc.	
00591-0845-01	Glipizide ER	Actavis Pharma, Inc.	
00591-0845-10	Glipizide ER	Actavis Pharma, Inc.	
00591-0845-15	Glipizide ER	Actavis Pharma, Inc.	
00591-0900-30	Glipizide ER	Actavis Pharma, Inc.	
68084-0111-01	Glipizide ER	American Health Packaging	Yes
68084-0112-01	Glipizide ER	American Health Packaging	Yes
68084-0295-21	Glipizide ER	American Health Packaging	Yes
00378-0340-93	Glipizide ER	Mylan	
00378-0342-01	Glipizide ER	Mylan	
00378-0431-01	Glipizide ER	Mylan	
10370-0745-01	Glipizide ER	Par Pharmaceutical, Inc.	
10370-0745-05	Glipizide ER	Par Pharmaceutical, Inc.	
10370-0746-01	Glipizide ER	Par Pharmaceutical, Inc.	
10370-0746-05	Glipizide ER	Par Pharmaceutical, Inc.	
10370-0190-01	Glipizide ER	Par Pharmaceuticals, Inc.	
10370-0190-05	Glipizide ER	Par Pharmaceuticals, Inc.	
10370-0191-01	Glipizide ER	Par Pharmaceuticals, Inc.	
10370-0191-05	Glipizide ER	Par Pharmaceuticals, Inc.	
64980-0279-03	Glipizide ER	Rising Pharmaceuticals, Inc.	
64980-0280-01	Glipizide ER	Rising Pharmaceuticals, Inc.	
64980-0280-05	Glipizide ER	Rising Pharmaceuticals, Inc.	
64980-0281-01	Glipizide ER	Rising Pharmaceuticals, Inc.	
64980-0281-05	Glipizide ER	Rising Pharmaceuticals, Inc.	
59762-0540-01	Glipizide XL	Greenstone LLC	
59762-0541-01	Glipizide XL	Greenstone LLC	
59762-0541-02	Glipizide XL	Greenstone LLC	
59762-0542-01	Glipizide XL	Greenstone LLC	
59762-0542-02	Glipizide XL	Greenstone LLC	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
23155-0116-01	Glipizide-Metformin	Heritage Pharmaceuticals Inc.	
23155-0117-01	Glipizide-Metformin	Heritage Pharmaceuticals Inc.	
00378-3132-01	Glipizide-Metformin	Mylan	
00378-3133-01	Glipizide-Metformin	Mylan	
00093-7455-01	Glipizide-Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7456-01	Glipizide-Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7457-01	Glipizide-Metformin	Teva Pharmaceuticals USA, Inc.	
68382-0185-01	Glipizide-Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0186-01	Glipizide-Metformin	Zydus Pharmaceuticals (USA) Inc.	
00169-7065-15	Glucagen	Novo Nordisk	Yes
00002-8031-01	Glucagon	Eli Lilly and Company	Yes
00087-6060-05	Glucophage	Bristol-Myers Squibb Company	
00087-6071-11	Glucophage	Bristol-Myers Squibb Company	
00087-6064-13	Glucophage XR	Bristol-Myers Squibb Company	
00049-4110-66	Glucotrol	Roerig	Yes
00049-4120-66	Glucotrol	Roerig	Yes
00049-0170-01	Glucotrol XL	Roerig	Yes
00049-0174-02	Glucotrol XL	Roerig	Yes
00049-0174-03	Glucotrol XL	Roerig	Yes
00049-0178-07	Glucotrol XL	Roerig	Yes
00049-0178-08	Glucotrol XL	Roerig	Yes
68012-0002-13	Glumetza ER	Santarus, Inc.	
68012-0003-16	Glumetza ER	Santarus, Inc.	
65862-0028-01	Glyburide	Aurobindo Pharma Limited	
65862-0029-01	Glyburide	Aurobindo Pharma Limited	
65862-0030-01	Glyburide	Aurobindo Pharma Limited	
65862-0030-99	Glyburide	Aurobindo Pharma Limited	
57237-0022-05	Glyburide	Citron Pharma LLC	
23155-0056-01	Glyburide	Heritage Pharmaceuticals Inc.	
23155-0057-01	Glyburide	Heritage Pharmaceuticals Inc.	
23155-0058-01	Glyburide	Heritage Pharmaceuticals Inc.	
23155-0058-10	Glyburide	Heritage Pharmaceuticals Inc.	
63739-0119-10	Glyburide	McKesson Corporation	
51079-0872-20	Glyburide	Mylan	
51079-0873-20	Glyburide	Mylan	
00093-9364-01	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9364-05	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9364-10	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9433-01	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9433-05	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9477-53	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-8342-01	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8343-01	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8343-05	Glyburide	Teva Pharmaceuticals USA, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00093-8343-10	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8343-98	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8344-01	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8344-05	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8344-10	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8344-98	Glyburide	Teva Pharmaceuticals USA, Inc.	
52817-0120-10	Glyburide	TruPharma, LLC	
52817-0121-10	Glyburide	TruPharma, LLC	
52817-0122-00	Glyburide	TruPharma, LLC	
52817-0122-10	Glyburide	TruPharma, LLC	
68382-0657-01	Glyburide	Zydus Pharmaceuticals (USA) Inc.	
68382-0658-10	Glyburide	Zydus Pharmaceuticals (USA) Inc.	
00378-1125-10	Glyburide Micro	Mylan	
00093-8034-01	Glyburide Micro	Teva Pharmaceuticals USA, Inc.	
00093-8035-01	Glyburide Micro	Teva Pharmaceuticals USA, Inc.	
00093-8035-05	Glyburide Micro	Teva Pharmaceuticals USA, Inc.	
00093-8036-01	Glyburide Micro	Teva Pharmaceuticals USA, Inc.	
00143-9918-01	Glyburide Micro	West-Ward Pharmaceuticals Corp	
00143-9919-01	Glyburide Micro	West-Ward Pharmaceuticals Corp	
00143-9920-01	Glyburide Micro	West-Ward Pharmaceuticals Corp	
00143-9920-05	Glyburide Micro	West-Ward Pharmaceuticals Corp	
00228-2752-11	Glyburide-Metformin	Actavis Pharma, Inc.	
00228-2753-11	Glyburide-Metformin	Actavis Pharma, Inc.	
65862-0081-01	Glyburide-Metformin	Aurobindo Pharma Limited	
65862-0082-01	Glyburide-Metformin	Aurobindo Pharma Limited	
65862-0082-05	Glyburide-Metformin	Aurobindo Pharma Limited	
57237-0024-01	Glyburide-Metformin	Rising Health, LLC	
57237-0024-05	Glyburide-Metformin	Rising Health, LLC	
57237-0025-01	Glyburide-Metformin	Rising Health, LLC	
57237-0025-05	Glyburide-Metformin	Rising Health, LLC	
00093-5712-05	Glyburide-Metformin	Teva Pharmaceuticals USA, Inc.	
68382-0654-05	Glyburide-Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0655-05	Glyburide-Metformin	Zydus Pharmaceuticals (USA) Inc.	
65862-0080-01	Glyburid-Metformin	Aurobindo Pharma Limited	
57237-0023-01	Glyburid-Metformin	Rising Health, LLC	
00009-0341-01	Glynase	Pharmacia and Upjohn Company LLC	Yes
00009-5012-01	Glyset	Pharmacia and Upjohn Company LLC	Yes
00009-5013-01	Glyset	Pharmacia and Upjohn Company LLC	Yes
00009-5014-01	Glyset	Pharmacia and Upjohn Company LLC	Yes
54868-4203-00	Glyset	Physicians Total Care, Inc.	
00597-0164-30	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00597-0164-39	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00597-0164-90	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00597-0182-30	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00597-0182-39	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00597-0182-90	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00002-7510-01	Humalog	Eli Lilly and Company	
00002-7510-17	Humalog	Eli Lilly and Company	
00002-7516-59	Humalog	Eli Lilly and Company	
00002-7712-01	Humalog	Eli Lilly and Company	
00002-7712-27	Humalog	Eli Lilly and Company	
00002-8799-01	Humalog	Eli Lilly and Company	
00002-8799-59	Humalog	Eli Lilly and Company	
00002-7512-01	Humalog 50-50	Eli Lilly and Company	
00002-8798-01	Humalog 50-50	Eli Lilly and Company	
00002-8798-59	Humalog 50-50	Eli Lilly and Company	
00002-7511-01	Humalog 75-25	Eli Lilly and Company	
00002-8797-59	Humalog 75-25	Eli Lilly and Company	
00002-7714-59	Humalog Jr	Eli Lilly and Company	
00002-8715-01	Humulin 70/30	Eli Lilly and Company	
00002-8715-17	Humulin 70/30	Eli Lilly and Company	
00002-8803-01	Humulin 70/30	Eli Lilly and Company	
00002-8803-59	Humulin 70/30	Eli Lilly and Company	
00002-8315-01	Humulin N	Eli Lilly and Company	
00002-8315-17	Humulin N	Eli Lilly and Company	
00002-8805-59	Humulin N	Eli Lilly and Company	
00002-8215-01	Humulin R	Eli Lilly and Company	
00002-8215-17	Humulin R	Eli Lilly and Company	
00002-8501-01	Humulin R500	Eli Lilly and Company	
00002-8824-27	Humulin R500	Eli Lilly and Company	
50458-0540-60	Invokamet	Janssen Pharmaceuticals, Inc.	Yes
50458-0541-60	Invokamet	Janssen Pharmaceuticals, Inc.	Yes
50458-0542-60	Invokamet	Janssen Pharmaceuticals, Inc.	Yes
50458-0543-60	Invokamet	Janssen Pharmaceuticals, Inc.	Yes
50458-0940-01	Invokamet XR	Janssen Pharmaceuticals, Inc.	Yes
50458-0941-01	Invokamet XR	Janssen Pharmaceuticals, Inc.	Yes
50458-0942-01	Invokamet XR	Janssen Pharmaceuticals, Inc.	Yes
50458-0943-01	Invokamet XR	Janssen Pharmaceuticals, Inc.	Yes
50458-0140-30	Invokana	Janssen Pharmaceuticals, Inc.	Yes
50458-0140-90	Invokana	Janssen Pharmaceuticals, Inc.	Yes
50458-0141-30	Invokana	Janssen Pharmaceuticals, Inc.	Yes
50458-0141-90	Invokana	Janssen Pharmaceuticals, Inc.	Yes
00006-0575-61	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0575-62	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0575-82	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0577-61	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0577-62	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0577-82	Janumet	Merck Sharp & Dohme Corp.	Yes

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00006-0078-61	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0078-62	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0080-61	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0080-62	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0080-82	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0081-31	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0081-54	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0081-82	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0112-28	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0112-31	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0112-54	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0221-28	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0221-31	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0221-54	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-01	Januvia	Merck Sharp & Dohme Corp.	
00006-0277-02	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-28	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-31	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-33	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-54	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-82	Januvia	Merck Sharp & Dohme Corp.	Yes
00597-0152-30	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0152-37	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0152-90	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0153-30	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0153-37	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0153-90	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0146-18	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0146-60	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0147-18	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0147-60	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0148-18	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0148-60	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0270-73	Jentadueto XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0270-94	Jentadueto XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0275-33	Jentadueto XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0275-81	Jentadueto XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
64764-0335-60	Kazano	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0337-60	Kazano	Takeda Pharmaceuticals U.S.A., Inc.	
00310-6125-60	Kombiglyze XR	AstraZeneca Pharmaceuticals LP	
00310-6135-30	Kombiglyze XR	AstraZeneca Pharmaceuticals LP	
00310-6145-30	Kombiglyze XR	AstraZeneca Pharmaceuticals LP	
00088-2219-05	Lantus	sanofi-aventis U.S. LLC	Yes
00088-2220-33	Lantus	sanofi-aventis U.S. LLC	Yes

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00088-5020-05	Lantus	sanofi-aventis U.S. LLC	Yes
00088-5021-01	Lantus	sanofi-aventis U.S. LLC	Yes
00169-3687-12	Levemir	Novo Nordisk	Yes
00169-6438-10	Levemir	Novo Nordisk	Yes
00591-2412-19	Metformin	Actavis Pharma, Inc.	
00591-2719-60	Metformin	Actavis Pharma, Inc.	
62037-0571-01	Metformin	Actavis Pharma, Inc.	
62037-0571-10	Metformin	Actavis Pharma, Inc.	
62037-0577-01	Metformin	Actavis Pharma, Inc.	
60687-0143-01	Metformin	American Health Packaging	Yes
65162-0220-10	Metformin	Amneal Pharmaceuticals LLC	
65162-0220-11	Metformin	Amneal Pharmaceuticals LLC	
65162-0220-50	Metformin	Amneal Pharmaceuticals LLC	
53746-0178-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0178-05	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0178-10	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0178-90	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0179-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0218-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0218-05	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0218-10	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0219-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0219-05	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0219-10	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0220-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0220-05	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0220-10	Metformin	Amneal Pharmaceuticals of New York LLC	
60505-0190-00	Metformin	Apotex Corp.	
60505-0260-01	Metformin	Apotex Corp.	
60505-0260-02	Metformin	Apotex Corp.	
60505-1329-01	Metformin	Apotex Corp.	
67877-0159-01	Metformin	Ascend Laboratories, LLC	
67877-0159-05	Metformin	Ascend Laboratories, LLC	
67877-0159-10	Metformin	Ascend Laboratories, LLC	
67877-0217-05	Metformin	Ascend Laboratories, LLC	
67877-0217-10	Metformin	Ascend Laboratories, LLC	
67877-0221-01	Metformin	Ascend Laboratories, LLC	
67877-0221-05	Metformin	Ascend Laboratories, LLC	
67877-0221-10	Metformin	Ascend Laboratories, LLC	
67877-0561-01	Metformin	Ascend Laboratories, LLC	
67877-0561-05	Metformin	Ascend Laboratories, LLC	
67877-0561-10	Metformin	Ascend Laboratories, LLC	
67877-0562-05	Metformin	Ascend Laboratories, LLC	
67877-0562-10	Metformin	Ascend Laboratories, LLC	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
67877-0563-01	Metformin	Ascend Laboratories, LLC	
67877-0563-05	Metformin	Ascend Laboratories, LLC	
67877-0563-10	Metformin	Ascend Laboratories, LLC	
65862-0008-01	Metformin	Aurobindo Pharma Limited	
65862-0008-05	Metformin	Aurobindo Pharma Limited	
65862-0008-99	Metformin	Aurobindo Pharma Limited	
65862-0009-01	Metformin	Aurobindo Pharma Limited	
65862-0009-05	Metformin	Aurobindo Pharma Limited	
65862-0010-01	Metformin	Aurobindo Pharma Limited	
65862-0010-05	Metformin	Aurobindo Pharma Limited	
65862-0010-99	Metformin	Aurobindo Pharma Limited	
00185-4416-01	Metformin	Eon Labs, Inc.	
42806-0213-05	Metformin	Epic Pharma, LLC	
42806-0213-10	Metformin	Epic Pharma, LLC	
42806-0215-01	Metformin	Epic Pharma, LLC	
42806-0221-05	Metformin	Epic Pharma, LLC	
42806-0313-05	Metformin	Epic Pharma, LLC	
42806-0314-01	Metformin	Epic Pharma, LLC	
42806-0315-05	Metformin	Epic Pharma, LLC	
68462-0159-01	Metformin	Glenmark Pharmaceuticals Inc., USA	
68462-0159-05	Metformin	Glenmark Pharmaceuticals Inc., USA	
68462-0159-10	Metformin	Glenmark Pharmaceuticals Inc., USA	
68462-0160-01	Metformin	Glenmark Pharmaceuticals Inc., USA	
68462-0161-05	Metformin	Glenmark Pharmaceuticals Inc., USA	
23155-0102-01	Metformin	Heritage Pharmaceuticals Inc.	
23155-0102-05	Metformin	Heritage Pharmaceuticals Inc.	
23155-0102-10	Metformin	Heritage Pharmaceuticals Inc.	
23155-0103-01	Metformin	Heritage Pharmaceuticals Inc.	
23155-0103-05	Metformin	Heritage Pharmaceuticals Inc.	
23155-0103-10	Metformin	Heritage Pharmaceuticals Inc.	
23155-0104-01	Metformin	Heritage Pharmaceuticals Inc.	
23155-0104-05	Metformin	Heritage Pharmaceuticals Inc.	
23155-0104-10	Metformin	Heritage Pharmaceuticals Inc.	
50742-0154-01	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0154-05	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0154-10	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0154-90	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0155-01	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0155-05	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0155-10	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0156-05	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0156-10	Metformin	Ingenus Pharmaceuticals, LLC	
68645-0300-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0539-59	Metformin	Legacy Pharmaceutical Packaging, LLC	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
68645-0544-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0545-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0546-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0547-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0549-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68180-0336-07	Metformin	Lupin Pharmaceuticals, Inc.	
68180-0338-01	Metformin	Lupin Pharmaceuticals, Inc.	
68180-0339-09	Metformin	Lupin Pharmaceuticals, Inc.	
33342-0240-11	Metformin	Macleods Pharmaceuticals Limited	
00904-6326-61	Metformin	Major Pharmaceuticals	
38779-2126-05	Metformin	Medisca, Inc.	
58657-0640-10	Metformin	Method Pharmaceuticals, LLC	
00378-6002-91	Metformin	Mylan	
00378-7185-05	Metformin	Mylan	
00378-7186-05	Metformin	Mylan	
00378-7187-05	Metformin	Mylan	
68682-0017-10	Metformin	Oceanside Pharmaceuticals	
68682-0018-90	Metformin	Oceanside Pharmaceuticals	
51927-3105-00	Metformin	Professional Co.	
00781-5503-01	Metformin	SANDOZ INC.	
43547-0248-50	Metformin	Solco healthcare U.S., LLC	
43547-0249-50	Metformin	Solco healthcare U.S., LLC	
43547-0357-10	Metformin	Solco healthcare U.S., LLC	
43547-0357-11	Metformin	Solco healthcare U.S., LLC	
43547-0357-50	Metformin	Solco healthcare U.S., LLC	
43547-0358-50	Metformin	Solco healthcare U.S., LLC	
43547-0359-10	Metformin	Solco healthcare U.S., LLC	
43547-0359-50	Metformin	Solco healthcare U.S., LLC	
57664-0397-51	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0397-53	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0397-58	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0435-51	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0435-53	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0435-58	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0435-88	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0474-51	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0474-53	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0474-58	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0474-88	Metformin	Sun Pharmaceutical Industries, Inc.	
62756-0142-01	Metformin	Sun Pharmaceutical Industries, Inc.	
62756-0142-02	Metformin	Sun Pharmaceutical Industries, Inc.	
62756-0143-01	Metformin	Sun Pharmaceutical Industries, Inc.	
51224-0007-50	Metformin	TAGI Pharma, Inc.	
51224-0007-60	Metformin	TAGI Pharma, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
51224-0107-50	Metformin	TAGI Pharma, Inc.	
51224-0107-60	Metformin	TAGI Pharma, Inc.	
00093-1048-01	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-1048-10	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-1049-10	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7212-01	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7214-01	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7214-10	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7267-01	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7267-10	Metformin	Teva Pharmaceuticals USA, Inc.	
49483-0620-10	Metformin	TIME CAP LABORATORIES, INC	
49483-0621-10	Metformin	TIME CAP LABORATORIES, INC	
49483-0623-01	Metformin	TIME CAP LABORATORIES, INC	Yes
49483-0623-09	Metformin	TIME CAP LABORATORIES, INC	
49483-0623-10	Metformin	TIME CAP LABORATORIES, INC	
49483-0623-50	Metformin	TIME CAP LABORATORIES, INC	Yes
49483-0624-01	Metformin	TIME CAP LABORATORIES, INC	
68382-0028-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0030-01	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0030-05	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0030-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0758-01	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0758-05	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0758-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0759-01	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0759-05	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0759-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0760-01	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0760-05	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0760-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
00591-2720-60	Metformin ER	Actavis Pharma, Inc.	
68180-0337-07	Metformin ER	Lupin Pharmaceuticals, Inc.	
00378-6001-91	Metformin ER	Mylan	
29033-0032-06	Metformin ER	Nostrum Laboratories, Inc.	
57664-0684-88	Miglitol	Sun Pharmaceutical Industries Ltd.	
57664-0685-88	Miglitol	Sun Pharmaceutical Industries Ltd.	
57664-0686-88	Miglitol	Sun Pharmaceutical Industries Ltd.	
00591-3354-01	Nateglinide	Actavis Pharma, Inc.	
00591-3355-01	Nateglinide	Actavis Pharma, Inc.	
68084-0458-21	Nateglinide	American Health Packaging	
68084-0459-21	Nateglinide	American Health Packaging	
55111-0328-90	Nateglinide	Dr. Reddy's Laboratories Limited	
55111-0329-90	Nateglinide	Dr. Reddy's Laboratories Limited	
49884-0984-01	Nateglinide	Par Pharmaceutical, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
49884-0985-01	Nateglinide	Par Pharmaceutical, Inc.	
68382-0721-16	Nateglinide	Zydus Pharmaceuticals (USA) Inc.	
68382-0722-16	Nateglinide	Zydus Pharmaceuticals (USA) Inc.	
64764-0125-30	Nesina	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0250-30	Nesina	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0625-30	Nesina	Takeda Pharmaceuticals U.S.A., Inc.	
00169-1837-02	Novolin 70-30	Novo Nordisk	
00169-1837-11	Novolin 70-30	Novo Nordisk	
00169-1834-02	Novolin N	Novo Nordisk	
00169-1834-11	Novolin N	Novo Nordisk	
00169-1833-02	Novolin R	Novo Nordisk	
00169-1833-11	Novolin R	Novo Nordisk	
00169-3303-12	Novolog	Novo Nordisk	Yes
00169-6339-10	Novolog	Novo Nordisk	Yes
00169-7501-11	Novolog	Novo Nordisk	Yes
32849-0500-81	Novolog	Novo Nordisk	
00169-3685-12	Novolog 70/30	Novo Nordisk	Yes
00169-3696-19	Novolog 70/30	Novo Nordisk	Yes
00310-6100-30	Onglyza	AstraZeneca Pharmaceuticals LP	
00310-6100-90	Onglyza	AstraZeneca Pharmaceuticals LP	
00310-6105-30	Onglyza	AstraZeneca Pharmaceuticals LP	
00310-6105-50	Onglyza	AstraZeneca Pharmaceuticals LP	
00310-6105-90	Onglyza	AstraZeneca Pharmaceuticals LP	
64764-0121-03	Oseni	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0251-03	Oseni	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0253-03	Oseni	Takeda Pharmaceuticals U.S.A., Inc.	
00169-4132-12	Ozempic	Novo Nordisk	Yes
00169-4136-02	Ozempic	Novo Nordisk	Yes
16729-0020-10	Pioglitazone	Accord Healthcare, Inc.	
16729-0020-15	Pioglitazone	Accord Healthcare, Inc.	
16729-0020-16	Pioglitazone	Accord Healthcare, Inc.	
16729-0021-10	Pioglitazone	Accord Healthcare, Inc.	
16729-0021-15	Pioglitazone	Accord Healthcare, Inc.	
16729-0021-16	Pioglitazone	Accord Healthcare, Inc.	
16729-0022-10	Pioglitazone	Accord Healthcare, Inc.	
16729-0022-15	Pioglitazone	Accord Healthcare, Inc.	
16729-0022-16	Pioglitazone	Accord Healthcare, Inc.	
00591-3205-05	Pioglitazone	Actavis Pharma, Inc.	
00591-3205-19	Pioglitazone	Actavis Pharma, Inc.	
00591-3205-30	Pioglitazone	Actavis Pharma, Inc.	
00591-3206-19	Pioglitazone	Actavis Pharma, Inc.	
00591-3206-30	Pioglitazone	Actavis Pharma, Inc.	
00591-3207-05	Pioglitazone	Actavis Pharma, Inc.	
00591-3207-19	Pioglitazone	Actavis Pharma, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00591-3207-30	Pioglitazone	Actavis Pharma, Inc.	
68084-0878-01	Pioglitazone	American Health Packaging	
54458-0864-10	Pioglitazone	International Laboratories, LLC	Yes
54458-0865-10	Pioglitazone	International Laboratories, LLC	Yes
54458-0866-10	Pioglitazone	International Laboratories, LLC	Yes
33342-0054-07	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0054-10	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0054-15	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0055-07	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0055-10	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0055-15	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0056-07	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0056-10	Pioglitazone	Macleods Pharmaceuticals Limited	
51079-0513-20	Pioglitazone	Mylan	
00378-0048-77	Pioglitazone	Mylan	
00378-0048-93	Pioglitazone	Mylan	
00378-0228-77	Pioglitazone	Mylan	
00378-0228-93	Pioglitazone	Mylan	
00378-0318-93	Pioglitazone	Mylan	
63304-0313-30	Pioglitazone	Ranbaxy Pharmaceuticals Inc.	
00781-5420-31	Pioglitazone	Sandoz Inc	
00781-5420-92	Pioglitazone	Sandoz Inc	
00781-5421-31	Pioglitazone	Sandoz Inc	
00781-5421-92	Pioglitazone	Sandoz Inc	
00781-5422-31	Pioglitazone	Sandoz Inc	
00781-5422-92	Pioglitazone	Sandoz Inc	
00093-2046-98	Pioglitazone	Teva Pharmaceuticals USA Inc	
00093-2047-98	Pioglitazone	Teva Pharmaceuticals USA Inc	
00093-7271-56	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7271-98	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7272-56	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7272-98	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7273-56	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7273-98	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
13668-0119-05	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0119-30	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0119-90	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0120-05	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0120-30	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0120-90	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0140-30	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0140-90	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
66993-0821-30	Pioglitazone-Glimepiride	Prasco Laboratories	
66993-0822-30	Pioglitazone-Glimepiride	Prasco Laboratories	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00781-5634-31	Pioglitazone-Glimepiride	Sandoz Inc	
00781-5635-31	Pioglitazone-Glimepiride	Sandoz Inc	
65862-0525-60	Pioglitazone-Metformin	Aurobindo Pharma Limited	
65862-0526-18	Pioglitazone-Metformin	Aurobindo Pharma Limited	
65862-0526-60	Pioglitazone-Metformin	Aurobindo Pharma Limited	
33342-0177-09	Pioglitazone-Metformin	Macleods Pharmaceuticals Limited	
00378-1550-91	Pioglitazone-Metformin	Mylan	
00378-1575-91	Pioglitazone-Metformin	Mylan	
57237-0218-60	Pioglitazone-Metformin	Rising Health, LLC	
00781-5626-60	Pioglitazone-Metformin	Sandoz Inc	
00781-5627-60	Pioglitazone-Metformin	Sandoz Inc	
00093-7677-06	Pioglitazone-Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7678-06	Pioglitazone-Metformin	Teva Pharmaceuticals USA, Inc.	
13668-0280-60	Pioglitazone-Metformin	TORRENT PHARMACEUTICALS LIMITED	
13668-0281-60	Pioglitazone-Metformin	TORRENT PHARMACEUTICALS LIMITED	
60846-0882-01	Prandin	Gemini Laboratories, LLC	Yes
60846-0884-01	Prandin	Gemini Laboratories, LLC	Yes
10631-0206-01	Riomet	Sun Pharmaceutical Industries, Inc.	Yes
10631-0206-02	Riomet	Sun Pharmaceutical Industries, Inc.	Yes
10631-0238-01	Riomet	Sun Pharmaceutical Industries, Inc.	Yes
10631-0238-02	Riomet	Sun Pharmaceutical Industries, Inc.	Yes
00006-5369-03	Segluromet	Merck Sharp & Dohme Corp.	
00006-5369-06	Segluromet	Merck Sharp & Dohme Corp.	
00006-5370-03	Segluromet	Merck Sharp & Dohme Corp.	
00006-5370-06	Segluromet	Merck Sharp & Dohme Corp.	
00006-5373-03	Segluromet	Merck Sharp & Dohme Corp.	
00006-5373-06	Segluromet	Merck Sharp & Dohme Corp.	
00006-5374-03	Segluromet	Merck Sharp & Dohme Corp.	
00006-5374-06	Segluromet	Merck Sharp & Dohme Corp.	
00024-5761-05	Soliqua 100/33	Sanofi-Aventis U.S. LLC	Yes
00078-0351-05	Starlix	Novartis Pharmaceuticals Corporation	Yes
00078-0352-05	Starlix	Novartis Pharmaceuticals Corporation	Yes
00006-5364-03	Steglatro	Merck Sharp & Dohme Corp.	
00006-5364-06	Steglatro	Merck Sharp & Dohme Corp.	
00006-5367-03	Steglujan	Merck Sharp & Dohme Corp.	
00006-5367-06	Steglujan	Merck Sharp & Dohme Corp.	
00006-5368-03	Steglujan	Merck Sharp & Dohme Corp.	
00006-5368-06	Steglujan	Merck Sharp & Dohme Corp.	
00310-6615-02	Symlinpen	AstraZeneca Pharmaceuticals LP	
00310-6627-02	Symlinpen	AstraZeneca Pharmaceuticals LP	
00597-0159-18	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0159-60	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0168-18	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0168-60	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00597-0175-18	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0175-60	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0180-18	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0180-60	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0280-90	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0290-74	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0280-73	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0290-59	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0295-78	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0295-88	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0300-45	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0300-93	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00173-0866-01	Tanzeum	GlaxoSmithKline LLC	
00173-0866-35	Tanzeum	GlaxoSmithKline LLC	
00173-0867-35	Tanzeum	GlaxoSmithKline LLC	
00024-5869-03	Toujeo	Sanofi-Aventis U.S. LLC	Yes
00024-5871-02	Toujeo	Sanofi-Aventis U.S. LLC	Yes
00597-0140-30	Tradjenta	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0140-61	Tradjenta	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0140-90	Tradjenta	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00169-2550-13	Tresiba	Novo Nordisk	Yes
00169-2660-15	Tresiba	Novo Nordisk	Yes
00002-1433-01	Trulicity	Eli Lilly and Company	
00002-1433-80	Trulicity	Eli Lilly and Company	Yes
00002-1434-01	Trulicity	Eli Lilly and Company	
00002-1434-80	Trulicity	Eli Lilly and Company	Yes
00169-4060-12	Victoza	Novo Nordisk	Yes
00169-4060-13	Victoza	Novo Nordisk	Yes
65597-0701-18	Welchol	Daiichi Sankyo Inc.	Yes
65597-0902-30	Welchol	Daiichi Sankyo Inc.	Yes
00310-6250-30	Xigduo XR	AstraZeneca Pharmaceuticals LP	Yes
00310-6260-60	Xigduo XR	AstraZeneca Pharmaceuticals LP	Yes
00310-6270-30	Xigduo XR	AstraZeneca Pharmaceuticals LP	Yes
00310-6280-30	Xigduo XR	AstraZeneca Pharmaceuticals LP	Yes
00169-2911-15	Xultophy 100/3.6	Novo Nordisk	Yes

# EXHIBIT 11

# EXHIBIT 11



**BY E-MAIL**

Nevada Department of Health and Human Services  
4150 Technology Way, Suite 300  
Carson City, NV 89703  
[drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov)

January 15, 2019

**Re: Sanofi US Trade Secret/Confidentiality Request Pursuant to Nevada SB 539**

To Whom It May Concern:

In accordance with Section 3(1) of approved regulation R042-18, which implements Senate Bill No. 539 ("SB 539"), Sanofi US hereby submits this request for confidentiality relating to certain confidential and proprietary information and data as specified below (the "Sanofi Confidential Information") submitted to the Nevada Department of Health and Human Services (the "Department") as required by Section 3.8 of SB 539 (NRS 439B.635). Sanofi US reasonably believes that public disclosure of the Sanofi Confidential Information to any person or entity outside of the Department including to state legislators, would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended (the "DTSA"). In addition, Sanofi submits this request in reliance upon the Joint Status Report filed on June 28, 2018 in the matter of Pharmaceutical Research and Manufacturers of America v. Sandoval, et. al. , United States District Court, District of Nevada, Case No.: 2:17-cv-023150JCM-CWH, in which the State of Nevada and the Department agreed that if the Department were to disclose trade secrets of Sanofi to any third party or use such trade secrets, such disclosure or use would constitute misappropriation for which a court may award relief to Sanofi pursuant to the DTSA.

As specified by Section 3(2) of the regulation, this request for confidentiality is divided into two parts.

In preparing this request, Sanofi US has exercised reasonable diligence to ensure that the Sanofi Confidential Information has in fact been kept secret and has not previously been disclosed, whether intentionally or unintentionally. To the extent the information has inadvertently been disclosed publicly, such inadvertent disclosure does not constitute a waiver of trade secret status.

Part 1: Description of Sanofi Confidential Information

Sanofi US seeks to protect from public disclosure the following Sanofi Confidential Information that is required to be submitted to the Department pursuant to Section 3.8 of SB 539 for certain of its diabetes drugs:

1. The costs of producing the drug (Section 3.8(1));
2. The total administrative expenditures relating to the drug, including marketing and advertising costs (Section 3.8(2));
3. The profit that Sanofi US has earned from the drug and the percentage of Sanofi US's total profit that is attributable to the drug (Section 3.8(3));
4. The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program (Section 3.8(4));



5. The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs (Section 3.8(5)); and
6. The aggregate amount of all rebates that Sanofi US has provided to pharmacy benefit managers for sales of the drug within the State of Nevada (Section 3.8(8)).

#### Part 2: Rationale for Trade Secret Protection Under the DTSA.

The Sanofi Confidential Information is confidential and proprietary information of Sanofi US and falls within the definition of a “trade secret” under the DTSA because it is of substantial independent value to Sanofi US by virtue of it being confidential and non-public. Any public disclosure of such Sanofi Confidential Information would cause significant harm to Sanofi US.

In satisfaction of 18 U.S.C. § 1839(3)(A), which requires that “the owner [of a trade secret] has taken reasonable measures to keep such information secret,” the Sanofi Confidential Information is not shared publicly, and access to it is restricted internally and only shared internally on a need-to-know basis. It is subject to non-disclosure requirements in Sanofi US's employment and other business agreements. Employees of Sanofi US are required to maintain the secrecy of the Sanofi Confidential Information, and are subject to discipline—up to and including termination—by Sanofi US for its unauthorized disclosure.

In satisfaction of 18 U.S. § 1839(3)(B), which requires that a trade secret be “information [which] derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information,” the Sanofi Confidential Information is valuable precisely because it is confidential, and it would lose value upon disclosure. The customers and competitors of Sanofi US would gain an unfair competitive advantage if they were to obtain the Sanofi Confidential Information through a public records request pursuant to NRS 239.010. In particular, Sanofi US's competitors and customers would receive the details of our cost structure, marketing and advertising costs, rebate strategies and profit information, which in turn provides insight into our pricing. This information could be used against us in negotiations with insurers and other intermediaries in the healthcare system. This could put Sanofi US at a significant disadvantage, especially if our competitors do not make a diabetes drug and thus are not subject to SB 539's disclosure requirements. Disclosure of the Sanofi Confidential Information could prejudice Sanofi US in competition involving non-diabetes products as well, given that Sanofi US considers the same or similar factors when establishing pricing, advertising and rebate strategies for its other therapeutic products. Such far-reaching effects on non-diabetes drugs would exceed the intent of the Nevada legislature in enacting this statute.



### Conclusion

For all of these reasons, the Sanofi Confidential Information qualifies for trade secret protection under the DTSA and public disclosure of the Sanofi Confidential Information by the Department would constitute misappropriation of a trade secret thereunder. Sanofi US therefore requests that the Department keep confidential the information described in Part 1 of this request and not disclose it upon any request for public records under NRS 239.010.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Phillip Ridolfi', written over a horizontal line.

Phillip Ridolfi

Head of Business Operations and Support, Sales Support

# EXHIBIT 12

# EXHIBIT 12



**BY E-MAIL**

Nevada Department of Health and Human Services  
4150 Technology Way, Suite 300  
Carson City, NV 89703  
[drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov)

April 1, 2019

**Re: Sanofi US Trade Secret/Confidentiality Request Pursuant to Nevada SB 539**

To Whom It May Concern:

In accordance with Section 3(1) of approved regulation R042-18, which implements Senate Bill No. 539 ("SB 539"), Sanofi US hereby submits this request for confidentiality relating to certain confidential and proprietary information and data as specified below (the "Sanofi Confidential Information") for the information reported for 2018 submitted to the Nevada Department of Health and Human Services (the "Department") as required by Section 3.8 of SB 539 (NRS 439B.635). Sanofi US reasonably believes that public disclosure of the Sanofi Confidential Information to any person or entity outside of the Department including to state legislators, would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended (the "DTSA"). In addition, Sanofi submits this request in reliance upon the Joint Status Report filed on June 28, 2018 in the matter of Pharmaceutical Research and Manufacturers of America v. Sandoval, et. al., United States District Court, District of Nevada, Case No.: 2:17-cv-023150JCM-CWH, in which the State of Nevada and the Department agreed that if the Department were to disclose trade secrets of Sanofi to any third party or use such trade secrets, such disclosure or use would constitute misappropriation for which a court may award relief to Sanofi pursuant to the DTSA.

As specified by Section 3(2) of the regulation, this request for confidentiality is divided into two parts.

In preparing this request, Sanofi US has exercised reasonable diligence to ensure that the Sanofi Confidential Information has in fact been kept secret and has not previously been disclosed, whether intentionally or unintentionally. To the extent the information has inadvertently been disclosed publicly, such inadvertent disclosure does not constitute a waiver of trade secret status.

**Part 1: Description of Sanofi Confidential Information**

Sanofi US seeks to protect from public disclosure the following Sanofi Confidential Information reported for 2018 that is required to be submitted to the Department pursuant to Section 3.8 of SB 539 for certain of its diabetes drugs:

1. The costs of producing the drug (Section 3.8(1));
2. The total administrative expenditures relating to the drug, including marketing and advertising costs (Section 3.8(2));
3. The profit that Sanofi US has earned from the drug and the percentage of Sanofi US's total profit that is attributable to the drug (Section 3.8(3));
4. The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program (Section 3.8(4));



5. The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs (Section 3.8(5)); and
6. The aggregate amount of all rebates that Sanofi US has provided to pharmacy benefit managers for sales of the drug within the State of Nevada (Section 3.8(8)).\*

#### Part 2: Rationale for Trade Secret Protection Under the DTSA.

The Sanofi Confidential Information is confidential and proprietary information of Sanofi US and falls within the definition of a "trade secret" under the DTSA because it is of substantial independent value to Sanofi US by virtue of it being confidential and non-public. Any public disclosure of such Sanofi Confidential Information would cause significant harm to Sanofi US.

In satisfaction of 18 U.S.C. § 1839(3)(A), which requires that "the owner [of a trade secret] has taken reasonable measures to keep such information secret," the Sanofi Confidential Information is not shared publicly, and access to it is restricted internally and only shared internally on a need-to-know basis. It is subject to non-disclosure requirements in Sanofi US's employment and other business agreements. Employees of Sanofi US are required to maintain the secrecy of the Sanofi Confidential Information, and are subject to discipline—up to and including termination—by Sanofi US for its unauthorized disclosure.

In satisfaction of 18 U.S. § 1839(3)(B), which requires that a trade secret be "information [which] derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information," the Sanofi Confidential Information is valuable precisely because it is confidential, and it would lose value upon disclosure. The customers and competitors of Sanofi US would gain an unfair competitive advantage if they were to obtain the Sanofi Confidential Information through a public records request pursuant to NRS 239.010. In particular, Sanofi US's competitors and customers would receive the details of our cost structure, marketing and advertising costs, rebate strategies and profit information, which in turn provides insight into our pricing. This information could be used against us in negotiations with insurers and other intermediaries in the healthcare system. This could put Sanofi US at a significant disadvantage, especially if our competitors do not make a diabetes drug and thus are not subject to SB 539's disclosure requirements. Disclosure of the Sanofi Confidential Information could prejudice Sanofi US in competition involving non-diabetes products as well, given that Sanofi US considers the same or similar factors when establishing pricing, advertising and rebate strategies for its other therapeutic products. Such far-reaching effects on non-diabetes drugs would exceed the intent of the Nevada legislature in enacting this statute.

\*Information reported is as of September 31, 2018 due to data availability. A revised report with Q4 data included will be submitted when all relevant information necessary for reporting is available, which we anticipate will be prior to August 31, 2019.



## Conclusion

For all of these reasons, the Sanofi Confidential Information qualifies for trade secret protection under the DTSA and public disclosure of the Sanofi Confidential Information by the Department would constitute misappropriation of a trade secret thereunder. Sanofi US therefore requests that the Department keep confidential the information described in Part 1 of this request and not disclose it upon any request for public records under NRS 239.010.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'PR', with a long horizontal flourish extending to the right.

Phillip Ridolfi

Head of Business Operations and Support, Sales Support



1 **OPP**

2 MATTHEW J. RASHBROOK  
3 Nevada State Bar No. 12477  
4 ROBERT L. LANGFORD, ESQ.  
5 Nevada State Bar No. 3988  
6 ROBERT L. LANGFORD & ASSOCIATES  
7 616 S. Eighth Street  
8 Las Vegas, NV 89101  
(702) 471-6565  
9 matt@robertlangford.com  
10 robert@robertlangford.com  
11 *Attorneys for Petitioner*  
12 *The Nevada Independent*

9 **EIGHTH JUDICIAL DISTRICT COURT**

10 **LAS VEGAS, NEVADA**

11 THE NEVADA INDEPENDENT,

12  
13 Petitioner,

14 vs.

15 RICHARD WHITLEY, in his official  
16 capacity as the Director of the Nevada  
17 Department of Health and Human Services,  
18 and THE STATE OF NEVADA, ex rel. the  
19 NEVADA DEPARTMENT OF HEALTH  
20 AND HUMAN SERVICES;

21 Respondents.

Case No.: A-19-799939-W

Dept. No.: 14

**PETITIONER'S OPPOSITION TO  
SANOFI-AVENTIS U.S. LLC'S MOTION  
TO INTERVENE AND TO CONTINUE  
HEARING**

22 COMES NOW Petitioner, The Nevada Independent, by and through their  
23 attorneys, Matthew J. Rashbrook, and Robert L. Langford, Esq., of the firm Robert L.  
24 Langford & Associates, and opposes Sanofi-Aventis U.S. LLC ("Sanofi")'s Motion to  
25 Intervene and to Continue Hearing.

26 ///

27 ///

28 ///

1 The opposition is based on the attached Memorandum of Points and Authorities,  
2 the papers and pleadings already on file in this matter, and such argument as the Court may  
3 entertain at the hearing of the Motion.

4 All of which is respectfully submitted, this 31st day of October, 2019.

5  
6 

7 MATTHEW J. RASHBROOK  
8 Nevada State Bar No. 12477  
9 ROBERT L. LANGFORD, ESQ.  
10 Nevada State Bar No. 3988  
11 ROBERT L. LANGFORD &  
12 ASSOCIATES  
13 616 S. Eighth Street  
14 Las Vegas, NV 89101  
15 (702) 471-6565  
16 matt@robertlangford.com  
17 robert@robertlangford.com  
18 *Attorneys for Petitioner*  
19 *The Nevada Independent*  
20  
21  
22  
23  
24  
25  
26  
27  
28

1  
2  
3  
4  
5  
6  
7  
8  
9  
0  
1  
2  
3  
4  
5  
6  
7  
8  
9  
0  
1  
2  
3  
4  
5  
6  
7  
8

6  
7  
8  
9  
0  
1  
2  
3  
4  
5  
6  
7  
8  
9  
0  
1  
2  
3  
4  
5  
6  
7  
8

9  
0  
1  
2  
3  
4  
5  
6  
7  
8  
9  
0  
1  
2  
3  
4  
5  
6  
7  
8

6  
7  
8  
9  
0  
1  
2  
3  
4  
5  
6  
7  
8

3  
4  
5  
6  
7  
8

5.  
6  
7  
8

6  
7  
8

JA - 000458

1 access must be narrowly construed.” See, e.g., *Reno Newspapers, Inc. v. Gibbons*, 127 Nev.  
2 873, 878, 266 P.3d 623, 626 (2011).

3 Sanofi has no interest in this matter which is not already being protected – as it  
4 concedes, *Motion to Intervene*, 7 (“While it is anticipated that the State of Nevada –  
5 through the Nevada Attorney General’s Office – can adequately represent Sanofi’s interest  
6 . . .”) – and the intervention would subject Petitioner to significant prejudice, including  
7 further delay and a dramatic escalation in the cost to litigate – which Respondent and  
8 Sanofi will both attempt to escape. The Nevada Independent therefore Opposes the Motion  
9 to Intervene, and accordingly, respectfully asks this Court to deny the Motion.

#### 10 Procedural History

11 On August 8, 2019, The Nevada Independent filed the instant action, seeking to  
12 vindicate its right to access certain public records in the possession of Respondents.

13 On August 9, 2019, this Court calendared a hearing on the Petition for September  
14 10, 2019.

15 On August 27, 2019, the Court continued the hearing to October 22, 2019, and  
16 directed the parties to file and provide briefs to chambers not later than October 17, 2019.

17 On October 15, 2019, Petitioner filed a Supplemental Brief. On October 17, 2019,  
18 Respondents filed their Opposition and Motion to Dismiss.

19 On October 17, Sanofi filed its Motion to Intervene and to Continue, together  
20 with a request for an Order Shortening Time, which Order this Court signed October 18,  
21 2019, setting a hearing on that Motion for November 5, 2019. Also, on October 18, 2019,  
22 the Court contacted counsel to advise that the hearing of the Petition, then scheduled to be  
23 heard October 22, 2019, would be continued to November 19, 2019.

#### 24 Legal Standard

25 Sanofi correctly states the standard for non-statutory intervention of right, under  
26 Nev. R. Civ. P. 24(a)(2): “(1) that [the proposed intervener] has a sufficient interest in the  
27 litigation’s subject matter, (2) that it could suffer an impairment of its ability to protect that  
28 interest if it does not intervene, (3) that its interest is not adequately represented by existing

1 parties, and (4) that its application is timely.” *Am. Home Assur. Co. v. Eighth Jud. Dist. Ct.*,  
2 122 Nev. 1229, 1238, 147 P.3d 1120, 1126 (2006). “Determining whether an applicant has  
3 met these four requirements is within the district court’s discretion.” *Id.*

4 Sanofi cannot show that its interest is not already adequately represented by  
5 Respondents, nor that its application is timely, and therefore the Motion must be denied.

6 Sanofi alternatively seeks intervention under Nev. R. Civ. P. 24(b)(1)(B), which  
7 outlines the standard for permissive intervention. Under Nev. R. Civ. P. 24(b)(1)(B), “On  
8 timely motion, the court may permit anyone to intervene who . . . has a claim or defense  
9 that shares with the main action a common question of law or fact.”

10 Nev. R. Civ. P. 24(b)(1)(B) allows for intervention only when a party shares a  
11 claim or defense with the main action. In this instance, because Sanofi is not a  
12 governmental entity and therefore cannot be the target of such a suit, they cannot be said to  
13 share a defense to the main action.

14 Further, under Nev. R. Civ. P. 24(b)(3), “the court must consider whether the  
15 intervention will unduly delay or prejudice adjudication of the original parties’ rights.”  
16 Because Petitioner will be unfairly prejudiced by the intervention, the Motion must be  
17 denied.

18 Sanofi’s Cannot be a Respondent in an NPRA Case and Therefore Cannot Share a Defense  
19 with Respondent

20 Permissive intervention, under Nev. R. Civ. P. 24(b)(1)(B), is only allowed where  
21 a proposed intervener “has a claim or defense that shares with the main action a common  
22 question of law or fact.” However, under the NPRA, only a “governmental entity,” is  
23 obligated to provide public records to those requesting them. NRS § 239.010. Sanofi is not  
24 a “governmental entity,” as that term is defined in Nev. Rev. Stat. § 239.005(5). Because  
25 Sanofi cannot be named as a Respondent in such an action, they cannot have a defense in  
26 such an action. Sanofi advances no claim in their Motion or proposed Response, and  
27 therefore the requirements of Nev. R. Civ. P. 24(b)(1)(B) are not, and indeed, cannot be,  
28 satisfied.

1                   Sanofi's Interests are Adequately Protected by Respondents

2           Sanofi concedes that it cannot satisfy the third prong of the Nev. R. Civ. P.  
3 24(a)(2) test ("that its interest is not adequately represented by existing parties," *Am. Home*  
4 *Assur. Co. v. Eighth Jud. Dist. Ct.*, 122 Nev. at 1238, 147 P.3d at 1126), and therefore must  
5 not be allowed to intervene. *See, Motion*, 7 ("... it is anticipated that the State of Nevada . .  
6 . can adequately represent Sanofi's interest"), 12 ("Sanofi anticipates that the State will  
7 adequately demonstrate statutory and/or regulatory basis").

8           Indeed, "when the [proposed intervenor's] interest or ultimate objective in the  
9 litigation is the same as the [main action party's] objective, the [main action party's]  
10 representation should generally be adequate[.]" *Am. Home Assur. Co.*, 122 Nev. at 1241,  
11 147 P.3d at 1128.

12           Sanofi has conceded that Respondents will adequately protect its interests.  
13 Respondents have throughout aligned themselves tightly with Sanofi and other  
14 pharmaceutical manufacturers and pharmacy benefit managers and have now filed briefing  
15 indicating they will continue to do the same. Sanofi suggests that it has particular  
16 knowledge outside that Respondents possess, but substantially what they propose to include  
17 in their Response are matters which are already public record. *See, e.g.*, Exhibits 3 – 8, 10,  
18 to proposed Response.

19                   Sanofi's Motion is Untimely Filed. Prejudicing Petitioner

20           Although Sanofi's Motion is brought before the court "[b]efore the trial [,]" Nev.  
21 Rev. Stat. § 12.130(1), "even when made before trial, an application must be 'timely' in the  
22 sense afforded the term under NRCP 24." *Am. Home. Assur. Co.*, 122 Nev. at 1244, 147  
23 P.3d at 1130. "Determining whether an application is timely under NRCP 24 involves  
24 examining 'the extent of the prejudice to the rights of existing parties resulting from the  
25 delay' and then weighing that prejudice resulting to the applicant if the intervention is  
26 denied." *Id.*, quoting *Dangberg Holdings v. Douglas Co.*, 115 Nev. 129, 141, 978 P.2d 311,  
27 318 (1999).

1 In this respect, Petitioner stands to be deeply prejudiced by the proposed  
2 intervention. Sanofi has already prejudiced Petitioner by forcing the Court to extend the  
3 hearing date approximately 30 days. The NRPA makes clear – and the recent amendments  
4 to the NRPA make even clearer, given that new statutory penalties for governmental  
5 entities are calculated based on the length of time records are withheld – that timely  
6 production of public records is critical to compliance with the NRPA. This follows  
7 naturally from the fact that the public must have timely access to public records in order to  
8 participate in government, whether by comment on proposed changes to legislation,  
9 regulations, or voting.

10 Sanofi's proposed intervention in the case has already prejudiced Petitioner by  
11 virtue of a delay of 28 days. Sanofi's proposed Response, including Exhibits, is  
12 approximately 180 pages in length. Petitioner will likely request an opportunity to respond  
13 in writing in the event that intervention is allowed, only exacerbating the prejudice  
14 suffered.

15 Sanofi filed its Motion to Intervene just two business days before the Petition was  
16 set to be heard, necessitating a delay of – so far – 28 days, despite the near certainty they  
17 were aware of the filing of the Petition at or around the time it was filed, approximately 70  
18 days earlier. Sanofi is attempting to use its effectively limitless resources to limit  
19 Petitioner's right to access public records by turning these proceedings into a war of  
20 attrition, as indicated by their near 200-page Motion to Intervene and to Continue Hearing.

21 Petitioner will be Further Prejudiced by Intervention

22 Under Nev. Rev. Stat. § 239.011, Petitioner is entitled to “priority over other civil  
23 matters to which priority is not given by other statutes.” Further, “If the requester prevails,  
24 the requester is entitled to recover his or her costs and reasonable attorney's fees in the  
25 proceeding from the governmental entity whose officer has custody of the book or record.”

26 If Sanofi is allowed to intervene, Petitioner will suffer additional increased  
27 expenditure of their limited resources in terms of costs and attorney's fees. Given the  
28 language of Nev. Rev. Stat. § 239.011, Petitioner anticipates an argument from Sanofi that

1 it isn't responsible for attorney's fees of Petitioner because it is not "the governmental  
2 entity whose officer has custody of the book or record[.]" and an argument from  
3 Respondents that it should not be held responsible for the actions of Sanofi which are  
4 beyond their control. Of course, Petitioner refutes these arguments, but the potential for  
5 extreme prejudice to Petitioner cannot be overlooked. When, as here, there is no need for  
6 intervention, as Sanofi concedes Respondents are adequately advocating on its behalf, the  
7 prejudice suffered by Petitioner overwhelms Sanofi's interest in intervention.

8 As Sanofi seeks to intervene, it aligns itself in the stance of Respondent, arguing  
9 that it has defenses in common with Respondent. However, when met with Petitioner's  
10 eventual motion for attorney's fees and costs, it will cite the above passage in seeking to  
11 escape responsibility and will argue there is a critical distinction between itself and  
12 Respondent – that it is not a governmental entity. In the event this Court is persuaded by  
13 Sanofi's motion, Sanofi must be responsible for whatever share of Petitioner's eventual  
14 attorney's fees are owed to its participation.

#### 15 Conclusion

16 Petitioners in NPRA cases are almost universally opposed by government  
17 agencies with effectively limitless resources, as The Nevada Independent is here. Sanofi,  
18 proposing to intervene, concedes that their interests are already adequately represented by  
19 the government's limitless resources, but still proposes to bring their own limitless  
20 resources to bear, and asks the Court to ignore the extensive prejudice Petitioner has  
21 already and will no doubt continue to suffer.

22 ///

23 ///

24 ///

25 ///

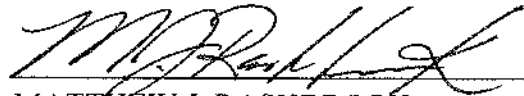
26 ///

27 ///

28 ///

1 Sanofi cannot satisfy the requirements of either permissive intervention, or  
2 intervention as of right, as its interests are adequately represented by Respondents, it is  
3 untimely in seeking to intervene, and because intervention will unreasonably prejudice  
4 Petitioners in terms of time and inability to recover significant attorney's fees. Sanofi's  
5 Motion should be denied in all respects.

6 All of which is respectfully submitted, this 31st day of October, 2019.

7  
8 

9 MATTHEW J. RASHBROOK  
10 Nevada State Bar No. 12477  
11 ROBERT L. LANGFORD, ESQ.  
12 Nevada State Bar No. 3988  
13 ROBERT L. LANGFORD &  
14 ASSOCIATES  
15 616 S. Eighth Street  
16 Las Vegas, NV 89101  
17 (702) 471-6565  
18 matt@robertlangford.com  
19 robert@robertlangford.com  
20 *Attorneys for Petitioner*  
21 *The Nevada Independent*  
22  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

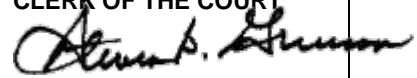
I hereby certify and affirm that on this 31st day of October, 2019, the foregoing  
**PETITIONER'S OPPOSITION TO SANOFI-AVENTIS U.S. LLC'S MOTION TO INTERVENE  
AND TO CONTINUE HEARING** was served by electronic mail to the following counsel of  
record:

Aaron D. Ford  
Nevada Attorney General  
Nevada Bar No. 7704  
Steve Shevorski  
Chief Litigation Counsel  
Nevada Bar No. 8256  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
Fax: 702-486-3768  
sshevorski@ag.nv.gov

John R. Bailey  
Nevada Bar No. 137  
Dennis L. Kennedy  
Nevada Bar No. 1462  
Sarah E. Harmon  
Nevada Bar No. 8106  
Bailey Kennedy  
8984 Spanish Ridge Avenue  
Las Vegas, NV 89148  
Fax: 702-562-8821  
jbailey@baileykennedy.com  
dkennedy@baileykennedy.com  
sharmon@baileykennedy.com

/s/ Dona Dines

An Employee of Robert L. Langford &  
Associates



1 **RIS**

JOHN R. BAILEY

2 Nevada Bar No. 0137

DENNIS L. KENNEDY

3 Nevada Bar No. 1462

SARAH E. HARMON

4 Nevada Bar No. 8106

**BAILEY ♦ KENNEDY**

5 8984 Spanish Ridge Avenue

Las Vegas, Nevada 89148-1302

6 Telephone: 702.562.8820

Facsimile: 702.562.8821

7 JBailey@BaileyKennedy.com

DKennedy@BaileyKennedy.com

8 SHarmon@BaileyKennedy.com

9 *Attorneys for Proposed Intervenor*

SANOFI-AVENTIS U.S. LLC

10  
11 DISTRICT COURT

12 CLARK COUNTY, NEVADA

13 THE NEVADA INDEPENDENT,

14 Petitioner,

15 vs.

16 RICHARD WHITLEY, in his official capacity as  
17 the Director of the Nevada Department of Health  
and Human Services, and THE STATE OF  
18 NEVADA ex rel. the NEVADA DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

19 Respondents.

Case No. A-19-799939-W

Dept. No. XIV

**Date of Hearing:** November 5, 2019

**Time of Hearing:** 9:30 a.m.

20  
21 **SANOFI-AVENTIS U.S. LLC'S REPLY IN SUPPORT OF MOTION TO INTERVENE**

22 It is undisputed that most of the information and records that the Petitioner seeks from the  
23 Respondents constitute Sanofi's trade secrets and confidential information; yet, the Petitioner's  
24 Opposition to Sanofi's Motion to Intervene misguidedly asserts that Sanofi should not be allowed to  
25 intervene in this case. NRCP 24 and NRS 12.130 specifically allow a non-party the right (both  
26 mandatory and permissively) to intervene in a case to protect its rights and interests. Here, that is

27 ///

28 ///

1 precisely what Sanofi is doing — seeking to protect its most sensitive information from public  
2 disclosure and competitor use. While the State can and has adequately represented Sanofi’s interests  
3 by demonstrating the statutory and regulatory basis for maintaining the confidentiality of Sanofi’s  
4 trade secrets, the State cannot provide adequate representation in informing this Court about the  
5 steps Sanofi takes to preserve and protect its trade secrets from public disclosure and the harm it will  
6 suffer as a result of such disclosure. Therefore, Sanofi may intervene both permissively and by  
7 right, and such an intervention will not cause any undue delay or prejudice to Petitioner.

## 8 I. ARGUMENT

### 9 A. Sanofi Has the Right to Intervene Pursuant to NRCP 24(a)(2).

10 The Court must permit any person or entity to intervene in the action, if the person or entity:  
11 (1) has a “sufficient interest in the litigation’s subject matter”; (2) can demonstrate that it “could  
12 suffer an impairment of its ability to protect that interest if it does not intervene”; (3) can  
13 demonstrate that “its interest is not adequately represented by existing parties;” and (4) has timely  
14 filed its application. *Am. Home Assurance Co. v. Eighth Jud. Dist. Ct. ex rel. Cty. of Clark*, 122  
15 Nev. 1229, 1238, 147 P.3d 1120, 1126 (2006). Petitioner concedes that Sanofi has satisfied the first  
16 two requirements and only contends that the Motion to Intervene is untimely and that Sanofi’s  
17 interests are adequately represented by the State. Petitioner is wrong on both counts.

#### 18 1. The State Cannot Fully and Adequately Represent Sanofi’s Interests in 19 Protecting Its Trade Secrets and Confidential Information.

20 The State and Sanofi ultimately share the same goal: both seek to protect trade secrets and  
21 confidential information entrusted to the Nevada Department of Health and Human Services (the  
22 “Department”) by private entities from public disclosure. While Sanofi is confident in the State’s  
23 ability to assert the statutory and regulatory bases for denying the Petitioner’s request, only Sanofi  
24 can fully inform this Court of the irreparable harm that Sanofi will suffer from the public disclosure  
25 of its trade secrets. As set forth in the Declaration of James Borneman, attached as Exhibit 2 to the  
26 Motion to Intervene, Sanofi possesses unique knowledge as to the steps it takes to protect its trade  
27 secrets and the irreparable harm that it will suffer if its trade secrets are publicly disseminated. (Mot.  
28 at Ex. 2, at ¶¶ 12-13, 15-23.) Because this information is relevant to this dispute and is not within

1 the State's knowledge, possession, or control, Sanofi must be permitted to intervene and present this  
2 information for the Court's consideration.

3 2. Sanofi's Motion to Intervene Was Timely Filed.

4 Despite the fact that Sanofi's Motion to Intervene was filed before trial, or in this case, just  
5 days after the Petitioner filed a Supplemental Brief in support of its Petition for Writ of Mandamus  
6 and before the hearing on the Petition, the Petitioner now contends that Sanofi's Motion is untimely.  
7 (Opp'n at 6:19-7:20.) Petitioner asserts that it has already been prejudiced by the 28-day  
8 continuance of the hearing on its Petition, and it argues that it will likely need to request a further  
9 delay of proceedings so that it can reply to Sanofi's Response to the Petition, should intervention be  
10 granted. (*Id.* at 7:10-14.)

11 First, there should be no need for any additional continuances of this action. Sanofi has  
12 already prepared a Response to the Petition, which it has attached as Exhibit 1 to the Motion to  
13 Intervene. If this Motion is granted and the Petitioner chooses to reply to Sanofi's brief, the  
14 Petitioner has sufficient time to file such reply prior to the November 19, 2019 hearing on the  
15 Petition (particularly since the Petitioner has had Sanofi's proposed Response since October 21,  
16 2019).

17 Second, while the Petitioner claims to have suffered prejudice as a result of the brief  
18 continuance of the hearing on its Petition, no details have been provided as to what prejudice has  
19 actually been suffered. The Petitioner merely asserts that NPRA actions are to be resolved in a  
20 timely manner. (Opp'n at 7:1-9.) However, there is no exception in NRS 12.130 or NRCP 24 which  
21 prohibits intervention in NPRA actions because of the brief delay that intervention may cause in the  
22 proceedings. Moreover, any inconvenience suffered by the Petitioner as a result of the short  
23 continuance of the hearing on the Petition is greatly outweighed by the irreparable harm that Sanofi  
24 will suffer if this Motion to Intervene is denied and Sanofi's trade secrets are ultimately disclosed to  
25 the public. *See Am. Home Assurance Co. v. Eighth Jud. Dist. Ct. ex rel. Cty. of Clark*, 122 Nev.  
26 1229, 1244, 147 P.3d 1120, 1130 (2006).

27 ///

28 ///

1           **B.     Sanofi Should Also Be Permitted to Intervene Pursuant to NRCP 24(b)(1)(B).**

2           Sanofi also satisfies the requirements for permissive intervention. NRCP 24(b)(1)(B) allows  
3 intervention where an individual “has a claim or defense that shares with the main action a common  
4 question of law or fact.” The State and Sanofi share an interest in protecting the confidentiality of  
5 these records.

6           The Petitioner contends that permissive intervention is not permitted in NPRA actions  
7 because non-governmental entities cannot be respondents in such actions and, therefore, have no  
8 common defenses to such actions. (Opp’n at 5:18-28.) Again, NPRA actions are not exempted from  
9 NRCP 24. The fact that Sanofi cannot be a named party in an NPRA action is the very reason that  
10 intervention is needed. Sanofi’s trade secrets and confidential information are at issue in this action,  
11 Sanofi will be irreparably harmed by the disclosure, and Sanofi’s opposition to the disclosure of such  
12 information shares a common question of law and/or fact with the State’s defense of this action.  
13 Therefore, Sanofi should be permitted to intervene pursuant to NRCP 24(b)(1)(B).

14           **C.     Petitioner’s Reluctance to Incur Fees Does Not Outweigh Sanofi’s Interest in**  
15           **Protecting Its Trade Secrets From Public Disclosure.**

16           Finally, Petitioner contends that Sanofi should not be permitted to intervene because Sanofi’s  
17 participation will cause the Petitioner to incur additional costs and attorney’s fees that it will not be  
18 able to recover should it prevail in this action. (Opp’n at 7:21-8:14.)<sup>1</sup> As Petitioner notes, NRS  
19 239.011 only allows it to recover its costs and fees for this proceeding from the Department — not  
20 from private individuals or entities that may intervene in the action.

21           However, as set forth above, neither NRS 12.130 nor NRCP 24 provides exceptions that  
22 would bar a third party from intervening in NPRA actions. Similarly, the NPRA itself does not  
23 prohibit intervention by private individuals and entities merely because there is no mechanism for  
24 the petitioner to recover its costs and fees should the petitioner prevail. This makes sense as the  
25 public has a right to request and review only *government-generated records*, not the confidential  
26

---

27           <sup>1</sup> Petitioner makes repeated references to Sanofi’s “200-page Motion to Intervene,” (Opp’n at 7:20); however,  
28 Sanofi’s Motion was only 15 pages long. Its proposed Response to the Petition is only 18 pages long and the remaining  
pages are exhibits in support of the Response to the Petition.

1 information and trade secrets submitted to the government pursuant to statutory and/or regulatory  
2 requirements. *See Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 266 P.3d 623, 628 (2011)  
3 (discussing the presumption that “all **government-generated records** are open to disclosure”)  
4 (emphasis added).

5       The Petitioner chose to file a Petition for Writ of Mandamus in an attempt to force the  
6 Department to disclose the trade secrets and confidential, proprietary information of pharmaceutical  
7 manufacturers, as opposed to government-generated records. Thus, the Petitioner assumed the risk  
8 of pharmaceutical manufacturers and other private individuals and entities intervening in the action  
9 to protect their trade secrets. Accordingly, any additional costs or fees that the Petitioner may incur  
10 as a result of Sanofi’s intervention is greatly outweighed by the harm that Sanofi will suffer if it is  
11 not permitted to intervene and its trade secrets and competitively-sensitive information are publicly  
12 disclosed.

13 ///

14 ///

15 ///

16 ///

17 ///

18 ///

19 ///

20 ///

21 ///

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

28 ///



CERTIFICATE OF SERVICE

I certify that I am an employee of BAILEY❖KENNEDY and that on the 1st day of November, 2019, service of the foregoing **SANOFI-AVENTIS U.S., LLC’S REPLY IN SUPPORT OF MOTION TO INTERVENE** was made by mandatory electronic service through the Eighth Judicial District Court’s electronic filing system and/or by depositing a true and correct copy in the U.S. Mail, first class postage prepaid, and addressed to the following at their last known address:

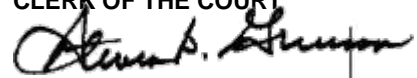
MATTHEW J. RASHBROOK  
ROBERT L. LANGFORD  
**ROBERT L. LANGFORD & ASSOCIATES**  
616 South Eighth Street  
Las Vegas, Nevada 89101

Email: matt@robertlangford.com  
robert@robertlangford.com  
  
*Attorneys for Petitioner*  
THE NEVADA INDEPENDENT

AARON D. FORD  
ATTORNEY GENERAL  
STEVE SHEVORSKI  
CHIEF LITIGATION COUNSEL  
**OFFICE OF NEVADA ATTORNEY GENERAL**  
555 East Washington Avenue, Suite 3900  
Las Vegas, Nevada 89101

Email: sshevorski@ag.nv.gov  
  
*Attorneys for Respondents*  
RICHARD WHITLEY, in his official capacity as the Director of the Nevada Department of Health and Human Services, and THE STATE OF NEVADA, ex rel. the NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES

/s/ Samantha Kishi  
Employee of BAILEY❖KENNEDY



TRAN

DISTRICT COURT  
CLARK COUNTY, NEVADA  
\* \* \* \* \*

NEVADA INDEPENDENT,	)	CASE NO. A-19-799939-W
	)	
Plaintiff,	)	DEPT NO. XIV
	)	
vs.	)	
	)	
RICHARD WHITLEY, et al,	)	
	)	
Defendants.	)	<b>Transcript of</b>
	)	<b>Proceedings</b>

BEFORE THE HONORABLE ADRIANA ESCOBAR, DISTRICT COURT JUDGE  
**MOTION TO INTERVENE AND TO CONTINUE HEARING ON SHORTENED TIME**

TUESDAY, NOVEMBER 5, 2019

APPEARANCES:

FOR THE PLAINTIFF:	MATTHEW J. RASHBROOK, ESQ. ROBERT L. LANGFORD, ESQ.
FOR THE DEFENDANTS:	STEVEN G. SHEVORSKI, ESQ.
FOR THE INTERVENOR:	JOHN R. BAILEY, ESQ.

RECORDED BY: SANDRA ANDERSON, COURT RECORDER  
TRANSCRIBED BY: JULIE POTTER, TRANSCRIBER

1       LAS VEGAS, NEVADA, TUESDAY, NOVEMBER 5, 2019, 11:36 A.M.

2                       (Court was called to order)

3               THE COURT: Nevada Independent versus Whitley. Okay.  
4 This is a motion to intervene and to continue hearing on  
5 shortening time. Okay. All right. Very good. Your  
6 appearances for the record, please.

7               MR. RASHBROOK: Good morning, Your Honor. Matthew  
8 Rashbrook and Robert Langford for the Nevada Independent  
9 petitioner.

10              THE COURT: Okay. Good morning.

11              MR. BAILEY: Good morning, Your Honor. John Bailey  
12 from Bailey Kennedy on behalf of the prospective intervenor --

13              THE COURT: Okay.

14              MR. BAILEY: -- Sanofi.

15              MR. SHEVORSKI: Sanofi. I was wondering how that was  
16 pronounced.

17              Steven Shevorski of the Office of the Attorney General  
18 on behalf of the State, Your Honor.

19              THE COURT: Okay. Very good. All right. Before we  
20 begin, I just want to -- and this was a long, long time ago, but  
21 I just want to disclose, I'm not trying to jump out of the case,  
22 that years ago I was Chief Deputy Attorney General, the  
23 consumer's advocate for the State.

24              And in reading your -- your pleadings, there is one  
25 argument by -- there is one argument that talks about the

1 consumers and the right for them to know or -- or that if  
2 consumers had information it would harm possibly the  
3 confidentiality of the -- the prospective intervenor. So I  
4 wanted to let you know that I can be fair and impartial, but  
5 that I was the consumer's advocate and it was for the entire  
6 state, okay. I just wanted to put that on the record.

7 MR. RASHBROOK: Thank you, Your Honor.

8 THE COURT: All right. Very good.

9 MR. BAILEY: Thank you, Your Honor.

10 THE COURT: Okay. All right. Please go ahead.

11 MR. BAILEY: Good morning, Your Honor. It sounds like  
12 you've had a long morning. I know that this Court is very  
13 diligent in reading all of the briefing, so I won't reiterate  
14 what we've already put in our motion, our reply, and the  
15 petitioner's opposition. What I do want to do, though, is just  
16 stress three points. Number one, the information that the  
17 petitioner is seeking in this case is my client's confidential  
18 trade secret protected information.

19 Number two, while the Attorney General's Office and  
20 Mr. Shevorski are clearly able to articulate for the Court the  
21 basis for their rationale in not disclosing my client's  
22 information, and we agree with that rationale, they have the  
23 ability to and have done so in their briefing so far, identify  
24 the statutory basis for their decision.

25 Here, though, in this case, and the reason why

1 intervention by my client is important is because the Attorney  
2 General's Office does not have the personal knowledge, the  
3 custody, or possession of information that would demonstrate to  
4 this Court the irreparable harm and prejudice to my client if  
5 their confidential and trade secret protected information was  
6 disclosed to the public, nor does the Attorney General's Office  
7 have the ability to address this Court with respect to what my  
8 client does internally and externally to protect that  
9 information.

10 Third point is that Rule 24, the ability for a  
11 non-party to come to court and to say to the Court we have a  
12 substantial interest in the outcome of what's going to happen in  
13 this case and we need to protect our interest is precisely the  
14 rule that shows why in this case you should grant the motion for  
15 intervention.

16 Again, I'm not going to go through everything that  
17 you've already read in the briefing, but I did want to stress  
18 those three points. And unless you have any questions, I will  
19 sit down.

20 THE COURT: I don't at this time.

21 MR. BAILEY: Great. Thank you, Your Honor.

22 MR. RASHBROOK: Good morning, Your Honor. I join Mr.  
23 Bailey in -- in sympathizing with Your Honor's calendar this  
24 morning and the length, and I think that the standards that  
25 we're discussing this morning are fairly well-known and probably

1 don't need to be rehashed.

2 I do want to point out, though, that we are looking at  
3 this motion to intervene in sort of a specific and not unique,  
4 but unusual, perhaps, context which is a petition under the  
5 Public Records Act. Where I think that the more, if there could  
6 be a typical intervention scenario, might be a defendant insured  
7 driver who decides to represent himself and an insurance company  
8 who feels, and probably correctly, that that pro se party might  
9 not adequately represent their interest.

10 That's decidedly different than what we're faced with  
11 here, which is a scenario in which the government has  
12 essentially taken the proposed intervenor's position, the  
13 proposed intervenor acknowledges that the government is  
14 essentially going to adequately represent their interest. And  
15 we can have a lot of confidence that realistically that's true  
16 when --

17 THE COURT: Partially acknowledged it.

18 MR. RASHBROOK: Fair enough.

19 THE COURT: Okay. I really like complete statements.  
20 The first part was that -- I am paraphrasing from what I've been  
21 reading, but that there was -- that the proposed intervenor  
22 thinks that the government can represent them with respect to  
23 statutory or administrative issues, but not confidentiality  
24 issues. It's written all over here.

25 MR. RASHBROOK: I understand, Your Honor.

1           THE COURT:  So that -- that would be more of a  
2 complete --

3           MR. RASHBROOK:  Perhaps a difference of opinion, but I  
4 think when we take it together with the fact that the intervenor  
5 is indicating that in their proposed response essentially what  
6 they seek to admit are things that are in the public record  
7 anyways.  I think when you take it together --

8           THE COURT:  Understood.

9           MR. RASHBROOK:  I apologize if Your Honor felt that  
10 was an incomplete statement.  That was --

11          THE COURT:  No.

12          MR. RASHBROOK:  -- certainly not my contention.

13          THE COURT:  That happened a little bit earlier, too,  
14 in a different case.  It happens sometimes.  It's okay.  Go on.

15          MR. RASHBROOK:  The other context that I think is  
16 important from the Public Records Act is that when we look at  
17 the prejudice and when we talk about timeliness under Rule 24, a  
18 large part of the analysis there focuses on the whether the main  
19 party cases will be prejudiced by the intervention.  I think we  
20 start with sort of a threshold test minimum standard of whether  
21 the motion is timely is whether it's filed in advance of trial.

22                 And in this instance, in all fairness, it was filed in  
23 advance of trial, although not very far in advance of trial,  
24 actually on the eve of trial, necessitating a continuous to deal  
25 with this matter.  I think it was filed two business days clear

1 of the hearing.

2           Now, in the context of the Nevada Public Records Act,  
3 we have numerous cases, and now indications directly from the  
4 legislature that delay is itself prejudicial. This perfectly  
5 encapsulates that old adage that justice delayed is justice  
6 denied. The Public Records Act exists for the purpose of  
7 fostering democratic principles. And for people to take  
8 advantage of these public records, for them to participate in  
9 their democracy, the records have got to be timely produced.

10           And that's why the legislature in this most recent  
11 session added this, and I think I've pointed out in the writing,  
12 but I do want to stress, I know that this is not at issue in  
13 this case because of the date that we filed and the date that  
14 the amendment becomes active, but day by day penalties and fines  
15 for failure to produce when production is eventually ordered.

16           THE COURT: I'm sorry. Will you repeat the last --  
17 the last point?

18           MR. RASHBROOK: So in the most recent legislative  
19 session --

20           THE COURT: Yes.

21           MR. RASHBROOK: -- the legislature amended the Public  
22 Records Act --

23           THE COURT: Yes.

24           MR. RASHBROOK: -- to include day by day penalties --

25           THE COURT: Correct.

1 MR. RASHBROOK: -- for failing to produce when  
2 production is eventually ordered. And those penalties are not  
3 at issue in this matter because of the date of our filing. But  
4 I do think it's instructive. I think it's an almost direct  
5 statement from the legislature on the need for prompt access to  
6 these records.

7 And so when we talk about whether this -- the motion  
8 to intervene is timely, I think that the delay in and of itself  
9 is prejudicial. We're not looking at a typical civil case where  
10 you may have spoliation of evidence or unavailability of  
11 witnesses is caused by the delay, but the delay itself here is  
12 prejudicial.

13 And the other thing that I think is important to  
14 consider is that in the Public Records Act context, the  
15 respondent is, by definition, a governmental entity. And the  
16 attorney's fees provisions, therefore, refer to a governmental  
17 entity and I think equity really demands that in the event that  
18 the intervenor, the proposed intervenor, is offered the chance  
19 to intervene, I think equity really demands that they are held  
20 to that same standard that the government would be and that they  
21 are required to compensate the petitioner for the reasonable  
22 attorney's fees and costs in the event that the petitioner is a  
23 prevailing party.

24 The other thing that I think would mitigate the  
25 prejudice if Your Honor is inclined to grant the motion, and I

1 don't want to put words into Mr. Bailey's mouth, but my  
2 understanding from the reply was that the proposed intervenor  
3 would have no objection to that, would be for the independent to  
4 have an opportunity to respond in writing in advance of the  
5 hearing and for the hearing date to remain on November 19th.  
6 And unless Your Honor has any other questions, those are my  
7 points.

8 THE COURT: I know when I was reviewing this I had all  
9 types of questions, and right now they're not coming to mind.

10 MR. RASHBROOK: Okay.

11 THE COURT: I mean, I just -- I have so many notes on  
12 this. It's very fascinating --

13 MR. RASHBROOK: I agree.

14 THE COURT: -- and very well briefed.

15 MR. RASHBROOK: Thank you.

16 THE COURT: So but --

17 MR. RASHBROOK: If they come --

18 THE COURT: -- don't go away.

19 MR. RASHBROOK: -- to your mind, certainly --

20 THE COURT: We may --

21 MR. RASHBROOK: -- call me back.

22 THE COURT: We may have -- we may have more questions  
23 -- or I may have more questions after. Thank you.

24 MR. BAILEY: Judge, just a very brief reply. I think  
25 the prejudice that he's referring to is 28 days because that's

1 what he says in his opposition. And what I would suggest to you  
2 that this case was filed on August 8th, and we will be having  
3 that hearing two weeks from today. And I think what he's saying  
4 is the 28 days, while he does not describe -- I'm sorry, I  
5 shouldn't say "he", his client, the petitioner does not describe  
6 any actual prejudice, they want you to imply some kind of  
7 prejudice because of 28 days.

8 And what I would suggest to the Court is that, one,  
9 that's not actual prejudice, but more importantly, that  
10 certainly is nominal when you look at the prejudice to  
11 potentially my client with respect to irreparable harm if our  
12 documents are disclosed publicly, which would clearly give us a  
13 competitive disadvantage in the marketplace.

14 So with that, again, Rule 24 talks about intervening  
15 as a matter of right, and I think that is clearly what you have  
16 here. We have a right to protect in this case that's discussing  
17 the disclosure, the potential disclosure of our trade secret and  
18 confidential information. So with that, Your Honor, unless you  
19 have any questions, I'll submit it.

20 MR. RASHBROOK: Nothing further, Your Honor, unless  
21 Your Honor has any questions for us.

22 THE COURT: Did I read 70 days somewhere?

23 MR. RASHBROOK: 70 days would be the time that elapsed  
24 between the date that we filed, which I believe was August 8th,  
25 and the date that Sanofi filed their motion to intervene, which

1 I believe came to chambers on the 17th, and then was filed, on  
2 believe, on the 21st, but please correct me if that's --

3 MR. BAILEY: I think those dates are correct. We  
4 filed our motion to intervene on the -- I believe the same day  
5 that you filed a supplement --

6 THE COURT: Correct.

7 MR. BAILEY: -- to their original petition.

8 THE COURT: Correct. Two days before.

9 MR. RASHBROOK: Right.

10 THE COURT: Two days.

11 MR. RASHBROOK: That's right. I think we filed our  
12 supplement actually on the 15th. The Attorney General filed  
13 theirs on the 17th.

14 MR. BAILEY: That's right.

15 THE COURT: Right.

16 MR. RASHBROOK: And then I believe Sanofi's motion was  
17 brought to your chambers. The only thing I would mention as far  
18 as the time which had elapsed was I believe by operation of the  
19 administrative code that Sanofi would have become aware of a  
20 request for public records probably some time in February and  
21 would have had, you know, something in the area of six months to  
22 consider their options before we actually filed.

23 MR. BAILEY: But, of course, Your Honor, following up  
24 on that point, the Attorney General's Office correctly made the  
25 decision not to disclose our information, so there was really

1 nothing for us to do until August 18th when they filed this  
2 petition for mandamus.

3           The other thing I will note for the record is we filed  
4 as Exhibit 1 to our motion our actual response. So everyone has  
5 had our actual response since, I believe, October the 17th or  
6 the 19th.

7           MR. RASHBROOK: The 21st, I think.

8           MR. BAILEY: 21st.

9           THE COURT: 21st.

10          MR. RASHBROOK: Yeah, within a couple of days.

11          MR. BAILEY: Exactly.

12          THE COURT: You may be seated. It's okay. We're sort  
13 of -- you can be a little bit more relaxed here. All right. So  
14 I read everything, and I need to -- we're talking about the four  
15 prongs in the American Home Insurance case.

16          MR. BAILEY: Yes. In Rule 24, yes.

17          THE COURT: I'd like -- I'd like to -- I know that  
18 you've briefed this extremely thoroughly, both parties, but I  
19 would like a discussion on prong -- on these prongs, especially,  
20 I believe, the third -- or the third number and the fourth. The  
21 third, is this deficient that the Attorney General's Office  
22 represents the proposed intervenor's interests. That's one  
23 issue that I think is very important.

24                 And the fourth, with the timing, I'm not -- I think --  
25 I think it's the 28 days. I understand -- I understand that

1 this needs to move quickly, but on the other hand I don't think  
2 that the timing is draconian and that it would harm anyone since  
3 we're trying to keep going with it.

4           So I'm more interested in, I think it was No. 4, the  
5 fourth prong. I don't want to call it a prong, but the fourth  
6 -- hold on a second, I have it here. The issue of whether or  
7 not the Attorney General's Office can, aside from statutory and  
8 administrative law, represent the interest. I believe that was  
9 one of your -- your points, counsel.

10           MR. BAILEY: If you want me to address, I think it's  
11 the third prong is --

12           THE COURT: Is it the third? Okay.

13           MR. BAILEY: Yeah. The third prong just --

14           THE COURT: It is the third prong.

15           MR. BAILEY: -- just to state it for the record is --

16           THE COURT: Okay.

17           MR. BAILEY: -- it must -- it must demonstrate that,  
18 quote, its interest is not adequately represented --

19           THE COURT: Correct.

20           MR. BAILEY: -- by existing parties, end quote.

21           THE COURT: Correct.

22           MR. BAILEY: And if you will look on page 12 of our  
23 motion, starting on line 3, we address that point. And that  
24 point is simply this. Number one, they have not, "they" being  
25 the petitioner, has not acknowledged the fact that our

1 information as submitted to the department is, in fact, a trade  
2 secret, something that the Attorney General's Office is not able  
3 to respond to.

4           Number two, and we've just kind of discussed this,  
5 Your Honor, when I wanted to stress the three points, the  
6 Attorney General's Office made a decision not to disclose my  
7 client's information --

8           THE COURT: Correct.

9           MR. BAILEY: -- as being confidential and statutorily  
10 protected trade secret information. And the Attorney General's  
11 Office is able to tell you, and has done so in their response to  
12 the petition, exactly why they took that -- that approach, the  
13 statutory -- the statutes that support that decision not to  
14 disclose that information.

15           Our point in answering No. 3 is that is correct and we  
16 agree with the Attorney General's position on that and they can,  
17 in fact, adequately represent our interest in articulating to  
18 the Court the basis for the decision --

19           THE COURT: Correct.

20           MR. BAILEY: -- both regulatory and statutory as to  
21 why they took that position. What they can't do, though, is  
22 they don't have the personal knowledge of what my client has  
23 done both internally and externally to protect this information  
24 because, as you'll recall, to maintain a trade secret protection  
25 for your information, you have to treat it as a trade secret.

1 You can't just generally throw it out to the public either  
2 internally or externally.

3           The Attorney General's Office is unable to make  
4 representations about what my client has done in that regard  
5 because they simply don't have the personal knowledge to do  
6 that. They're not in custody, control, or possession of that  
7 information. We're the only ones that can come to this Court  
8 and say to you, Your Honor, we've done the following things to  
9 protect this information.

10           So to the extent the petitioner is trying to suggest,  
11 no, they don't treat this information as a trade secret, they  
12 don't treat it as confidential, we're the ones who can respond  
13 to that to the Court and say, wrong, this is what we do to  
14 protect this information.

15           The other thing that the Attorney General's office  
16 cannot adequately represent us on is advising the Court and  
17 coming to the Court and telling you what will happen, what is  
18 the irreparable harm to my client if that information becomes  
19 public. The prejudice to my client can be articulated by really  
20 only my client, and that's why it's important that when you look  
21 at prong No. 3, it's a global, can the AG's Office adequately  
22 protect us in all aspects of what we have an interest in, and  
23 the answer is no.

24           They can protect us in terms of what they did to  
25 protect our information regulatorily and statutorily. What they

1 can't do is to come to this Court and tell you this is why this  
2 information is a trade secret, this is why it's confidential,  
3 this is how we treat that information, and by the way, if it  
4 becomes public, it would cause us irreparable harm, it will be  
5 prejudicial to us, it will put us at an unfair competitive  
6 advantage or disadvantage, not only in Nevada, but nationwide.

7           And so I'm the one on behalf of my client who can come  
8 to this Court with evidence from my client to give you that  
9 information, that's why it's important with respect to prong No.  
10 3 that we be allowed to intervene so that I can present that  
11 evidence to you before you make an ultimate decision.

12           THE COURT: Understood. Thank you.

13           MR. RASHBROOK: Your Honor, on the question of prong  
14 No. 3, I think the language from the American Home Insurance  
15 case is pretty instructive. When the proposed intervenor's  
16 interest or ultimate objective in the litigation is the same as  
17 the main action party's objective, the main action party's  
18 representation should generally be adequate. That's American  
19 Home Insurance 122 Nev. 1241, our opposition, page 6, line 8.

20           I think in this case it's particularly true where the  
21 main party is not an unsophisticated party. They are government  
22 lawyers with effectively limitless resources who have advocated  
23 on behalf of the respondent, who are expert in this area of law,  
24 probably just about as expert as anyone can be.

25           Beyond that, if there are particular facts that are

1 solely within the knowledge of the proposed intervenor, then  
2 that may make the proposed intervenor an appropriate witness for  
3 the Attorney General to call, but I don't think that we've seen  
4 any indication that the proposed intervenor is the only one who  
5 is capable of arguing these points.

6           And, lastly, I suppose what I would point out is that  
7 substantially what Sanofi proposes to introduce into the  
8 litigation are things that are matters of public record already  
9 that were admitted, I think, probably in the area of half or  
10 maybe two-thirds of what was -- what is proposed as exhibits to  
11 their response, are filings from the federal case. And so,  
12 certainly, these are things that the Attorney General has access  
13 to already.

14           So our position certainly is that the Attorney General  
15 has given every indication that he intends to represent their  
16 interests, he is entirely capable of so doing, and so Sanofi is  
17 really not a necessary party to the litigation.

18           THE COURT: Okay. Thank you.

19           MR. BAILEY: The only last thing I would say to you,  
20 Your Honor, is close enough never is. For the petitioner to  
21 say, well, we think our adversary, the Attorney General's Office  
22 should be representing a non-party and can do that, I know  
23 that's what they think, but close enough never is. I should  
24 have the right on behalf of my client to protect our interest.  
25 That's what Rule 24 does as a matter of right.

1           Now, we've also talked about permissive intervention  
2 in our pleadings, but in my view, we don't even get to the  
3 permissive part. We should have the absolute right to intervene  
4 in this case to protect our interest, particularly given the  
5 circumstances of this case. Thank you, Your Honor.

6           THE COURT: Okay. Thank you.

7           Is there anything else?

8           MR. BAILEY: We'll submit it.

9           MR. RASHBROOK: We'll submit it, Your Honor.

10          THE COURT: Okay. Thank you. Your pleadings were, I  
11 mean it, I'm not a sarcastic person, they were a delight to  
12 read. They really were very interesting, very well put. And I  
13 will -- I'm going to issue a written order, okay.

14          MR. BAILEY: Great.

15          MR. RASHBROOK: Thank you, Your Honor.

16          MR. BAILEY: Thank you, Your Honor.

17          THE COURT: All right. Have a great day. Sorry this  
18 took so -- you know, you waited all morning.

19          MR. SHEVORSKI: Thank you, Your Honor.

20          THE COURT: You're very welcome. Have a great day,  
21 counsel.

22          MR. SHEVORSKI: You too. Thanks.

23                       (Proceedings concluded at 11:59 a.m.)

24                       \* \* \* \* \*

25


**CERTIFICATION**

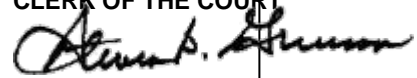
I CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE AUDIO-VISUAL RECORDING OF THE PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

**AFFIRMATION**

I AFFIRM THAT THIS TRANSCRIPT DOES NOT CONTAIN THE SOCIAL SECURITY OR TAX IDENTIFICATION NUMBER OF ANY PERSON OR ENTITY.

**Julie Potter  
Kingman, AZ 86402  
(702) 635-0301**

  
\_\_\_\_\_  
JULIE POTTER  
TRANSCRIBER



1 **ERR**

2 MATTHEW J. RASHBROOK  
3 Nevada State Bar No. 12477  
4 ROBERT L. LANGFORD, ESQ.  
5 Nevada State Bar No. 3988  
6 ROBERT L. LANGFORD & ASSOCIATES  
7 616 S. Eighth Street  
8 Las Vegas, NV 89101  
(702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

9 **EIGHTH JUDICIAL DISTRICT COURT**

10 **LAS VEGAS, NEVADA**

11 THE NEVADA INDEPENDENT,

Case No.: A-19-799939-W

12  
13 Petitioner,

Dept. No.: 14

14 vs.

**ERRATA**

15 RICHARD WHITLEY, in his official  
16 capacity as the Director of the Nevada  
17 Department of Health and Human Services,  
18 and THE STATE OF NEVADA, ex rel. the  
19 NEVADA DEPARTMENT OF HEALTH  
AND HUMAN SERVICES;

20 Respondents.

21  
22 COMES NOW Petitioner, The Nevada Independent, by and through their  
23 attorneys, Matthew J. Rashbrook, and Robert L. Langford, Esq., of the firm Robert L.  
24 Langford & Associates, and hereby offers the following Errata:

25 On November 5, 2019, during oral argument on Sanofi-Aventis U.S. LLC's  
26 Motion to Intervene and to Continue Hearing, the undersigned made reference to an  
27 amendment to the Nevada Public Records Act ("NPRO"), Nev. Rev. Stat. § 239.001 *et*  
28 *seq.*, which was in error. Roughly, counsel stated that during the 2019 Legislative Session,

1 the Nevada Legislature had amended the NPRA to allow for a civil penalty to be assessed  
2 on a daily basis and levied against a governmental entity who withheld public records from  
3 a requester and who was later ordered by the District Court to disclose those records. This  
4 provision was also mentioned in Petitioner's Opposition to Sanofi-Aventis U.S. LLC's  
5 Motion to Intervene and to Continue Hearing. *Opposition*, 7, line 3 – 6. (" . . . recent  
6 amendments to the NPRA make even clearer, given that new statutory penalties for  
7 governmental entities are calculated based on the length of time records are withheld . . . ")

8         The undersigned was mistaken. In fact, the daily civil penalty of one hundred  
9 dollars per day was drafted and debated, but ultimately did not survive the amendment  
10 process. *See*, S.B. 287, March 15, 2019 Draft, a true and correct copy of which is attached  
11 hereto as Exhibit ("Ex.") 1, 11. Instead, a civil penalty was created whereby the District  
12 Court must impose upon governmental entities a civil penalty of \$1,000, \$5,000, or  
13 \$10,000, for the first, second, or third and subsequent failures to comply with the NPRA  
14 within a given 10-year period.. *See* Ex. 2, S.B. 287 as enrolled, 2 – 3.

15         As mentioned previously, the provisions discussed herein and during argument do  
16 not apply to this case, as it was filed before the effective date of S.B. 287, October 1, 2019.

17         All of which is respectfully submitted, this 11th day of November, 2019.

18  
19 /s/ Matthew J. Rashbrook

20 MATTHEW J. RASHBROOK  
21 Nevada State Bar No. 12477  
22 ROBERT L. LANGFORD, ESQ.  
23 Nevada State Bar No. 3988  
24 ROBERT L. LANGFORD &  
25 ASSOCIATES  
26 616 S. Eighth Street  
27 Las Vegas, NV 89101  
28 (702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

I hereby certify and affirm that on this 11th day of November, 2019, the foregoing  
**ERRATA** was served by electronic mail to the following counsel of record:

Aaron D. Ford  
Nevada Attorney General  
Nevada Bar No. 7704  
Steve Shevorski  
Chief Litigation Counsel  
Nevada Bar No. 8256  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
Fax: 702-486-3768  
sshevorski@ag.nv.gov

John R. Bailey  
Nevada Bar No. 137  
Dennis L. Kennedy  
Nevada Bar No. 1462  
Sarah E. Harmon  
Nevada Bar No. 8106  
Bailey Kennedy  
8984 Spanish Ridge Avenue  
Las Vegas, NV 89148  
Fax: 702-562-8821  
jbailey@baileykennedy.com  
dkennedy@baileykennedy.com  
sharmon@baileykennedy.com

/s/ Matthew J. Rashbrook

An Employee of Robert L. Langford &  
Associates

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 1

# EXHIBIT 1

SENATE BILL NO. 287—SENATORS PARKS, HANSEN,  
SPEARMAN; DENIS AND WOODHOUSE

MARCH 15, 2019

Referred to Committee on Government Affairs

SUMMARY—Revises provisions governing public records.  
(BDR 19-648)

FISCAL NOTE: Effect on Local Government: May have Fiscal Impact.  
Effect on the State: Yes.

~

EXPLANATION – Matter in **bolded italics** is new; matter between brackets ~~omitted material~~ is material to be omitted.

AN ACT relating to public records; clarifying the records of a governmental entity that must be made available to the public to inspect, copy or receive a copy thereof; revising provisions relating to the manner of providing copies of public records; revising provisions governing the actions taken by governmental entities in response to requests for public records; revising provisions relating to the relief provided for a requester of a public record who prevails in a legal proceeding; revising provisions governing immunity from liability for public officers and employees who disclose or refuse to disclose certain information; revising provisions governing the fees that governmental entities are authorized to charge for a copy of a public record; providing civil penalties; and providing other matters properly relating thereto.

**Legislative Counsel's Digest:**

Existing law provides that all public books and public records of a state or local governmental entity, unless otherwise declared by law to be confidential, are required to be open at all times during office hours for the public to inspect, copy or receive a copy thereof. Existing law also authorizes a person to request a copy of a public record in any medium in which the public record is readily available. (NRS 239.010) The purpose of the existing law governing public records, as stated in the legislative declaration for that law, is, in part, to foster democratic principles by providing members of the public with access to inspect and copy public books and records to the extent permitted by law. (NRS 239.001) **Section 2** of this bill provides that the legislative intent is for such access to be provided promptly. **Section 3** of this bill defines "public record" to mean any of several types of



JA \* S B 2 8 1 9 \*

records and information prepared, created, used, owned, retained or received in connection with the transaction of official business or the provision of a public service. **Section 12** of this bill provides for making conforming changes relating to this definition. **Sections 2 and 4** of this bill make changes to conform with existing law which provides that, in addition to the right to inspect and copy a public record, members of the public have the right to receive a copy of a public record upon request.

With certain exceptions, existing law prohibits a governmental entity from charging a fee for providing a copy of a public record that exceeds the actual cost to the governmental entity to provide the copy. (NRS 239.052) **Section 3** clarifies that the actual cost to a governmental entity: (1) includes such direct costs as the cost of ink, toner, paper, media and postage; and (2) does not include overhead and labor costs that a governmental entity incurs regardless of the request. **Section 13** of this bill eliminates the authority of a governmental entity to charge an additional fee for providing a copy of a public record when extraordinary use of personnel or resources is required. (NRS 239.055)

Existing law generally places certain requirements on a governmental entity that has legal custody or control of a public record. (NRS 239.010, 239.0107, 239.011, 239.0113, 239.0115) **Sections 5-9** of this bill change the applicable type of custody or control of a public record from "legal custody or control" to "possession, custody or control." **Section 5** of this bill specifically authorizes the electronic redaction of public records. **Section 5** also requires a governmental entity to provide a copy of a public record in an electronic format by means of an electronic medium unless the public record was requested in a different medium. **Section 5** further requires that a public record be provided in the electronic format in which it was created or prepared, if requested.

Under existing law, if a person requests to inspect or copy a public record or receive a copy of a public record which the governmental entity is unable to make available by the end of the fifth business day after the request was received, the governmental entity is required to provide written notice of that fact to the person who made the request and the date and time after which the public record or the copy of the public record will be available. (NRS 239.0107) **Section 6** of this bill clarifies that the date and time provided to the requester must reflect the earliest date and time after which the governmental entity reasonably believes the public record will be available. If the public record is not made available by this date and time, **section 6** requires the governmental entity to provide to the requester, in writing, an explanation of the reason the public record is not available and a date and time after which the governmental entity reasonably believes the public record will be available. **Section 6** also requires a governmental entity that is unable to provide access to a public record within the prescribed time period to make a reasonable effort to assist the requester to focus the request in such a manner as to maximize the likelihood the requester will be able to inspect, copy or receive a copy of the public record as expeditiously as possible. **Section 6** additionally requires a person who has possession, custody or control of a public record of a governmental entity to provide to a requester certain contact information regarding the person who is responsible for making the decision on behalf of the governmental entity concerning the action the governmental entity will take with respect to the request for the public record or any other decision in connection with the request.

If a request for inspection, copying or copies of a public record is denied, existing law authorizes a requester to apply to a district court for an order permitting the requester to inspect or copy the record or requiring the person who has legal custody or control of the public record to provide a copy to the requester. Existing law provides that if the requester prevails in such a proceeding, the requester is entitled to recover his or her costs and reasonable attorney's fees in the



proceeding from the governmental entity whose officer has custody of the record. (NRS 239.011) **Section 7** of this bill authorizes a requester of a public record to apply to a district court for a similar order if a request for inspection, copying or copies of a public record is unreasonably delayed or if a person who requests a copy of a public record believes that the fee charged by the governmental entity for providing the copy of the public record is excessive or improper. **Section 7** additionally provides that if the requester prevails in a proceeding involving an unreasonable delay in the provision of a public record or the imposition of an excessive or improper fee for the public record, the requester is entitled to recover from the governmental entity his or her costs and reasonable attorney's fees and \$100 per day for each day that the requester was denied the right to inspect, copy or receive a copy of the public record. **Section 7** also authorizes the recovery of this daily monetary penalty for the denial of a request for a public record. **Section 7** further provides that if the governmental entity appeals the decision of the district court and the decision is affirmed in whole or in part, the requester is also entitled to recover from the governmental entity his or her costs and reasonable attorney's fees for the appeal and \$100 per day for each day that the requester was denied the right to inspect, copy or receive a copy of the public record. **Section 1** of this bill provides that, in addition to any such costs, attorney's fees or other monetary awards, the requester of a public record is entitled to recover a civil penalty and to any additional relief deemed proper by the court if a governmental entity or the person who is responsible for making decisions on behalf of the governmental entity relating to the public record request fails to comply with the existing law governing public records.

Existing law confers immunity from liability for damages upon public officers and employees who act in good faith in disclosing or refusing to disclose information. (NRS 239.012) **Section 10** of this bill provides that the burden of proof that a public officer or employee acted in good faith in refusing to disclose information is on the public officer or employee or his or her employer. **Section 10** also clarifies that the immunity from liability for damages for public officers and employees does not include immunity from liability for paying the costs and reasonable attorney's fees and other monetary relief awarded to a prevailing requester. **Section 11** of this bill provides that the provisions of the bill apply to actions that are currently pending on October 1, 2019, which is the effective date of this bill, as well as to actions filed on and after October 1, 2019.

---

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN  
SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

**Section 1.** Chapter 239 of NRS is hereby amended by adding thereto a new section to read as follows:

*1. In addition to any relief awarded pursuant to NRS 239.011, if a court determines that a governmental entity or the person identified pursuant to subsection 3 of NRS 239.0107 as responsible for making the decision on behalf of the governmental entity concerning the request to inspect, copy or receive a copy of a public record failed to comply with the provisions of this chapter, the requester of the public record is entitled to:*

*(a) Recover from the governmental entity or the person identified pursuant to subsection 3 of NRS 239.0107, or both, a*



*civil penalty of not less than \$1,000 or more than \$250,000 per offense.*

*(b) Any such additional relief as the court deems proper to punish and deter violations of the provisions of this chapter.*

*2. The rights and remedies recognized by this section are in addition to any other rights or remedies that may exist in law or in equity.*

**Sec. 2.** NRS 239.001 is hereby amended to read as follows:

239.001 The Legislature hereby finds and declares that:

1. The purpose of this chapter is to foster democratic principles by providing members of the public with *prompt* access to inspect , ~~and~~ *copy or receive a copy of, including, without limitation, in an electronic format by means of an electronic medium,* public ~~books~~ *and* records to the extent permitted by law;

2. The provisions of this chapter must be construed liberally to carry out this important purpose;

3. Any exemption, exception or balancing of interests which limits or restricts access to public ~~books-and~~ records by members of the public must be construed narrowly;

4. The use of private entities in the provision of public services must not deprive members of the public access to inspect , ~~and~~ copy ~~books-and~~ *or receive a copy of* records relating to the provision of those services; and

5. If a public ~~book-or~~ record is declared by law to be open to the public, such a declaration does not imply, and must not be construed to mean, that a public ~~book-or~~ record is confidential if it is not declared by law to be open to the public and is not otherwise declared by law to be confidential.

**Sec. 3.** NRS 239.005 is hereby amended to read as follows:

239.005 As used in this chapter, unless the context otherwise requires:

1. "Actual cost" means the direct cost ~~related to the reproduction~~ *incurred by a governmental entity in the provision* of a public record ~~it~~ *, including, without limitation, the cost of ink, toner, paper, media and postage.* The term does not include a cost that a governmental entity incurs regardless of whether or not a person requests a copy of a particular public record ~~it~~ *, including, without limitation, any overhead costs of the governmental entity and any labor costs incurred by a governmental entity in the provision of a public record.*

2. "Agency of the Executive Department" means an agency, board, commission, bureau, council, department, division, authority or other unit of the Executive Department of the State Government. The term does not include the Nevada System of Higher Education.



3. "Committee" means the Committee to Approve Schedules for the Retention and Disposition of Official State Records.

4. "Division" means the Division of State Library, Archives and Public Records of the Department of Administration.

5. "Governmental entity" means:

(a) An elected or appointed officer of this State or of a political subdivision of this State;

(b) An institution, board, commission, bureau, council, department, division, authority or other unit of government of this State, including, without limitation, an agency of the Executive Department, or of a political subdivision of this State;

(c) A university foundation, as defined in NRS 396.405;

(d) An educational foundation, as defined in NRS 388.750, to the extent that the foundation is dedicated to the assistance of public schools; or

(e) A library foundation, as defined in NRS 379.0056, to the extent that the foundation is dedicated to the assistance of a public library.

6. "Official state record" includes, without limitation:

(a) Papers, unpublished books, maps and photographs;

(b) Information stored on magnetic tape or computer, laser or optical disc;

(c) Materials that are capable of being read by a machine, including, without limitation, microforms and audio and visual materials; and

(d) Materials that are made or received by a state agency and preserved by that agency or its successor as evidence of the organization, operation, policy or any other activity of that agency or because of the information contained in the material.

7. "Privatization contract" means a contract executed by or on behalf of a governmental entity which authorizes a private entity to provide public services that are:

(a) Substantially similar to the services provided by the public employees of the governmental entity; and

(b) In lieu of the services otherwise authorized or required to be provided by the governmental entity.

8. *"Public record" means any record, document, paper, letter, map, notes, calendar, spreadsheet, database, book, tape, photograph, film, sound recording, video recording, data processing software, computer and other electronic data, metadata, electronic mail or any other material or means of recording information, regardless of the physical form, characteristics or means of transmission, which is prepared, created, used, owned, retained or received in connection with the transaction of official business or the provision of a public service.*



1  
2 **IN THE SUPREME COURT OF THE STATE OF NEVADA**

3 THE NEVADA INDEPENDENT,

4 Appellant,

No.: 81844

5  
6 vs.

DC No.: A-19-799939-W

7 RICHARD WHITLEY, IN HIS  
8 OFFICIAL CAPACITY AS THE  
9 DIRECTOR OF THE NEVADA  
10 DEPARTMENT OF HEALTH AND  
11 HUMAN SERVICES, THE STATE  
12 OF NEVADA, EX REL. THE  
13 NEVADA DEPARTMENT OF  
14 HEALTH AND HUMAN  
SERVICES, AND SANOFI-  
AVENTIS U.S. LLC,

15 Respondent.

16  
17  
18 **JOINT APPENDIX**  
19 **VOLUME III**  
20 **PGS. 501-750**  
21

22 MATTHEW J. RASHBROOK  
Nevada State Bar No. 12477  
23 ROBERT L. LANGFORD, ESQ.  
Nevada State Bar No. 3988  
24 ROBERT L. LANGFORD & ASSOCIATES  
25 616 S. Eighth St.  
Las Vegas, NV 89101  
26 (702) 471-6565  
27 *Attorneys for Appellant*  
*The Nevada Independent*  
28

AARON D. FORD  
Nevada Attorney General  
Nevada State Bar No. 7704  
HEIDI PARRY STERN  
Nevada State Bar No. 8873  
STEVE SHEVORSKI  
Nevada State Bar No. 8256  
Office of the Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101

1 JOHN R. BAILEY  
Nevada State Bar No. 137  
2 DENNIS KENNEDY  
Nevada State Bar No. 1462  
3 SARAH E. HARMON  
Nevada State Bar No. 8106  
4 REBECCA L. CROOKER  
Nevada State Bar No. 15202  
5 BAILEY KENNEDY  
8984 Spanish Ridge Avenue  
6 Las Vegas, NV 89148-1302  
7 (702) 562-8820  
8 *Attorneys for Respondent Sanofi-Aventis U.S.*  
9 *LLC*

(702) 486-3594  
*Attorneys for Respondents Whitley, and  
the State of Nevada ex rel. The Nevada  
Department of Health and Human  
Services*

### **TABLE OF CONTENTS**

<b><u>VOL.</u></b>	<b><u>DOCUMENT</u></b>	<b><u>DATE</u></b>	<b><u>PAGE NUMBERS</u></b>
I	Petition for a Writ of Mandamus	8/8/2019	JA-000001 – JA-000014
I	Appendix to Petition for a Writ of Mandamus	8/8/2019	JA-000015 – JA-000232
I	Order Setting Hearing re Petition for Writ of Mandamus	8/27/2019	JA-000233 – JA-000234
I	Supplemental Brief in Support of Petition for a Writ of Mandamus	10/15/2019	JA-000235 – JA-000246
I	Opposition to The Nevada Independent's Petition for Writ of Mandamus and Motion to Dismiss	10/17/2019	JA-000247 – JA-000256
II	Motion to Intervene and to Continue Hearing, on Shortened Time	10/21/2019	JA-000257 – JA-000455
II	Petitioner's Opposition to Sanofi- Aventis U.S. LLC's Motion to Intervene and to Continue Hearing	10/31/2019	JA-000456 – JA-000465

1	II	Sanofi-Aventis U.S. LLC's Reply in Support of Motion to Intervene	11/1/2019	JA-000466 – JA-000472
2				
3	II	Transcript of Proceedings – Motion to Intervene and to Continue Hearing on Shortened Time	11/5/2019	JA-000473 – JA-000491
4				
5	II	Errata	11/11/2019	JA-000492 – JA-000520
6				
7	III	Minute Order	11/14/2019	JA-000521 – JA-000522
8				
9	III	Sanofi-Aventis U.S. LLC's Supplemental Brief in Support of Motion to Intervene	11/21/2019	JA-000523 – JA-000528
10				
11	III	Supplemental Brief in Opposition to Motion to Intervene and Reply to Proposed Response	12/5/2019	JA-000529 – JA-000544
12				
13	III	Minute Order	12/16/2019	JA-000545 – JA-000548
14				
15	III	Order Granting Sanofi-Aventis U.S. LLC's Motion to Intervene	12/23/2019	JA-000549 – JA-000553
16				
17	III	Intervenor Sanofi-Aventis U.S. LLC's Response to Petitioner's Petition for a Writ of Mandamus	12/23/2019	JA-000554 – JA-000738
18				
19	III	Reply to Intervenor's Response	1/3/2020	JA-000739 – JA-000758
20				
21	IV	Petitioner The Nevada Independent's Witness List	1/17/2020	JA-000759 – JA-000761
22				
23	IV	Sanofi-Aventis U.S. LLC's Disclosure of Witnesses	1/17/2020	JA-000762 – JA-000764
24				
25	IV	Defendants' Disclosure of Witnesses	1/17/2020	JA-000765 – JA-000766
26				
27	IV	Reply in Support of Motion to Dismiss	1/23/2020	JA-000767 – JA-000775
28				
	IV	Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	1/30/2020	JA-000776 – JA-000815

IV	Sanofi's Opposition to Petitioner's Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	2/3/2020	JA-000816 – JA-000841
IV	Transcript of Proceedings – Motion to Compel Testimony of James Borneman, or in the Alternative, To Strike his Declaration	2/4/2020	JA-000842 – JA-000890
IV	Motion for Leave to File Brief Amicus Curiae	2/13/2010	JA-000891 – JA-000917
IV	Notice of Non-Opposition	2/14/2020	JA-000918 – JA-000920
IV	Minute Order	2/14/2020	JA-000921 – JA-000922
IV	Notice of Non-Opposition to Culinary union's Motion for Leave to file an Amicus Brief	2/14/2010	JA-000923 – JA-000924
IV	Transcript of Proceedings – Petition for Writ of Mandamus	2/21/2020	JA-000925 – JA-000968
IV	Minute Order	4/21/20	JA-000969 – JA-000973
IV	Order Denying Petition for Writ of Mandamus	9/4/2020	JA-000974 – JA-000984
IV	Notice of Entry of Order	9/9/2020	JA-000985 – JA-000998
IV	Notice of Appeal	9/22/2020	JA-000999 – JA-001001
V	Notice of Appeal (cont.)	9/22/2020	JA-001001

1       **Sec. 4.** NRS 239.008 is hereby amended to read as follows:

2       239.008 1. The head of each agency of the Executive  
3 Department shall designate one or more employees of the agency to  
4 act as records official for the agency.

5       2. A records official designated pursuant to subsection 1 shall  
6 carry out the duties imposed pursuant to this chapter on the agency  
7 of the Executive Department that designated him or her with respect  
8 to a request to inspect , ~~to~~ *copy or receive a copy of* a public ~~book~~  
9 ~~or~~ record of the agency.

10       3. The State Library, Archives and Public Records  
11 Administrator, pursuant to NRS 378.255 and in cooperation with the  
12 Attorney General, shall prescribe:

13       (a) The form for a request by a person to inspect , ~~to~~ *copy or*  
14 *receive a copy of* a public ~~book-or~~ record of an agency of the  
15 Executive Department pursuant to NRS 239.0107;

16       (b) The form for the written notice required to be provided by an  
17 agency of the Executive Department pursuant to paragraph (b), (c)  
18 or (d) of subsection 1 of NRS 239.0107; and

19       (c) By regulation the procedures with which a records official  
20 must comply in carrying out his or her duties.

21       4. Each agency of the Executive Department shall make  
22 available on any website maintained by the agency on the Internet or  
23 its successor the forms and procedures prescribed by the State  
24 Library, Archives and Public Records Administrator and the  
25 Attorney General pursuant to subsection 3.

26       **Sec. 5.** NRS 239.010 is hereby amended to read as follows:

27       239.010 1. Except as otherwise provided in this section and  
28 NRS 1.4683, 1.4687, 1A.110, 3.2203, 41.071, 49.095, 49.293,  
29 62D.420, 62D.440, 62E.516, 62E.620, 62H.025, 62H.030, 62H.170,  
30 62H.220, 62H.320, 75A.100, 75A.150, 76.160, 78.152, 80.113,  
31 81.850, 82.183, 86.246, 86.54615, 87.515, 87.5413, 87A.200,  
32 87A.580, 87A.640, 88.3355, 88.5927, 88.6067, 88A.345, 88A.7345,  
33 89.045, 89.251, 90.730, 91.160, 116.757, 116A.270, 116B.880,  
34 118B.026, 119.260, 119.265, 119.267, 119.280, 119A.280,  
35 119A.653, 119B.370, 119B.382, 120A.690, 125.130, 125B.140,  
36 126.141, 126.161, 126.163, 126.730, 127.007, 127.057, 127.130,  
37 127.140, 127.2817, 128.090, 130.312, 130.712, 136.050, 159.044,  
38 159A.044, 172.075, 172.245, 176.01249, 176.015, 176.0625,  
39 176.09129, 176.156, 176A.630, 178.39801, 178.4715, 178.5691,  
40 179.495, 179A.070, 179A.165, 179D.160, 200.3771, 200.3772,  
41 200.5095, 200.604, 202.3662, 205.4651, 209.392, 209.3925,  
42 209.419, 209.521, 211A.140, 213.010, 213.040, 213.095, 213.131,  
43 217.105, 217.110, 217.464, 217.475, 218A.350, 218E.625,  
44 218F.150, 218G.130, 218G.240, 218G.350, 228.270, 228.450,  
45 228.495, 228.570, 231.069, 231.1473, 233.190, 237.300, 239.0105,



1 239.0113, 239B.030, 239B.040, 239B.050, 239C.140, 239C.210,  
2 239C.230, 239C.250, 239C.270, 240.007, 241.020, 241.030,  
3 241.039, 242.105, 244.264, 244.335, 247.540, 247.550, 247.560,  
4 250.087, 250.130, 250.140, 250.150, 268.095, 268.490, 268.910,  
5 271A.105, 281.195, 281.805, 281A.350, 281A.680, 281A.685,  
6 281A.750, 281A.755, 281A.780, 284.4068, 286.110, 287.0438,  
7 289.025, 289.080, 289.387, 289.830, 293.4855, 293.5002, 293.503,  
8 293.504, 293.558, 293.906, 293.908, 293.910, 293B.135, 293D.510,  
9 331.110, 332.061, 332.351, 333.333, 333.335, 338.070, 338.1379,  
10 338.1593, 338.1725, 338.1727, 348.420, 349.597, 349.775, 353.205,  
11 353A.049, 353A.085, 353A.100, 353C.240, 360.240, 360.247,  
12 360.255, 360.755, 361.044, 361.610, 365.138, 366.160, 368A.180,  
13 370.257, 370.327, 372A.080, 378.290, 378.300, 379.008, 379.1495,  
14 385A.830, 385B.100, 387.626, 387.631, 388.1455, 388.259,  
15 388.501, 388.503, 388.513, 388.750, 388A.247, 388A.249, 391.035,  
16 391.120, 391.925, 392.029, 392.147, 392.264, 392.271, 392.315,  
17 392.317, 392.325, 392.327, 392.335, 392.850, 394.167, 394.1698,  
18 394.447, 394.460, 394.465, 396.3295, 396.405, 396.525, 396.535,  
19 396.9685, 398A.115, 408.3885, 408.3886, 408.3888, 408.5484,  
20 412.153, 416.070, 422.2749, 422.305, 422A.342, 422A.350,  
21 425.400, 427A.1236, 427A.872, 432.028, 432.205, 432B.175,  
22 432B.280, 432B.290, 432B.407, 432B.430, 432B.560, 432B.5902,  
23 433.534, 433A.360, 437.145, 439.840, 439B.420, 440.170,  
24 441A.195, 441A.220, 441A.230, 442.330, 442.395, 442.735,  
25 445A.665, 445B.570, 449.209, 449.245, 449A.112, 450.140,  
26 453.164, 453.720, 453A.610, 453A.700, 458.055, 458.280, 459.050,  
27 459.3866, 459.555, 459.7056, 459.846, 463.120, 463.15993,  
28 463.240, 463.3403, 463.3407, 463.790, 467.1005, 480.365, 480.940,  
29 481.063, 481.091, 481.093, 482.170, 482.5536, 483.340, 483.363,  
30 483.575, 483.659, 483.800, 484E.070, 485.316, 501.344, 503.452,  
31 522.040, 534A.031, 561.285, 571.160, 584.655, 587.877, 598.0964,  
32 598.098, 598A.110, 599B.090, 603.070, 603A.210, 604A.710,  
33 612.265, 616B.012, 616B.015, 616B.315, 616B.350, 618.341,  
34 618.425, 622.310, 623.131, 623A.137, 624.110, 624.265, 624.327,  
35 625.425, 625A.185, 628.418, 628B.230, 628B.760, 629.047,  
36 629.069, 630.133, 630.30665, 630.336, 630A.555, 631.368,  
37 632.121, 632.125, 632.405, 633.283, 633.301, 633.524, 634.055,  
38 634.214, 634A.185, 635.158, 636.107, 637.085, 637B.288, 638.087,  
39 638.089, 639.2485, 639.570, 640.075, 640A.220, 640B.730,  
40 640C.400, 640C.600, 640C.620, 640C.745, 640C.760, 640D.190,  
41 640E.340, 641.090, 641.325, 641A.191, 641A.289, 641B.170,  
42 641B.460, 641C.760, 641C.800, 642.524, 643.189, 644A.870,  
43 645.180, 645.625, 645A.050, 645A.082, 645B.060, 645B.092,  
44 645C.220, 645C.225, 645D.130, 645D.135, 645E.300, 645E.375,  
45 645G.510, 645H.320, 645H.330, 647.0945, 647.0947, 648.033,



\* S B 2 8 7 4 \*

1 648.197, 649.065, 649.067, 652.228, 654.110, 656.105, 661.115,  
2 665.130, 665.133, 669.275, 669.285, 669A.310, 671.170, 673.450,  
3 673.480, 675.380, 676A.340, 676A.370, 677.243, 679B.122,  
4 679B.152, 679B.159, 679B.190, 679B.285, 679B.690, 680A.270,  
5 681A.440, 681B.260, 681B.410, 681B.540, 683A.0873, 685A.077,  
6 686A.289, 686B.170, 686C.306, 687A.110, 687A.115, 687C.010,  
7 688C.230, 688C.480, 688C.490, 689A.696, 692A.117, 692C.190,  
8 692C.3507, 692C.3536, 692C.3538, 692C.354, 692C.420,  
9 693A.480, 693A.615, 696B.550, 696C.120, 703.196, 704B.320,  
10 704B.325, 706.1725, 706A.230, 710.159, 711.600, sections 35, 38  
11 and 41 of chapter 478, Statutes of Nevada 2011 and section 2 of  
12 chapter 391, Statutes of Nevada 2013 and unless otherwise declared  
13 by law to be confidential, all public ~~{books and public}~~ records of a  
14 governmental entity must be open at all times during office hours to  
15 inspection by any person, and may be fully copied or an abstract or  
16 memorandum may be prepared from those public ~~{books and public}~~  
17 records. Any such copies, abstracts or memoranda may be used to  
18 supply the general public with copies, abstracts or memoranda of the  
19 records or may be used in any other way to the advantage of the  
20 governmental entity or of the general public. This section does not  
21 supersede or in any manner affect the federal laws governing  
22 copyrights or enlarge, diminish or affect in any other manner the  
23 rights of a person in any written ~~{book or}~~ record which is  
24 copyrighted pursuant to federal law.

25 2. A governmental entity may not reject a ~~{book or}~~ record  
26 which is copyrighted solely because it is copyrighted.

27 3. A governmental entity that has ~~{legal}~~ *possession*, custody  
28 or control of a public ~~{book or}~~ record shall not deny a request made  
29 pursuant to subsection 1 to inspect or copy or receive a copy of a  
30 public ~~{book or}~~ record on the basis that the requested public ~~{book~~  
31 ~~or}~~ record contains information that is confidential if the  
32 governmental entity can redact, delete, conceal or separate ,  
33 *including, without limitation, electronically*, the confidential  
34 information from the information included in the public ~~{book or}~~  
35 record that is not otherwise confidential.

36 4. A ~~{person may request}~~ *governmental entity shall provide a*  
37 *copy of a public record in {any} an electronic format by means of*  
38 *an electronic medium {in which the public record is readily*  
39 *available.} unless the public record was requested in a different*  
40 *medium. If requested, a copy of a public record must be provided*  
41 *in the electronic format in which the public record was created or*  
42 *prepared.*



1       5. An officer, employee or agent of a governmental entity who  
2 has ~~legal~~ **possession**, custody or control of a public record:

3       (a) Shall not refuse to provide a copy of that public record in ~~the~~  
4 ~~readily available~~ **the medium that is requested** because the officer,  
5 employee or agent has already prepared or would prefer to provide  
6 the copy in a different medium.

7       (b) Except as otherwise provided in NRS 239.030, shall, upon  
8 request, prepare the copy of the public record and shall not require  
9 the person who has requested the copy to prepare the copy himself  
10 or herself.

11       **Sec. 6.** NRS 239.0107 is hereby amended to read as follows:

12       239.0107 1. Not later than the end of the fifth business day  
13 after the date on which the person who has ~~legal~~ **possession**,  
14 custody or control of a public ~~book or~~ record of a governmental  
15 entity receives a written or oral request from a person to inspect,  
16 copy or receive a copy of the public ~~book or~~ record, a  
17 governmental entity shall do one of the following, as applicable:

18       (a) Except as otherwise provided in subsection 2, allow the  
19 person to inspect or copy the public ~~book or~~ record or, if the  
20 request is for the person to receive a copy of the public ~~book or~~  
21 record, provide such a copy to the person.

22       (b) If the governmental entity does not have ~~legal~~ **possession**,  
23 custody or control of the public ~~book or~~ record, provide to the  
24 person, in writing:

25       (1) Notice of ~~that~~ **the fact that it does not have**  
26 **possession, custody or control of the public record;** and

27       (2) The name and address of the governmental entity that has  
28 ~~legal~~ **possession**, custody or control of the public ~~book or~~ record,  
29 if known.

30       (c) Except as otherwise provided in paragraph (d), if the  
31 governmental entity is unable to make the public ~~book or~~ record  
32 available by the end of the fifth business day after the date on which  
33 the person who has ~~legal~~ **possession**, custody or control of the  
34 public ~~book or~~ record received the request ~~provide~~ :

35       **(1) Provide** to the person, in writing ~~the~~

36       ~~(1) Notice~~ **notice** of ~~that~~ **the fact that it is unable to**  
37 **make the public record available by that date and**

38       ~~(2) At~~ **the earliest** date and time after which the  
39 **governmental entity reasonably believes the** public ~~book or~~ record  
40 will be available for the person to inspect or copy or after which a  
41 copy of the public ~~book or~~ record will be available to the person. If  
42 the public ~~book or~~ record or the copy of the public ~~book or~~  
43 record is not available to the person by that date and time, the  
44 ~~person may inquire regarding the status of the request.~~  
45 **governmental entity shall provide to the person, in writing, an**



1 *explanation of the reason the public record is not available and a*  
2 *date and time after which the governmental entity reasonably*  
3 *believes the public record will be available for the person to*  
4 *inspect or copy or after which a copy of the public record will be*  
5 *available to the person.*

6 (2) *Make a reasonable effort to assist the requester to focus*  
7 *the request in such a manner as to maximize the likelihood the*  
8 *requester will be able to inspect, copy or receive a copy of the*  
9 *public record as expeditiously as possible, including, without*  
10 *limitation, by:*

11 (I) *Advising the requester regarding terms to be used or*  
12 *the applicable database in which to perform a search for the*  
13 *public record;*

14 (II) *Eliciting additional clarifying information from the*  
15 *requester that will assist the person who has possession, custody or*  
16 *control of a public record in identifying the public record;*

17 (III) *Providing suggestions for overcoming any practical*  
18 *basis that would deny or otherwise limit access to the public*  
19 *record; and*

20 (IV) *Describing the manner in which the public record*  
21 *is stored, including, without limitation, whether the public record*  
22 *is stored electronically.*

23 (d) *If the governmental entity must deny the person's request*  
24 *because the public ~~book or~~ record, or a part thereof, is*  
25 *confidential, provide to the person, in writing:*

26 (1) *Notice of that fact; and*

27 (2) *A citation to the specific statute or other legal authority*  
28 *that makes the public ~~book or~~ record, or a part thereof,*  
29 *confidential.*

30 2. *If a public ~~book or~~ record of a governmental entity is*  
31 *readily available for inspection or copying, the person who has*  
32 *legal possession, custody or control of the public ~~book or~~ record*  
33 *shall allow a person who has submitted a request to inspect, copy or*  
34 *receive a copy of a public ~~book or~~ record ~~to~~ as expeditiously as*  
35 *practicable.*

36 3. *In addition to performing the actions required by*  
37 *subsections 1 and 2, the person who has possession, custody or*  
38 *control of a public record of a governmental entity shall provide in*  
39 *writing to a person who makes a request for the public record:*

40 (a) *The name and title or position of the person responsible for*  
41 *making the decision on behalf of the governmental entity*  
42 *concerning the action the governmental entity will take pursuant*  
43 *to this section concerning the request or any other decision in*  
44 *connection with the request; and*



*(b) Contact information for the person described in paragraph (a), including, without limitation, his or her business address, telephone number and electronic mail address.*

**Sec. 7.** NRS 239.011 is hereby amended to read as follows:

239.011 1. If a request for inspection, copying or copies of a public ~~book or~~ record open to inspection and copying is denied ~~[-]~~ *or unreasonably delayed or if a person who requests a copy of a public record believes that the fee charged by the governmental entity for providing the copy of the public record is excessive or improper*, the requester may apply to the district court in the county in which the ~~book or~~ record is located for an order:

(a) Permitting the requester to inspect or copy the ~~book or~~ record; ~~or~~

(b) Requiring the person who has ~~legal~~ **possession**, custody or control of the public ~~book or~~ record to provide a copy to the requester ~~[-]~~; **or**

(c) *Providing relief relating to the amount of the fee,*  
 ➤ as applicable.

2. The court shall give this matter priority over other civil matters to which priority is not given by other statutes. If the requester prevails, the requester is entitled to recover ~~this~~ *from the governmental entity that has possession, custody or control of the record*:

(a) *His* or her costs and reasonable attorney's fees in the proceeding ~~from the governmental entity whose officer has custody of the book or record.~~ ; and

*(b) One hundred dollars per day for each day he or she was denied the right to inspect, copy or receive a copy of the public record.*

*3. If the governmental entity appeals the decision of the district court and the decision is affirmed in whole or in part, the requester is entitled to recover from the governmental entity that has possession, custody or control of the record:*

(a) His or her costs and reasonable attorney's fees for the appeal; and

(b) *One hundred dollars per day for each day he or she was denied the right to inspect, copy or receive a copy of the public record.*

4. *The rights and remedies recognized by this section are in addition to any other rights or remedies that may exist in law or in equity.*

**Sec. 8.** NRS 239.0113 is hereby amended to read as follows:

239.0113 Except as otherwise provided in NRS 239.0115, if:

1. The confidentiality of a public ~~book or~~ record, or a part thereof, is at issue in a judicial or administrative proceeding; and



1       2. The governmental entity that has ~~legal~~ *possession*, custody  
2 or control of the public ~~book or~~ record asserts that the public ~~book~~  
3 ~~or~~ record, or a part thereof, is confidential,  
4       ↳ the governmental entity has the burden of proving by a  
5 preponderance of the evidence that the public ~~book or~~ record, or a  
6 part thereof, is confidential.

7       **Sec. 9.** NRS 239.0115 is hereby amended to read as follows:

8       239.0115 1. Except as otherwise provided in this subsection  
9 and subsection 3, notwithstanding any provision of law that has  
10 declared a public ~~book or~~ record, or a part thereof, to be  
11 confidential, if a public ~~book or~~ record has been in the ~~legal~~  
12 *possession*, custody or control of one or more governmental entities  
13 for at least 30 years, a person may apply to the district court of the  
14 county in which the governmental entity that currently has ~~legal~~  
15 *possession*, custody or control of the public ~~book or~~ record is  
16 located for an order directing that governmental entity to allow the  
17 person to inspect or copy the public ~~book or~~ record, or a part  
18 thereof. If the public ~~book or~~ record pertains to a natural person, a  
19 person may not apply for an order pursuant to this subsection until  
20 the public ~~book or~~ record has been in the ~~legal~~ *possession*,  
21 custody or control of one or more governmental entities for at least  
22 30 years or until the death of the person to whom the public ~~book~~  
23 ~~or~~ record pertains, whichever is later.

24       2. There is a rebuttable presumption that a person who applies  
25 for an order as described in subsection 1 is entitled to inspect or  
26 copy the public ~~book or~~ record, or a part thereof, that the person  
27 seeks to inspect or copy.

28       3. The provisions of subsection 1 do not apply to any ~~book or~~  
29 record:

30       (a) Declared confidential pursuant to NRS 463.120.

31       (b) Containing personal information pertaining to a victim of  
32 crime that has been declared by law to be confidential.

33       **Sec. 10.** NRS 239.012 is hereby amended to read as follows:

34       239.012 1. A public officer or employee who acts in good  
35 faith in disclosing or refusing to disclose information and the  
36 employer of the public officer or employee are immune from  
37 liability for damages, either to the requester or to the person whom  
38 the information concerns. *Such damages do not include any costs*  
39 *and reasonable attorney's fees or other monetary amount awarded*  
40 *to the requester pursuant to NRS 239.011 or section 1 of this act.*

41       2. *For the purposes of subsection 1, the public officer or*  
42 *employee or his or her employer, as applicable, has the burden of*  
43 *proving by a preponderance of the evidence that the public officer*  
44 *or employee acted in good faith in refusing to disclose*  
45 *information.*



1     **Sec. 11.** The amendatory provisions of this act apply to all  
2 actions pending or filed on or after October 1, 2019.

3     **Sec. 12.** 1. When the next reprint of Nevada Revised  
4 Statutes is prepared by the Legislative Counsel, the Legislative  
5 Counsel shall replace the term “public book or record” as it appears  
6 in the Nevada Revised Statutes with the term “public record” in the  
7 manner provided in this act.

8     2. The Legislative Counsel shall, in preparing supplements to  
9 the Nevada Administrative Code, make such changes as necessary  
10 so that the term “public book or record” is replaced with the term  
11 “public record” as provided for in this act.

12     3. To the extent that revisions are made to Nevada Revised  
13 Statutes pursuant to subsection 1, the revisions shall be construed as  
14 nonsubstantive and it is not the intent of the Nevada Legislature to  
15 modify any existing interpretations of any statute which is so  
16 revised.

17     **Sec. 13.** NRS 239.055 is hereby repealed.

---

---

#### TEXT OF REPEALED SECTION

---

---

#### **239.055 Additional fee when extraordinary use of personnel or resources is required; limitation.**

1. Except as otherwise provided in NRS 239.054 regarding information provided from a geographic information system, if a request for a copy of a public record would require a governmental entity to make extraordinary use of its personnel or technological resources, the governmental entity may, in addition to any other fee authorized pursuant to this chapter, charge a fee not to exceed 50 cents per page for such extraordinary use. Such a request must be made in writing, and upon receiving such a request, the governmental entity shall inform the requester, in writing, of the amount of the fee before preparing the requested information. The fee charged by the governmental entity must be reasonable and must be based on the cost that the governmental entity actually incurs for the extraordinary use of its personnel or technological resources. The governmental entity shall not charge such a fee if the governmental entity is not required to make extraordinary use of its personnel or technological resources to fulfill additional requests for the same information.



2. As used in this section, “technological resources” means any information, information system or information service acquired, developed, operated, maintained or otherwise used by a governmental entity.

③⑩



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 2

# EXHIBIT 2

Senate Bill No. 287—Senators Parks, Hansen, Spearman;  
Cancela, Denis, Kieckhefer, Scheible and Woodhouse

CHAPTER.....

AN ACT relating to public records; revising provisions relating to the manner of providing copies of public records; revising provisions governing the actions taken by governmental entities in response to requests for public records; revising provisions relating to the relief provided for a requester of a public record who prevails in a legal proceeding; revising provisions governing the fees that governmental entities are authorized to charge for a copy of a public record; providing civil penalties; and providing other matters properly relating thereto.

**Legislative Counsel's Digest:**

Existing law provides that all public books and public records of a state or local governmental entity, unless otherwise declared by law to be confidential, are required to be open at all times during office hours for the public to inspect, copy or receive a copy thereof. Existing law also authorizes a person to request a copy of a public record in any medium in which the public record is readily available. (NRS 239.010) The purpose of the existing law governing public records, as stated in the legislative declaration for that law, is, in part, to foster democratic principles by providing members of the public with access to inspect and copy public books and records to the extent permitted by law. (NRS 239.001) **Section 2** of this bill provides that the legislative intent is for such access to be provided promptly. **Sections 2 and 4** of this bill make changes to conform with existing law which provides that, in addition to the right to inspect and copy a public record, members of the public have the right to receive a copy of a public record upon request.

With certain exceptions, existing law prohibits a governmental entity from charging a fee for providing a copy of a public record that exceeds the actual cost to the governmental entity to provide the copy. (NRS 239.052) **Section 3** of this bill clarifies that the actual cost to a governmental entity includes such direct costs as the cost of ink, toner, paper, media and postage. **Section 13** of this bill eliminates the authority of a governmental entity to charge an additional fee for providing a copy of a public record when extraordinary use of personnel or resources is required. (NRS 239.055)

**Section 5** of this bill specifically authorizes the electronic redaction of public books and records. **Section 5** also requires, with limited exception, a governmental entity, if requested, to provide a copy of a public record in an electronic format by means of an electronic medium unless the public record was requested in a different medium.

Under existing law, if a person requests to inspect or copy a public book or record or receive a copy of a public book or record which the governmental entity is unable to make available by the end of the fifth business day after the request was received, the governmental entity is required to provide written notice of that fact to the person who made the request and the date and time after which the public record or the copy of the public book or record will be available. (NRS 239.0107) **Section 6** of this bill clarifies that the date and time provided to the requester must reflect the earliest date and time after which the governmental entity reasonably believes the public book or record will be available. If the public book



or record is not made available by this date and time, **section 6** requires the governmental entity to provide to the requester, in writing, an explanation of the reason the public book or record is not available and a date and time after which the governmental entity reasonably believes the public book or record will be available. **Section 6** also requires a governmental entity that is unable to provide access to a public book or record within the prescribed time period to make a reasonable effort to assist the requester to focus the request in such a manner as to maximize the likelihood the requester will be able to inspect, copy or receive a copy of the public book or record as expeditiously as possible.

If a request for inspection, copying or copies of a public book or record is denied, existing law authorizes a requester to apply to a district court for an order permitting the requester to inspect or copy the record or requiring the person who has legal custody or control of the public record to provide a copy to the requester. Existing law provides that if the requester prevails in such a proceeding, the requester is entitled to recover his or her costs and reasonable attorney's fees in the proceeding from the governmental entity whose officer has custody of the book or record. (NRS 239.011) **Section 7** of this bill authorizes a requester of a public record to apply to a district court for a similar order if a request for inspection, copying or copies of a public record is unreasonably delayed or if a person who requests a copy of a public book or record believes that the fee charged by the governmental entity for providing the copy of the public book or record is excessive or improper. **Section 1** of this bill provides that if a court determines that a governmental entity willfully failed to comply with the existing law governing public books and records concerning a request to inspect, copy or receive a copy of a public book or record, the court must impose on the governmental entity a civil penalty.

**Section 11** of this bill provides that the provisions of the bill apply to actions filed on and after October 1, 2019, which is the effective date of this bill.

EXPLANATION - Matter in *bolded italics* is new; matter between brackets ~~{omitted material}~~ is material to be omitted.

---

---

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN  
SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

**Section 1.** Chapter 239 of NRS is hereby amended by adding thereto a new section to read as follows:

*1. In addition to any relief awarded pursuant to NRS 239.011, if a court determines that a governmental entity willfully failed to comply with the provisions of this chapter concerning a request to inspect, copy or receive a copy of a public book or record, the court must impose on the governmental entity a civil penalty of:*

- (a) For a first violation within a 10-year period, \$1,000.*
- (b) For a second violation within a 10-year period, \$5,000.*
- (c) For a third or subsequent violation within a 10-year period, \$10,000.*

*2. A civil penalty imposed pursuant to subsection 1 must be deposited in and accounted for separately in the State General*



*Fund. The money in the account may be used only by the Division of State Library, Archives and Public Records of the Department of Administration to improve access to public records, and is hereby authorized for expenditure as a continuing appropriation for this purpose.*

*3. The rights and remedies recognized by this section are in addition to any other rights or remedies that may exist in law or in equity.*

**Sec. 2.** NRS 239.001 is hereby amended to read as follows:

239.001 The Legislature hereby finds and declares that:

1. The purpose of this chapter is to foster democratic principles by providing members of the public with *prompt* access to inspect , ~~and~~ copy *or receive a copy of* public books and records to the extent permitted by law;

2. The provisions of this chapter must be construed liberally to carry out this important purpose;

3. Any exemption, exception or balancing of interests which limits or restricts access to public books and records by members of the public must be construed narrowly;

4. The use of private entities in the provision of public services must not deprive members of the public access to inspect , ~~and~~ copy ~~books and~~ *or receive a copy of books and* records relating to the provision of those services; and

5. If a public book or record is declared by law to be open to the public, such a declaration does not imply, and must not be construed to mean, that a public book or record is confidential if it is not declared by law to be open to the public and is not otherwise declared by law to be confidential.

**Sec. 3.** NRS 239.005 is hereby amended to read as follows:

239.005 As used in this chapter, unless the context otherwise requires:

1. "Actual cost" means the direct cost ~~related to the reproduction~~ *incurred by a governmental entity in the provision of* a public record ~~+~~ , *including, without limitation, the cost of ink, toner, paper, media and postage.* The term does not include a cost that a governmental entity incurs regardless of whether or not a person requests a copy of a particular public record.

2. "Agency of the Executive Department" means an agency, board, commission, bureau, council, department, division, authority or other unit of the Executive Department of the State Government. The term does not include the Nevada System of Higher Education.

3. "Committee" means the Committee to Approve Schedules for the Retention and Disposition of Official State Records.



4. "Division" means the Division of State Library, Archives and Public Records of the Department of Administration.

5. "Governmental entity" means:

(a) An elected or appointed officer of this State or of a political subdivision of this State;

(b) An institution, board, commission, bureau, council, department, division, authority or other unit of government of this State, including, without limitation, an agency of the Executive Department, or of a political subdivision of this State;

(c) A university foundation, as defined in NRS 396.405;

(d) An educational foundation, as defined in NRS 388.750, to the extent that the foundation is dedicated to the assistance of public schools; or

(e) A library foundation, as defined in NRS 379.0056, to the extent that the foundation is dedicated to the assistance of a public library.

6. "Official state record" includes, without limitation:

(a) Papers, unpublished books, maps and photographs;

(b) Information stored on magnetic tape or computer, laser or optical disc;

(c) Materials that are capable of being read by a machine, including, without limitation, microforms and audio and visual materials; and

(d) Materials that are made or received by a state agency and preserved by that agency or its successor as evidence of the organization, operation, policy or any other activity of that agency or because of the information contained in the material.

7. "Privatization contract" means a contract executed by or on behalf of a governmental entity which authorizes a private entity to provide public services that are:

(a) Substantially similar to the services provided by the public employees of the governmental entity; and

(b) In lieu of the services otherwise authorized or required to be provided by the governmental entity.

**Sec. 4.** NRS 239.008 is hereby amended to read as follows:

239.008 1. The head of each agency of the Executive Department shall designate one or more employees of the agency to act as records official for the agency.

2. A records official designated pursuant to subsection 1 shall carry out the duties imposed pursuant to this chapter on the agency of the Executive Department that designated him or her with respect to a request to inspect, ~~for~~ copy *or receive a copy of* a public book or record of the agency.



3. The State Library, Archives and Public Records Administrator, pursuant to NRS 378.255 and in cooperation with the Attorney General, shall prescribe:

(a) The form for a request by a person to inspect, ~~{or}~~ copy *or receive a copy of* a public book or record of an agency of the Executive Department pursuant to NRS 239.0107;

(b) The form for the written notice required to be provided by an agency of the Executive Department pursuant to paragraph (b), (c) or (d) of subsection 1 of NRS 239.0107; and

(c) By regulation the procedures with which a records official must comply in carrying out his or her duties.

4. Each agency of the Executive Department shall make available on any website maintained by the agency on the Internet or its successor the forms and procedures prescribed by the State Library, Archives and Public Records Administrator and the Attorney General pursuant to subsection 3.

**Sec. 5.** NRS 239.010 is hereby amended to read as follows:

239.010 1. Except as otherwise provided in this section and NRS 1.4683, 1.4687, 1A.110, 3.2203, 41.071, 49.095, 49.293, 62D.420, 62D.440, 62E.516, 62E.620, 62H.025, 62H.030, 62H.170, 62H.220, 62H.320, 75A.100, 75A.150, 76.160, 78.152, 80.113, 81.850, 82.183, 86.246, 86.54615, 87.515, 87.5413, 87A.200, 87A.580, 87A.640, 88.3355, 88.5927, 88.6067, 88A.345, 88A.7345, 89.045, 89.251, 90.730, 91.160, 116.757, 116A.270, 116B.880, 118B.026, 119.260, 119.265, 119.267, 119.280, 119A.280, 119A.653, 119B.370, 119B.382, 120A.690, 125.130, 125B.140, 126.141, 126.161, 126.163, 126.730, 127.007, 127.057, 127.130, 127.140, 127.2817, 128.090, 130.312, 130.712, 136.050, 159.044, 159A.044, 172.075, 172.245, 176.01249, 176.015, 176.0625, 176.09129, 176.156, 176A.630, 178.39801, 178.4715, 178.5691, 179.495, 179A.070, 179A.165, 179D.160, 200.3771, 200.3772, 200.5095, 200.604, 202.3662, 205.4651, 209.392, 209.3925, 209.419, 209.521, 211A.140, 213.010, 213.040, 213.095, 213.131, 217.105, 217.110, 217.464, 217.475, 218A.350, 218E.625, 218F.150, 218G.130, 218G.240, 218G.350, 228.270, 228.450, 228.495, 228.570, 231.069, 231.1473, 233.190, 237.300, 239.0105, 239.0113, 239B.030, 239B.040, 239B.050, 239C.140, 239C.210, 239C.230, 239C.250, 239C.270, 240.007, 241.020, 241.030, 241.039, 242.105, 244.264, 244.335, 247.540, 247.550, 247.560, 250.087, 250.130, 250.140, 250.150, 268.095, 268.490, 268.910, 271A.105, 281.195, 281.805, 281A.350, 281A.680, 281A.685, 281A.750, 281A.755, 281A.780, 284.4068, 286.110, 287.0438, 289.025, 289.080, 289.387, 289.830, 293.4855, 293.5002, 293.503,



293.504, 293.558, 293.906, 293.908, 293.910, 293B.135, 293D.510, 331.110, 332.061, 332.351, 333.333, 333.335, 338.070, 338.1379, 338.1593, 338.1725, 338.1727, 348.420, 349.597, 349.775, 353.205, 353A.049, 353A.085, 353A.100, 353C.240, 360.240, 360.247, 360.255, 360.755, 361.044, 361.610, 365.138, 366.160, 368A.180, 370.257, 370.327, 372A.080, 378.290, 378.300, 379.008, 379.1495, 385A.830, 385B.100, 387.626, 387.631, 388.1455, 388.259, 388.501, 388.503, 388.513, 388.750, 388A.247, 388A.249, 391.035, 391.120, 391.925, 392.029, 392.147, 392.264, 392.271, 392.315, 392.317, 392.325, 392.327, 392.335, 392.850, 394.167, 394.1698, 394.447, 394.460, 394.465, 396.3295, 396.405, 396.525, 396.535, 396.9685, 398A.115, 408.3885, 408.3886, 408.3888, 408.5484, 412.153, 416.070, 422.2749, 422.305, 422A.342, 422A.350, 425.400, 427A.1236, 427A.872, 432.028, 432.205, 432B.175, 432B.280, 432B.290, 432B.407, 432B.430, 432B.560, 432B.5902, 433.534, 433A.360, 437.145, 439.840, 439B.420, 440.170, 441A.195, 441A.220, 441A.230, 442.330, 442.395, 442.735, 445A.665, 445B.570, 449.209, 449.245, 449A.112, 450.140, 453.164, 453.720, 453A.610, 453A.700, 458.055, 458.280, 459.050, 459.3866, 459.555, 459.7056, 459.846, 463.120, 463.15993, 463.240, 463.3403, 463.3407, 463.790, 467.1005, 480.365, 480.940, 481.063, 481.091, 481.093, 482.170, 482.5536, 483.340, 483.363, 483.575, 483.659, 483.800, 484E.070, 485.316, 501.344, 503.452, 522.040, 534A.031, 561.285, 571.160, 584.655, 587.877, 598.0964, 598.098, 598A.110, 599B.090, 603.070, 603A.210, 604A.710, 612.265, 616B.012, 616B.015, 616B.315, 616B.350, 618.341, 618.425, 622.310, 623.131, 623A.137, 624.110, 624.265, 624.327, 625.425, 625A.185, 628.418, 628B.230, 628B.760, 629.047, 629.069, 630.133, 630.30665, 630.336, 630A.555, 631.368, 632.121, 632.125, 632.405, 633.283, 633.301, 633.524, 634.055, 634.214, 634A.185, 635.158, 636.107, 637.085, 637B.288, 638.087, 638.089, 639.2485, 639.570, 640.075, 640A.220, 640B.730, 640C.400, 640C.600, 640C.620, 640C.745, 640C.760, 640D.190, 640E.340, 641.090, 641.325, 641A.191, 641A.289, 641B.170, 641B.460, 641C.760, 641C.800, 642.524, 643.189, 644A.870, 645.180, 645.625, 645A.050, 645A.082, 645B.060, 645B.092, 645C.220, 645C.225, 645D.130, 645D.135, 645E.300, 645E.375, 645G.510, 645H.320, 645H.330, 647.0945, 647.0947, 648.033, 648.197, 649.065, 649.067, 652.228, 654.110, 656.105, 661.115, 665.130, 665.133, 669.275, 669.285, 669A.310, 671.170, 673.450, 673.480, 675.380, 676A.340, 676A.370, 677.243, 679B.122, 679B.152, 679B.159, 679B.190, 679B.285, 679B.690, 680A.270, 681A.440, 681B.260, 681B.410, 681B.540, 683A.0873, 685A.077,



686A.289, 686B.170, 686C.306, 687A.110, 687A.115, 687C.010, 688C.230, 688C.480, 688C.490, 689A.696, 692A.117, 692C.190, 692C.3507, 692C.3536, 692C.3538, 692C.354, 692C.420, 693A.480, 693A.615, 696B.550, 696C.120, 703.196, 704B.320, 704B.325, 706.1725, 706A.230, 710.159, 711.600, sections 35, 38 and 41 of chapter 478, Statutes of Nevada 2011 and section 2 of chapter 391, Statutes of Nevada 2013 and unless otherwise declared by law to be confidential, all public books and public records of a governmental entity must be open at all times during office hours to inspection by any person, and may be fully copied or an abstract or memorandum may be prepared from those public books and public records. Any such copies, abstracts or memoranda may be used to supply the general public with copies, abstracts or memoranda of the records or may be used in any other way to the advantage of the governmental entity or of the general public. This section does not supersede or in any manner affect the federal laws governing copyrights or enlarge, diminish or affect in any other manner the rights of a person in any written book or record which is copyrighted pursuant to federal law.

2. A governmental entity may not reject a book or record which is copyrighted solely because it is copyrighted.

3. A governmental entity that has legal custody or control of a public book or record shall not deny a request made pursuant to subsection 1 to inspect or copy or receive a copy of a public book or record on the basis that the requested public book or record contains information that is confidential if the governmental entity can redact, delete, conceal or separate , *including, without limitation, electronically*, the confidential information from the information included in the public book or record that is not otherwise confidential.

4. ~~{A person may request}~~ *If requested, a governmental entity shall provide a copy of a public record in ~~{any}~~ an electronic format by means of an electronic medium . ~~{in which the public record is readily available.}~~ Nothing in this subsection requires a governmental entity to provide a copy of a public record in an electronic format or by means of an electronic medium if:*

*(a) The public record:*

*(1) Was not created or prepared in an electronic format;*

*and*

*(2) Is not available in an electronic format; or*

*(b) Providing the public record in an electronic format or by means of an electronic medium would:*

*(1) Give access to proprietary software; or*



*(2) Require the production of information that is confidential and that cannot be redacted, deleted, concealed or separated from information that is not otherwise confidential.*

5. An officer, employee or agent of a governmental entity who has legal custody or control of a public record:

(a) Shall not refuse to provide a copy of that public record in ~~the~~ readily available ~~the~~ medium *that is requested* because the officer, employee or agent has already prepared or would prefer to provide the copy in a different medium.

(b) Except as otherwise provided in NRS 239.030, shall, upon request, prepare the copy of the public record and shall not require the person who has requested the copy to prepare the copy himself or herself.

**Sec. 6.** NRS 239.0107 is hereby amended to read as follows:

239.0107 1. Not later than the end of the fifth business day after the date on which the person who has legal custody or control of a public book or record of a governmental entity receives a written or oral request from a person to inspect, copy or receive a copy of the public book or record, a governmental entity shall do one of the following, as applicable:

(a) Except as otherwise provided in subsection 2, allow the person to inspect or copy the public book or record or, if the request is for the person to receive a copy of the public book or record, provide such a copy to the person.

(b) If the governmental entity does not have legal custody or control of the public book or record, provide to the person, in writing:

(1) Notice of ~~that~~ *the fact that it does not have legal custody or control of the public book or record;* and

(2) The name and address of the governmental entity that has legal custody or control of the public book or record, if known.

(c) Except as otherwise provided in paragraph (d), if the governmental entity is unable to make the public book or record available by the end of the fifth business day after the date on which the person who has legal custody or control of the public book or record received the request ~~provide~~:

*(1) Provide to the person, in writing:*

~~(1) Notice~~ *notice of the fact that it is unable to make the public book or record available by that date and*

~~(2) At~~ *the earliest date and time after which the governmental entity reasonably believes the public book or record will be available for the person to inspect or copy or after which a copy of the public book or record will be available to the person. If*



the public book or record or the copy of the public book or record is not available to the person by that date and time, the ~~person may inquire regarding the status of the request.~~ ***governmental entity shall provide to the person, in writing, an explanation of the reason the public book or record is not available and a date and time after which the governmental entity reasonably believes the public book or record will be available for the person to inspect or copy or after which a copy of the public book or record will be available to the person.***

***(2) Make a reasonable effort to assist the requester to focus the request in such a manner as to maximize the likelihood the requester will be able to inspect, copy or receive a copy of the public book or record as expeditiously as possible.***

(d) If the governmental entity must deny the person's request because the public book or record, or a part thereof, is confidential, provide to the person, in writing:

(1) Notice of that fact; and

(2) A citation to the specific statute or other legal authority that makes the public book or record, or a part thereof, confidential.

2. If a public book or record of a governmental entity is readily available for inspection or copying, the person who has legal custody or control of the public book or record shall allow a person who has submitted a request to inspect, copy or receive a copy of a public book or record ~~to~~ ***as expeditiously as practicable.***

**Sec. 7.** NRS 239.011 is hereby amended to read as follows:

239.011 1. If a request for inspection, copying or copies of a public book or record open to inspection and copying is denied ~~to~~ ***or unreasonably delayed or if a person who requests a copy of a public book or record believes that the fee charged by the governmental entity for providing the copy of the public book or record is excessive or improper,*** the requester may apply to the district court in the county in which the book or record is located for an order:

(a) Permitting the requester to inspect or copy the book or record; ~~to~~

(b) Requiring the person who has legal custody or control of the public book or record to provide a copy to the requester ~~to~~ ; or

(c) ***Providing relief relating to the amount of the fee,***  
→ as applicable.

2. The court shall give this matter priority over other civil matters to which priority is not given by other statutes. If the requester prevails, the requester is entitled to recover ~~this~~ ***from the governmental entity that has legal custody or control of the record***



*his* or her costs and reasonable attorney's fees in the proceeding .  
~~{from the governmental entity whose officer has custody of the book  
or record.}~~

*3. If the governmental entity appeals the decision of the district court and the decision is affirmed in whole or in part, the requester is entitled to recover from the governmental entity that has legal custody or control of the record his or her costs and reasonable attorney's fees for the appeal.*

*4. The rights and remedies recognized by this section are in addition to any other rights or remedies that may exist in law or in equity.*

**Secs. 8-10.** (Deleted by amendment.)

**Sec. 11.** The amendatory provisions of this act apply to all actions filed on or after October 1, 2019.

**Sec. 12.** (Deleted by amendment.)

**Sec. 13.** NRS 239.055 is hereby repealed.



DISTRICT COURT  
CLARK COUNTY, NEVADA

Writ of Mandamus

COURT MINUTES

November 14, 2019

---

A-19-799939-W      Nevada Independent, Plaintiff(s)  
vs.  
Richard Whitley, Defendant(s)

---

November 14, 2019      08:30 AM      Minute Order

HEARD BY:      Escobar, Adriana      COURTROOM: Chambers

COURT CLERK: Husted, Denise

RECORDER:      Anderson, Sandra

REPORTER:

PARTIES PRESENT:

**JOURNAL ENTRIES**

Sanofi-Aventis U.S. LLC s (Sanofi) Motion to Intervene (Motion) came on for hearing before Department XIV of the Eighth Judicial District Court, the Honorable Adriana Escobar presiding, on November 5, 2019. Attorney Matthew J. Rashbrook appeared on behalf of Petitioner Nevada Independent (Petitioner). Attorney John R. Bailey appeared on behalf of Potential Intervenor Sanofi-Aventis U.S., LLC (Sanofi).

After reviewing the pleadings and hearing the arguments regarding Sanofi s Motion to Intervene, the Court hereby CONTINUES the Hearing on Petitioner s Writ of Mandamus to Tuesday, December 17, 2019, and ORDERS supplemental briefing as discussed herein under Inadequate Representation from Current Respondent.

**Legal Standard**

The Nevada Supreme Court has held that the moving party must meet four requirements to intervene pursuant to NRCP 24(a)(2) (2019):

1. That it has a sufficient interest in the litigation s subject matter.
2. That it could suffer an impairment of its ability to protect that interest if it does not intervene.
3. That its interest is not adequately represented by existing parties.
4. That its application is timely.

Am. Home Assur. Co. v. Eighth Judicial Dist. Court ex rel. Cty. of Clark, 122 Nev. 1229, 1238 (2006). Determining whether an applicant has met these four requirements is within the district court s discretion. Id.

**Inadequate Representation from Current Respondent**

The third element Sanofi must establish to intervene and the nexus of the Court s request for supplemental briefing is that its interest is not adequately represented by the state. Am. Home Assur. Co., 122 Nev. at 1238.

Sanofi argues that the State cannot adequately represent its interest because the State cannot fully detail the steps Sanofi takes to maintain and protect its trade secrets and confidential information, cannot fully and adequately describe the irreparable harm, and cannot sufficiently describe the prejudice Sanofi would suffer if the Court issues the writ.

The Court requires more detailed information regarding Sanofi's arguments. It is therefore ORDERED that Sanofi and the parties submit supplemental briefs addressing the following questions:

- 1) Sanofi argues that the State cannot fully detail the steps Sanofi takes to maintain and protect its trade secrets and confidential information. However, Sanofi has already provided such information to the Department in support of its successful effort to convince the Department to keep the contents of its annual reports confidential. Intervenor's Response to Petitioner's Petition for a Writ of Habeas Corpus 8-9. Based in part on this information, the Department denied the records request.
  - a. Is the information already disclosed by Sanofi to the Department regarding the steps it takes to maintain the confidentiality of its trade secrets and confidential information insufficient? Why?
  - b. Can any such inadequacy be remedied by Sanofi augmenting the information it has already submitted to the Department? Why?
- 2) Similarly, Sanofi argues that the State cannot fully and adequately describe the irreparable harm and prejudice Sanofi would suffer if the Court issues the writ. However, Sanofi has already provided the Department with information about the harm it would suffer if its annual reports are disclosed. Intervenor's Resp. 10:7.
  - a. Is the information already disclosed by Sanofi to the Department regarding the harm it may suffer from disclosure adequate? Why?
  - b. Can any inadequacy be remedied by Sanofi augmenting the information it has already submitted to the Department? Why?
- 3) Sanofi's argument, which focuses on the information available to the State, overlooks important considerations in determining whether Sanofi's interests can be adequately represented by the State. The State's ability to represent Sanofi's interests does not necessarily mean their respective interests are and will continue to be aligned. Accordingly, Sanofi and the parties should brief the following:
  - a. Are the interests of Sanofi and the State aligned?
  - b. How and to what extent should the Court consider the potential for the interests of the State and Sanofi to diverge in determining whether the State can adequately represent Sanofi's interests?

#### Briefing Schedule

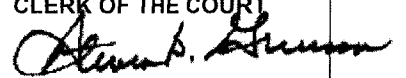
Sanofi must file supplemental briefing on the above by Thursday, November 21, 2019.

Petitioner must submit supplemental briefing in response to Sanofi's supplemental briefing by Thursday, December 5, 2019. That supplemental briefing should also address the arguments Sanofi makes regarding confidentiality and trade secrets in its Response to the Writ. See Motion to Intervene, Ex. 1.

Thus, the Court hereby CONTINUES the hearing on Petitioner's Petition for Writ of Mandamus and Motion to Intervene to Tuesday, December 17, 2019 at 9:30 am.

CLERK'S NOTE: Counsel notified via e-mail:

Matthew Rashbrook (matt@nvlitigation.com)  
 John Bailey (jbailey@baileykennedy.com)  
 Robert Langford (robert@robertlangford.com)



1 **SB**

2 JOHN R. BAILEY

3 Nevada Bar No. 0137

4 DENNIS L. KENNEDY

5 Nevada Bar No. 1462

6 SARAH E. HARMON

7 Nevada Bar No. 8106

8 **BAILEY ♦ KENNEDY**

9 8984 Spanish Ridge Avenue

10 Las Vegas, Nevada 89148-1302

11 Telephone: 702.562.8820

12 Facsimile: 702.562.8821

13 [JBailey@BaileyKennedy.com](mailto:JBailey@BaileyKennedy.com)

14 [DKennedy@BaileyKennedy.com](mailto:DKennedy@BaileyKennedy.com)

15 [SHarmon@BaileyKennedy.com](mailto:SHarmon@BaileyKennedy.com)

16 *Attorneys for Proposed Intervenor*

17 SANOFI-AVENTIS U.S. LLC

18 DISTRICT COURT

19 CLARK COUNTY, NEVADA

20 THE NEVADA INDEPENDENT,

21 Petitioner,

22 vs.

23 RICHARD WHITLEY, in his official capacity as  
24 the Director of the Nevada Department of Health  
25 and Human Services, and THE STATE OF  
26 NEVADA ex rel. the NEVADA DEPARTMENT  
27 OF HEALTH AND HUMAN SERVICES,

28 Respondents.

Case No. A-19-799939-W  
Dept. No. XIV

**Date of Hearing:** December 17, 2019

**Time of Hearing:** 9:30 a.m.

29 **SANOFI-AVENTIS U.S. LLC'S SUPPLEMENTAL BRIEF IN SUPPORT OF**  
30 **ITS MOTION TO INTERVENE**

31 On November 14, 2019, the Court issued a Minute Order requesting additional briefing on  
32 several points. Sanofi-Aventis U.S. LLC ("Sanofi") hereby answers the specific questions set forth  
33 by the Court regarding mandatory intervention, and it reiterates that should the Court find that  
34 mandatory intervention is not warranted, it should nonetheless grant Sanofi's motion for permissive  
35 intervention under NRCP 24(b)(1)(B).

36 ///

Sanofi agrees that if the Court limits its analysis to the interplay between NRCP 24, NRS 12.130, and the third prong of *Am. Home Assurance Co. v. Eighth Jud. Dist. Ct. ex rel. Cty of Clark*,<sup>1</sup> the State is well equipped to protect Sanofi's interests in this matter, and has adequately done so through its opposition to Plaintiff's Writ Petition. However, the Court may seek to expand its analysis to include both the scope of Sanofi's protectable interest and the irreparable harm it will experience should the Court grant Plaintiff's Writ Petition. In that regard, the Court will find Sanofi uniquely situated to provide additional evidence and argument on these issues (as it has in the Declaration of James Borneman, attached as an exhibit to Sanofi's proposed Response to the Writ Petition), permitting the Court to enter a decision with a more complete understanding of both the law and facts.

#### I. RESPONSES TO THE COURT'S QUESTIONS

The following responds to each of the questions raised by this Court in its Minute Order.

A. **Whether the Information Sanofi Has Provided to the Department Regarding the Steps It Takes to Protect Its Trade Secrets and Confidential Information Is Insufficient; If So, Why?**

Sanofi believes the Department possesses generalized knowledge of the safeguards that Sanofi employs to protect its trade secrets and confidential information. Specifically, Sanofi has provided the Department with the *requisite* amount of information necessary to support its request for confidentiality pursuant to NRS Ch. 439B, including through letters that accompanied Sanofi's reports. The Court may find that this information sufficiently demonstrates that the information included in Sanofi's reports to the Department is protectable as a trade secret; however, to the extent that the Court might have questions that go beyond the information already provided, if permitted to intervene Sanofi can respond to the Court directly at that time.

B. **Can Any Such Inadequacy in the Information the Department Possesses [Regarding Confidentiality] Be Remedied by Sanofi Augmenting the Information It Has Submitted to the Department; If Not, Why?**

Sanofi has already supplemented the information it provided to the Department through the Borneman Declaration submitted in support of Sanofi's proposed Response to the Writ Petition.

---

<sup>1</sup> 122 Nev. 1229, 1238, 147 P.3d 1120, 1126 (2006).

1 Sanofi believes that this additional information may be of assistance to the Court in rendering a  
2 decision on the Writ Petition.

3 **C. Whether the Information Sanofi Has Provided to the Department Regarding the**  
4 **Irreparable Harm It Would Suffer If Its Annual Reports Are Disclosed Is**  
5 **Insufficient; If So, Why?**

6 Irreparable harm has been described as harm “which cannot be repaired, retrieved, put down  
7 again, atoned for . . .” *Graham v. Medical Mut.*, 130 F.3d 293, 296 (7th Cir. 1997). The Department  
8 certainly appreciates, based on the information Sanofi has provided, that Sanofi will suffer harm that  
9 “cannot be repaired” should its trade secrets be made public. However, the Department cannot know  
10 the depth of harm Sanofi will experience, the myriad of ways in which Sanofi will suffer, and the  
11 utter lack of repair available to Sanofi should the Court grant Plaintiff’s Writ Petition. Sanofi has  
12 outlined this additional information in the Borneman Declaration.

13 **D. Can Any Such Inadequacy in the Information the Department Possesses**  
14 **[Regarding Irreparable Harm] be Remedied by Sanofi Augmenting the**  
15 **Information It Has Submitted to the Department; If Not, Why?**

16 Sanofi cannot correct any shortfalls in the Department’s knowledge without risking public  
17 disclosure of additional trade secrets and confidential information, including via this and other future  
18 NPRA requests. Sanofi has already provided this Court — and, by extension, the Department —  
19 with some additional information concerning irreparable harm though the Borneman Declaration,  
20 submitted in support of Sanofi’s proposed Response to the Petition for Writ of Mandamus.  
21 However, Sanofi is a global life sciences company that provides healthcare solutions through  
22 scientific innovations in human vaccines, rare disease, multiple sclerosis, oncology, immunology,  
23 infectious diseases, diabetes, cardiovascular diseases, consumer healthcare, established prescription  
24 products, and generics. Sanofi’s Mot. Ex. 2, Decl. of James Borneman, at ¶ 2. Providing the  
25 Department with further additional information regarding the irreparable harm Sanofi would suffer if  
26 its confidential pricing and marketing information were publicly disclosed would essentially provide  
27 a roadmap of harm for Sanofi’s competitors.

28 If permitted to intervene, Sanofi can directly respond to further inquiries the Court may have.

///

///

1           **E.       Are the Interests of Sanofi and the State Aligned?**

2           At this point, the interests of Sanofi and the State are aligned with regard to the interpretation  
3 and application of the relevant Statutes (NPRA, DTSA, NRS Ch. 439B, and NRS 600A.030).  
4 However, the State does not have the same vested interest in protecting Sanofi's trade secrets from  
5 public disclosure or in protecting Sanofi from irreparable harm. The Department's main role is to  
6 protect and promote the health and safety of Nevada residents — not to ensure that Sanofi is able to  
7 competitively develop, market, and sell pharmaceuticals and healthcare solutions in the global  
8 market. Again, only Sanofi can fully protect its trade secrets from public disclosure and prevent  
9 harm to its competitive position.

10           **F.       How and to What Extent Should the Court Consider the Potential for the**  
11           **Interests of Sanofi and the State to Diverge in Determining Whether the State**  
12           **Can Adequately Represent Sanofi's Interest?**

13           Sanofi respectfully submits that it is unable to speculate on the hypothetical ways in which its  
14 interests may someday diverge from the State's interests. However, the relationship between Sanofi  
15 and the State is that of a licensee and regulator. Historically, this kind of relationship has often  
16 experienced a divergence of interests since each party has different objectives, and the possibility  
17 certainly exists that Sanofi and the State may one day be at odds. However, the reality of diverging  
18 interests and the recognition that a party is best situated to protect its own interests is why  
19 intervention exists. "The very purpose of intervention is to permit the parties *to protect their own*  
20 *interests* when it might otherwise cause irreparable harm to permit the litigation to go forward  
21 [without the intervenor]." *United States v. City of Detroit*, 712 F.3d 925, 944 (6th Cir. 2013)  
(emphasis added).

22           **II.       THE COURT SHOULD NONETHELESS GRANT SANOFI'S MOTION FOR**  
23           **PERMISSIVE INTERVENTION.**

24           While Sanofi satisfies the requirements for mandatory intervention, the Court should  
25 nonetheless allow permissive intervention. Under NRCP 24(b)(1)(B), intervention is permitted  
26 where a party "has a claim or defense that shares with the main action a common question of law or  
27 fact." Sanofi and the State maintain the same interest in protecting the confidentiality of the trade  
28 secrets included in the annual reports. While the State has a duty to defend Sanofi's records from

1 public disclosure, it is Sanofi that stands to lose should the Court grant Plaintiff's Writ Petition. At  
2 the end of the day, Sanofi, and only Sanofi, will suffer irreparable harm if its confidential  
3 information and trade secrets are laid out for public view. Neither Sanofi nor the Court presently  
4 knows the contours of what questions or issues may arise or what evidence is needed in order for this  
5 Court to decide Plaintiff's Writ Petition. However, Sanofi has attempted, through the Borneman  
6 Declaration, to provide the Court with additional information regarding its safeguards for protecting  
7 its trade secrets and the irreparable harm it will suffer if the information in its reports to the  
8 Department is publicly disclosed. Thus Sanofi seeks the opportunity to be available to the Court in  
9 its decision-making process regarding the Writ Petition.

10 DATED this 21<sup>st</sup> day of November, 2019.

11 BAILEY ♦ KENNEDY

12  
13 By: /s/ Sarah E. Harmon

14 JOHN R. BAILEY  
15 DENNIS L. KENNEDY  
16 SARAH E. HARMON

17 *Attorneys for Proposed Intervenors*  
18 SANOFI-AVENTIS U.S. LLC  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

I certify that I am an employee of BAILEY ♦ KENNEDY and that on the 21<sup>st</sup> day of November, 2019, service of the foregoing **SANOFI-AVENTIS U.S. LLC'S SUPPLEMENTAL BRIEF IN SUPPORT OF ITS MOTION TO INTERVENE** was made by mandatory electronic service through the Eighth Judicial District Court's electronic filing system and/or by depositing a true and correct copy in the U.S. Mail, first class postage prepaid, and addressed to the following at their last known address:

MATTHEW J. RASHBROOK  
ROBERT L. LANGFORD

Email: matt@robertlangford.com  
robert@robertlangford.com

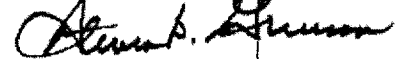
**ROBERT L. LANGFORD & ASSOCIATES**  
616 South Eighth Street  
Las Vegas, Nevada 89101

*Attorneys for Petitioner*  
**THE NEVADA INDEPENDENT**

AARON D. FORD  
ATTORNEY GENERAL  
STEVE SHEVORSKI  
CHIEF LITIGATION COUNSEL  
**OFFICE OF NEVADA ATTORNEY GENERAL**  
555 East Washington Avenue, Suite 3900  
Las Vegas, Nevada 89101

Email: sshevorski@ag.nv.gov  
*Attorneys for Respondents*  
RICHARD WHITLEY, in his official capacity as the Director of the Nevada Department of Health and Human Services, and THE STATE OF NEVADA, ex rel. the NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES

/s/ Josephine Baltazar  
Employee of BAILEY ♦ KENNEDY



1 **SB**  
2 MATTHEW J. RASHBROOK  
3 Nevada State Bar No. 12477  
4 ROBERT L. LANGFORD, ESQ.  
5 Nevada State Bar No. 3988  
6 ROBERT L. LANGFORD & ASSOCIATES  
7 616 S. Eighth Street  
8 Las Vegas, NV 89101  
9 (702) 471-6565  
10 matt@robertlangford.com  
11 robert@robertlangford.com  
12 *Attorneys for Petitioner*  
13 *The Nevada Independent*

9 **EIGHTH JUDICIAL DISTRICT COURT**  
10 **LAS VEGAS, NEVADA**

11 THE NEVADA INDEPENDENT,  
12

13 Petitioner,

14 vs.

15 RICHARD WHITLEY, in his official  
16 capacity as the Director of the Nevada  
17 Department of Health and Human Services,  
18 and THE STATE OF NEVADA, ex rel. the  
19 NEVADA DEPARTMENT OF HEALTH  
20 AND HUMAN SERVICES;

21 Respondents.

Case No.: A-19-799939-W

Dept. No.: 14

**SUPPLEMENTAL BRIEF IN OPPOSITION  
TO MOTION TO INTERVENE AND  
REPLY TO PROPOSED RESPONSE**

22 COMES NOW Petitioner, The Nevada Independent, and submits this  
23 Supplemental Brief in Opposition to Sanofi-U.S. LLC ("Sanofi")'s Motion to Intervene and  
24 Reply to Proposed Response. This Supplemental Brief is

25 ///

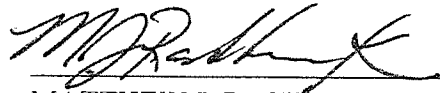
26 ///

27 ///

28 ///

1 based on the attached Memorandum of Points and Authorities and further based on the  
2 papers and pleadings already on file in this matter.

3 All of which is respectfully submitted, this 5th day of December, 2019.

4  
5 

6 MATTHEW J. RASHBROOK  
7 Nevada State Bar No. 12477  
8 ROBERT L. LANGFORD, ESQ.  
9 Nevada State Bar No. 3988  
10 ROBERT L. LANGFORD &  
11 ASSOCIATES  
12 616 S. Eighth Street  
13 Las Vegas, NV 89101  
14 (702) 471-6565  
15 matt@robertlangford.com  
16 robert@robertlangford.com  
17 *Attorneys for Petitioner*  
18 *The Nevada Independent*  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

1 Points and Authorities

2 Following the November 5, 2019 hearing on Sanofi's Motion to Intervene, the  
3 Court requested of the parties further briefing regarding the proposed intervention.  
4 Additionally, the Court requested of The Independent that it respond to arguments raised by  
5 Sanofi in its proposed Response.

6 At the outset, it must be carefully noted that Sanofi concedes, "the State is well  
7 equipped to protect Sanofi's interests in this matter, and has adequately done so through its  
8 opposition to Plaintiff's Writ Petition." *Supplemental Brief in Support of its Motion to*  
9 *Intervene ("Supplemental Brief in Support")*, 2:1-4.

10 As explained by the Nevada Supreme Court in *Am. Home Assur. Co. v. Eighth*  
11 *Jud. Dist. Ct.*, 122 Nev. 1229, 1238, 147 P.3d 1120, 1126 (2006), the four-part test to  
12 determine whether a party may intervene under Nev. R. Civ. P. 24(a)(2) is a conjunctive  
13 test, and therefore no further analysis in this regard is strictly necessary – Sanofi's  
14 concession that they cannot satisfy the third prong is determinative.

15 The Court's questions are addressed below, and The Independent's reply to  
16 Sanofi's proposed Response follows.

17 Supplemental Briefing Regarding Intervention

18 **Respondent Possesses Adequate Information to Describe Sanofi's Internal Practices**

19 The Court's first set of questions deal, roughly, with whether the information  
20 already in Respondents' possession regarding confidentiality, if any, and steps taken to  
21 maintain it, if any, is sufficient to defend the case, and, if insufficient, whether Sanofi could  
22 remedy the inadequacy by augmenting that information.

23 Sanofi appears to indicate, *Supplemental Brief in Support*, 2:13 – 3:2 that the  
24 information in the possession of Respondents – including the Declaration of James  
25 Borneman, Exhibit 2 to the proposed Response – is what it expects to offer to the Court in  
26 support of its positions that Respondents should continue to withhold the public records at  
27 issue in this matter.

1 Sanofi suggests that if allowed to intervene they will be available to answer  
2 further questions the Court may have at the time of the hearing, and notes further that they  
3 have provided further information to the State in the form of the Borneman Declaration.  
4 *Supplemental Brief in Support*, 2:19 – 3:2. At root, this is not an argument in support of  
5 intervention, but rather, that Sanofi, whether by Mr. Borneman or others in their employ,  
6 may have relevant evidence to offer as a witness.

7 **Sanofi Offers no Further Information Regarding Irreparable Harm**

8 Sanofi claims throughout that when the public records at issue in this case are  
9 produced, it will suffer irreparable harm. However, Sanofi offers nothing beyond  
10 conjecture and assertions in support of these claims. It assumes, and assumes that all will  
11 agree, that when the records at issue are produced, it will suffer some nebulous – but  
12 irreparable – harm.

13 However, the Nevada Supreme Court has expressly indicated that such “non-  
14 particularized hypothetical concerns” are not grounds upon which to withhold public  
15 records. *DR Partners v. Board of County Comm’rs*, 116 Nev. 616, 628, 6 P.3d 465, 473 –  
16 74 (2000).

17 Further, Sanofi’s position in this regard speaks to a larger problem Petitioners  
18 frequently face in public records cases: those seeking public records frequently suffer an  
19 information deficit specifically because they don’t have the records in dispute, and are  
20 therefore reduced to being forced to guess at what is contained within the public records,  
21 while debating the merits against entities armed with perfect information. *Reno*  
22 *Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 882, 266 P.3d 623, 629 (2011). (“[I]t is  
23 anomalous’ and inequitable to deny the requesting party basic information about the  
24 withheld records, thereby relegating it to advocating from a nebulous position where it is  
25 powerless to contest a claim of confidentiality.”)

26 If Sanofi will not offer further information beyond what is already available to  
27 Respondents, then it is not necessary to the determination of this matter – and its “non-  
28

1 particularized hypothetical concerns” regarding irreparable harm are an inadequate basis  
2 under Nevada law to withhold the public records at issue herein.

### 3 **Respondents and Sanofi’s Interests are Aligned**

4 Respondents have had ample time within which to consider their approach to this  
5 matter, together with counsel. At every opportunity, they have defended the case as if they  
6 were an arm of Sanofi. There is no basis in fact presently available from which to speculate  
7 that Respondents will at any future time deviate from their present course.

8 In the Ninth Circuit, where a proposed intervenor “and an existing party ‘have the  
9 same ultimate objective, a presumption of adequacy of representation arises.” *Northwest*  
10 *Forest Res. Council v. Glickman*, 82 F.3d 825, 838 (9th Cir. 1996), *quoting Oregon Envtl.*  
11 *Council v. Oregon Dept. of Envtl. Quality*, 775 F. Supp. 353, 359 (D. Ore. 1991) (*citing*  
12 *American Nat’l Bank and Trust Co. of Chicago v. City of Chicago*, 865 F.2d 144, 148 n. 3  
13 (7th Cir. 1989)). *But, see Utah Ass’n of Counties v. Clinton*, 255 F.3d 1246, 1254 (10th Cir.  
14 2001). (“The possibility that the interests of the applicant and the parties may diverge ‘need  
15 not be great’ in order to [show inadequate representation].” *Quoting Natural Res. Def.*  
16 *Council v. U.S. Nuclear Reg. Comm’n*, 578 F.2d 1341, 1346 (10th Cir. 1978).) *Contra*  
17 *Swepi LP v. Mora County*, 2014 U.S. Dist. LEXIS 170638, U.S. Dist. N.M. CIV 14-0035,  
18 December 5, 2014. (“In this area, the Tenth Circuit does not rely on concrete facts, or  
19 reasonable assumptions based on the case’s facts or the parties’ conduct. The Tenth Circuit  
20 relies on possibilities that lead to the possibility of other possibilities. The Tenth Circuit  
21 holds that it is possible that the government’s interests diverge from the intervenor’s  
22 interests, which makes it possible that the government may change its policy down the  
23 road, which makes it possible that it will no longer represent the intervenor’s interests.”  
24 *Citing WildEarth Guardians v. U.S. Forest Serv.*, 573 F.3d 992, 996 – 97 (10th Cir. 2009).)

### 25 Reply to Sanofi’s Proposed Response

26 Under the Nevada Public Records Act (“NPRA”), Nev. Rev. Stat. § 239.001 *et*  
27 *seq.*, disclosure of public records is presumed unless the public records at issue are made  
28 confidential by statute. NRS § 239.010, *Reno Newspapers, Inc. v. Haley*, 126 Nev. Adv.

1 Rep. 23, 234 P.3d 922, 924 (2010). Where records are not made confidential by statute, the  
2 governmental entity seeking to withhold them bears the burden of proving that the  
3 governmental interest in maintaining secrecy clearly outweighs “the liberal policy for an  
4 open and accessible government.” *Reno Newspapers, Inc. v. Haley*, 234 P.3d at 926. In  
5 analyzing the NPRA, the Nevada Supreme Court has frequently stressed the significance of  
6 the Legislature’s stated interest in maintaining an open and democratic government. *E.g.*,  
7 *id.*, *DR Partners v. Board of County Comm’rs*, 116 Nev. 616, 621, 6 P.3d 465, 468 (2000),  
8 *Las Vegas Metro. Police Dep’t v. Blackjack Bonding, Inc.*, 131 Nev. Adv. Rep. 10, 343  
9 P.3d 608, 614 (2015), *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 877 – 78, 266 P.3d  
10 623, 626 (2011).

11       Herein, the public records at issue are not made confidential by statute, and so the  
12 burden is on Respondents to prove that their interest in secrecy clearly outweighs the public  
13 interest in an open and democratic government. The public’s desire for disclosure was  
14 clearly displayed by the Legislature when it enacted S.B. 539 – including the provision  
15 found at Nev. Rev. Stat. § 600A.030(5)(b), specifically exempting records such as those  
16 sought herein from even the possibility of being considered a trade secret.

17       Although Respondents and Sanofi both suggest that the administrative codes  
18 established by Respondents have relevance, the Nevada Supreme Court has explained this  
19 is impossible: “A court will not hesitate to declare a regulation invalid when the regulation  
20 . . . conflicts with existing statutory provisions[.]” *Division of Ins. v. State Farm Mutual Ins.*  
21 *Co.*, 116 Nev. 290, 293, 995 P.2d 482, 485 (2000), *citing* NRS § 233B.110, *Clark Co.*  
22 *Social Service Dep’t v. Newkirk*, 106 Nev. 177, 179, 789 P.2d 227, 228 (1990); *Roberts v.*  
23 *State*, 104 Nev. 33, 37, 752 P.2d 221, 223 (1988).

24       If they frustrate the NPRA, the offending administrative codes must be stricken,  
25 because the failure to do so represents an enormous separation of powers problem: to  
26 whatever extent Respondents, or other department or agency heads – unelected members of  
27 the executive branch of government – are entitled to create administrative codes to frustrate  
28 the NPRA or any other Nevada law, they are effectively granted line-item veto over duly

1 enacted acts of the Legislature.<sup>1</sup> This result cannot stand in a democratic government. So,  
2 to any extent the NAC sections cited by Respondents or Sanofi frustrate the NPRA, they  
3 are invalid.

4 The records at issue herein are indisputably public records. There is no privilege  
5 or confidence, whether statutorily created or otherwise, which allows them to be withheld.  
6 The Nevada Legislature specifically enacted S.B. 539 to create transparency in this market,  
7 and included in that legislation an amendment to the state's trade secret definition to make  
8 clear that such information is not a trade secret. The result herein must be the issuance of a  
9 Writ of Mandamus directing Respondents to produce the requested public records in their  
10 entirety.

### 11 The DTSA Does Not Create Confidentiality

12 The public records at issue in this case are not made confidential by the DTSA.  
13 This is because the DTSA does not make any particular thing confidential, or place  
14 anything outside the reach of a state public records law: "In this context, the DTSA is  
15 comparable to the Copyright Act, 17 U.S.C. §§ 101 – 1332, in that neither federal statute  
16 exempts records from disclosure." *Baron v. Dep't of Human Servs.*, 169 A.3d 1268, 1276  
17 n. 6 (Pa. Cmwlth. 2017), citing *Ali v. Phila. Planning Comm'n*, 125 A.3d 92 (Pa. Cmwlth.  
18 2015)<sup>2</sup>. "The DTSA does not expressly provide the rates are confidential or trade secrets;  
19 rather, the statute creates a private right of action to prosecute the improper use of trade  
20 secrets." *Id.*

---

23 <sup>1</sup> Although Sanofi suggests, *Proposed Response*, 12:23 – 24, that Respondents created the  
24 relevant NAC sections to "clarify any confusion created by NRS 600A.030(5)(b)," in fact,  
25 "It is emphatically the province and duty of the judicial department to say what the law is."  
*Marbury v. Madison*, 5 U.S. 137, 177, 2 L. Ed. 60 (1803).

26 <sup>2</sup> "Based on our review of the Copyright Act and our precedent, we conclude that  
27 Copyright Act is not a federal law that exempts materials from disclosure . . . It neither  
28 expressly makes copyrighted material private or confidential, nor does it expressly preclude  
a government agency, lawfully in possession of the copyrighted material, from disclosing  
that material to the public." *Ali v. Phila Planning Comm'n*, 125 A.3d 92, 101 – 102 (Pa.  
Cmwlth. 2015).

1 These decisions comport with the Congressional intent in creating the DTSA:  
2 “Congress went out of its way to make clear that the DTSA does not preempt state trade  
3 secret laws. *Id.* Rather, the DTSA merely provides ‘a complementary Federal remedy if the  
4 jurisdictional threshold for Federal jurisdiction is satisfied.’ *Id.*” *Brand Energy &*  
5 *Infrastructure Servs. v. Irex Contracting Grp.*, 2017 U.S. Dist. LEXIS 43497, 17 n. 17,  
6 E.D. Pa. 16-2499, Mar. 23, 2017, citing H.R. REP. NO. 114-529, at 5.

7 The DTSA simply provides a federal forum for an aggrieved party to seek redress  
8 if they can prove they held a trade secret, and that another person misappropriated it.  
9 However, it is incumbent upon the party to prove that a given thing was in fact a trade  
10 secret.<sup>3</sup> The import for this case is clear: the DTSA does not create trade secret status for  
11 the public records requested by The Independent.

12 In contrast, consider for example Nev. Rev. Stat. § 202.3662, examined by the  
13 Nevada Supreme Court in *Reno Newspapers, Inc. v. Haley*, 126 Nev. Adv. Rep., 23, 234  
14 P.3d 922 (2010), which creates confidentiality over certain documents (and the information  
15 created or contained therein) explicitly:

- 16 1. Except as otherwise provided in this section and NRS  
17 202.3665 and 239.0115:  
18 a. An application for a permit, and all information  
19 contained within that application;  
20 b. All information provided to a sheriff or obtained  
21 by a sheriff in the course of the investigation of  
22 an application or permittee;  
23 c. The identity of the permittee; and  
24 d. Any records regarding the suspension,  
restoration or revocation of a permit,  
are confidential.

24 <sup>3</sup> NB: The cases Sanofi cites at *Proposed Response*, 6 – 7, n. 6, deal with pre-trial motions,  
25 and therefore represent findings by the respective courts that the Plaintiff had alleged  
26 sufficient facts to survive a motion to dismiss, *Mastronardi Int’l Ltd. v. SunSelect Prod.*  
27 *(Cal.), Inc.*, 2019 U.S. Dist. LEXIS 143934, Civ. No. 1:18-cv-00737 (E.D. Cal. August 23,  
28 2019), or alleged sufficient facts to merit the court granting a temporary restraining order,  
*H.Q. Milton, Inc. v. Webster*, 2017 U.S. Dist. LEXIS 193646, 17-cv-06598 (N.D. Cal.  
November 22, 2017), rather than legal findings that the DTSA rendered any certain thing  
confidential.

1 The contrast between the statutes enumerated within Nev. Rev. Stat. § 239.010(1),  
2 which specifically declare, e.g., specific items, forms, and applications (as discussed above,  
3 in the case of Nev. Rev. Stat. § 202.3662), and the DTSA is stark: the NPRA contemplates  
4 statutory exemptions which clearly outline specific documents or information contained  
5 within documents (such as personal identifying information) which are exempted from  
6 production, whereas the DTSA describes broad categories of information which a person  
7 may protect as trade secrets by their own conduct.

8 The DTSA provides a federal forum for persons to sue over the misappropriation  
9 of trade secrets. It does not create confidentiality, nor does it prevent a state from  
10 complying with its own public records law. *Fast Enterprises, LLC v. Pollack*, 2018 U.S.  
11 Dist. LEXIS 161518, 2018 WL 4539685, U.S. Dist. Mass. 16-cv-12149, Sept. 21, 2018,  
12 *Medsense, LLC v. Univ. Sys. of Md.*, U.S. Dist. LEXIS 166730, 2019 WL 4735430, D. Md.  
13 GLS-18-3262, Sept. 27, 2019. The DTSA does not provide any shelter for Respondents'  
14 failure to produce the public records at issue herein.

15 **Nevada Law Specifies the Records at Issue are not Trade Secrets**

16 As a part of S.B. 539, the Nevada Legislature amended Nev. Rev. Stat. §  
17 600A.030(5)(b), establishing that the information pharmaceutical manufacturers, pharmacy  
18 benefit managers, or pharmaceutical sales representatives are required to report to  
19 Respondents are not trade secrets.

20 “Where the language of a statute is plain and unambiguous and its meaning clear  
21 and unmistakable, there is no room for construction and [we] are not permitted to search for  
22 its meaning beyond the statute itself.” *Sandpointe Apts. LLC v. Eighth Jud. Dist. Ct.*, 129  
23 Nev. 813, 822, 313 P.3d 849, 858 *quoting Walters v. Eighth Jud. Dist. Ct.*, 127 Nev. 723,  
24 727, 263 P.3d 231, 234 (2011) (*quoting Madera v. SIIS*, 114 Nev. 253, 257, 956 P.2d 117,  
25 120 (1998)).

26 In this instance, the language of Nev. Rev. Stat. § 600A.030(5)(b) is totally clear,  
27 stating that the term Trade Secret in Nevada:

28 Does not include any information that a manufacturer is  
required to report pursuant to NRS 439B.635 or 439B.640,

1 information that a pharmaceutical sales representative is  
2 required to report pursuant to NRS 439B.660 or  
3 information that a pharmacy benefit manager is required to  
report pursuant to NRS 439B.645, to the extent that such  
information is required to be disclosed by those statutes.

4 The meaning of this statute is clear, on its face: under S.B. 539, certain  
5 information must be reported to Respondents, and it is no defense or exemption from the  
6 obligations pharmaceutical manufacturers, PBMs, or pharmaceutical sales representatives  
7 have under S.B. 539 to claim that such information has any protection as a trade secret,  
8 because it is, by definition, not a trade secret.

9 Even if this Court determines the clear language of Nev. Rev. Stat. §  
10 600A.030(5)(b) contains an ambiguity, there is a wealth of legislative history which  
11 indicates the very clear intention of the Legislature to get this very information into the  
12 public domain. *Petition*, 6, n. 4. Further, the Legislative Digest is very clear on this specific  
13 point, describing S.B. 539, in pertinent part as, “AN ACT relating to prescription drugs . . .  
14 providing that certain information *does not constitute a trade secret*[.]” 2017 Statutes of  
15 Nevada, ch. 592, Legislative Counsel’s Digest, at 4295 – 96. (emphasis added).

16 No inquiry into the legislative intent behind Nev. Rev. Stat. § 600A.030(5)(b) is  
17 required, as the language is clear on its face and the public records sought herein are  
18 exempted from even the possibility of being trade secrets. In the event an examination of  
19 the legislative history surrounding S.B. 539 is deemed necessary, that examination  
20 unequivocally reveals the specific intent of the Nevada Legislature to exempt these records  
21 from the possibility of being considered trade secrets.

#### 22 **Administrative Codes are Invalid if They Offend the NPRA**

23 As discussed above, as well as in the *Petition*, and Petitioner’s October 15, 2019  
24 *Supplemental Brief in Support of Petition for Writ of Mandamus*, to whatever extent NAC  
25 §§ 439.730 – .740 conflict either with the NPRA, S.B. 539, or any other statute, they are  
26 invalid. *Division of Ins. v. State Farm Mutual Ins. Co.*, 116 Nev. 290, 293, 995 P.2d 482,  
27 485 (2000), *citing* NRS § 233B.110, *Clark Co. Social Service Dep’t v. Newkirk*, 106 Nev.

1 177, 179, 789 P.2d 227, 228 (1990); *Roberts v. State*, 104 Nev. 33, 37, 752 P.2d 221, 223  
2 (1988).

3 Sanofi cites, *Supplemental Brief in Support*, 15, *City of Sparks v. Reno*  
4 *Newspapers, Inc.*, 133 Nev. Adv. Rep. 56, 399 P.3d 352 (2017) in support of its suggestion  
5 that administrative codes that offend the NPRA are nonetheless valid. However, this  
6 reliance is misplaced, as the case discusses legislation and associated administrative codes  
7 which have critical differences from those discussed herein and is therefore inapposite.

8 In *City of Sparks v. Reno Newspapers, Inc.*, the Nevada Supreme Court examined  
9 certain legislation and administrative codes surrounding the establishment and regulation of  
10 medical marijuana establishments. “[T]he Legislature may authorize administrative  
11 agencies to make rules and regulations supplementing legislation if the power given is  
12 prescribed in terms sufficiently definite to serve as a guide in exercising that power.” *Id.*, at  
13 356, quoting *Banegas v. State Indus. Ins. Sys.*, 117 Nev. 222, 227, 19 P.3d 245, 248 (2001).  
14 In enacting the laws regarding medical marijuana establishments, the Nevada Legislature  
15 included the following at Nev. Rev. Stat. 453A.370: “The Department shall adopt such  
16 regulations as it determines to be necessary or advisable to carry out the provisions  
17 [concerning the production and distribution of medical marijuana].” *City of Sparks v. Reno*  
18 *Newspapers, Inc.*, 399 P.3d at 355 – 56, quoting NRS 453A.370. Further, “In drafting and  
19 adopting those regulations, under NRS 453A.370(5), the Division “*must . . . [a]s far as*  
20 *possible while maintaining accountability, protect the identity and personal identifying*  
21 *information* of each person who receives, facilitates or delivers services.” *Id.* at 356,  
22 quoting NRS 453A.370(5) (emphasis added in *City of Sparks v. Reno Newspapers, Inc.*).

23 When the Nevada Supreme Court upheld the administrative codes at issue in the  
24 *City of Sparks* case, it was specifically because the Nevada Legislature had authorized the  
25 Department in that case to create administrative codes to protect the “identity and personal  
26 identifying information” as described in the statute, a delegation allowed because it was  
27 “prescribed in terms sufficiently definite to serve as a guide in exercising that power.” *Id.* at  
28 356.

1           However, no provision enabling confidentiality or any NPRA carve-out is found  
2 in S.B. 539.<sup>4</sup> The Nevada Legislature did not authorize the Department to enact  
3 administrative codes that would have the function of rendering any particular information  
4 confidential or privileged, and indeed such an authorization would stand in direct conflict  
5 with the portion of S.B. 539 at Nev. Rev. Stat. § 600A.030(5)(b). Therefore, their  
6 enactment represents a usurpation of the power granted by Nevadans to the duly elected  
7 Nevada Legislature, and as discussed *supra*, a very clear separation of powers problem.

8           If the agency-created administrative codes herein are determined to properly  
9 exempt records from the NPRA, the effect will be to allow every twig in the executive  
10 branch a line-item veto over the Legislature. Of course, such a result cannot stand – the  
11 same conclusion reached by the Nevada Supreme Court in more recent cases *Clark Cty.*  
12 *Sch. Dist. v. Las Vegas Review-Journal*, 134 Nev. Adv. Rep. 84, 9 – 10, 429 P.3d 313, 317  
13 – 18 (2018) (“Ascribing a force to such regulations that limits the NPRA would create an  
14 opportunity for government organizations to make an end-run around the NPRA by  
15 drafting internal regulations that render documents confidential by law.”) and *Comstock*  
16 *Residents Ass’n v. Lyon Cty. Bd. of Comm’rs*, 134 Nev. Adv. Rep. 19, 10, 414 P.3d 318,  
17 322 (2018) (“Administrative regulations do not limit the reach of the NPRA[.]”).

18           The NPRA exists “to foster democratic principles,” Nev. Rev. Stat. § 239.001(1),  
19 and to whatever extent an arm of the executive branch attempts to escape its reach, courts  
20 must invalidate administrative codes or regulations which offend the separation of powers.  
21 The NAC sections discussed herein are exactly such codes, and as such are invalid.

22 ///

23 ///

---

24 <sup>4</sup> There is an enabling provision in Nev. Rev. Stat. § 439B, found at §439B.685, but a close  
25 review reveals that the language substantially predates S.B. 539, and was previously found  
26 at Nev. Rev. Stat. § 439.930 (a section dealing with establishment of an internet site to  
27 publish prices of commonly prescribed drugs), and which still largely deals with that goal.  
28 There is no language in the enabling provision which indicates any desire on the part of the  
legislature to exempt any information from the view of the public via the NPRA, as was  
found necessary in *City of Sparks v. Reno Newspapers, Inc.*, 399 P.3d 352, 355 – 56  
(2017).

1     **No Privilege or Confidence Exempts the Public Records at Issue from Disclosure**

2           Neither the DTSA, nor any Nevada statute grants any confidentiality over the  
3 records discussed herein throughout. Although Sanofi asserts that it has gone to lengths to  
4 keep the information confidential, it acknowledges having passed the information to  
5 Respondents without any guarantee from Respondents that the information would be kept  
6 confidential. Thus, no confidentiality exists. Even if some confidentiality is found to exist,  
7 nonetheless, Respondents bear the burden of proving that their interest in maintaining the  
8 confidentiality clearly outweighs the public interest in transparency. *Reno Newspapers, Inc.*  
9 *v. Haley*, 126 Nev. Adv. Rep. 23, 6, 234 P.3d 922, 924 (2010).

10           There can be no confidentiality found where, as here, a party passes information  
11 or documents within their exclusive control to another party without any guarantee of  
12 confidentiality. “[I]t is clear that a private party cannot render public records exempt from  
13 disclosure merely by designating information it furnishes a governmental agency  
14 confidential. Neither the desire for nor the expectation of non-disclosure is determinative.”  
15 *Sepro Corp. v. Fla. Dep’t of Env’tl. Prot.*, 839 So.2d 781, 784 (Fla. Dist. Ct. App. 2003).

16           “It is well settled that privileges, whether creatures of statute or the common law,  
17 should be interpreted and applied narrowly.” *DR Partners v. Board of County Comm’rs*,  
18 116 Nev. 616, 621 (2000), *citing Ashokan v. State Dept. of Ins.*, 109 Nev. 662, 668, 856  
19 P.2d 244, 247 (1993) (*citing U.S. v. Nixon*, 418 U.S. 683, 710, 41 L. Ed. 2d 1039, 94 S. Ct.  
20 3090 (1974)).

21           Furthermore, even if Respondents had made a promise to keep certain material  
22 collected pursuant to S.B. 539 confidential, nonetheless, Petitioner would prevail:  
23 “[E]ntities doing business with government agencies and submitting records to them in  
24 connection therewith should be aware that regardless of agency promises that documents  
25 will be kept confidential, public record suits can nevertheless be successful. Thus, it is not  
26 safe to assume confidentiality agreements with government agencies will be legally  
27 enforceable.” *Tenn. Valley Printing Co. v. Health Care Auth.*, 61 So. 3d 1027, 1037,  
28 *quoting Theresa M. Costonis, What Constitutes Commercial or Financial Information*,

1 *Exempt from Disclosure Under State Freedom of Information Acts*, 5 A.L.R. 6th 327, § 3  
2 (2005) (footnotes omitted).

3 Indeed, “The right to examine these records is a right belonging to the public; it  
4 cannot be bargained away by a representative of the government.” *Nat’l Collegiate Athletic*  
5 *Ass’n v. Associated Press*, 18 So. 3d 1201, 1208 – 09 (Fla. Dist. Ct. App. 2009).

6 Notwithstanding Respondents’ apparent desire to put the interests of pharmaceutical  
7 manufacturers ahead of those of the public they serve, the people of the State of Nevada are  
8 entitled, under the NPRA, to examine public records.

9 So, even if this Court finds that some confidentiality existed, because it is not of a  
10 statutory creation Respondents would nonetheless be obligated to prove that under the  
11 balancing test outlined by the Nevada Supreme Court in, e.g., *Reno Newspapers, Inc. v.*  
12 *Haley*, 126 Nev. Adv. Rep. 23, 6, 234 P.3d 922, 924 (2010), the stated government interest  
13 in avoiding some phantom liability under the DTSA, and Sanofi’s private interest in  
14 continuing to extract the maximum profit possible from those afflicted with diabetes are  
15 interests that clearly outweigh Nevadans’ collective interest in having an open and  
16 democratic government – and of not dying of diabetes, or poverty, or both – in the face of  
17 the clearly stated preference of the Legislature that transparency in this area is necessary for  
18 the health and welfare of Nevadans. A Writ of Mandamus directing Respondents to comply  
19 with the NPRA by forthwith producing the records requested herein must issue.

#### 20 Conclusion

21 The records sought by Petitioners herein are not made confidential by any statute.  
22 There is no confidentiality in a scenario, such as this one, in which information or  
23 documents pass from those obligated to maintain a confidence to those with no such  
24 obligation. Further, even if this Court finds the documents subject to a non-statutory  
25 privilege or confidence, nonetheless the public interest in transparency dramatically  
26 outweighs the government’s interest in escaping liability under the DTSA – a law which by  
27 its own terms does not apply to Respondents.

1 The result must be an order mandating Respondents to disclose to Petitioners the  
2 public records they seek in their entirety, together with an order for the reasonable  
3 attorney's fees and costs incurred in the prosecution of this matter.

4 All of which is respectfully submitted, this 5th day of December, 2019.

5  
6 

7 MATTHEW J. RASHBROOK  
8 Nevada State Bar No. 12477  
9 ROBERT L. LANGFORD, ESQ.  
10 Nevada State Bar No. 3988  
11 ROBERT L. LANGFORD &  
12 ASSOCIATES  
13 616 S. Eighth Street  
14 Las Vegas, NV 89101  
15 (702) 471-6565  
16 matt@robertlangford.com  
17 robert@robertlangford.com  
18 *Attorneys for Petitioner*  
19 *The Nevada Independent*  
20  
21  
22  
23  
24  
25  
26  
27  
28

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

Aaron D. Ford  
Nevada Attorney General  
Nevada Bar No. 7704  
Steve Shevorsi  
Chief Deputy Attorney General  
Nevada Bar No. 8256  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
Fax: 702-486-3768  
sshevorsi@ag.nv.gov

/s/ Matthew J. Rashbrook  
An Employee of Robert L. Langford &  
Associates

DISTRICT COURT  
CLARK COUNTY, NEVADA

Writ of Mandamus

COURT MINUTES

December 16, 2019

---

A-19-799939-W      Nevada Independent, Plaintiff(s)  
vs.  
Richard Whitley, Defendant(s)

---

December 16, 2019      10:30 AM      Minute Order

HEARD BY:      Escobar, Adriana      COURTROOM: Chambers

COURT CLERK: Husted, Denise

RECORDER:      Anderson, Sandra

REPORTER:

PARTIES PRESENT:

**JOURNAL ENTRIES**

Proposed Intervenor Sanofi-Aventis U.S. LLC s (Sanofi) Motion to Intervene (Motion) came on for hearing before Department XIV of the Eighth Judicial District Court, the Honorable Adriana Escobar presiding, on November 5, 2019. Attorneys Robert Langford and Matthew J. Rashbrook appeared on behalf of Petitioner Nevada Independent (Petitioner). Attorney John R. Bailey appeared on behalf of Sanofi. Steven Shevorski appeared on behalf of the State of Nevada Department of Health and Human Services (the State or the Department). After considering the moving papers and arguments of counsel, the Court requested supplemental briefing, which Sanofi and Petitioner provided.

After considering the moving papers, arguments of counsel, and supplemental briefing, the Court enters the following order GRANTING Sanofi s Motion:

NRCP 24(a)

Nevada requires a party show the following to intervene as a matter of right, pursuant to NRCP 24(a):

- (1) That it has a sufficient interest in the litigation's subject matter
- (2) That it could suffer an impairment of its ability to protect that interest if it does not intervene,
- (3) That its interest is not adequately represented by existing parties, and
- (4) That its application is timely.

Am. Home Assur. Co. v. Eighth Jud. Dist. Ct. ex rel. Cty. of Clark, 122 Nev. 1229, 1238 (2006).

Determining whether an applicant has met these four requirements is within the district court's discretion. Id.

The very purpose of intervention is to permit the parties to protect their own interests when it might otherwise cause irreparable harm to permit the litigation to go forward [without the intervenor]. United States v. City of Detroit, 712 F.3d 925, 944 (6th Cir. 2013).

Here, Sanofi meets all requirements to allow it to intervene as a matter of right in this case on a Writ of Mandamus (Writ):

### I. Sufficient Interest

The resolution of Petitioner's claims will actually affect Sanofi's interests. *S. Cal. Edison Co. v. Lynch*, 307 F.3d 794, 803 (9th Cir.). Petitioner seeks disclosure of Sanofi's annual reports, which includes information about producing, manufacturing, marketing, and selling its drugs. While a trade secret defense does not excuse Sanofi from disclosing its report to the Department, it does apply to third parties. This information is so confidential that Sanofi protects it even internally within the company.

### II. Irreparable Harm

Sanofi argues that competitors would gain unfair competitive advantage by learning its business strategies and tactics. Further, Consumers would gain an unfair advantage and use this information in negotiations with insurers and other parties in the healthcare system. Additionally, Sanofi contends that requiring disclosure here would affect its negotiations all over the nation.

Petitioner argues that Sanofi's reports cannot qualify as having trade secrets because NRS 600A.030(5)(b) expressly de-categorizes information within these disclosures as a trade secret, and NRS 600A preempts NAC 439.735. However, Petitioner only cites to cases that predate the statutes and administrative codes in question, and the Legislative intent points to a different interpretation. *Division of Ins.*, 116 Nev. 290, 293 (2000); *Roberts*, 104 Nev. 33, 37 (1988).

To illustrate, page four (4) of the Approved Regulation of the Department of Health and Human Services document LCB File No. R042-18 (R042-18) explains that when the Department decides on whether the public disclosure of information would constitute misappropriation of a trade secret under federal Defend Trade Secrets Act (DTSA), it may consider the trade secrets definition under Exemption 4 of Freedom of Information Act (FOIA), which 18 U.S.C. 1839 covers.

Additionally, the Supremacy Clause of the U.S. Constitution explains that when state and federal law conflict, federal law preempts state law. U.S. Const. art. VI, cl. 2. Here, NRS 600A.030(5)(b) conflicts with 18 U.S.C. 1839 by expressly de-categorizing information within these disclosures as a trade secret. Thus, 18 U.S.C. 1839 preempts 600A.030(5)(b), to the extent it conflicts.

Taking all of these facts collectively, the Court finds that Sanofi sufficiently showed irreparable harm could result if the Court does not allow it to intervene.

### III. Inadequate Representation

Sanofi explains that while the State can adequately represent the confidentiality issues generally the State cannot fully detail the steps Sanofi takes to maintain and protect its trade secrets and confidential information; nor can the State adequately articulate the irreparable harm and prejudice Sanofi will suffer if the Court grants Petitioner's Writ.

Sanofi explains that the State has generalized knowledge of Sanofi's safeguards for its confidential information. To the extent that the Court might have questions that go beyond the information already provided, if permitted to intervene Sanofi can respond to the Court directly at that time.

Moreover, Sanofi avers that the State does not have the same vested interest in protecting Sanofi's trade secrets from public disclosure or in protecting Sanofi from irreparable harm. The Department's main role is to protect and promote the health and safety of Nevada residents not to ensure that Sanofi is able to competitively develop, market, and sell pharmaceuticals and healthcare solutions in the global market. Sanofi claims that only it can fully protect its

trade secrets from public disclosure and prevent harm to its competitive position.

R042-18 also touches on this issue. Page four (4) of R042-18 explains that an implicated entity whose interests could be impacted by disclosures may file a motion to intervene on the matter.

The Court concludes that these facts show that the State cannot adequately represent Sanofi's individual interests.

#### IV. Timeliness

Sanofi's Motion is timely under NRCP 24 since it was filed prior to trial, and will not cause Petitioner prejudice. Rather, Sanofi would be prejudiced if it is not allowed to intervene and represent its interests.

The Court finds that Sanofi timely filed its Motion.

#### Conclusion

Petitioner failed to present argument to sufficiently overcome the arguments for each NRCP 24(a) element that Sanofi provides.

#### NRCP 24(b)

Sanofi also satisfies the requirements for the Court to discretionarily grant its intervention, pursuant to NRCP 24(b). The public records request at issue in Petitioner's Writ seeks trade secrets and other confidential information from Sanofi. Thus, adverse effects or irreparable harm could impact Sanofi through the decision on this matter.

#### Costs and Attorney's Fees Issue

Petitioner contends that Sanofi should not be permitted to intervene because Sanofi's participation will cause the Petitioner to incur additional costs and attorney's fees that it will not be able to recover should it prevail in this action. Opp'n. at 7:21-8:14. However, neither NRS 12.130 nor NRCP 24 provides exceptions that would bar a third party from intervening in an action because there is no mechanism for a petitioner to recover its costs and fees should the petitioner prevail.

The Court finds that Petitioner's argument on this point not persuasive in determining whether to allow Sanofi to intervene in this matter.

#### Conclusion

Based on the foregoing, the Court GRANTS Sanofi's Motion to Intervene.

To allow all parties additional time to brief the issues in the Writ, and to disclose any witnesses, the Court hereby continues the hearing on the Writ to January 31, 2020 at 10:00 am.

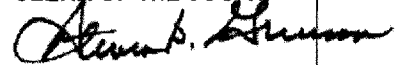
The final day for supplemental briefing from all parties will be January 3, 2020.

The final day to disclose any witnesses will be January 17, 2020.

The Court will issue an order granting the same.

CLERK'S NOTE: This minute order was electronically served by Courtroom Clerk, Denise

Husted, to all registered parties for Odyssey File and Serve. 12/16/19 //dh



ORD

DISTRICT COURT  
CLARK COUNTY, NEVADA

THE NEVADA INDEPENDENT,

Petitioner,

vs.

RICHARD WHITLEY, in his official  
capacity as the Director of the Nevada  
Department of Health and Human Services,  
and THE STATE OF NEVADA ex rel. the  
NEVADA DEPARTMENT OF HEALTH  
AND HUMAN SERVICES,

Respondents.

Case No. : A-19-799939-W

Dept. No.: 14

**ORDER GRANTING SANOFI-AVENTIS  
U.S. LLC'S MOTION TO INTERVENE**

Proposed Intervenor Sanofi-Aventis U.S. LLC's (Sanofi) Motion to Intervene (Motion) came on for hearing before Department XIV of the Eighth Judicial District Court, the Honorable Adriana Escobar presiding, on **November 5, 2019**. Attorneys Robert Langford and Matthew J. Rashbrook appeared on behalf of Petitioner Nevada Independent (Petitioner). Attorney John R. Bailey appeared on behalf of Sanofi. Steven Shevorski appeared on behalf of the State of Nevada Department of Health and Human Services (the State or the Department). After considering the moving papers and arguments of counsel, the Court requested supplemental briefing, which Sanofi and Petitioner provided.

After considering the moving papers, arguments of counsel, and supplemental briefing, the Court enters the following order **GRANTING** Sanofi's Motion:

///

///

///

///

///

**NRCP 24(a)**

Nevada requires a party show the following to intervene as a matter of right, pursuant to Rule 24(a) of the Nevada Rules of Civil Procedure (NRCP):

- (1) That it has a sufficient interest in the litigation's subject matter
- (2) That it could suffer an impairment of its ability to protect that interest if it does not intervene,
- (3) That its interest is not adequately represented by existing parties, and
- (4) That its application is timely.

Am. Home Assur. Co. v. Eighth Jud. Dist. Ct. ex rel. Cty. of Clark, 122 Nev. 1229, 1238 (2006).

Determining whether an applicant has met these four requirements is within the district court's discretion. Id. "The very purpose of intervention is to permit the parties to protect their own interests when it might otherwise cause irreparable harm to permit the litigation to go forward [without the intervenor]." United States v. City of Detroit, 712 F.3d 925, 944 (6th Cir. 2013).

Here, Sanofi meets all requirements to allow it to intervene as a matter of right in this case on a Writ of Mandamus (Writ):

**I. Sufficient Interest**

The resolution of Petitioner's claims will actually affect Sanofi's interests. S. Cal. Edison Co. v. Lynch, 307 F.3d 794, 803 (9th Cir.). Petitioner seeks disclosure of Sanofi's annual reports, which includes information about producing, manufacturing, marketing, and selling its drugs. While a trade secret defense does not excuse Sanofi from disclosing its report to the Department, it does apply to third parties. This information is so confidential that Sanofi protects it even internally within the company.

**II. Irreparable Harm**

Sanofi argues that competitors would gain unfair competitive advantage by learning its business strategies and tactics. Further, Sanofi contends that requiring disclosure here would affect its negotiations all over the nation.

///

///

1           Petitioner argues that Sanofi's reports cannot qualify as having "trade secrets" because  
2 NRS 600A.030(5)(b) expressly de-categorizes information within these disclosures as a "trade  
3 secret," and NRS 600A preempts NAC 439.735. However, Petitioner only cites to cases that  
4 predate the statutes and administrative codes in question, and the Legislative intent points to a  
5 different interpretation. Division of Ins., 116 Nev. 290, 293 (2000); Roberts, 104 Nev. 33, 37  
6 (1988).

7           Page four (4) of the "Approved Regulation of the Department of Health and Human  
8 Services" document—LCB File No. R042-18 (R042-18) explains that when the Department  
9 decides on whether the public disclosure of information would constitute misappropriation of a  
10 trade secret under federal Defend Trade Secrets Act (DTSA), it may consider the "trade secrets"  
11 definition under Exemption 4 of Freedom of Information Act (FOIA), which 18 U.S.C. § 1839  
12 covers.

13           Taking all of these facts collectively, the Court finds that Sanofi sufficiently showed  
14 irreparable harm could result if the Court does not allow it to intervene.

15       **III. Inadequate Representation**

16           Sanofi explains that—while the State can adequately represent the confidentiality issues  
17 generally—the State cannot fully detail the steps Sanofi takes to maintain and protect its trade  
18 secrets and confidential information; nor can the State adequately articulate the irreparable harm  
19 and prejudice Sanofi will suffer if the Court grants Petitioner's Writ.

20           Sanofi explains that the State has generalized knowledge of Sanofi's safeguards for its  
21 confidential information. To the extent that the Court might have questions that go beyond the  
22 information already provided, if permitted to intervene Sanofi can respond to the Court directly  
23 at that time.

24           Moreover, Sanofi avers that the State does not have the same vested interest in protecting  
25 Sanofi's trade secrets from public disclosure or in protecting Sanofi from irreparable harm. The  
26 Department's main role is to protect and promote the health and safety of Nevada residents—not  
27 to ensure that Sanofi is able to competitively develop, market, and sell pharmaceuticals and  
28 healthcare solutions in the global market. Sanofi claims that only it can fully protect its trade

1 secrets from public disclosure and prevent harm to its competitive position.

2 R042-18 also touches on this issue. Page four (4) of R042-18 explains that an implicated  
3 entity whose interests could be impacted by disclosures may file a motion to intervene on the  
4 matter.

5 The Court concludes that these facts show that the State cannot adequately represent  
6 Sanofi's individual interests.

7 **IV. Timeliness**

8 Sanofi's Motion is timely under NRCP 24 since it was filed prior to trial, and will not  
9 cause Petitioner prejudice. Rather, Sanofi would be prejudiced if it is not allowed to intervene  
10 and represent its interests. The Court finds that Sanofi timely filed its Motion.

11 **NRCP 24(b)**

12 NRCP 24(b)(1) allows timely intervention from anyone who is has a claim or defense  
13 that shares with the main action a common question of law or fact. Sanofi satisfies the  
14 requirements for the Court to discretionarily grant its intervention, pursuant to NRCP 24(b). The  
15 public records request at issue in Petitioner's Writ seeks information which may be trade secrets  
16 or confidential information from Sanofi. The request from Petitioner—to obtain the reports from  
17 Respondent—shares a common question of law and fact: whether the reports Sanofi submitted to  
18 Respondent involve trade secrets which should be protected under DTSA.

19 **Conclusion**

20 Sanofi presented sufficient proof that is qualifies to intervene in this matter under NRCP  
21 24(a) and NRCP 24(b).

22 **Costs and Attorney's Fees Issue**

23 Petitioner contends that Sanofi should not be permitted to intervene because Sanofi's  
24 participation will cause the Petitioner to incur additional costs and attorney's fees that it will not  
25 be able to recover should it prevail in this action. Opp'n. at 7:21-8:14. However, neither NRS  
26 12.130 nor NRCP 24 provides exceptions that would bar a third party from intervening in an  
27 action because there is no mechanism for a petitioner to recover its costs and fees should the  
28 petitioner prevail. The Court finds that Petitioner's argument on this point not persuasive in

determining whether to allow Sanofi to intervene in this matter.

**ORDER**

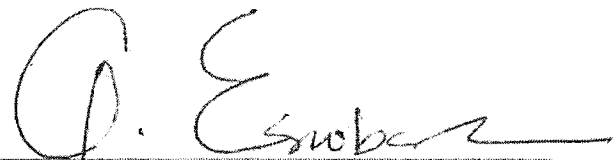
Based on the foregoing, the Court **GRANTS** Sanofi's Motion to Intervene.

To allow all parties additional time to brief the issues in the Writ, and to disclose any witnesses, the Court hereby **continues the hearing on the Writ to January 31, 2020 at 10:00 am.**

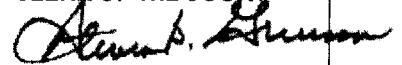
The final day for supplemental briefing from all parties for the Writ will be **January 3, 2020.**

The final day to disclose any witnesses for the hearing on the Writ will be **January 17, 2020.**

DATED this 23<sup>RD</sup> day of December, 2019.



THE HONORABLE ADRIANA ESCOBAR  
DISTRICT COURT JUDGE



1 **RSPN**

JOHN R. BAILEY

2 Nevada Bar No. 0137

DENNIS L. KENNEDY

3 Nevada Bar No. 1462

SARAH E. HARMON

4 Nevada Bar No. 8106

REBECCA L. CROOKER

5 Nevada Bar No. 15202

**BAILEY❖KENNEDY**

6 8984 Spanish Ridge Avenue

Las Vegas, Nevada 89148-1302

7 Telephone: 702.562.8820

Facsimile: 702.562.8821

8 JBailey@BaileyKennedy.com

DKennedy@BaileyKennedy.com

9 SHarmon@BaileyKennedy.com

RCrooker@BaileyKennedy.com

10 *Attorneys for Intervenor*

11 SANOFI-AVENTIS U.S. LLC

12 DISTRICT COURT

13 CLARK COUNTY, NEVADA

14  
15 THE NEVADA INDEPENDENT,

16 Petitioner,

17 vs.

18 RICHARD WHITLEY, in his official capacity as  
19 the Director of the Nevada Department of Health  
and Human Services, and THE STATE OF  
20 NEVADA ex rel. the NEVADA DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

21 Respondents,

22 and

23 SANOFI-AVENTIS U.S. LLC,

24 Intervenor.

Case No. A-19-799939-W

Dept. No. XIV

**Date of Hearing: January 31, 2020**

**Time of Hearing: 10:00 a.m.**

**INTERVENOR SANOFI-AVENTIS U.S.  
LLC'S RESPONSE TO PETITIONER'S  
PETITION FOR A WRIT OF  
MANDAMUS**

**BAILEY❖KENNEDY**  
8984 SPANISH RIDGE AVENUE  
LAS VEGAS, NEVADA 89148-1302  
702.562.8820

**INTERVENOR SANOFI-AVENTIS U.S. LLC'S RESPONSE TO  
PETITIONER'S PETITION FOR A WRIT OF MANDAMUS**

Intervenor Sanofi-Aventis U.S. LLC ("Sanofi" or "Sanofi US"<sup>1</sup>) hereby submits its Response to The Nevada Independent's ("Petitioner") Petition for a Writ of Mandamus ("Petition"). This Response is based upon the following Memorandum of Points and Authorities, the exhibits attached hereto, the pleadings and papers on file in this action, and any oral argument heard by this Court.

DATED this 23rd day of December, 2019.

BAILEY ♦ KENNEDY

By: /s/ John R. Bailey

JOHN R. BAILEY  
DENNIS L. KENNEDY  
SARAH E. HARMON  
REBECCA L. CROOKER

*Attorneys for Intervenor* SANOFI-AVENTIS  
U.S. LLC

---

<sup>1</sup> "Sanofi US" is the registered trade name of Sanofi-Aventis U.S. LLC.

**MEMORANDUM OF POINTS AND AUTHORITIES**

**I. INTRODUCTION**

Sanofi is a manufacturer of several drugs that the Nevada Department of Health and Human Services (the “Department”) has determined to be essential to the treatment of diabetes. As such, Sanofi must submit annual reports to the Department regarding the cost of these drugs. The annual reports include information about Sanofi’s production costs, marketing costs, profits, resource allocation, and price setting, among other things. Such information is confidential and/or a trade secret and is vigorously protected from public disclosure by Sanofi. The public disclosure of this information would irreparably harm Sanofi by providing a competitive advantage to other pharmaceutical manufacturers and undermining Sanofi’s negotiations with insurers and other intermediaries in the healthcare industry.

In recognition of the harm that would be caused by the public disclosure of such information, the Department adopted a regulation allowing pharmaceutical manufacturers (like Sanofi) to submit requests for confidentiality. Specifically, manufacturers may request that the Department maintain the confidentiality of certain information included within the annual reports that are submitted to the Department. Moreover, when the Department receives public records requests for the annual reports, or information included within the annual reports, the regulation expressly permits the Department to: (i) conduct a review to determine if public disclosure of the requested information would constitute a misappropriation of a trade secret; and (ii) deny the request for public records on the basis that the requested information is confidential pursuant to the federal Defend Trade Secrets Act of 2016 (18 U.S.C. § 1836) (“DTSA”). For the information sought by the Petitioner, Sanofi expressly submitted to the Department a request for confidentiality pursuant to this regulation.

The Petitioner, a news and opinion website, submitted two public records requests to the Department for all annual reports received from pharmaceutical manufacturers since 2017. In response to these requests, the Department released certain limited information and withheld all confidential information and trade secrets. The Petitioner now seeks a Writ of Mandamus from the Court instructing the Department to produce and publicly disclose the withheld confidential information and trade secrets.

Sanofi respectfully requests that the Court deny the Petition. Disclosure of the annual reports, and/or certain categories of information included in the reports, will cause Sanofi irreparable harm in its dealings with competitors, consumers, insurers, and others in the health care industry. The Nevada Public Records Act (NRS Ch. 239 et seq.) (“NPRA”) does not allow the public to have unfettered access to all information in the possession, custody, or control of a governmental agency. All information “declared by law to be confidential” is expressly excluded from the NPRA. NRS 239.010; NRS 239.030. The information sought by the Petitioner has been declared confidential by NAC 439.735, the DTSA, and NRS 600A.030. Therefore, the Department has properly denied the Petitioner’s public records request (as it pertains to the confidential information and trade secrets), and the Petition should be denied.

## II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

### A. Enactment of Senate Bill 539.

In or around 2017, Nevada passed Senate Bill 539, which was designed to address the increasing costs of diabetes health care. Specifically, NRS 439B.630 was enacted to require the Department, on February 1<sup>st</sup> of each year, to compile a list of all prescription drugs deemed essential to treating diabetes. Then, on April 1<sup>st</sup> of each year, the manufacturers of any prescription drugs on this list must submit a report to the Department that includes, but is not limited to, the following information:

- The costs of producing the drug;
- The total administrative expenditures relating to the drug, including marketing and advertising costs;
- The profit that the manufacturer has earned from the drug and the percentage of the manufacturer’s total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug;
- The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;
- The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs;

\* \* \*

- The aggregate amount of all rebates that the manufacturer has provided to pharmacy benefit managers for sales of the drug within this State; and
- Any additional information prescribed by regulation of the Department for the purpose of analyzing the cost of prescription drugs . . . , trends in those costs and rebates available for such drugs.

NRS 439B.635. Moreover, for all prescription diabetes drugs which experienced an increase in the wholesale acquisition cost of the drug, manufacturers must also disclose the reasons for the increase in this cost, including:

- A list of each factor that has contributed to the increase;
- The percentage of the total increase that is attributable to each factor;
- An explanation of the role of each factor in the increase; and
- Any other information prescribed by regulation by the Department.

NRS 439B.640.

In addition, the Nevada Legislature amended the definition of a “trade secret” in NRS 600A.030, and stated that the term “[d]oes not include any information that a manufacturer is required to report pursuant to NRS 439B.635 or 439B.640, . . . to the extent that such information is required to be disclosed by those sections.” NRS 600A.030(5)(b).

**B. The *PhRMA Action* and New Department Regulations.**

Approximately 1 month before these regulations were scheduled to take effect, Pharmaceutical Research and Manufacturers of America (“PhRMA”) and Biotechnology Innovation Organization (“BIO”) filed a federal action against the Governor of Nevada and the Director of the Department (the “*PhRMA Action*”) alleging that the statutes were unconstitutional and were preempted by the DTSA. (*See generally* Ex. 3.<sup>2</sup>) Sanofi is a member of both PhRMA and BIO. (Ex. 4,<sup>3</sup> at ¶ 2.) On October 3, 2017, the Nevada Legislature was granted the right to intervene in the *PhRMA Action*. (Ex. 5.<sup>4</sup>)

<sup>2</sup> Compl. for Declaratory & Injunctive Relief (Sept. 1, 2017) [ECF No. 1], filed in *Pharm. Research & Mfrs. of Am. v. Sandoval*, 2:17-cv-02315-JCM-CWH, U.S. Dist. Ct., Dist. of Nev. (“*PhRMA Action*”), attached as Exhibit 3.

<sup>3</sup> Decl. of James Borneman (Sept. 13, 2017) [ECF No. 26-6], filed in *PhRMA Action*, attached as Exhibit 4.

<sup>4</sup> Order (Oct. 3, 2017) [ECF No. 43], filed in *PhRMA Action*, attached as Exhibit 5.

1 In sum, the plaintiffs in the *PhRMA Action* asserted that Senate Bill 539 was unconstitutional  
2 and violated trade secret law because it required manufacturers to submit confidential information  
3 and trade secrets to the Department, placed no limitations upon the Department's use or  
4 dissemination of the information, and directed the Department to publicly disclose reports regarding  
5 such information. (Ex. 6,<sup>5</sup> at 16:4-17.) The plaintiffs contended that Senate Bill 539 would  
6 essentially strip pharmaceutical manufacturers of any trade secret protections nationwide, because  
7 once the information was publicly disclosed in Nevada, it could no longer qualify as a trade secret in  
8 any other state. (*Id.* at 16:18-17:2 (citing *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir.  
9 2002) (holding that it is "paradigmatic" that compelled disclosure to a party not required to keep the  
10 secret extinguishes the property right).)

11 In May 2018, in recognition of the problems posed by Senate Bill 539, the Department  
12 adopted and implemented new regulations which provided pharmaceutical manufacturers with  
13 procedures to safeguard the confidentiality of the information included in the required annual  
14 reports. Specifically, NAC 439.735 provides that if a manufacturer reasonably believes that public  
15 disclosure of information provided pursuant to NRS 439B.635 or NRS 439B.640 would constitute  
16 the misappropriation of a trade secret pursuant to the DTSA, the manufacturer can request that the  
17 Department maintain the confidentiality of the information. NAC 439.735(1). The request for  
18 confidentiality requires the manufacturer to "describe, with particularity, the information sought to  
19 be protected from public disclosure" and to explain "the reasons why public disclosure of the  
20 information would constitute misappropriation of a trade secret." NAC 439.735(2).

21 Further, under the regulation, if the Department receives a request for public records pursuant  
22 to NRS 239.010, seeking information from the manufacturer's annual reports, the Department must  
23 inform the manufacturer of the request and conduct an "initial review to determine whether the  
24 Department reasonably believes that public disclosure of the information would constitute  
25 misappropriation of a trade secret" pursuant to the DTSA.<sup>6</sup> NAC 439.735(3). If the Department

26 \_\_\_\_\_  
27 <sup>5</sup> Pls.' Mot. for TRO & Prelim. Inj., & Supporting Mem. of Points & Auth. (Sept. 13, 2017) [ECF No. 26], filed  
in *PhRMA Action*, attached as Exhibit 6.

28 <sup>6</sup> The DTSA explicitly defines a "trade secret" as any all "forms and types of financial, business, scientific,  
technical, economic, or engineering information," including plans, methods, techniques, processes, and procedures. 18

determines that public disclosure of the information would constitute the misappropriation of a trade secret pursuant to the DTSA, the Department must deny the public records request on that ground. NAC 439.735(4).

The Department's regulations also provided manufacturers with some additional protections with regard to the Department's reporting requirements; specifically, NRS 439B.650 requires the Department to compile an annual report on the price of the prescription diabetes drugs based on the information submitted by the manufacturers pursuant to NRS 439B.635 and NRS 439B.640. However, the Department's regulations provide that this report will only include "aggregated data that does not disclose the identity of any drug [or] manufacturer" and a "description of trends concerning the prices of [the] prescription drugs" along with an explanation of how such prices and trends may affect the "prevalence and severity of diabetes" in Nevada and the "system of health care" in Nevada. NAC 439.740.

On June 28, 2018, shortly after the adoption of the Department's regulations, the plaintiffs in the *PhRMA Action, along with the Department and the Nevada Legislature*, informed the court that they had resolved their dispute. (Ex. 7,<sup>7</sup> at 2:23-3:5.) The parties informed the court that they *agreed and acknowledged* that:

- (1) *"under SB 539, the Department may acquire manufacturer trade secrets, such as a manufacturer's costs or production and other internal costs, 'under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret'"; and*
- (2) *"that so long as such trade secrets continue to satisfy the definition of 'trade secret' in 18 U.S.C. § 1839, if the Department were to disclose such trade secrets to any third party or use such trade secrets, such disclosure or use would constitute 'misappropriation' for which a court may award relief pursuant to the DTSA."*

(*Id.* at 3:6-21 (emphasis added).)

U.S.C. 1839(3); *see also* *Mastronardi Int'l Ltd. v. SunSelect Produce (Cal.), Inc.*, Civ. No. 1:18-cv-00737-AWI-JLT, 2019 WL 3996608 (E.D. Cal. Aug. 23, 2019) (finding that plaintiff sufficiently alleged that its pricing information and other financial information constituted a protectable trade secret and did not dismiss DTSA claims for failure to state a claim); *H.Q. Milton, Inc. v. Webster*, Civ. No. 17-cv-06598-PJH, 2017 WL 5625929 (N.D. Cal. Nov. 22, 2017) (granting temporary restraining order under the DTSA where plaintiff alleged misappropriation of "customer list and contact information, sales leads, customer interests, and H.Q. Milton's proprietary pricing (e.g., final sales price and profit margins)" where that "information constitutes protectable trade secrets under the DTSA).

<sup>7</sup> Joint Status Report (June 28, 2018) [ECF No. 95], filed in *PhRMA Action*, attached as Exhibit 7.

As a result of this regulatory resolution, the plaintiffs agreed to dismiss the action and their challenge to the constitutionality of NRS 439B.600 to NRS 439B.695. Thus, the court granted the plaintiffs' unopposed motion for voluntary dismissal of the action without prejudice. (Ex. 8.<sup>8</sup>)

C. **Sanofi Submitted a Request for Confidentiality for Certain Information Included in Its Annual Report to the Department.**

Sanofi US is the United States affiliate of Sanofi, a global life sciences company committed to improving access to healthcare and supporting the people it serves throughout the continuum of care. (Ex. 2,<sup>9</sup> at ¶ 2.) Specifically, Sanofi transforms scientific innovation into healthcare solutions in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious disease, diabetes and cardiovascular, consumer healthcare, established prescription products, and generics. (*Id.*) Some of the drugs that Sanofi manufactures include Adlyxin, Admelog, Amaryl, Apidra, DiaBeta, Lantus, Soliqua, and Toujeo, which are all FDA-approved for the treatment of diabetes. (*Id.* at ¶ 6.)

On October 31, 2017, the Department's list of essential diabetes drugs included the following Sanofi products: DiaBeta, Amaryl Glimepiride, Basaglar, Lantus, Toujeo, Soliqua, and Apidra. (Ex. 9.<sup>10</sup>) Similarly, the Department's February 1, 2019 list included Adlyxin, Admelog, Amaryl, Apidra, Lantus, Soliqua, and Toujeo. (Ex. 10.<sup>11</sup>) Therefore, Sanofi was required to submit the necessary annual reports to the Department pursuant to NRS 439B.635 and NRS 439B.640.

On January 15, 2019, and again on April 1, 2019, *in reliance upon the Department's new regulations*, Sanofi submitted requests for confidentiality to the Department along with its January, April, and subsequent August 2019 supplemental submissions pursuant to NRS 439B.635 and NRS

///

///

---

<sup>8</sup> Pls.' Unopposed Mot. for Voluntary Dismissal Without Prejudice (June 28, 2018) [ECF No. 97], filed in *PhRMA Action*, attached as Exhibit 8.

<sup>9</sup> Decl. of John Borneman, attached as Exhibit 2.

<sup>10</sup> 2017 List of Essential Diabetes Drugs v02.13.2018, [dhhs.nv.gov/HCPWD/Drug\\_Transparency\\_Essential\\_Lists\\_Reports\\_Resources/](https://dhhs.nv.gov/HCPWD/Drug_Transparency_Essential_Lists_Reports_Resources/) (Oct. 31, 2017), attached as Exhibit 9.

<sup>11</sup> 2019 Essential Diabetes Drug List v02.01.2019, [dhhs.nv.gov/HCPWD/Drug\\_Transparency\\_Essential\\_Lists\\_Reports\\_Resources/](https://dhhs.nv.gov/HCPWD/Drug_Transparency_Essential_Lists_Reports_Resources/) (Feb. 1, 2019), attached as Exhibit 10.

1 439B.640. (Ex. 11;<sup>12</sup> Ex. 12.<sup>13</sup>) Sanofi requested that the Department keep the following  
2 information confidential:

- 3 • The costs of producing the drug;
- 4 • The total administrative expenditures relating to the drug, including marketing and  
5 advertising costs;
- 6 • The profit that Sanofi has earned from the drug and the percentage of Sanofi's total  
7 profit that is attributable to the drug;
- 8 • The total amount of financial assistance that the manufacturer has provided through  
9 any patient prescription assistance program;
- 10 • The cost associated with coupons provided directly to consumers and for programs to  
11 assist consumers in paying copayments, and the cost to the manufacturer attributable  
12 to the redemption of those coupons and the use of those programs; and
- 13 • The aggregate amount of all rebates that Sanofi has provided to pharmacy benefit  
14 managers for sales of the drug within the State of Nevada.<sup>14</sup>

15 (collectively, the "Sanofi Confidential Information") (Ex. 11, at 1-2; Ex. 12, at 1-2.)

16 In order for information to qualify as a trade secret under the DTSA or NRS 600A.030, the  
17 federal and state laws require that the owners of trade secrets take reasonable steps to keep the trade  
18 secrets and/or confidential information secret. 18 U.S.C. § 1839(3)(A); NRS 600A.030(5)(a)(2).  
19 Therefore, Sanofi's requests for confidentiality to the Department detailed the steps it has taken to  
20 protect and maintain the confidentiality of the Sanofi Confidential Information; namely:

21 [T]he Sanofi Confidential Information is not shared publicly, and  
22 access to it is restricted internally and only shared internally on a need-  
23 to-know basis. It is subject to non-disclosure requirements in  
24 [Sanofi's] employment and other business agreements. Employees of  
25 [Sanofi] are required to maintain the secrecy of the Sanofi Confidential  
26 Information, and are subject to discipline — up to and including  
27 termination — by [Sanofi] for its unauthorized disclosure.

28 (Ex. 11, at 2; Ex. 12, at 2; *see also* Ex. 2, at ¶¶ 12-13.)

///

---

<sup>12</sup> A true and correct copy of Sanofi's Letter to the Department (Jan. 15, 2019) is attached as Exhibit 11. *See* Ex. 2, at ¶ 11.

<sup>13</sup> A true and correct copy of Sanofi's Letter to the Department (Apr. 1, 2019) is attached as Exhibit 12. *See* Ex. 2, at ¶ 11.

<sup>14</sup> To the extent that any of Sanofi's Confidential Information might be disclosed by publication of another party's report, Sanofi opposes such disclosure.

1 The DTSA also defines a trade secret as “information [which] derives independent economic  
2 value, actual or potential, from not being generally known to, and not being readily ascertainable  
3 through proper means by, another person who can obtain economic value from the disclosure or use  
4 of the information.” 18 U.S.C. 1839(3)(B). NRS 600A.030 includes a substantially similar  
5 requirement. NRS 600A.030(5)(a)(1). Thus, in Sanofi’s requests for confidentiality, Sanofi  
6 explained:

7 The customers and competitors of [Sanofi] would gain an unfair  
8 competitive advantage if they were to obtain the Sanofi Confidential  
9 Information through a public records request pursuant to NRS  
10 239.010. In particular, [Sanofi’s] competitors and customers would  
11 receive the details of our cost structure, marketing and advertising  
12 costs, rebate strategies and profit information, which in turn provides  
13 insight into our pricing. This information could be used against us in  
14 negotiations with insurers and other intermediaries in the healthcare  
15 system. This could put [Sanofi] at a significant disadvantage,  
16 especially if our competitors do not make a diabetes drug and thus are  
17 not subject to [NRS 439B.635’s and NRS 439B.640’s] disclosure  
18 requirements. Disclosure of the Sanofi Confidential Information could  
19 prejudice [Sanofi] in competition involving non-diabetes products as  
20 well, given that [Sanofi] considers the same or similar factors when  
21 establishing pricing, advertising and rebate strategies for its other  
22 therapeutic products.

23 (Ex. 11, at 2; Ex. 12, at 2; *see also* Ex. 2, at ¶¶ 16-17.)

24 **D. The Petitioner’s Public Records Request to the Department.**

25 Just two days after Sanofi submitted its request for confidentiality to the Department, the  
26 Petitioner sent the Department a public records request for the annual reports submitted by any  
27 pharmaceutical manufacturer pursuant to NRS 439B.635 and/or NRS 439B.640. (Pet. at Ex. 2-1, at  
28 1.) The Petitioner’s request specifically named Sanofi as one of the manufacturers subject to the  
records request. (*Id.* at 2.)

On April 3, 2019, the Department responded to the Petitioner’s records request and informed  
the Petitioner that the “source reports” it sought were subject to Requests for Confidentiality made  
by the manufacturers. (*Id.* at Ex. 2-2, at 1.) Thus, the Department would only provide the Petitioner  
with the following (non-confidential) information:

///

///

- From the manufacturers reports pursuant to NRS 439B.635:
  - Drug manufacturer name;
  - Nonproprietary prescription drug name;
  - Proprietary prescription drug name;
  - National Drug Code (NDC);
  - Wholesale Acquisition Cost (WAC) price history;
  - Increase in WAC unit price; and
  - Date of increase in WAC price.
- From the manufacturers reports pursuant to NRS 439B.640:
  - Drug manufacturer name;
  - Non-proprietary drug name;
  - Proprietary drug name; and
  - NDC.

(*Id.* at 4.) The Department denied the public records request as to all other information in the annual reports, deeming such information confidential pursuant to the DTSA. (*Id.* at 1.)

On June 11, 2019, the Petitioner submitted a second public records request to the Department, seeking all annual reports submitted by pharmaceutical manufacturers pursuant to NRS 439B.635 and NRS 439B.640. (*Id.* at Ex. 2-3.) Again, Sanofi was included in the list of manufacturers subject to the public records request. (*Id.* at 2.)

On June 24, 2019, the Department responded to the Petitioner's records request and again informed the Petitioner that the source reports sought in the request were subject to Requests for Confidentiality submitted by the manufacturers. (*Id.* at Ex. 2-4, at 1.) The Department further reiterated that it would only disclose the information detailed in its April 3, 2019 response letter, and that the Petitioner's request was denied as to all other information in the annual reports, as such information was confidential pursuant to the DTSA. (*Id.* at 2, 4.)

In response, the Petitioner filed its Petition for Writ of Mandamus.

///

///

### III. ARGUMENT

#### A. The Nevada Legislature Never Intended for Pharmaceutical Manufacturers' Trade Secrets to Be Publicly Disclosed.

In an effort to ensure that Nevadans have access to affordable diabetes medications and treatments, the Nevada Legislature passed Senate Bill 539. The goal of this legislation was to increase transparency as it relates to the price of diabetes drugs. Thus, NRS 439B.635 and NRS 439B.640 were enacted to require pharmaceutical manufacturers to disclose cost, profit, and pricing information to the *Department*. The Nevada Legislature did not require such information to be disclosed to the *general public*. (See generally NRS 439B.600 to NRS 439B.695; see also Pet. at 6 n.4.) Rather, the Nevada Legislature intended that pharmaceutical manufacturers would provide cost, profit, and pricing information to the Department, and the Department would then produce its own reports on prescription drug prices for public disclosure. NRS 439B.650; NRS 439B.670.

This legislative intent is confirmed by the Legislature's amendment to NRS 600A.030. The statute provides that a trade secret "[d]oes not include any information that a manufacturer is *required to report* pursuant to NRS 439B.635 or 439B.640 . . . *to the extent that such information is required to be disclosed by those sections.*" NRS 600A.030(5)(b) (emphasis added). By use of both the words "report" and "disclosed," it is clear that the Legislature intended to remove the trade secret protection only for the specific information which the manufacturers report to the Department *and* which the Department subsequently reports to the public pursuant to NRS 439B.650 and NRS 439B.670. Therefore, any other information which the manufacturers report to the Department pursuant to NRS 439B.635 or NRS 438B.640, still qualifies as a trade secret pursuant to NRS 600A.030.

To clarify any confusion created by NRS 600A.030(5)(b), the Department adopted NAC 439A.735 and 439A.740. NAC 439A.735 allows manufacturers to maintain the confidentiality of their proprietary, financial, business, and/or economic information by submitting a request for confidentiality to the Department. If the Department receives a public records request for information covered by a request for confidentiality, the Department must: (i) conduct a review of the information to determine if it reasonably believes that public disclosure of the information would

1 constitute a misappropriation of a trade secret under the DTSA; and (ii) if so, deny the public records  
2 request. NAC 439.735(3), (4).

3 NAC 439.740 limits the type of information that the Department can publicly disclose  
4 pursuant to NRS 439B.650. It states that the Department's report required by NRS 439B.650 can  
5 only include **aggregated data that does not disclose the identity of any drug or manufacturer**, along  
6 with pricing trends and an explanation of how prices and trends affect the prevalence and severity of  
7 diabetes in Nevada and the healthcare system in Nevada. NAC 439.740. The Department is not  
8 required to disclose any of the manufacturers' production costs, marketing costs, profits, price  
9 setting decisions, rebate information, or financial assistance information. Similarly, the information  
10 included on the Department's website can only include the **wholesale acquisition cost of each**  
11 **prescription drug**, as reported by the manufacturers in their reports submitted pursuant to NRS  
12 439B.635. NRS 439B.670(1)(a)(4). No other categories of information from the manufacturers'  
13 annual reports is included in NRS 439B.670 for disclosure on the Department's website.

14 Neither of these administrative regulations conflict with Senate Bill 539 or NRS 439B.600 to  
15 NRS 439B.695. In fact, NRS 439B.685 empowers the Department to "adopt such regulations as it  
16 determines to be necessary or advisable to carry out the provisions of NRS 439B.600 to NRS  
17 439B.695, inclusive." The statute further provides that "[s]uch regulations **must** provide for,  
18 **without limitation . . . the form and manner in which manufacturers are to provide to the**  
19 **Department the information described in NRS 439B.635, 439B.640 and 439B.660.**" NRS  
20 439B.685(6) (emphasis added).

21 The Nevada Supreme Court has determined that such regulations are valid and can be used to  
22 supplement legislation where appropriate. Specifically, in *Banegas v. State Indus. Ins. Sys.*, 117  
23 Nev. 222, 19 P.3d 245 (2001), the Supreme Court held that "the Legislature may authorize  
24 administrative agencies to make rules and regulations supplementing legislation if the power given is  
25 prescribed in terms sufficiently definite to serve as a guide in exercising that power." *Id.* at 227, 19  
26 P.3d at 248. Here, NAC 439.740 was needed to clarify the types of information from the  
27 manufacturers' annual reports which would be publicly disclosed by the Department. Similarly,  
28 NAC 439.735 was needed to clarify that disclosure of trade secrets to the Department to effectuate

1 the purpose and intent of Senate Bill 539 did not eliminate or waive trade secret protection for such  
2 information for any other purpose.

3 Finally, the Department's adoption of NAC 439.735 and NAC 439.740 not only clarified any  
4 confusion created by NRS 600A.030(5)(b), but it also resolved the *PhRMA Action* and challenges to  
5 the constitutionality of NRS 439B.600 to NRS 439B.695. The Nevada Legislature was a party to the  
6 *PhRMA Action*, and it confirmed to the Court that under Senate Bill 539, the Department has a duty  
7 to maintain the secrecy of the manufacturers' trade secrets and/or to limit the use of such trade  
8 secrets. (Ex. 7, at 3:6-14.) The Nevada Legislature also represented to the federal district court that  
9 if the Department were to disclose the manufacturers' trade secrets to a third party, such disclosure  
10 would constitute a misappropriation under the DTSA. (*Id.* at 14-21.) These statements  
11 unequivocally demonstrate the legislative intent for Senate Bill 539. The Legislature never intended  
12 for the pharmaceutical manufacturers' trade secrets to be publicly disclosed — they merely intended  
13 for the information to be reported to the Department for analysis and oversight. The Legislature  
14 recognized the importance of maintaining the secrecy of the manufacturers' cost, profit, and pricing  
15 information and agreed that NAC 439.735 and NAC 439.740 were necessary to provide  
16 manufacturers with sufficient protection for their trade secrets.

17 Sanofi relied upon the Department's and Legislature's representations in the resolution of the  
18 *PhRMA Action* in submitting its trade secret information to the Department. Sanofi vigorously  
19 protects its Confidential Information from public disclosure. It also takes great steps to internally  
20 restrict access to this information, by only sharing the information internally on a need-to-know  
21 basis, utilizing non-disclosure provisions in its employment and business agreements, and  
22 disciplining employees (up to and including termination) for any unauthorized disclosure of the  
23 Sanofi Confidential Information. (Ex. 2, at ¶¶12-13.)

24 Sanofi takes these steps to maintain the secrecy of its Confidential Information because it  
25 will suffer irreparable harm if the information is publicly disclosed. Sanofi's competitors and  
26 consumers would gain an unfair competitive advantage if they were to obtain the Sanofi Confidential  
27 Information. (*Id.* at ¶ 16.) Specifically, Sanofi's consumers could use the information against it in  
28 negotiations with insurers and others in the healthcare system. (*Id.*) Similarly, Sanofi's competitors

1 will learn how it allocates its resources and sets its prices, not only for diabetes drugs, but for all of  
2 its products (as Sanofi considers the same or similar factors when setting prices for all of its  
3 products). (*Id.* at ¶ 17.) The impact of this would be felt nationwide, as the prices Sanofi sets and  
4 the methods it uses to set them are substantially the same from state-to-state. (*Id.* at ¶ 18.)

5 **B. NAC 439.735 Does Not Conflict with the NPRA.**

6 The Petitioner contends that the Department cannot adopt any regulations which conflict with  
7 the NPRA. (Pet. at 65.) However, in *City of Sparks v. Reno Newspapers, Inc.*, 133 Nev. 398, 399  
8 P.3d 352 (2017), the Reno-Gazette Journal requested that the City disclose copies of the business  
9 licenses of persons operating medical marijuana establishments (“MME”) in Reno *Id.* at 398-99,  
10 399 P.3d at 354. The City produced the business licenses, but redacted the licensees’ identities  
11 pursuant to NAC 453A.714, which specifically exempts the identities of MME business license  
12 holders from disclosure under the NPRA. *Id.* The Court found that NRS 453A.370 specifically  
13 authorized the Department’s Division of Public and Behavioral Health to make rules and regulations  
14 supplementing NRS Ch. 453A, and, therefore, NAC 453A.714 was valid. *Id.* at 402, 399 P.3d at  
15 356. The Reno-Gazette Journal argued that NRS 453A.370(5) did not authorize the Division to  
16 create a regulation exempting information from the NPRA “because any exceptions to the NPRA  
17 can only exist when explicitly provided for under NRS 239.010.” *Id.* However, the Court held that  
18 “*in addition to* the specific exemptions listed in NRS 239.010, the NPRA also *does not apply* to  
19 records ‘*otherwise declared by law to be confidential.*’” *Id.* (quoting NRS 239.010(1)). Thus, the  
20 creation of an exception to the NPRA is not a “conflict” that would render an administrative  
21 regulation invalid.

22 As set forth above, NAC 439.735 sets forth procedures pursuant to which the Department can  
23 deny public records requests for information submitted to the Department pursuant to NRS  
24 439B.635 or NRS 439B.640. The Legislature gave the Department the authority to adopt this  
25 regulation and approved of the Department’s regulation as a means to avoid any challenges to the  
26 constitutionality of NRS 439B.600 to NRS 439B.695.

27 ///

28 ///

1 Sanofi complied with all of the requirements of NAC 439.735. Sanofi submitted a request  
2 for confidentiality for the Sanofi Confidential Information. (Ex. 11, at 1-2; Ex. 12, at 1-2.) Sanofi  
3 set forth detailed information about the steps it takes to protect the secrecy of this information. (Ex/  
4 11, at 2; Ex. 12, at 2.) Sanofi also set forth detailed information about the value of such information  
5 to its competitors and the irreparable harm it would suffer if these trade secrets were publicly  
6 disclosed. (*Id.*) Thus, the trade secrets required to be disclosed in Sanofi's annual reports to the  
7 Department have been "declared confidential under the law" and are exempt from the NPRA.

8 In addition to the confidentiality provided by NAC 439.735, the information included in  
9 Sanofi's annual reports also qualifies as a trade secret under the DTSA. Specifically, the DTSA  
10 defines a "trade secret" as "all forms and types of *financial, business*, scientific, technical, *economic*  
11 or engineering information, including patterns, plans, compilations, program devices, formulas,  
12 designs, prototypes, methods, techniques, processes, procedures, programs, or codes . . . if — (A) the  
13 owner thereof has taken reasonable measures to keep such information secret; and (B) the  
14 information derives independent economic value, actual or potential, from not being generally  
15 known to, and not being readily ascertainable through proper means by, another person who can  
16 obtain economic value from the disclosure or use of the information." 18 U.S.C. § 1839(3).  
17 Sanofi's production costs, advertising costs, marketing costs, profits, the amount of financial  
18 assistance it provides to patient prescription assistance programs, costs associated with coupons  
19 provided to consumers, and the amount of rebates provided to pharmacy benefit managers constitute  
20 financial and/or economic information protected by the DTSA. Similarly, Sanofi's methods,  
21 techniques, processes, and/or procedures for setting prices qualifies as business information  
22 protected by the DTSA. As such, this information is "declared confidential by law" and is not  
23 subject to disclosure pursuant to the NPRA.

24 The Petitioner asserts that the Department cannot withhold the manufacturers' annual reports  
25 on the basis of confidentiality unless it can demonstrate that its interest in nondisclosure clearly  
26 outweighs the public's interest in access. (Pet. at ¶ 62.) Here, the interest in protecting the  
27 manufacturers' trade secrets clearly outweighs the public's interest in having access to the annual  
28 reports. The information that the Legislature deemed necessary for assessing the reasonableness of

1 prescription drug prices is already included in the Department's reports and in the Department's  
2 disclosures on its website. The transparency objective of NRS 439B.600 to NRS 439B.695 is  
3 satisfied by the manufacturers' disclosures to the Department. The underlying data assessed by the  
4 Department need not be publicly disclosed, particularly when such disclosure would only serve to  
5 irreparably harm manufacturers in their dealings with competitors and consumers, not just in  
6 Nevada, but nationwide.

7 Finally, as noted by the Petitioner, "[t]he Supreme Court of Nevada has repeatedly held that a  
8 court considering a claim of confidentiality in response to a public records request[] 'begin[s] with  
9 the presumption that all **government-generated records** are open to disclosure.'" (*Id.* at ¶ 61  
10 (quoting *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 266 P.3d 623, 628 (2011)).)  
11 However, the annual reports that pharmaceutical manufacturers are required to submit to the  
12 Department pursuant to NRS 439B.635 and NRS 439B.640 **are not government-generated records**.  
13 Rather, the relevant government-generated records for the purposes of the NPRA are the reports the  
14 Department prepares pursuant to NRS 439B.650/NAC 439.740 and NRS 439B.670. Therefore, the  
15 Sanofi Confidential Information included in its annual reports to the Department is not subject to  
16 disclosure under the NPRA. *See e.g., Donrey of Nev., Inc. v. Bradshaw*, 106 Nev. 630, 631-32, 798  
17 P.2d 144, 145 (1990) (concerning a request for a police investigative report); *DR Partners v. Bd. of*  
18 *Cty. Comm'rs of Clark Cty.*, 116 Nev. 616, 619, 6 P.3d 465, 467 (2000) (concerning a request for  
19 Clark County's phone records); *Reno Newspapers, Inc. v. Haley*, 126 Nev. 211, 213, 234 P.3d 922,  
20 923-24 (2010) (concerning firearms permits); *Pub. Employees' Ret. Sys. of Nev. v. Reno*  
21 *Newspapers, Inc.*, 129 Nev. 833, 834-35, 313 P.3d 221, 222-23 (2013) (concerning government  
22 employee personnel files); *Clark Cty. Sch. Dist. v. Las Vegas Review-Journal*, 134 Nev. Adv. Op.  
23 84, 429 P.3d 313, 315-16 (2018) (concerning Clark County School District's internal investigative  
24 records). The Petitioner has failed to cite to any authority demonstrating that the NPRA is a tool that  
25 allows the public to obtain access to confidential information and/or trade secrets in reports prepared  
26 by private business entities and submitted to administrative agencies as required by law, as opposed  
27 to voluntary submissions in bid proposals and license applications.

28 ///

IV. CONCLUSION

For the foregoing reasons, Sanofi respectfully requests that the Court deny the Petition for Writ of Mandamus.

DATED this 23rd day of December, 2019.

BAILEY ♦ KENNEDY

By: /s/ John R. Bailey

JOHN R. BAILEY

DENNIS L. KENNEDY

SARAH E. HARMON

REBECCA L. CROOKER

*Attorneys for Intervenor* SANOFI-AVENTIS  
U.S. LLC

**CERTIFICATE OF SERVICE**

I certify that I am an employee of BAILEY ♦ KENNEDY and that on the 23rd day of December, 2019, service of the foregoing **INTERVENOR SANOFI-AVENTIS U.S. LLC'S RESPONSE TO PETITIONER'S PETITION FOR A WRIT OF MANDAMUS** was made by mandatory electronic service through the Eighth Judicial District Court's electronic filing system and/or by depositing a true and correct copy in the U.S. Mail, first class postage prepaid, and addressed to the following at their last known address:

MATTHEW J. RASHBROOK  
ROBERT L. LANGFORD  
**ROBERT L. LANGFORD & ASSOCIATES**  
616 South Eighth Street  
Las Vegas, Nevada 89101

Email: matt@robertlangford.com  
robert@robertlangford.com

*Attorneys for Petitioner*  
THE NEVADA INDEPENDENT

AARON D. FORD  
ATTORNEY GENERAL  
STEVE SHEVORSKI  
CHIEF LITIGATION COUNSEL  
**OFFICE OF NEVADA ATTORNEY GENERAL**  
555 East Washington Avenue, Suite 3900  
Las Vegas, Nevada 89101

Email: sshevorski@ag.nv.gov  
*Attorneys for Respondents*  
RICHARD WHITLEY, in his official capacity as the Director of the Nevada Department of Health and Human Services, and THE STATE OF NEVADA, ex rel. the NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES

/s/ Josephine Baltazar  
Employee of BAILEY ♦ KENNEDY

# EXHIBIT 1

**\*\*\*Exhibit intentionally omitted\*\*\***

# EXHIBIT 1

# EXHIBIT 2

# EXHIBIT 2

**DECLARATION OF JAMES BORNEMAN**

I, James Borneman, declare as follows:

1. I am currently the Vice President and Head, Diabetes and Primary Care Sales, for Sanofi US. From July 2014 — May 2017, I was Vice President, Strategic Pricing and Contract Management, and from June 2017 — July 2018, I was the Head, Customer Engagement & Insights, both for Sanofi US. In these capacities, I was responsible for and am knowledgeable about the establishment of all gross and net pricing strategies for all Sanofi US pharmaceutical products to include oversight of the organization's gross-to-net investments. I am knowledgeable about Sanofi US's pricing and contracting for its prescription drugs, including its diabetes therapies.

2. Sanofi US is the U.S. affiliate of Sanofi, a global life sciences company committed to improving access to healthcare and supporting the people we serve throughout the continuum of care. From prevention to treatment, Sanofi transforms scientific innovation into healthcare solutions in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes and cardiovascular, consumer healthcare, established prescription products and generics. More than 100,000 people at Sanofi are dedicated to making a difference in patients' daily lives, wherever they live, and enabling them to enjoy a healthier life.

3. Headquartered in Bridgewater, New Jersey, Sanofi US employs approximately 12,500 professionals throughout the country, including at a distribution center in Reno, Nevada. In addition to Diabetes & Cardiovascular and General Medicines, our other businesses operating in the United States include Sanofi Genzyme (specialty care), Sanofi Pasteur (vaccines), Winthrop (generics) and Chattem (consumer healthcare).

4. Sanofi has a rich history of innovation dating back more than 100 years. We are tremendously proud of our heritage, which over the years has combined steady growth and expansion with an exceptional commitment to research and development.

5. For example, since the launch of Lantus (insulin glargine injection) 100 units/ml, Sanofi has continued investing to better support clinical decision making for patients with diabetes through comprehensive research including over 2200 full-text publications from results of

///

1 approximately 500 randomized controlled clinical trials, over 220 real-life patient studies and over  
2 50 meta-analyses.

3 6. Sanofi holds or has had rights to patents protecting prescription drugs marketed and  
4 sold by Sanofi US, including patents protecting Adlyxin, Admelog, Amaryl, Apidra, DiaBeta,  
5 Lantus, Soliqua and Toujeo which are FDA-approved for the treatment of diabetes. I understand  
6 that Sanofi is required to provide certain information to the Nevada Department of Health and  
7 Human Services ("Department") pursuant to Nevada Senate Bill No. 539 ("SB 539" or "the Act")  
8 for drugs that are "essential" to the treatment of diabetes, which includes the above products.

9 7. I understand that on at least January 15, 2019, April 1, 2019 and August 7, 2019,  
10 pursuant to the requirements of the Act, Sanofi US confidentially reported substantial financial and  
11 marketing information related to Adlyxin, Admelog, Amaryl, Apidra, DiaBeta, Lantus, Soliqua and  
12 Toujeo to the Department ("Sanofi Reports").

13 8. Pursuant to Section 3.8 of the Act, the Sanofi Reports included confidential  
14 information regarding the above products in response to the following categories of information:

- 15 • The total cost of producing the drug;
- 16 • Total administrative expenditures relating to the drug;
- 17 • Profit manufacturer earned from the drug;
- 18 • Percentage of manufacturer's total profit attributed to drug during marketing  
19 period for drug sale;
- 20 • Total amount of financial assistance provided through patient Prescription  
Assistance Programs;
- 21 • Cost associated with consumer coupons for consumer Copayment Assistance  
22 Programs;
- 23 • Manufacturer cost attributable to redemption of consumer coupons and use of  
consumer Copayment Assistance Program; and
- 24 • Aggregate amount of all rebates manufacturer provided to Pharmacy Benefit  
25 Managers for drug sales in Nevada in dollars.

26 ///

27 ///

28 ///

9. Pursuant to Section 4.0 of the Act, the Reports also included confidential information regarding recent wholesale acquisition cost (“WAC”) increases for Adlyxin, Apidra, Lantus, Soliqua and Toujeo in response to the following categories of information:

- A list of factors that has contributed to the increase;
- The explanation for the percent increase attributable to each factor; and
- An explanation of the role each factor played in the increase.

10. As part of the Sanofi Reports, Sanofi US also included letters (re: “Sanofi US Trade Secret/Confidentiality Request Pursuant to Nevada SB 539”) pursuant to, and in reliance on, Nevada Administrative Code §§439.730-740 regarding the trade secret status of Sanofi’s confidential information. The letters, among other things, referenced the Defend Trade Secrets Act of 2016 and a litigation captioned *Pharmaceutical Research and Manufacturers of America v. Sandoval, et. al.*, United States District Court, District of Nevada, Case No. 2:17-cv-02315-JCM-CWH.

11. A true and correct copy of the Letter dated January 15, 2019 is attached hereto as Exhibit 11. A true and correct copy of the Letter dated April 1, 2019 is attached hereto as Exhibit 12.

12. The Sanofi Reports comprise information that is of substantial independent economic value to Sanofi US by virtue of being confidential and non-public. Information such as pricing inputs and rationale is restricted internally, is only shared internally on a need-to-know basis, and is subject to non-disclosure provisions in Sanofi US’s employment and other business agreements. Employees are required to maintain the secrecy of this information, and are subject to discipline — up to and including termination — by Sanofi US for its unauthorized disclosure.

13. Information such as the factors considered in setting and adjusting the prices of our products and the percentage of our profits that derive from diabetes drugs are confidential and proprietary. This information is not shared publicly, and access to it is restricted internally and only shared internally on a need-to-know basis. It is subject to non-disclosure provisions in Sanofi US’s employment and other business agreements. Employees are required to maintain the secrecy of this information, and are subject to discipline — up to and including termination — by Sanofi US for its unauthorized disclosure.

1           14. I understand that the Department has received, from a reporter for The Nevada  
2 Independent website, at least one request for information under the Nevada Public Records Act.  
3 (Petition for Writ of Mandamus, at Ex. 2-1.) This request seeks, among other things, a disclosure of  
4 the confidential information in the Sanofi Reports.

5           15. Disclosure of the Sanofi Reports to The Nevada Independent would significantly  
6 harm Sanofi US. Once this information is publicly disclosed in Nevada, including to the readers of  
7 the Nevada Independent, it is permanently public everywhere.

8           16. Our customers and competitors would gain an unfair competitive advantage over  
9 Sanofi US if they were to obtain the financial and marketing information in the Sanofi Reports,  
10 which have now been requested by The Nevada Independent. In particular, our customers would  
11 learn how we develop our pricing, which in turn could be used against us in negotiations with  
12 insurers and other intermediaries in the healthcare system — and ultimately negatively impact  
13 patients, by discouraging innovations that would benefit them.

14           17. Likewise, our competitors would learn how we allocate our resources and set our  
15 prices. This in turn could put Sanofi US at a significant disadvantage, especially if our competitors  
16 do not make a diabetes drug and thus are not subject to SB 539's disclosure requirements. We  
17 consider the same or similar factors when setting prices for other products. Thus, the information  
18 disclosed would significantly harm Sanofi US in competition involving non-diabetes products as  
19 well.

20           18. These impacts will not just be felt in Nevada, but will be felt nationally. The prices  
21 Sanofi US sets and the methods that it uses to set them are substantially the same from state-to-state.  
22 Thus, the information disclosed under SB 539 would have implications on our negotiations with  
23 customers and our competitive positioning nationwide.

24           19. For example, many of the other healthcare supply chain stakeholders are national  
25 companies that negotiate national contracts. Healthcare purchasers such as the Culinary Union  
26 #226, which was a major public proponent of SB 539, are affiliated with Unite Here, a national  
27 union with affiliates in 37 states.

28 ///

1           20.     Sanofi US has a longstanding commitment to research in the diabetes space and there  
2 is much remaining to be done in the diabetes space to ensure better outcomes for patients. Sanofi  
3 invested significant capital in developing Adlyxin Admelog, Amaryl, Apidra, DiaBeta, Lantus,  
4 Soliqua and Toujeo, despite the substantial risk that this investment would not bear fruit. Sanofi  
5 obtained patents on these products, which gives Sanofi US the exclusive legal right to market these  
6 drugs for the term of those patents. Such patent exclusivity enables Sanofi US to price Adlyxin  
7 Admelog, Amaryl, Apidra, DiaBeta, Lantus, Soliqua and Toujeo at a level that helps to recoup the  
8 investment in this research and development, given that many experimental products do not even  
9 make it to the submission or approval stages. Now, however, if the Sanofi Reports were to be  
10 subject to public disclosure, Sanofi faces the unenviable choice of either forgoing its right under the  
11 patent laws to price the products at this level, or suffering the substantial penalty of disclosure of  
12 trade secret information. The risks of competitive harm will lower the value of existing and future  
13 patents on diabetes products, diminishing the incentive, or creating a disincentive, to invest in  
14 developing and enhancing those drugs. Ultimately, this could slow or blunt the process of providing  
15 better treatments for patients.

16           21.     Disclosure of the Sanofi Reports also could have severe unintended consequences.  
17 Given the significant investment required to fund research and development, such a focus could have  
18 a chilling effect on Sanofi's efforts in the diabetes space. For example, the lack of reporting  
19 thresholds in Section 3.8 of the Act (other than the requirement that the drug be "essential" to  
20 diabetes treatment) and a very low threshold for reporting price increases in Section 4 of the Act  
21 (any price greater than the CPI for medical products) could result in lower return on the patent rights  
22 and other innovations in the diabetes space than in other disease spaces. Further, Sanofi could be  
23 placed at a competitive disadvantage relative to companies who do NOT manufacture diabetes  
24 medicines, who reap an unexpected benefit by virtue of the publication of the Sanofi Reports. Given  
25 that Sanofi US considers the same or similar factors when setting the prices for other products, the  
26 information disclosed could disadvantage Sanofi US in competition involving non-diabetes products  
27 as well.

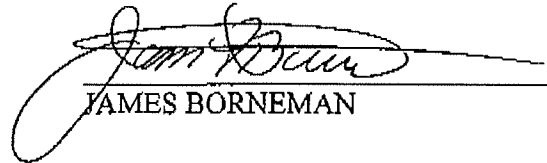
28     ///

1           22. Disclosure of the Sanofi Reports would defeat Sanofi's legitimate investment  
2 expectations regarding its current products, and will necessitate review of our research and  
3 development priorities for diabetes products going forward. Indeed Sanofi may be forced to  
4 consider the costs and risks imposed by SB 539 in deciding what resources to allocate to enhancing  
5 its products and/or to research and development of new diabetes treatments.

6           23. Given Sanofi's confidence in our researchers and our mission to continue finding  
7 solutions for patients with diabetes — and balancing that with our duties towards those who invest in  
8 Sanofi's lifesaving and life improving treatments and patients awaiting cures and treatments in other  
9 areas — Sanofi may be forced to weigh the difficult decision of whether to reduce its efforts in  
10 continuing to pursue promising medical advances in the area of diabetes because of these  
11 disincentives.

12           I declare under penalty of perjury, under the laws of the State of Nevada, and the State of  
13 New Jersey, that the foregoing is true and correct.

14           EXECUTED on this 17<sup>th</sup> day of October, 2019.

15   
16 JAMES BORNEMAN  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

BAILEY ♦ KENNEDY  
8964 SPANISH RIDGE AVENUE  
LAS VEGAS, NEVADA 89148-4302  
702.567.8820

# EXHIBIT 3

# EXHIBIT 3

Pat Lundvall  
Nevada Bar No. 3761  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
plundvall@mcdonaldcarano.com

Robert N. Weiner  
Pending Admission *Pro Hac Vice*  
Jeffrey L. Handwerker  
Pending Admission *Pro Hac Vice*  
R. Stanton Jones  
Pending Admission *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA, and  
  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity  
as Governor of the State of Nevada, and

RICHARD WHITLEY, in his official capacity  
as Director of the Nevada Department for  
Health and Human Services,

Defendants.

Case No.:

**COMPLAINT FOR DECLARATORY  
AND INJUNCTIVE RELIEF**

1 Plaintiffs Pharmaceutical Research and Manufacturers of America (“PhRMA”) and  
 2 Biotechnology Innovation Organization (“BIO”) (together, “Plaintiffs”), on behalf of themselves  
 3 and their members, for their Complaint against Brian Sandoval, in his official capacity as Governor  
 4 of the State of Nevada (the “State”), and Richard Whitley, in his official capacity as Director of the  
 5 Nevada Department of Health and Human Services (together, “Defendants”), allege as follows:

## 6 INTRODUCTION

7 1. Plaintiffs bring this action to block an unprecedented and unconstitutional Nevada  
 8 law that interferes with the federal patent and trade-secret laws, deprives manufacturers of their  
 9 property interest in their trade secrets, and improperly overrides the regulatory choices of every  
 10 other state. Because the new Nevada statute violates multiple provisions of the United States  
 11 Constitution, this Court has subject matter jurisdiction under 28 U.S.C. § 1331.

12 2. Nevada recently enacted Senate Bill No. 539 (“SB 539” or the “Act,” attached as  
 13 Exhibit A), a statute novel in its scope, ambition, and nationwide effect. As a penalty for exercising  
 14 rights protected under the U.S. patent laws, SB 539 strips pharmaceutical manufacturers of trade-  
 15 secret protection for confidential, competitively sensitive, proprietary information regarding the  
 16 advertising, cost, marketing, pricing, and production of their patented diabetes medicines. The Act  
 17 then compels manufacturers to disclose this information to the Nevada Department of Health and  
 18 Human Services (the “Department”), which must publish at least some of the information on its  
 19 website and may disseminate the rest as it pleases.

20 3. By extinguishing trade-secret protection for manufacturers’ confidential, proprietary  
 21 information, burdening the lawful exercise of longstanding federal patent rights, and interfering  
 22 with the national market for diabetes medicines, the Act violates the U.S. Constitution in at least  
 23 four ways.

24 4. *First*, SB 539 violates the Supremacy Clause because it conflicts with federal patent  
 25 law, including the Drug Price Competition and Patent Term Restoration Act of 1984, known as the  
 26 Hatch-Waxman Act. The federal patent laws allow a patent holder to exclude others from making,  
 27 using, or selling new inventions. The Hatch-Waxman Act adapts this system to pharmaceuticals  
 28 through a comprehensive federal scheme to provide broad access to affordable medicines while

1 offering economic incentives sufficiently potent to motivate innovators to shoulder the enormous  
2 costs and risks to develop pioneering new treatments. SB 539 upsets this legislative balance by  
3 burdening a patent holder's right to price its product in a manner reflecting the economic incentives  
4 the federal patent laws are intended to ensure.

5 5. *Second*, SB 539 also conflicts with, and is therefore preempted by, federal trade-  
6 secret law. Recognizing that protection of trade secrets is critical to the success of U.S. businesses,  
7 Congress enhanced existing state-law safeguards by enacting the Defend Trade Secrets Act of 2016  
8 ("DTSA"). The DTSA sets a federal baseline for trade-secret protection. SB 539 does not merely  
9 fall below this baseline. It effectively nullifies federal protection for valuable trade secrets,  
10 undermining innovation and competition in the American pharmaceutical industry.

11 6. *Third*, SB 539 violates the Takings Clause of the Fifth Amendment by depriving  
12 affected manufacturers of trade-secret protection for their confidential information, forcing them to  
13 disclose it to the State, and ensuring that much of it is disseminated on the Internet, including to  
14 third-party payers and competitors. Before SB 539, these materials qualified as trade secrets under  
15 the laws of every state, including Nevada. Trade secrets are property. SB 539 destroys the value of  
16 that property without recompense. It thus deprives manufacturers of their property "without just  
17 compensation," in violation of the Takings Clause.

18 7. *Fourth*, SB 539 violates the dormant Commerce Clause because the penalty it  
19 imposes in Nevada impedes commerce in other states. By tying penalties to the national list price  
20 for a drug, SB 539 affects drug prices throughout the country, even for drugs bought and sold  
21 entirely outside of Nevada. The Act also eviscerates trade-secret protection not only in Nevada, but  
22 in every other state as well. Requiring disclosures, rescinding trade-secret protection for the  
23 information disclosed, and mandating its publication on the Internet destroys its confidentiality.  
24 Such disclosures cannot be undone—information cannot be undisclosed. SB 539 overrides the  
25 protections of other states that treat the information as trade secrets, including states where the  
26 affected manufacturers reside, pay taxes, and employ thousands of workers. Whatever purported  
27 local benefit SB 539 might seek for Nevada purchasers of diabetes medicines is far less substantial  
28 than the displacement of the laws of every other state in the Union. Only Congress has the authority

1 to override state trade-secret law or to impose national economic policies. Nevada cannot do so  
2 unilaterally.

3 8. SB 539's constitutional infirmities led Governor Brian Sandoval to veto a  
4 substantially similar bill—Senate Bill 265 (“SB 265”)—just three months ago. Governor Sandoval  
5 warned that provisions of the earlier bill “could be challenged under theories of federal preemption,  
6 the Fifth Amendment’s prohibition on uncompensated takings, and the Dormant Commerce  
7 Clause.” Veto Letter from Gov. Brian Sandoval to Sen. Maj. Leader Aaron Ford 3 (June 2, 2017)  
8 (“Veto Letter,” attached as Exhibit B). The Governor was right, but SB 539 did not alleviate the  
9 defects he identified.

10 9. Governor Sandoval further recognized that, beyond these constitutional defects, SB  
11 265 could seriously harm Nevada residents suffering from diabetes. The bill, in the Governor’s  
12 view, posed “serious risks of unintended and potentially detrimental consequences for Nevada’s  
13 consumer patients, not the least of which is the possibility that access to critical care will become  
14 more expensive, more restricted, and less equitable.” *Id.* at 2. He cautioned that the bill “could  
15 cause more harm than good for Nevada’s families.” *Id.* “Before I support a bill [this] uncertain,”  
16 he wrote, “which deals so directly and extensively with the health and well-being of countless  
17 Nevadans, there must be compelling evidence that the benefits are worth the risks.” *Id.* at 3. There  
18 was no such evidence, and the Legislature did not remedy that deficit in adopting SB 539.

19 10. Accordingly, Plaintiffs seek a declaration that the challenged provisions of SB 539  
20 are preempted by federal law and also violate the Takings Clause and the dormant Commerce  
21 Clause. Plaintiffs also seek an injunction prohibiting the defendants from implementing or  
22 enforcing those provisions.

## 23 PARTIES

24 11. PhRMA is a non-profit corporation organized under Delaware law, with its  
25 headquarters in Washington, D.C. PhRMA serves as the pharmaceutical industry’s principal public  
26 policy advocate, representing the interests of its members before Congress, the Executive Branch,  
27 state regulatory agencies and legislatures, and the courts. Among other objectives, PhRMA seeks to  
28 advance public policies that foster continued medical innovation and to educate the public about the

1 process for discovering and developing new drugs. PhRMA members are the leading research-  
 2 based pharmaceutical and biotechnology companies in America, devoted to discovering and  
 3 developing new medications that allow people to live longer, healthier, and more productive lives.<sup>1</sup>

4 12. BIO is the world's largest trade association representing more than 1,000  
 5 biotechnology companies, academic institutions, state biotechnology centers and related  
 6 organizations across the United States and in more than 30 other nations. BIO members are  
 7 involved in the research and development of innovative healthcare, agricultural, industrial and  
 8 environmental biotechnology products.<sup>2</sup>

9 13. Defendant Brian Sandoval is the Governor of the State of Nevada and is sued in his  
 10 official capacity only. As Governor, Defendant Sandoval is responsible for the execution of SB  
 11 539.

12 14. Defendant Richard Whitley is the Director of the Department and is sued in his  
 13 official capacity only. As Director of the Department, Defendant Whitley is responsible for the  
 14 implementation and execution of SB 539, including the promulgation of rules and the assessment of  
 15 administrative penalties authorized by the Act. *See* SB 539, 2017 Leg., 79th Sess. §§ 7–8 (Nev.  
 16 2017).

### 17 JURISDICTION AND VENUE

18 15. Plaintiffs' causes of action arise under 42 U.S.C. § 1983 and the United States  
 19 Constitution. The Court thus has jurisdiction under 28 U.S.C. § 1331.

20 16. Venue is proper in this district under 28 U.S.C. § 1391(b) because Plaintiffs' claims  
 21 arise in this judicial district and because Defendants reside and perform their official duties in this  
 22 district.

23 17. An actual controversy exists between the parties within the meaning of 28 U.S.C.  
 24 § 2201, and this Court has the authority to grant declaratory and injunctive relief pursuant to 28  
 25 U.S.C. §§ 2201 and 2202.

26 <sup>1</sup> A list of PhRMA members is available at *Members*, <http://www.phrma.org/about/members>.

27 <sup>2</sup> A list of BIO members is available at *BIO Member Directory*, [http://www.bio.org/bio-member-](http://www.bio.org/bio-member-directory)  
 28 [directory](http://www.bio.org/bio-member-directory).

## BACKGROUND

### ***Plaintiffs' Members Devote Billions of Dollars Each Year to Developing Innovative Diabetes Medicines in Reliance on Patent and Trade-Secret Law***

18. Diabetes is an epidemic in the United States, with more than 30 million Americans diagnosed with either Type 1 or Type 2 diabetes. Type 1 diabetes is an autoimmune disease in which the immune system attacks the insulin-producing cells of the pancreas, and the body as a result produces too little insulin, the principal hormone regulating the body's absorption of glucose (sugar) from the blood. In Type 2 diabetes, the body resists the effects of insulin and, although the pancreas produces abnormally high levels of insulin to overcome this resistance, blood glucose rises to higher levels than normal. About 5 to 10% of diabetes diagnoses are Type 1, and 90 to 95% are Type 2. *See What Is Diabetes?*, Nat'l Inst. of Diabetes & Digestive & Kidney Diseases, Nat'l Insts. of Health, <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes>. High levels of glucose in the blood can result in a number of complications, including vision loss, kidney disease, and cardiovascular disease. *Id.*

19. Diabetes is the seventh leading cause of death in the United States. In addition to the 30 million Americans diagnosed with the disease itself, another 84 million have pre-diabetes—abnormally high blood sugar levels that increase the risk of developing diabetes in the future. All told, over half the adults in the United States have either diabetes or pre-diabetes. *See A. Menke et al., Prevalence of and Trends in Diabetes Among Adults in the United States, 1988-2012*, 314 JAMA 1021 (2015), [www.jamanetwork.com/journals/jama/fullarticle/2434682](http://www.jamanetwork.com/journals/jama/fullarticle/2434682).

20. For a century, Plaintiffs' members have been at the forefront of the fight against diabetes, starting with the mass production of early animal-based insulins by Eli Lilly in 1922. Before the discovery of insulin as a diabetes treatment, a diagnosis of diabetes was a swift death sentence. Even with a strict diet, a patient typically survived "no more than three or four years." *Diabetes Que., Treating Diabetes: 1921 to the Present Day* (Nov. 2016), <http://www.diabete.qc.ca/en/understand-diabetes/all-about-diabetes/history-of-diabetes/treating-diabetes-1921-to-the-present-day>. In 1897, the average life expectancy of a 10-year-old child diagnosed with diabetes was just one year and, for a 30-year-old, only four years. *See Dawn*

Swidorski, *Diabetes History*, Defeat Diabetes Found. (Jan. 22, 2014), <https://www.defeatdiabetes.org/diabetes-history>. Their quality of life was also poor. Blood vessel or nerve damage resulted in dizziness and fainting, frequent urination, blindness, kidney failure, and infections leading to amputation.

21. While the disease “is still associated with a reduced life expectancy, the outlook for patients with th[e] disease has improved dramatically,” Kenneth S. Polonsky, *The Past 200 Years in Diabetes*, 367 New Eng. J. Med. 1332, 1332 (2012), <http://www.nejm.org/doi/full/10.1056/NEJMra1110560>, owing significantly to the enormous investments by Plaintiffs’ members in research and development of innovative diabetes treatments. Many innovative treatments have broken new scientific ground and significantly improved patients’ life expectancy and quality of life.

22. In 1921, a pair of scientists discovered that they could reverse diabetes in dogs by injecting them with an extract—insulin—from the pancreatic islets of healthy dogs. *See* Brian Wu, *History of Diabetes: Past Treatments and New Discoveries*, Med. News Today (May 2017), <http://www.medicalnewstoday.com/articles/317484.php>. The following year, Eli Lilly began mass producing animal-based insulin and, in 1925, Novo Nordisk gained the rights to produce insulin outside North America, allowing diabetes patients across the world to better manage their condition. *Id.*; Novo Nordisk, *The Founders*, [www.novonordisk.com/about-novo-nordisk/novo-nordisk-history/the-founders.html](http://www.novonordisk.com/about-novo-nordisk/novo-nordisk-history/the-founders.html).

23. Since then, pharmaceutical manufacturers have devoted very substantial resources to improving insulin treatment and otherwise controlling diabetes. For example:

- In 1936, a scientist discovered that adding protamine prolonged the effects of injected insulin.
- In 1950, Novo Nordisk introduced Neutral Protamine Hagedorn (“NPH”) Insulin, a drug so important in treating diabetes that it is on the World Health Organization model list of essential medicines. *See* WHO Model List of Essential Medicines, World Health Org. (20th ed.) (Mar. 2017), [http://www.who.int/medicines/publications/essentialmedicines/20th\\_EML2017.pdf](http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017.pdf).
- In 1964, the Ames Company, a subsidiary of the Dr. Miles Medical Company that later merged into Bayer AG, introduced the first strips for testing blood

glucose, which allowed diabetes patients to monitor and regulate their glucose levels frequently and conveniently. *See* Am. Diabetes Ass'n, *75th Anniversary Timeline*, <http://www.diabetes.org/about-us/75th-anniversary/timeline.html> ("75th Anniversary Timeline"). By 1981, the Ames Company introduced home glucose meters, allowing patients to accurately check their own blood glucose levels without having to visit a doctor's office. S.F. Clarke & J.R. Foster, *A History of Blood Glucose Meters and Their Role in Self-Monitoring of Diabetes Mellitus*, 69 *Brit. J. of Biomed. Sci.* 83, 86 (2012).

- In 1982, FDA approved Eli Lilly's Humulin, the first human insulin product, freeing the world's supply of insulin from its supply using animal sources. *See* Lawrence K. Altman, *A New Insulin Given Approval for Use In U.S.*, N.Y. Times, Oct. 30, 1982, <http://www.nytimes.com/1982/10/30/us/a-new-insulin-given-approval-for-use-in-us.html?mcubz=0>.
- In 1985, Novo Nordisk developed, introduced, and marketed the first insulin pen, which allows patients to vary the injected dose and to administer insulin discreetly. Since 1985, innovators have made significant investments into designing insulin pens that improve patient satisfaction and safety.
- In 1994, Bristol Myers Squibb became the first company to secure FDA approval for the drug metformin, an oral biguanide that prevents glucose production in the liver. Press Release, U.S. Food & Drug Admin., FDA Approves New Diabetes Drug (Dec. 30, 1994), <https://web.archive.org/web/20070929152824/http://www.fda.gov/bbs/topics/ANSWERS/ANS00627.html>. Metformin is the recommended first line of treatment for Type 2 diabetes after diet and exercise. *See* Randy Dotinga, *Metformin Still Best as First Type 2 Diabetes Treatment*, WebMD (Jan. 2, 2017), <http://www.webmd.com/diabetes/news/20170102/metformin-still-best-choice-for-first-type-2-diabetes-treatment>.
- In 2000, Aventis Pharmaceuticals, a predecessor company of Sanofi U.S., received FDA approval for Lantus, the first FDA approved long-acting (basal) recombinant human insulin analog with a once-daily administration. *See* 75th Anniversary Timeline. With Lantus, the reduced risk of nighttime hypoglycemia and the flexibility of once-daily dosing made insulin a more acceptable option for patients to start insulin earlier and intensify their insulin sooner, leading to long-term improvements and reducing complications in diabetes.
- In 2005, FDA approved the first patient-use continuous glucose monitoring system, which automatically reads blood sugar levels every 5 to 15 minutes and can detect trends and patterns. *See id.*
- Also in 2005, Eli Lilly and Amylin Pharmaceuticals received FDA approval for Byetta, a first-in-class glucagon-like peptide-1 (GLP-1) receptor agonist that improves glycemic control and delays or reduces the need for insulin in patients with Type 2 diabetes. *Id.* Significant innovation in the GLP-1 space has continued since, including, for example, the development of once-weekly agents that can significantly increase patient adherence.
- In 2006, Merck & Co. received FDA approval for Januvia, a first-in-class dipeptidyl peptidase 4 (DPP-4) inhibitor that enhances the body's ability to lower

elevated blood sugar by increasing incretin levels, thereby inhibiting glucagon release and decreasing blood glucose levels. *Id.*

- In 2013, Janssen, a Johnson & Johnson subsidiary, secured FDA approval for Invokana, a first-in-class sodium/glucose cotransporter 2 (SGLT-2) inhibitor that prevents the kidneys from reabsorbing glucose back into the blood, allowing them to lower blood glucose levels and remove excess blood glucose through urination. *Id.*
- Also in 2013, Takeda Pharmaceuticals obtained FDA approval for Nesina, a new “DPP-4 inhibitor” that allows the pancreas to secrete insulin and better manage blood glucose levels. *See* Press Release, Takeda Receives FDA Approval for Three New Type 2 Diabetes Therapies, Takeda (Jan. 26, 2013), [http://www.takeda.us/newsroom/press\\_release\\_detail.aspx?year=2013&id=269](http://www.takeda.us/newsroom/press_release_detail.aspx?year=2013&id=269).
- In 2015, Novo Nordisk and Sanofi U.S. received FDA approval for Tresiba and Toujeo, respectively, which are ultra-long-acting insulins. These latest advances offer a more stable delivery of insulin and afford patients more flexibility in dosing. *See* Press Release, Novo Nordisk Receives FDA Approval for Tresiba® (insulin degludec injection) for Adults with Type 1 and Type 2 Diabetes, Novo Nordisk (Sept. 25, 2015), <http://press.novonordisk-us.com/2015-09-25-Novo-Nordisk-Receives-FDA-Approval-for-Tresiba-insulin-degludec-injection-for-Adults-with-Type-1-and-Type-2-Diabetes>; Press Release, Sanofi Receives FDA Approval of Once-Daily Basal Insulin Toujeo®, Sanofi (Feb. 25, 2015), <http://www.news.sanofi.us/2015-02-25-Sanofi-Receives-FDA-Approval-of-Once-Daily-Basal-Insulin-Toujeo>.

24. All told, FDA has approved 39 diabetes medicines since 2000. These 39 medicines are the product of decades of investment in research and development, including both successes and failures. As shown in the chart below, Plaintiffs’ members were responsible for developing the vast majority of these medicines.

Drug name	Type of drug	Manufacturer	Approval year
Adlyxin	Glucagon-like peptide	Sanofi U.S.	2016
Soliqua	Injectable combination therapy	Sanofi U.S.	2016
Xultophy	Injectable combination therapy	Novo Nordisk	2016
Basaglar	Long-acting insulin	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2015
Tresiba	Long-acting insulin	Novo Nordisk	2015

1	Ryzodeg	Combination insulin	Novo Nordisk	2015
2	Toujeo	Long-acting insulin	Sanofi U.S.	2015
3	Glyxambi	Combination SGLT-2	Eli Lilly and Boehringer	2015
4		inhibitor and DPP-4	Ingelheim	
5		inhibitor	Pharmaceuticals	
6	Trulicity	Glucagon-like peptide	Eli Lilly	2014
7	Invokamet	Combination SGLT-2	Janssen Pharmaceuticals	2014
8		inhibitor and biguanide		
9	Jardiance	SGLT-2 inhibitor	Boehringer Ingelheim	2014
10			Pharmaceuticals	
11	Afrezza Inhalation	Inhaled insulin	Sanofi U.S. and	2014
12	Powder		MannKind	
13	Tanzeum	Glucagon-like peptide	GlaxoSmithKline	2014
14	Xigduo XR	Combination	AstraZeneca	2014
15		Dapagliflozin and		
16		Metformin		
17	Farxiga	SGLT-2 inhibitor	AstraZeneca and Bristol-	2014
18			Myers Squibb	
19	Invokana	SGLT-2 inhibitor	Janssen Pharmaceuticals	2013
20	Nesina	DPP-4 inhibitor	Takeda Pharmaceuticals	2013
21	Janumet XR	DPP-4 inhibitor	Merck	2012
22	Jentadueto	Combination DPP-4	Eli Lilly and Boehringer	2012
23		inhibitor and biguanide	Ingelheim	
24			Pharmaceuticals	
25	Bydureon	Glucagon-like peptide	Amylin Pharmaceuticals	2012
26			and Alkermes PLC	
27	Juvisync	Combination statin and	Merck	2011
28				

	DPP-4 inhibitor		
Tradjenta	DPP-4 inhibitor	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2011
Kombiglyze XR	Combination DPP-4 inhibitor and biguanide	AstraZeneca and Bristol- Myers Squibb	2010
Victoza	Glucagon-like peptide	Novo Nordisk	2010
Onglyza	DPP-4 inhibitor	AstraZeneca and Bristol- Myers Squibb	2009
PrandiMet	Combination repaglinide and biguanide	Sciele Pharma and Novo Nordisk	2008
Janumet	DPP-4 inhibitor and Biguanide	Merck	2007
Januvia	DPP-4 inhibitor	Merck	2006
Duetact	Combination pioglitazone (directly targets insulin resistance) and sulfonylurea (increases amount of insulin produced by pancreas)	Takeda Pharmaceuticals	2006
ACTOplus met	Combination pioglitazone and biguanide	Takeda Pharmaceuticals	2005
Levemir	Long-acting insulin	Novo Nordisk	2005
Byetta	Glucagon-like peptide	Amylin Pharmaceuticals and Eli Lilly	2005

1	Symlin	Antihyperglycemic drug	Amylin Pharmaceuticals	2005
2	Apidra	Rapid-acting insulin	Aventis Pharmaceuticals	2004
3	Metaglip	Combination glipizide	Bristol-Myers Squibb	2002
4		and biguanide		
5	Avandamet	Combination	GlaxoSmithKline	2002
6		rosiglitazone and		
7		biguanide		
8	Novolog 70/30	Combination insulin	Novo Nordisk	2001
9	Lantus	Long-acting insulin	Aventis Pharmaceuticals	2000
10	Novolog	Rapid-acting insulin	Novo Nordisk	2000

11 See U.S. Food & Drug Admin., *FDA-Approved Diabetes Medicines*,

12 <https://www.fda.gov/forpatients/illness/diabetes/ucm408682.htm>.

13 25. Although there have been substantial advances in diabetes treatments, 1.7 million  
14 people are newly diagnosed with diabetes in the United States every year. Developing innovative  
15 new diabetes treatments and improving existing treatments requires continuing research. To that  
16 end, Plaintiffs' members invest billions each year. See, e.g., *2016 Biopharmaceutical Research*  
17 *Industry Profile*, PhRMA (April 2016), [phrma-](http://docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf)  
18 [docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf](http://docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf); David Thomas &  
19 Chad Wessel, *Emerging Therapeutic Company Investment and Deal Trends*, BIO (June 2017),  
20 [https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report](https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf)  
21 [%202007-2016.pdf](https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf). In 2016 alone, more than 170 medicines for diabetes and related conditions  
22 were in development. See *Medicines in Development for Diabetes: A Report on Diabetes and*  
23 *Related Conditions*, PhRMA (2016), [phrma-docs.phrma.org/files/dmfile/medicines-in-](http://phrma-docs.phrma.org/files/dmfile/medicines-in-development-report-diabetes.pdf)  
24 [development-report-diabetes.pdf](http://phrma-docs.phrma.org/files/dmfile/medicines-in-development-report-diabetes.pdf). The vast majority of drugs in development are potentially “first-  
25 in-class medicines” that offer a new approach to fighting the disease. See, e.g., Genia Long,  
26 Analysis Grp., *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development*  
27 (July 2017),  
28 [http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the\\_biopharmaceutical\\_pi](http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the_biopharmaceutical_pi)

1 peline\_report\_2017.pdf (noting that 69% of diabetes drugs in development were potential first-in-  
2 class medicines).

3 26. Among the approximately 170 medicines in the development pipeline, innovations  
4 include a potential first-in-class oral medicine that provides a new way for addressing Type 1 and  
5 Type 2 diabetes; a fully recombinant monoclonal antibody that treats patients with newly diagnosed  
6 Type 1 diabetes; and a medicine for diabetic nephropathy, damage to the kidneys from Type 1 or 2  
7 diabetes. Many new innovations improve the convenience of dosing and thus increase adherence,  
8 which helps patients with diabetes avoid emergency room visits and hospitalizations, and could  
9 save the healthcare system as much as \$8.3 billion annually. Ashish Jha et al., *Greater Adherence*  
10 *to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually*, 31  
11 *Health Aff.* 1836, 1836 (2012). For instance, oral versions of both insulin and GLP-1 agents are  
12 included in the development pipeline of several manufacturers, and these have the potential to  
13 significantly increase adherence to these much needed diabetes therapies for millions of patients in  
14 the U.S. New diabetes therapies have also had beneficial secondary effects, including weight loss, a  
15 reduction in cardiovascular disease, and improved renal function. *See* A. Kuhn et al., *Intensifying*  
16 *Treatment Beyond Monotherapy in Type 2 Diabetes Mellitus: Where Do Newer Therapies Fit?*,  
17 *Current Cardiology Reports* (March 2017).

18 27. Another emphasis in diabetes research and development is prevention: researchers at  
19 top universities, hospitals, and pharmaceutical companies devote significant time and resources to  
20 developing a vaccine that could teach the immune system not to react to and attack beta cells (the  
21 cells in the pancreas that produce insulin), thus preventing the onset of Type 1 diabetes. In fact, a  
22 trial at a Massachusetts General Hospital lab is aimed not only at preventing Type 1 diabetes, but  
23 also reversing it in patients who have had the disease for under 5 years. *See* Andrew Curry,  
24 *Pathways to a Type 1 Vaccine*, *Diabetes Forecast* (July 2016),  
25 <http://www.diabetesforecast.org/2016/jul-aug/vaccines.html>. Congress recognized the importance  
26 of prevention and adherence in the Affordable Care Act by establishing Diabetes Prevention  
27 Programs that offer lifestyle interventions for individuals at risk for diabetes, providing grants to  
28 states for prevention activity initiatives, and requiring the U.S. Department of Health and Human

1 Services to prepare a biannual diabetes report card that assesses quality of care indicators, including  
2 adherence, in each state.<sup>3</sup>

3 28. Many potentially first-in-class medicines may reach the market in the next few years.  
4 Sanofi and Lexicon are developing sotagliflozin, a SGLT-1/SGLT-2 dual inhibitor, which has  
5 shown promising Phase 2 and 3 results in Type 1 diabetes. The drug advanced into Phase 3 trials  
6 for Type 2 diabetes in March 2017. Merck and Pfizer are developing ertugliflozin, an SGLT-2  
7 inhibitor. Novo Nordisk is developing semaglutide, a GLP-1 receptor agonist, in a once-weekly,  
8 injected formulation and a once-daily oral formulation that are both active in lowering glucose and  
9 improving weight loss for Type 2 diabetes patients. And researchers at the University of North  
10 Carolina are working on developing glucose-responsive “smart” insulin, which is an injection that  
11 releases insulin only when glucose levels are too high. *See* John B. Buse & Mark Harmel, *New*  
12 *Diabetes Drugs in Development*, Medscape (Mar. 10, 2017),  
13 [www.medscape.com/viewarticle/876853](http://www.medscape.com/viewarticle/876853).

14 29. Meanwhile, costly and labor-intensive research continues to lay the groundwork for  
15 the next generation of treatments. Researchers at the Harvard Stem Cell Institute discovered a  
16 hormone that can stimulate insulin-secreting pancreatic cells to reproduce at up to 30 times the  
17 normal rate in mice. *See* Harvard Stem Cell Inst., *From Stem Cells to Billions of Human Insulin-*  
18 *Producing Cells* (Oct. 9, 2014), [https://hsci.harvard.edu/news/stem-cells-billions-human-insulin-](https://hsci.harvard.edu/news/stem-cells-billions-human-insulin-producing-cells)  
19 [producing-cells](https://hsci.harvard.edu/news/stem-cells-billions-human-insulin-producing-cells). Recreating this effect in diabetes patients could lead to the body’s natural  
20 regulation of insulin as the new cells produce insulin only as needed. *Id.*

21 30. The cost of developing these innovative diabetes medicines is staggering. On  
22 average, a manufacturer spends between 10 and 15 years—and \$2.6 billion—developing a new  
23 medicine. Developing diabetes medicines is particularly costly, as all new medicines must comply

---

24  
25 <sup>3</sup> *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 4108, 4202, 10407,  
26 10501, 124 Stat. 119 (2010); Nat’l Conference of State Legislatures, *Federal Health Reform*  
27 *Provisions Related to Diabetes* (May 2011),  
28 <http://www.ncsl.org/portals/1/documents/health/DiabetesinHR511.pdf>; Ctr. for Disease Control &  
Prevention, *Diabetes 2014 Report Card* (2014),  
<https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2014.pdf>.

1 with FDA's 2008 guidance requiring new diabetes medicines to undergo costly testing on  
2 cardiovascular risk that other new medicines need not undergo. These costs are all the more  
3 daunting given the very small success rate. Between 1988 and 2014, on average only 12% of drug  
4 candidates that entered clinical testing were approved for use. From May 27 to December 29, 2016,  
5 ten different advanced drug candidates for FDA approval in different drug product areas  
6 experienced setbacks ranging from manufacturing issues, FDA requirements to conduct new trials,  
7 failing Phase II or Phase III trials altogether, and patient deaths during trial. *See* Lisa M. Jarvis, *The*  
8 *Year in New Drugs*, Chem. & Eng'g News (Jan. 30, 2017),  
9 <http://cen.acs.org/content/cen/articles/95/i5/year-new-drugs.html>.

10 31. Even when a product reaches the market, there is no guarantee that the manufacturer  
11 will earn back the cost of research and development. In 2015, for example, FDA approved Afrezza,  
12 the only available inhalable insulin, manufactured by Sanofi in partnership with another  
13 pharmaceutical company. Press Release, Sanofi and MannKind Announce Afrezza®, the Only  
14 Inhaled Insulin, Now Available in the U.S., Sanofi (Feb. 3, 2015),  
15 [en.sanofi.com/images/38264\\_20150203\\_Afrezza\\_en.pdf](http://en.sanofi.com/images/38264_20150203_Afrezza_en.pdf). However, Afrezza appealed only to a  
16 small segment of the market and suffered from lackluster sales. Ed Silverman, *Breathe Deeply:*  
17 *Sanofi Will No Longer Market Afrezza Inhaled Insulin*, Stat (Jan. 6, 2016),  
18 <https://www.statnews.com/pharmalot/2016/01/05/insulin-sanofi-diabetes/>. It is unlikely that  
19 Afrezza will ever generate enough revenue to cover the cost of its development.

20 32. Pharmaceutical manufacturers can invest these billions of dollars each year in  
21 research and development only if they have an appropriate opportunity to recoup that investment  
22 through the sales of the small fraction of products that ultimately make it to market. Patents are  
23 especially important to the biotechnology industry, as they are often the sole or the most valuable  
24 asset of a start-up venture. *See* Charles W. Wessner, *Capitalizing on New Needs and New*  
25 *Opportunities: Government-Industry Partnerships in Biotechnology and Information Technologies*  
26 40 (2001), [https://www.ncbi.nlm.nih.gov/books/NBK208686/pdf/Bookshelf\\_NBK208686.pdf](https://www.ncbi.nlm.nih.gov/books/NBK208686/pdf/Bookshelf_NBK208686.pdf).

1           **Overview of Nevada Senate Bill 539**

2           33.     Like all states, Nevada over the past 20 years has seen a marked increase in the  
3     number of adults living with diabetes. In 1995, the estimated diabetes rate in Nevada was 4.7%.  
4     Today, an estimated 12.4% of Nevada’s adult population—281,355 people—have diabetes. An  
5     additional 787,000 people in Nevada, 38.5% of Nevada’s adult population, have pre-diabetes, with  
6     abnormally high blood glucose levels, but not at a level warranting a diabetes diagnosis.

7           34.     SB 265, introduced in the Nevada Senate in February 2017, “sought to lower the cost  
8     of certain essential diabetes drugs, such as insulin, by requiring companies that manufacture them  
9     [to] report the costs of producing and marketing the drug along with any rebates that they provide  
10    for the drugs.” Megan Messerly, *Sandoval Vetoes Major Pharmaceutical Transparency Legislation*  
11    *Citing Concerns Over “Nascent, Unproven and Disruptive” Changes*, Nev. Indep., (June 2, 2017,  
12    10:12 PM), [https://thenevadaindependent.com/article/sandoval-vetoes-major-pharmaceutical-](https://thenevadaindependent.com/article/sandoval-vetoes-major-pharmaceutical-transparency-legislation-citing-concerns-over-nascent-unproven-and-disruptive-changes)  
13    [transparency-legislation-citing-concerns-over-nascent-unproven-and-disruptive-changes](https://thenevadaindependent.com/article/sandoval-vetoes-major-pharmaceutical-transparency-legislation-citing-concerns-over-nascent-unproven-and-disruptive-changes). SB 539  
14    later incorporated many of SB 265’s provisions.

15          35.     As the legislative history of SB 265 shows, the State’s primary focus was on  
16    controlling the list prices of insulin and other patented diabetes medicines. At the very outset of the  
17    first Senate hearing on SB 265, its author cited a putative class action lawsuit charging insulin  
18    manufacturers with antitrust violations. *Hearing on S.B. 265 Before the Sen. Comm. on Health &*  
19    *Human Servs.*, 2017 Leg., 79th Sess. 33 (Nev. Mar. 29, 2017) (“Mar. 29 Mins.”) (statement of Sen.  
20    Yvanna D. Cancela). Proponents repeatedly criticized the prices of patented diabetes drugs as the  
21    main target of the bill, complaining that “competition has not led to lower [insulin] prices” and  
22    asserting that manufacturers would simply “tweak” insulin “to keep it under patent status, so the  
23    patent does not expire and become eligible for generic versions.” *Id.* at 36 (statement of Bobette  
24    Bond, Exec. Dir., Nev. Healthcare Policy, Unite Here Health); *see also id.* at 58–60 (discussion of  
25    patent protection). In reference to the patented diabetes medicines Janumet and Jardiance, one  
26    proponent argued that he “should not [have to] depend on [manufacturer] coupons on the Internet to  
27    offset the cost of diabetic medications.” *Id.* at 45 (statement of Ruben R. Murillo, Nev. State Educ.  
28    Ass’n). As another explained, the bill was designed to “hit directly to the root of the problem” of

1 high diabetes drug prices because “pharma will react accordingly with rebate dollars and trying to  
2 unwind what has been done” in order to “meet the terms of what [SB 265] puts out.” *Id.* at 37  
3 (testimony of Kevin Hooks, a managed care clinical pharmacist).

4 36. SB 265 sought to achieve these goals in several ways. First, SB 265 directed the  
5 Department to compile a list of prescription drugs “essential” for treating diabetes. SB 265, 2017  
6 Leg., 79th Sess. § 6 (Nev. 2017). It then compelled the manufacturers of those drugs to submit to  
7 the Department a report disclosing certain cost and pricing information for each of their essential  
8 diabetes drugs. *Id.* § 7(1). SB 265 excluded this cost and pricing information from the definition of  
9 “trade secret” under Nevada law, *id.* § 27.5(5), and it required the Department to compile and  
10 publish on its website a report concerning the prices of essential diabetes drugs and the effect of  
11 those prices on overall spending on health care in Nevada, *id.* § 7(2). SB 265 also required  
12 manufacturers to provide the Department with 90 days’ notice of any planned increase in the  
13 national list price, also known as the wholesale acquisition cost or “WAC,” of any essential diabetes  
14 drug. *Id.* § 8.

15 37. On May 16, 2017, a second bill targeting list price increases for diabetes drugs was  
16 introduced, SB 539. Originally a “complement” to SB 265, *see Hearing on S.B. 265 Before the Sen.*  
17 *Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 3 (Nev. May 26, 2017) (“May 26 Mins.”),  
18 SB 539 added requirements that “Pharmacy Benefit Managers” (PBMs)—intermediaries between  
19 manufacturers and payers—disclose, among other things, the amount of rebates received from  
20 manufacturers during the preceding calendar year. *See id.* at 5. The author of SB 539 justified the  
21 legislation on the ground that the “retail price [of prescription diabetes medicine] paid by patients is  
22 unpredictable and can escalate to unaffordable levels over short periods.” *Id.* at 3.

23 38. On May 19, 2017, the Nevada State Senate passed the first bill, SB 265. On May 25,  
24 2017, the Nevada State Assembly passed SB 265 and sent the bill to the Governor for approval.

25 39. On June 2, 2017, Nevada Governor Brian Sandoval vetoed SB 265. His explanation  
26 acknowledged that SB 265 was “well-intentioned,” but concluded that the bill “poses serious risks  
27 of unintended and potentially detrimental consequences for Nevada’s consumer patients, not the  
28 least of which is the possibility that access to critical care will become more expensive, more

1 restricted, and less equitable.” Veto Letter at 2. The bill, he wrote, “could cause more harm than  
2 good for Nevada’s families.” *Id.*

3 40. Governor Sandoval also concluded that “constitutional and other legal concerns”  
4 rendered the bill “problematic.” *Id.* at 3. He found the bill vulnerable to “challenge[s] under  
5 theories of federal preemption, the Fifth Amendment’s prohibition on uncompensated takings, and  
6 the Dormant Commerce Clause.” *Id.* at 2.

7 41. On June 5, 2017, just three days after Governor Sandoval vetoed SB 265, both the  
8 Nevada Senate and the Nevada State Assembly passed SB 539, which, as amended, included almost  
9 all the same provisions as SB 265. With respect to the drug pricing and reporting provisions, the  
10 primary exception was the 90-day notice period for increasing the WAC of an essential diabetes  
11 drug, to which Governor Sandoval had objected on the ground that it could lead to purchasers  
12 stockpiling drugs that they knew would have price increases in 90 days. *See id.*

13 42. Aside from the lack of the 90-day notice period, SB 539 essentially replicated  
14 SB 265. Even though SB 539 did not remedy the constitutional problems that Governor Sandoval  
15 had identified, he signed the bill on June 15, 2017.

16 43. Like SB 265, SB 539 directs the Department to compile, by February 1 of each year,  
17 “[a] list of prescription drugs . . . essential for treating diabetes.” SB 539 § 3.6(1). The Act does  
18 not define “essential,” but the list “must include, without limitation, all forms of insulin and  
19 biguanides marketed for sale in this State.” *Id.*<sup>4</sup>

20 44. In August 2017, the Nevada State Primary Care Office distributed a draft list of  
21 “essential diabetes drugs” with 46 major drug products, including Afrezza, Byetta, Duetact, Farxiga,  
22 Humulin, Invokana, Janumet, Januvia, Jardiance, Lantus, Nesina, Novolog, PrandiMet, Trulicity,  
23 and others. *See Exhibit C, Draft List of Essential Diabetes Drugs.*

24  
25 <sup>4</sup> Both insulin and biguanides seek to lower blood glucose levels. Insulin injections replace the  
26 insulin that the body would produce naturally in patients with diabetes who do not produce enough  
27 insulin. Biguanides, such as metformin, lower blood sugar by decreasing the amount of sugar  
28 produced by the liver, increasing the amount of sugar absorbed by muscle cells, and decreasing the  
body’s need for insulin. *See Biguanides (Metformin) for Prediabetes and Type 2 Diabetes*,  
WebMD, <http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes>.

1           45. Once the Department releases its final list of “essential” diabetes drugs, Section 3.8  
2 of the Act requires manufacturers of those drugs to “prepare and submit to the Department,” by  
3 April 1 of each year, a “report which must include”:

- 4           • “[t]he costs of producing the drug”;
- 5           • “marketing and advertising costs” associated with the drug;
- 6           • profit “earned from the drug” and “the percentage of the manufacturer’s total  
7 profit . . . attributable to the drug”;
- 8           • the amount spent on “patient prescription assistance program[s]”;
- 9           • “[t]he cost associated with coupons provided directly to consumers and for  
10 programs to assist consumers in paying copayments, and the cost to the  
11 manufacturer attributable to the redemption of those coupons and the use of those  
12 programs”;
- 13           • the “wholesale acquisition cost of the drug,” defined as “the manufacturer’s list  
14 price for a prescription drug to wholesalers or direct purchasers in the United  
15 States, not including any discounts, rebates or reductions in price, as reported in  
16 wholesale price guides or other publications of drug pricing date”;
- 17           • “[a] history of any increases in the wholesale acquisition cost of the drug over the  
18 5 years immediately preceding the date on which the report is submitted,  
19 including the amount of each such increase expressed as a percentage of the total  
20 wholesale acquisition cost of the drug, the month and year in which each increase  
21 became effective any explanation for the increase”;
- 22           • “[t]he aggregate amount of all rebates” in Nevada; and
- 23           • “[a]ny additional information prescribed by regulation . . . for the purpose of  
24 analyzing the cost of prescription drugs . . . on the list.”

25 *Id.* § 3.8.

26           46. Beyond these disclosures, any manufacturer that increases the WAC of an  
27 “essential” diabetes drug by more than the “Consumer Price Index, Medical Care Component”  
28 (“CPI”) during the preceding year, or by double the percentage increase in the CPI for Medical Care  
over the previous two years, must make additional disclosures pursuant to Section 4 of the Act.  
These disclosures include:

- “[a] list of each factor that has contributed to the increase”;
- “[t]he percentage of the total increase that is attributable to each factor”;
- “[a]n explanation of the role of each factor”; and
- “[a]ny other information prescribed by regulation.”

1 *Id.* §§ 3.6(2), 4.

2 47. For many manufacturers, the types of information that must be disclosed under  
3 Sections 3.8 and 4 are generally factors relevant to pricing decisions for *all* of their pharmaceutical  
4 products, not just the essential diabetes medicines they produce.

5 48. By tying these disclosures to the CPI for Medical Care, the Act penalizes those  
6 manufacturers whose diabetes drug prices exceed the index. This penalty is especially harsh, as the  
7 CPI for Medical Care includes the list prices of not only pharmaceutical products, but also  
8 professional and hospital services. Successful diabetes therapies improve the convenience and  
9 efficacy of treatment, which reduces doctor and hospital visits, which, in turn, lowers the costs  
10 factored into the CPI for Medical Care. Thus, the more successful a product is at reducing or  
11 preventing medical costs, the lower the prices the manufacturer can charge and still avoid the  
12 penalty of disclosing its confidential information. While the CPI for Medical Care is a useful  
13 benchmark for certain purposes relating to overall health care spending, it is not an appropriate  
14 measuring stick for imposing penalties on manufacturers for price increases on drug products.

15 49. Once manufacturers have submitted the disclosures required by Sections 3.8 and 4,  
16 the Department must, by June 1 of each year, “analyze the information submitted . . . and compile a  
17 report on the price of the prescription drugs that appear on the most current lists . . . , the reasons for  
18 any increases in those prices and the effect of those prices on overall spending on prescription drugs  
19 in this State.” *Id.* § 4.3.

20 50. The Department must post the report on its website, *id.* § 6(a)(5), “organized so that  
21 each individual . . . manufacturer . . . has its own separate entry,” *id.* § 6(b).

22 51. Critically, SB 539 does not prevent the Department from publishing the information,  
23 sharing it with other entities, or using it for other purposes such as the Department’s own rebate  
24 negotiations with manufacturers.

25 52. What is more, SB 539 expressly eliminates trade-secret protection for all information  
26 manufacturers must disclose concerning “essential” diabetes drugs. *Id.* § 4.3. Specifically, the Act  
27 alters the definition of “trade secret” in NRS 600A.030 to exclude “any information that a  
28

1 manufacturer is required to report pursuant to section 3.8 or 4 of [the Act], . . . to the extent that  
2 such information is required to be disclosed by [that] section[.]” *Id.* § 9(5)(b).<sup>5</sup>

3 53. Any manufacturer that fails to disclose the required information is subject to “an  
4 administrative penalty of not more than \$5,000 for each day of such failure.” *Id.* § 8(2).

5 54. The provisions of SB 539 relevant to this lawsuit “become effective upon passage  
6 and approval for the purpose of adopting regulations and performing any other administrative tasks  
7 that are necessary to carry out the provisions of this act and on October 1, 2017, for all other  
8 purposes.” *Id.* § 28(3). Thus, while the Department has until February 1, 2018 to publish its first  
9 list of “essential” diabetes drugs, it could publish the list as early as October 1, 2017, and, in fact,  
10 the Department has represented that it intends to publish the list on October 15, 2017.

11 ***SB 539’s Harm to Plaintiffs’ Members and Innovation of Diabetes Treatments***

12 55. SB 539, if implemented, will seriously harm Plaintiffs’ members, including the  
13 largest U.S. manufacturers of insulin and other diabetes medicines. Several of Plaintiffs’ members  
14 produce drugs that appear on the Department’s draft list of “essential” diabetes drugs. None of  
15 these companies is headquartered in Nevada.

16 56. For example, Eli Lilly and Company manufactures the diabetes drugs Basaglar (a  
17 long-acting insulin), Glyxambi (a combination drug of SGLT-2 inhibitor and DPP-4 inhibitor),  
18 Humalog, Humulin, Jardiance (a SGLT-2 inhibitor), Jentadueto (a combination DPP-4 inhibitor  
19 with metformin), Synjardy, Tradjenta (a DPP-4 inhibitor), and Trulicity (a glucagon-like peptide).  
20 The drugs Glyxambi, Jardiance, Jentadueto, Synjardy, Tradjenta, and Trulicity are patented.  
21 Patients administer Humalog and Humalin using a patented device. And the clinical testing for  
22 Basaglar and Trulicity is protected by test data exclusivity—*i.e.*, because this information is costly  
23 to produce, FDA maintains its confidentiality for a number of years to prevent competitors from  
24 benefitting at Lilly’s expense. Eli Lilly is headquartered in Indianapolis, Indiana and employs

---

25  
26 <sup>5</sup> By contrast, every other state to legislate on pharmaceutical price transparency has acknowledged  
27 the trade-secret status of the information to be disclosed, erecting safeguards to prevent its  
28 dissemination. *See, e.g.*, Vt. Stat. Ann., tit. 18, § 4635(e); H.B. 631, Gen. Assemb., 437th Sess. § 1,  
2-803(F) (Md. 2017).

1 approximately 12,600 people in Indiana. Indiana law confers trade-secret protection for the  
 2 confidential information concerning advertising, cost, marketing, pricing, and production that SB  
 3 539 requires Eli Lilly to disclose. *See Hydraulic Exch. & Repair, Inc. v. KM Specialty Pumps, Inc.*,  
 4 690 N.E.2d 782, 786 (Ind. Ct. App. 1998) (holding that customer and pricing information, including  
 5 compilations of profits and sales, were trade secrets under Indiana Uniform Trade Secrets Act);  
 6 *Ackerman v. Kimball Int'l, Inc.*, 634 N.E.2d 778, 783 (Ind. Ct. App. 1994) (affirming trial court  
 7 conclusion that pricing information was a trade secret).

8 57. Johnson & Johnson manufactures the diabetes drugs Invokamet (a combination  
 9 SGLT-2 inhibitor with metformin), Invokamet XR (extended release), and Invokana (an SGLT-2  
 10 inhibitor). The drugs Invokamet, Invokamet XR, and Invokana are patented. Johnson & Johnson is  
 11 headquartered in New Brunswick, New Jersey and employs approximately 9,300 people in New  
 12 Jersey. New Jersey law confers trade-secret protection for the confidential information that SB 539  
 13 requires Johnson & Johnson to disclose. *See Commc'ns Workers of Am. v. Rousseau*, 9 A.3d 1064,  
 14 1076 (N.J. Super. Ct. App. Div. 2010) ("A trade secret may also include pricing and marketing  
 15 techniques."); *Lamorte Burns & Co. v. Walters*, 770 A.2d 1158, 1166 (N.J. 2001) (citing with  
 16 approval treatise stating that "information relating to customers, merchandising, costs, and pricing  
 17 may be considered trade secrets" (citing 1 Roger M. Milgrim, *Milgrim on Trade Secrets* § 2.09  
 18 (1995))).

19 58. Merck Sharp & Dohme Corp. manufactures the diabetes drugs Januvia (sitagliptin)  
 20 (a dipeptidyl peptidase 4 (DPP-4) inhibitor), Janumet (sitagliptin and metformin HCl) and Janumet  
 21 XR (sitagliptin and metformin HCl extended release). The drugs Januvia, Janumet, and Janumet  
 22 XR are patented. Merck is headquartered in Kenilworth, New Jersey and employs approximately  
 23 5,200 people in New Jersey. As noted, New Jersey law confers trade-secret protection for the  
 24 confidential information that SB 539 requires Merck to disclose.

25 59. Novo Nordisk Inc. markets, sells, and distributes the diabetes drugs Levemir (insulin  
 26 detemir, a long-acting recombinant human insulin analog), Victoza (liraglutide, a long-acting,  
 27 acylated glucagon-like peptide-1 (GLP-1) analog), Tresiba (insulin degludec, an ultralong-acting  
 28 basal human insulin analog), Ryzodeg 70/30 (insulin degludec and insulin aspart injection, a

1 combination of a long-acting basal human insulin analog and a fast-acting human insulin analog),  
 2 and Xultophy 100/3.6 (insulin degludec and liraglutide injection, a combination of an ultralong-  
 3 acting basal human insulin analog and a long-acting, acylated glucagon-like peptide-1 (GLP-1)  
 4 analog). The drugs Levemir, Victoza, Tresiba, Ryzodeg 70/30 and Xultophy 100/3.6 have U.S.  
 5 patent protection. Novo Nordisk Inc. is headquartered in Plainsboro, New Jersey. As noted, New  
 6 Jersey law confers trade-secret protection for the confidential information that SB 539 requires  
 7 Novo Nordisk to disclose.

8 60. Sanofi U.S. markets, sells, and distributes the diabetes drugs Lantus (insulin  
 9 glargine, a long acting human insulin analog), Apidra (insulin glulisine, a fast acting, mealtime  
 10 insulin), Toujeo (insulin glargine, a long acting human insulin analog), Adlyxin (lixisenatide, a  
 11 GLP-1 receptor agonist) and Soliqua 100/33 (insulin glargine and lixisenatide injection, a  
 12 combination of long acting insulin and GLP-1). The drugs Lantus, Apidra, Toujeo, Adlyxin and  
 13 Soliqua 100/33 are patented. Sanofi U.S. is headquartered in Bridgewater, New Jersey and employs  
 14 approximately 2,500 people in New Jersey. As noted, New Jersey law confers trade-secret  
 15 protection for the confidential information that SB 539 requires Sanofi to disclose.

16 61. Section 3.8 of SB 539 requires these manufacturers and other PhRMA and BIO  
 17 members that manufacture “essential” diabetes medicines to report advertising, cost, marketing,  
 18 pricing, and production information related to those drugs to the Department. The required  
 19 disclosures include information that qualifies as trade secret under federal law and the law of every  
 20 state—including Nevada until SB 539 takes effect.

21 62. These companies face additional reporting requirements under Section 4 of SB 539 if  
 22 the list prices for the diabetes drugs they manufacture increased during the prior year by a  
 23 percentage greater than the CPI for Medical Care, or increased over the last two years by a  
 24 percentage more than twice the two-year increase for that index. The additional disclosures  
 25 required under Section 4 of the Act include information that qualifies as a trade secret under federal  
 26 law and the law of every state—including Nevada until SB 539 takes effect.

27 63. Plaintiffs’ members zealously guard the secrecy and confidentiality of the trade-  
 28 secret information that SB 539 requires them to disclose. Among other things, Plaintiffs’ members

1 require their employees to sign confidentiality agreements and nondisclosure agreements requiring  
2 them to hold this information in confidence. These companies also use a variety of security  
3 measures to ensure that such information is kept secret, including video camera monitoring,  
4 restricting access to their facilities, limiting computer system access, marking documents that reflect  
5 such information as confidential or proprietary, training their employees on the importance of not  
6 disclosing such information, adopting policies that prohibit employees from removing such  
7 information from company property, and imposing other internal controls.

8         64. Plaintiffs' members expend significant resources determining how to allocate their  
9 resources and set prices for their products. This information would be extremely valuable to  
10 competitors, who could use the information to allocate their own resources and set their own prices  
11 without expending the same level of resources. As a consequence, the companies that lost trade-  
12 secret protection would suffer serious competitive harm. This harm would undermine competition  
13 involving non-diabetes products as well, because manufacturers consider similar factors  
14 manufacturers in setting prices for non-diabetes products.

15         65. Similarly, third-party payers who learn how a manufacturer prices its diabetes drugs  
16 would gain an advantage over the manufacturer in purchase or rebate negotiations for all of the  
17 manufacturer's products.

18         66. The economic harm from SB 539 will spread to the entire Nation. Because the  
19 WAC is a national list price, SB 539's effective cap on a drug's WAC will apply throughout the  
20 country. And because drug prices and the way manufacturers set them generally apply nationally,  
21 the information disclosed under SB 539 will affect a company's negotiations and competitive  
22 positioning nationwide. Similarly, because trade-secret protection is moot in every state once the  
23 information becomes public in Nevada, the impact of SB 539 will extend across the Nation.

24         67. The competitive harm arising from SB 539's punitive and coercive effects will  
25 undermine the incentives that trade secret and patent law provides for Plaintiffs' members to invest  
26 in developing innovative diabetes medicines. Absent judicial intervention, SB 539 could force  
27 innovators into the unfortunate position of having to review and revise their research and  
28 development priorities for diabetes products, including projects underway.

## SB 539'S CONSTITUTIONAL DEFECTS

### *The Constitution Vests Congress With Sole Authority To Establish Patent Policy*

68. The Framers of the Constitution understood Congress's paramount role in setting national patent policy. Article I vests Congress with the power to "secur[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. The stated objective of this clause is to "promote the Progress of Science and useful Arts." *Id.* As James Madison observed in *The Federalist*:

The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals. The States cannot separately make effectual provisions for either of the cases, and most of them have anticipated the decision of this point, by laws passed at the instance of Congress.

*The Federalist* No. 43 (James Madison).

69. "From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). The patent laws achieve this balance first by granting an inventor the exclusive right to make, use, and sell its patented invention for a limited period of time. 35 U.S.C. § 154. Then, once the exclusivity period expires, others may enter the market and compete with the patent holder, driving down the cost of the patented product and, in turn, stimulating further innovation in the search for greater returns. Critically here, Congress has long recognized that "the right to exclude others from making, using, or selling an invention . . . enable[s] innovators to obtain greater profits than could have been obtained if direct competition existed," and that "[t]hese profits act as incentives for innovative activities." H.R. Rep. No. 98-857(I), at 17 (June 21, 1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 (Committee on Energy and Commerce).

70. During the exclusivity period, a patent holder may set the price for its product in a manner that takes into account the patent holder's ability to preclude others from marketing an infringing product. The United States Court of Appeals for the Federal Circuit has described the

1 increased return on innovation investment due to the patent holder's legal monopoly as the "carrot"  
 2 that incentivizes would-be inventors to expend the substantial resources and to take the significant  
 3 research and development risks required to invent a new product. *King Instruments Corp. v.*  
 4 *Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). As the Federal Circuit has noted, "the only limitation on  
 5 the size of the carrot should be the dictates of the marketplace." *Id.*

6 71. Patent protection is particularly necessary to promote the research and development  
 7 of pharmaceutical products because it is extraordinarily difficult, costly, and rare to discover a  
 8 successful new drug. By one estimate focusing on the most prolific developers of new drugs, "95%  
 9 of the experimental medicines that are studied in humans fail to be both effective and safe. . . .  
 10 [B]ecause so many drugs fail, large pharmaceutical companies . . . spend \$5 billion per new  
 11 medicine." Matthew Herper, *The Cost of Creating A New Drug Now \$5 Billion, Pushing Big*  
 12 *Pharma To Change*, Forbes.com (Aug. 11, 2013, 11:10 AM),  
 13 [http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-](http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine)  
 14 [drugs-is-shaping-the-future-of-medicine](http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine). Even drugs that are ultimately approved cost billions of  
 15 dollars to research and develop. See Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug*  
 16 *Development*, Chem. & Eng'g News (Nov. 20, 2014),  
 17 <http://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html> (study found that  
 18 "developing a prescription drug that gains market approval [costs] \$2.6 billion, a 145% increase"  
 19 from 2003).

20 72. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration  
 21 Act of 1984, commonly known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585  
 22 (1984). In light of the unique economic challenges to pharmaceutical research and development,  
 23 the Hatch-Waxman Act extended the patent term for pharmaceuticals to "create a significant, new  
 24 incentive which would result in increased expenditures for research and development, and  
 25 ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18; see also *Biotech. Indus. Org.*  
 26 *v. District of Columbia* ("BIO"), 496 F.3d 1362, 1373 (Fed. Cir. 2007). President Reagan reiterated  
 27 this goal when he signed the bill into law: "The bill will promote medical breakthroughs and drug  
 28 innovation by granting drug companies up to 5 more years of patent protection for new drugs. And

1 this extension will help compensate for the years of patent life lost due to the time-consuming, but  
2 essential, testing required by the Food and Drug Administration.” Presidential Statement on  
3 Signing S. 1538 Into Law, 20 Weekly Comp. Pres. Doc. 1359 (Sept. 24, 1984).

4 73. Balancing consumer access to affordable medication against the critical need for  
5 sufficient economic incentives to invest in innovation, the Hatch-Waxman Act allows other  
6 manufacturers to sell generic versions of an innovator’s drug after the period of patent exclusivity  
7 expires. This carefully crafted framework provides substantial incentives for innovators to invest in  
8 research and development of new life-saving and life-enhancing treatments that will benefit patients  
9 while also “get[ting] generic drugs into the hands of patients at reasonable prices—fast.” *Andrx*  
10 *Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Lab.,*  
11 *Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

12 74. Congress, moreover, has bestowed patent protection on “[w]hoever invents or  
13 discovers any new and useful process, machine, manufacture, or composition of matter, or any new  
14 and useful improvement thereof.” 35 U.S.C. § 101. Thus, the federal patent system, including the  
15 Hatch-Waxman Act, encourages not only the discovery of new pharmacological compounds, but  
16 also new methods of manufacturing or improving the effectiveness of existing drugs.

17 75. Under the Supremacy Clause of the United States Constitution, federal statutes are  
18 “the supreme Law of the Land.” U.S. Const. art. IV, cl. 2. And under settled principles of federal  
19 “conflict” preemption, no state law may “stand[] as an obstacle to the accomplishment and  
20 execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U.S. 52, 67  
21 (1941).

22 76. State laws penalizing patent holders for exercising the right to set prices that the  
23 patent affords and coercing them to forgo those rights “stand as an obstacle to the federal patent  
24 law’s balance of objectives as established by Congress” and thus are invalid under the Supremacy  
25 Clause. *BIO*, 496 F.3d at 1374. In *BIO*, the Federal Circuit struck down a District of Columbia  
26 statute that prohibited pharmaceutical manufacturers from selling or supplying a “patented  
27 prescription drug that results in the prescription drug being sold in the District for an excessive  
28 price.” *Id.* at 1365. The court held that the statute was a “clear attempt to restrain . . . excessive

1 [drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to  
2 District drug consumers.” *Id.* at 1374. Because Congress—and Congress alone—is the  
3 “promulgator of patent policy,” federal law preempted the District’s attempt to “re-balance the  
4 statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* at  
5 1373–74.

6 77. Just like the District of Columbia statute invalidated in *BIO*, SB 539 “attempt[s] to  
7 restrain . . . excessive [essential diabetes drug] prices, in effect diminishing the reward to patentees  
8 in order to provide greater benefit to [Nevada] drug consumers.” *Id.* at 1374. In purpose and effect,  
9 the Act punishes manufacturers for the price of their “essential” diabetes drugs as well as for list  
10 price increases by more than the “percentage increase in the Consumer Price Index, Medical Care  
11 Component during the immediately preceding calendar year; or . . . [t]wice the percentage increase  
12 in the Consumer Price Index, Medical Care Component during the immediately preceding 2  
13 calendar years.” SB 539 §§ 3.6(2), 4. If an essential diabetes drug’s list price increases by more  
14 than these benchmarks, then the Act compels the manufacturer to report to the Department  
15 additional confidential, competitively sensitive, proprietary information about that price increase,  
16 including a list of “factors” that contributed to the increase and an “explanation” of the role of each  
17 factor. *Id.* § 4. The Act also strips trade-secret protection for that information. *Id.* § 9. The only  
18 way a manufacturer can avoid forfeiting trade-secret protection for the “factors” of a price increase  
19 is by limiting its list prices to the Act’s effective cap. SB 539 thus restrains patent holders from  
20 setting list prices in a manner that the federal patent laws secure in order to incentivize innovation.

21 78. Further, the Act impermissibly burdens the federal patent rights of diabetes drug  
22 manufacturers by requiring disclosure of trade secrets associated with these patented products—and  
23 hence it eliminates trade-secret protection in retaliation for pricing diabetes drugs as the patent laws  
24 specifically allow. *See BIO*, 496 F.3d at 1374 (holding invalid District of Columbia law that had  
25 the effect of “diminishing the reward” federal law grants to patentees). The mandatory disclosures  
26 chill the exercise of patent rights by penalizing past exercises and forcing manufacturers either to  
27 charge less than the patent laws permit or to furnish their proprietary information to third-party  
28 payers and competitors and thereby suffer significant economic loss.

79. As a result of SB 539, innovators cannot raise list prices without being stripped of valuable trade-secret protection for their confidential, proprietary information. SB 539 thus interferes with the objectives of the patent laws by undermining, if not defeating altogether, affected manufacturers' ability to recover the enormous up-front costs to research and develop diabetes medicines.

80. The Act's burdens on federal patent rights will discourage research and development of new diabetes drugs—a chilling of innovation itself. *See, e.g., Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1351–53 (Fed. Cir. 2014) (Newman, J., dissenting) (quoting *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757 (2014)) (burdening patentees who file infringement claims with threat of antitrust liability chills innovation); *In re Microsoft Corp. Antitrust Litig.*, 274 F. Supp. 2d 743, 745 (D. Md. 2003) (finding that “to require one company to provide its intellectual property to a competitor would significantly chill innovation”).

81. The Nevada Legislature jettisoned concerns that “transparency in prescription drug pricing will stifle innovation.” Mar. 29 Mins. at 34. They chose to elevate other, insular considerations over the law's interference with federal innovation incentives. But whether the Nevada Legislature's judgment is right or wrong is beside the point. The policy choice of whether the benefits of innovation in the treatment of diabetes justify the prices of existing drugs is reserved exclusively to the United States Congress, not to the State of Nevada. *See BIO*, 496 F.3d at 1374; H.R. Rep. 98-857(I), at 17–18. Congress exercised that choice through the patent laws. Nevada cannot unilaterally displace it.

#### ***SB 539 Conflicts with Federal Trade-Secret Law***

82. Federal and state trade-secret laws play a similarly important role in fueling the American economy. Legal protection for trade secrets “encourage[s] invention in areas where patent law does not reach, and . . . prompt[s] the independent innovator to proceed with the discovery and exploitation of his invention.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 485 (1974). “Competition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention.” *Id.*

83. Every state in the nation protects trade secrets. Initially, the common law provided safeguards “for the advantage of the public, to encourage and protect invention and commercial enterprise.” *Peabody v. Norfolk*, 98 Mass. 452, 457 (1868). “Traditionally defined as relating to technical matters in the production of goods, trade secrets now encompass non-technical aspects of a business including, customer lists, price codes economic studies, costs reports, customer tracking and marketing strategies.” *First Mfg. Co. v. Young*, 3 N.Y.S.3d 284, at \*3 (Sup. Ct. 2014).

84. In evaluating whether information is a trade secret under the common law, courts consider, among other things, “[1] the extent of measures taken by the employer to guard the secrecy of the information; [2] the value of the information to the employer and to his competitors; [3] the amount of effort or money expended by the employer in developing the information; and [4] the ease or difficulty with which the information could be properly acquired or duplicated by others.” *Jet Spray Cooler, Inc. v. Crampton*, 385 N.E.2d 1349, 1355 n.9 (Mass. 1979) (citation omitted); *Frantz v. Johnson*, 999 P.2d 351, 358–59 (Nev. 2000) (“Factors to be considered include: (1) the extent to which the information is known outside of the business and the ease or difficulty with which the acquired information could be properly acquired by others; (2) whether the information was confidential or secret; (3) the extent and manner in which the [company] guarded the secrecy of the information; and (4) . . . whether this information is known by the [company’s] competitors.”).

85. Forty-eight states, including Nevada, have adopted, with slight variations in some states, the Uniform Trade Secrets Act (“UTSA”), which “codifie[d] the common law elements of misappropriation of confidential information.” *Frantz*, 999 P.2d at 357–58. The UTSA defines a “trade secret” as:

[I]nformation, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.”

UTSA, § 1(4).

86. Courts in UTSA jurisdictions routinely hold that confidential information concerning advertising, cost, marketing, pricing, and production constitutes a trade secret. *See, e.g., Finkel v. Cashman Prof'l, Inc.*, 270 P.3d 1259, 1263 (Nev. 2012) (holding that “confidential pricing structures and marketing plans” were trade secrets); *Frantz*, 999 P.2d at 359 (holding pricing information was trade secret because “its secrecy was guarded, and it was not readily available to others because the plastic gaming card industry is highly specialized”); *Aerodynamics Inc. v. Ceasars Entm’t Operating Co.*, No. 2:15-CV-01344, 2015 WL 5679843, at \*8 (D. Nev. Sept. 24, 2015) (a company’s “confidential pricing information, . . . marketing strategies, . . . exact pricing for [certain] bid[s], payment terms, and credits and discounts provided” are trade secrets); *accord In re Dana Corp.*, 574 F.3d 129, 152 (2d Cir. 2009) (recognizing that under New York law, “[c]onfidential proprietary data relating to pricing, costs, systems, and methods are protected by trade secret law”); *S.I. Handling Sys., Inc. v. Heisley*, 753 F.2d 1244, 1260 (3d Cir.1985) (same under Pennsylvania law); *Burbank Grease Servs., LLC v. Sokolowski*, 693 N.W.2d 89, 96 (Wis. App. 2005) (“Generally, it appears that when prices are based on complicated or unique formulas that the customers do not know about, courts conclude the information meets the standard embodied in [the UTSA].”), *aff’d in part, rev’d in part*, 717 N.W.2d 781 (Wis. 2006); *Whyte v. Schlage Lock Co.*, 101 Cal. App. 4th 1443, 1455 (2002) (“[P]ricing, profit margins, costs of production, pricing concessions, promotional discounts, advertising allowances, volume rebates, marketing concessions, payment terms and rebate incentives” have independent economic value as trade secrets).

87. In 2016, Congress enacted the Defend Trade Secrets Act (“DTSA”), creating for the first time a federal private right of action for misappropriation of trade secrets “related to a product or service used in, or intended for use in, interstate or foreign commerce.” Pub. L. No. 114-153, 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)).

88. Congress enacted the DTSA because “trade secrets are increasingly becoming the foundation of businesses across the country, with one estimate placing the value of trade secrets in the United States at \$5 trillion. . . . With so much at stake, it is absolutely vital . . . [to] include strong protections against theft of trade secrets.” 162 Cong. Rec. H2028-01, H2033 (Apr. 27, 2016)

(comments of Rep. Nadler). “By improving trade secret protection,” Congress intended the DTSA to “incentivize future innovation while protecting and encouraging the creation of American jobs.” S. Rep. No. 114-220, at 3 (2016).

89. Although every state protects confidential and proprietary advertising, cost, marketing, pricing, and production information, Congress intended the DTSA to provide businesses engaged in interstate commerce with a uniform remedy for misappropriation. Congress expressed concerns that “state laws vary in a number of ways and contain built-in limitations that make them not wholly effective in a national and global economy.” H.R. Rep. No. 114-529, at 4 (Apr. 26, 2016) (Committee on the Judiciary). Congress acknowledged that “trade secret cases often require swift action by courts across state lines to preserve evidence.” *Id.* “[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist.” 162 Cong. Rec. H2034 (comments of Rep. Jackson Lee). Thus, the DTSA allows businesses “to move quickly to Federal court . . . to stop trade secrets from winding up being disseminated and losing their value.” H.R. Rep. No. 114-529, at 6; *accord* S. Rep. No. 114-220, at 3. The primary goal was to create “remedies that, first, halt the misappropriator’s use and dissemination of the . . . trade secret.” H.R. Rep. No. 114-529, at 13.

90. Congress likewise modeled the DTSA definition of “trade secret” on the UTSA, as did Nevada—that is, until SB 539. *Compare* UTSA § 1, *with* 18 U.S.C. § 1839(4), *and* Nev. Rev. Stat. § 600A.030(5) (1999); *see also* H.R. Rep. 114-529, at 14 (“[T]he Committee does not intend for the definition of a trade secret to be meaningfully different from the scope of that definition as understood by courts in States that have adopted the UTSA.”). Reflecting Congress’s intention to provide a uniform remedy, the DTSA makes information related to advertising, cost, marketing, pricing, and production a protectable trade secret, just as it is in UTSA jurisdictions. *See supra*, ¶ 86.

91. SB 539 compels manufacturers to disclose to the Department confidential and proprietary advertising, cost, marketing, pricing, and production information that derives independent value from not being generally known to third parties and competitors. This valuable

1 information constitutes a trade secret under the DTSA—and also under Nevada law until SB 539  
2 takes effect.

3 92. Further, the Act amends Nevada’s trade-secret statute expressly to eliminate trade-  
4 secret protection for all information “that a manufacturer is required to report” to the Department.  
5 SB 539 § 9. Thus, the manufacturer loses trade-secret protection the moment the Department issues  
6 its annual list of “essential” diabetes drugs, even before the manufacturer actually turns the  
7 information over to the State.

8 93. Furthermore, the Act places no restriction on how the Department may use or  
9 disseminate the information disclosed. To the contrary, SB 539 affirmatively requires the  
10 Department to publish a report on its website that identifies the information belonging to each  
11 manufacturer. *Id.* § 6(a)(5), (b). Once published on the Internet or otherwise publicly disseminated  
12 under the authority of SB 539, the information no longer constitutes a trade secret under either the  
13 UTSA or the DTSA. *See, e.g.*, 18 U.S.C. § 1839. As a practical matter, even if there were some  
14 residual trade-secret protection from the laws of other states, it would be ineffective once the  
15 previously protected information is in the public domain for all to see.

16 94. The destruction of trade-secret protection in Nevada will thwart the ability of  
17 manufacturers subject to the Act’s disclosure requirements to sue for misappropriation in any  
18 jurisdiction, including in federal court under the DTSA.

19 95. In effect, SB 539 alters the operation of the DTSA—and the laws of every other  
20 jurisdiction in the nation—to eliminate trade-secret protection for confidential advertising, cost,  
21 marketing, pricing, and production information associated with diabetes drugs. This, in turn,  
22 undercuts both of Congress’s goals in enacting the DTSA—to “incentivize future innovation while  
23 protecting and encouraging the creation of American jobs.” S. Rep. No. 114-220, at 3.

24 96. Thus, SB 539 “stands as an obstacle to the accomplishment and execution of the full  
25 purposes and objectives of Congress.” *Hines*, 312 U.S. at 67. Indeed, the Act jeopardizes the \$5  
26 trillion worth of trade secrets that Congress enacted the DTSA to protect.  
27  
28

***SB 539's Uncompensated Elimination of Trade-Secret Protection for Valuable Information Violates the Fifth Amendment Takings Clause***

97. The Fifth Amendment provides that “private property [shall not] be taken for public use, without just compensation.” U.S. Const. amend. V. This proscription applies to the states through the Fourteenth Amendment.

98. Government regulation of private property can constitute a taking. *See Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992). “Private property” includes not only tangible property, but also intangible property, such as trade secrets. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984). A state’s “failure to provide adequate protection to assure [a trade secret’s] confidentiality, when disclosure is compelled . . . , can amount to an unconstitutional taking of property by destroying [the trade secret], or by exposing it to the risk of destruction by public disclosure or by disclosure to competitors.” *St. Michael’s Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981) (alteration omitted) (quoting *Wearly v. FTC*, 462 F. Supp. 589, 598 (D.N.J. 1978)).

99. There are two kinds of regulatory takings: (1) categorical and (2) noncategorical. *See Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005). A categorical taking occurs where a state statute “denies all economically beneficial or productive use” of property. *Lucas*, 505 U.S. at 1015. By contrast, a noncategorical taking may occur where a regulation “fall[s] short of eliminating *all* economically beneficial use,” *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001), yet still goes “too far” for purposes of the Fifth Amendment, *Lucas*, 505 U.S. at 1014–15 (quoting *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)). To determine whether a noncategorical regulatory taking goes “too far,” courts apply the three-part test articulated in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978), and its progeny. That test assesses: “[1] the character of the governmental action, [2] its economic impact, and [3] its interference with reasonable investment-backed expectations.” *Ruckelshaus*, 467 U.S. at 1005.

100. SB 539 works as a categorical taking of property rights. “With respect to a trade secret, the right to exclude others is central to the very definition of the property interest.” *Id.* at 1011. SB 539 does not merely “expos[e] [manufacturers’ trade secrets] to the *risk* of destruction by

1 public disclosure or by disclosure to competitors.” *St. Michael’s*, 643 F.2d at 1374 (emphasis  
2 added). Rather, the Act strips trade-secret protection and *mandates* public disclosure of  
3 manufacturers’ confidential advertising, cost, marketing, pricing, and production information on the  
4 Department’s website, *see* SB 539 §§ 6(a)(5), 9, thus destroying for all time any trade-secret  
5 protection for the information disclosed. The normal operation of the Act ensures that  
6 manufacturers lose any claim of confidentiality, the *sine qua non* of what makes a trade secret  
7 valuable. *See Ruckelshaus*, 467 U.S. at 1011–12; *see also* 162 Cong. Rec. H2034 (“[U]nlike  
8 patents, once this information is disclosed it instantly loses its value and the property right itself  
9 ceases to exist.” (comments of Rep. Jackson Lee in support of DTSA)).

10 101. In the alternative, even if SB 539 did not work a categorical taking by destroying  
11 manufacturers’ property interests in their trade secrets, the Act would still constitute an  
12 impermissible regulatory taking under the three-part test articulated in *Penn Central*.

13 102. First, the “character” of Nevada’s legislative action weighs heavily against sustaining  
14 the Act. It prevents pharmaceutical manufacturers from “exclud[ing] others from their trade  
15 secrets,” causing the trade secrets to “lose all value.” *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41  
16 (1st Cir. 2002) (en banc) (citing this aspect of state disclosure statute’s “character” to show a  
17 regulatory taking). “Therefore, if the [pharmaceutical manufacturers] comply with the requirements  
18 of [SB 539], their property right will be extinguished.” *Id.* at 42. “[T]his is precisely what the  
19 Takings Clause is designed to prevent.” *Id.* at 43.

20 103. Second, eliminating trade-secret protection for confidential advertising, cost,  
21 marketing, pricing, and production information relating to diabetes drugs will have a devastating  
22 “economic impact” not only on manufacturers subject to the disclosure requirements, but also on  
23 the market for diabetes drugs. *See Penn Cent.*, 438 U.S. at 124. Manufacturers forced to disclose  
24 such information will be at a severe disadvantage against competing diabetes-drug manufacturers  
25 not subject to the Act. These competitors will be able to obtain the information that Sections 3.8  
26 and 4 of the Act require to be disclosed, and will gain a competitive advantage by knowing how the  
27 manufacturer allocates its resources and sets its prices. Because manufacturers consider similar  
28 factors in setting prices for non-diabetes products, disclosure of pricing information under SB 539

1 will also impair the ability of the affected manufacturers to compete with regard to non-diabetes  
2 products. Similarly, the Act disadvantages affected manufacturers in their dealings with third-party  
3 payers, who will be able to use the manufacturer's pricing information against it in negotiations.

4 104. These adverse effects are not confined to Nevada, but rather will be nationwide. A  
5 trade secret published in Nevada may be used in New York, Ohio, Florida, or any other state, as a  
6 trade secret must in fact be "secret" to be protected. *See, e.g.*, UTSA § 1(4) (restricting definition of  
7 "trade secret" to information "not . . . generally known" or "readily ascertainable by proper  
8 means"); 18 U.S.C. § 1839(3) (same). Thus, losing trade-secret protection anywhere means losing  
9 it everywhere. This substantial competitive harm increases the penalty for Plaintiffs' members who  
10 exercise their patent rights to set prices on their diabetes products, thereby diminishing the incentive  
11 to invest in the development of diabetes drugs. *See supra* ¶¶ 77–81.

12 105. Third, manufacturers investing in diabetes treatments had the reasonable  
13 "investment-backed expectation" that their confidential and proprietary information would remain  
14 secret. *See Penn Cent.*, 438 U.S. at 124. For many years Nevada has treated confidential  
15 advertising, cost, marketing, pricing, and production information as entitled to trade-secret  
16 protection without any exception for manufacturers of diabetes drugs, as has virtually every other  
17 state. *See, e.g.*, Nev. Rev. Stat § 600A.030 (1987); *Finkel*, 270 P.3d at 1263; *Frantz*, 999 P.2d at  
18 359. Manufacturers thus had reasonable investment-backed expectations in the secrecy of this  
19 information, because of longstanding trade-secret protection and because no state has ever required  
20 such intrusive disclosures. *See Reilly*, 312 F.3d at 40. Manufacturers did not expect and could not  
21 reasonably have expected the economic impact detailed above, or the erosion of the anticipated  
22 returns on their investments in researching, developing, and marketing their diabetes drugs, in  
23 reliance on the protection of their valuable trade secrets.

24 106. Thus, under any Takings analysis, SB 539's disclosure requirements destroy  
25 valuable trade secrets related to diabetes drugs without any compensation, let alone just  
26 compensation, in violation of the Takings Clause. U.S. Const. amends. V, XIV.  
27  
28

***SB 539 Violates the Commerce Clause by Overriding the Laws of Every Other State***

107. The Constitution grants Congress the power “[t]o regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. The Commerce Clause “reflect[s] a central concern of the Framers . . . : the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.” *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979).

108. Thus, the Supreme Court has “long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute.” *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This is the “so-called ‘dormant’ aspect of the Commerce Clause.” *Id.*

109. When a state “directly regulates” interstate commerce, the Supreme Court has “generally struck down the statute without further inquiry.” *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see also Edgar v. MITE Corp.*, 457 U.S. 624, 640 (1982) (“The Commerce Clause, however, permits only *incidental* regulation of interstate commerce by the States; direct regulation is prohibited.”). By contrast, when a state law directly regulates only *intrastate* commerce, the regulation will not survive scrutiny if “the burden imposed on [*interstate*] commerce is clearly excessive in relation to the putative local benefits” of the statute. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

110. SB 539 imposes a burden on interstate commerce that “is clearly excessive in relation to [its] putative local benefits.” *Id.* The Act strips trade-secret protection for broad categories of proprietary information belonging to “essential” diabetes drug manufacturers, *none* of whom is headquartered in Nevada. By doing so, the Act directly negates the trade-secret laws of every other state and the federal government. The extraterritorial effects of SB 539 are substantial and unavoidable because the market for diabetes drugs—especially “essential” diabetes drugs—is inherently national. *See Nat’l Ass’n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir. 2012) (“[S]ignificant burdens on interstate commerce generally result from inconsistent regulation of activities that are inherently national or require a uniform system of regulation.”). SB

1 539 will prevent manufacturers from protecting and enforcing their trade secrets in every state.  
2 This in turn will impose significant burdens on other states that host a substantial part of these  
3 manufacturers' operations. Those jurisdictions have a legitimate interest in promoting the economic  
4 success of these manufacturers by protecting their trade secrets. *See Healy v. Beer Inst., Inc.*, 491  
5 U.S. 324, 336–37 (1989); *Rocky Mtn. Farmers Union v. Corey*, 730 F.3d 1070, 1101 (9th Cir.  
6 2013).

7 111. Take, for example, Eli Lilly—one of the major manufacturers of diabetes drugs. Eli  
8 Lilly is headquartered in Indianapolis, Indiana. It has *no* offices or operations in Nevada. The State  
9 of Indiana and the other states where Eli Lilly has operations protect Eli Lilly's trade secrets—  
10 including its pricing and cost information for essential diabetes drugs. *See, e.g., Hydraulic Exch. &*  
11 *Repair*, 690 N.E.2d at 786. These states have an interest in protecting Eli Lilly's trade secrets in  
12 order to promote the company's growth, which creates local jobs and fuels the local economy. SB  
13 539, however, overthrows the protection these other states provide by compelling Eli Lilly to  
14 disclose the information that the other states protect as trade secrets. By enacting SB 539, Nevada  
15 legislators have told legislators in every other state that Nevada knows best, and its decision  
16 controls, when balancing the interest in protecting trade secrets against the interest in price  
17 transparency. The dormant Commerce Clause does not tolerate such efforts by one state to impose  
18 its preferred regulation on every other state.

19 112. Furthermore, because WAC is a national list price, SB 539's effective cap on a  
20 drug's WAC will apply throughout the country, including to drugs that are bought and sold outside  
21 of Nevada. A manufacturer of essential diabetes drugs based in New York selling to a purchaser in  
22 California will not be able to raise list prices without having the state of *Nevada* stripping the New  
23 York manufacturer of its valuable trade secrets.

24 113. These substantial effects on interstate commerce will clearly exceed any putative  
25 local benefit to the residents of Nevada. While the purpose of the Act is apparently to control prices  
26 for diabetes drugs, neither the Act nor its legislative history explain how transparency will lower  
27 prices apart from impermissibly burdening manufacturers' lawful exercise of federal patent rights.  
28 The Act is precisely the kind of attempt by a state to "extend [its] police power beyond its

jurisdictional bounds” that offends the dormant Commerce Clause. *C & A Carbone*, 511 U.S. at 393.

114. In fact, SB 539’s publication of competitively sensitive price and cost information may lead to unintended anticompetitive effects that prevent drug prices from falling as quickly as they would have without the Act. “Too much transparency can harm competition in any market, including in health care markets. . . . [W]hen information disclosures allow competitors to figure out what their rivals are charging, [it] dampens each competitor’s incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices.” Tara Isa Koslov & Elizabeth Jex, *Price Transparency or TMI?*, Fed. Trade Comm’n (July 2, 2015, 2:31 PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi>. The Congressional Budget Office has found that compelled disclosure of drug pricing information, specifically rebates, “could set in place conditions for tacit collusion, as manufacturers would find it more difficult to set prices below their competitors’ without detection.” Cong. Budget Office, *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals* 6 (June 5, 2008), <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf>.

115. The Federal Trade Commission has also explained, “If, for example, pharmaceutical manufacturers know the precise details of rebate arrangements offered by their competitors, then tacit collusion among them may be more feasible. Absent such knowledge, manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment may yield increased sales. Unprotected disclosures thus may raise the price that . . . consumers pay for pharmaceutical coverage by undermining competition among pharmaceutical companies for preferred formulary treatment.” Letter from James Cooper, Pauline M. Ippolito, & David P. Wales of the Fed. Trade Comm’n to Hon. James L. Seward (Mar. 31, 2009), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf).

116. In sum, the Act excessively burdens interstate commerce without a commensurate local benefit. The Constitution entrusts national economic policy to Congress precisely to avoid such outcomes. U.S. Const. art. I, § 8, cl. 3.

## CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF

#### **(Declaratory/Injunctive Relief – SB 539 Is Preempted By Federal Patent Law In Violation Of The Supremacy Clause Of The U.S. Constitution)**

117. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

118. Under the Supremacy Clause of the United States Constitution, federal statutes are “the supreme Law of the Land.” U.S. Const. art. IV, cl. 2. No state law may “stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Hines*, 312 U.S. at 67.

119. The federal patent laws embody “a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.” *Bonito Boats*, 489 U.S. at 146. Federal patent laws, including the Hatch-Waxman Act, grant an inventor the exclusive right to make, use, and sell his patented invention for a limited period of time. During this exclusivity period, a patent holder may set the price for its product in a manner that takes into account the patent holder’s ability to preclude others from marketing an infringing product. *See BIO*, 496 F.3d at 1373–74. This protection extends to “[whom]ever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101. By this means, the federal patent system, including the Hatch-Waxman Act, encourages not only the discovery of new pharmacological compounds, but also new methods of manufacturing or improving the effectiveness of drugs already discovered.

120. Federal patent law preempts SB 539 because the Act stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the federal law. The Act impermissibly burdens the federal patent rights of diabetes drug manufacturers by requiring the

disclosure of trade secrets associated with these patented products if manufacturers raise the list prices of those patented drugs.

121. Accordingly, the Act constitutes an impermissible and “clear attempt to restrain . . . excessive [drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to [Nevada] drug consumers.” *BIO*, 496 F.3d at 1374.

## SECOND CLAIM FOR RELIEF

### **(Declaratory/Injunctive Relief – SB 539 Is Preempted By Federal Trade-Secret Law In Violation Of The Supremacy Clause Of The U.S. Constitution)**

122. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

123. SB 539 violates the Supremacy Clause for the independent reason that eliminating trade-secret protection for the information disclosed by manufacturers stands as an obstacle to the accomplishment and execution of the full purposes and objectives of, and is therefore preempted by, the federal Defend Trade Secrets Act of 2016.

124. SB 539 compels manufacturers to disclose to the Department confidential and proprietary advertising, cost, marketing, pricing, and production information that derives independent value from not being generally known to third-party payers and competitors. These categories of information are “trade secrets” under the DTSA. SB 539, however, removes trade-secret protection from these categories of information by requiring their disclosure and by amending Nevada’s trade-secret statute expressly to eliminate trade-secret protection for all information “that a manufacturer is required to report.” SB 539 § 9. These provisions stand as an obstacle to the purposes and objectives of the DTSA.

125. Although the DTSA provides that it “shall not be construed to preempt or displace any other remedies . . . provided by . . . [s]tate . . . law for the misappropriation of a trade secret,” 18 U.S.C. § 1838, that provision has no applicability here. SB 539 does not merely provide a *different* remedy for the misappropriation that must be disclosed. Rather, SB 539 *eliminates all remedies*, not only in Nevada, but throughout the Nation. Thus, the rule of construction set forth in Section 1838 does not save SB 539 from federal preemption.

### THIRD CLAIM FOR RELIEF

#### **(Declaratory/Injunctive Relief – The Act Works A Taking Without Just Compensation In Violation Of The Fifth And Fourteenth Amendments To The U.S. Constitution)**

126. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

127. The Fifth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, provides that “private property [shall not] be taken for public use, without just compensation.”

128. SB 539 constitutes a categorical taking of Plaintiffs’ members’ intellectual property rights because it guarantees public disclosure of their trade secrets, which in turn negates the value of those trade secrets.

129. Alternatively, the Act works a regulatory taking under the three-part test set out in *Penn Central*. First, SB 539 has the “character” of a total interference with manufacturers’ property rights in their trade secrets. *Penn Cent.*, 438 U.S. at 124–25. Second, eliminating all trade-secret protection for the confidential advertising, cost, marketing, pricing, and production information for diabetes drugs will have a devastating “economic impact” not only on manufacturers subject to the disclosure requirements, but also on the market for diabetes drugs. *Id.* at 124. Third, manufacturers invest in diabetes treatments with the reasonable “investment-backed expectation” that their confidential and proprietary information will remain a secret. *Id.* at 124, 127.

130. Thus, SB 539’s disclosure requirements destroy valuable trade secrets related to diabetes drugs without any compensation, let alone just compensation, in violation of the Takings Clause. U.S. Const. amends. V, XIV.

### FOURTH CLAIM FOR RELIEF

#### **(Declaratory/Injunctive Relief – The Act Imposes An Excessive Burden On Interstate Commerce In Violation Of The Commerce Clause Of The U.S. Constitution)**

131. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

132. The Constitution grants Congress the power “[t]o regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. The Commerce Clause places an implicit restraint, known as the dormant Commerce Clause, on state laws that are inimical to national commerce.

133. SB 539 violates the dormant Commerce Clause because the burden it imposes on interstate commerce is clearly excessive in relation to any putative local benefits. Because WAC is a national list price, SB 539's effects will be felt throughout the country. SB 539 also will prevent manufacturers from protecting and enforcing their trade secrets in every state. These other jurisdictions, especially those in which manufacturers reside, have a legitimate interest in promoting the economic success of manufacturers. These substantial effects on interstate commerce clearly exceed any putative local benefit to the residents of Nevada. While the purpose of the Act is to control prices for diabetes drugs, neither the Act nor its legislative history explain how transparency will lower prices apart from impermissibly burdening manufacturers' lawful exercise of federal patent rights. The Constitution entrusts national economic policy to Congress precisely to avoid such outcomes. U.S. Const. art. I, § 8, cl. 3.

#### PRAYER FOR RELIEF

**NOW, THEREFORE**, Plaintiffs request a judgment in their favor against Defendants as follows:

1. A declaration that Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of SB 539 are unconstitutional and void;
2. A preliminary and permanent injunction preventing Defendants from implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of SB 539;
3. That Plaintiffs be awarded attorneys' fees and costs, plus interest accruing thereon, in their favor at the maximum rate allowed by law; and

///

///

///

///

///

///

1           4.       That the Court award such other and further relief as it may deem appropriate.

2       DATED this 1st day of September, 2017.

3                       Respectfully submitted,

4                       /s/ Pat Lundvall

5                       Pat Lundvall

6                       Nevada Bar No. 3761

7                       McDONALD CARANO LLP

8                       2300 West Sahara Avenue, Suite 1200

9                       Las Vegas, NV 89102

10                      Telephone: (702) 873-4100

11                      plundvall@mcdonaldcarano.com

12                      Robert N. Weiner

13                      Pending Admission *Pro Hac Vice*

14                      Jeffrey L. Handwerker

15                      Pending Admission *Pro Hac Vice*

16                      R. Stanton Jones

17                      Pending Admission *Pro Hac Vice*

18                      ARNOLD & PORTER KAYE SCHOLER LLP

19                      601 Massachusetts Avenue, NW

20                      Washington, DC 20001

21                      Telephone: (202) 942-5000

22                      robert.weiner@apks.com

23                      jeffrey.handwerker@apks.com

24                      stanton.jones@apks.com

25                      Attorneys for Plaintiffs Pharmaceutical Research  
26                      and Manufacturers of America and Biotechnology  
27                      Innovation Organization  
28

# EXHIBIT 4

# EXHIBIT 4

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA, and

BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official  
capacity  
as Governor of the State of Nevada, and

RICHARD WHITLEY, in his official  
capacity as Director of the Nevada  
Department for Health and Human  
Services,

Defendants.

Case No.: 2:17-cv-02315

**DECLARATION OF JAMES  
BORNEMAN**

1 I, James Borneman, declare pursuant to 28 U.S.C. § 1746 as follows:

2  
3 1. I am the Head, Customer Engagement & Insights for Sanofi US. From  
4 July 2014 – May 2017, I was Vice President, Strategic Pricing and Contract  
5 Management for Sanofi US. In that capacity, I was responsible for the establishment  
6 of all gross and net pricing strategies for all Sanofi US pharmaceutical products to  
7 include oversight of the organization's gross-to-net investments. I am knowledgeable  
8 about Sanofi US's pricing and contracting for its prescription drugs, including its  
9 diabetes therapies.  
10  
11

12  
13 2. Sanofi US is a member of the Pharmaceutical Research and  
14 Manufacturers of America ("PhRMA"), a plaintiff in this action. Sanofi US is the  
15 U.S. affiliate of Sanofi, a global life sciences company committed to improving  
16 access to healthcare and supporting the people we serve throughout the continuum of  
17 care. Sanofi is a member of PhRMA as well as the Biotechnology Innovation  
18 Organization ("BIO"), also a plaintiff in this action. From prevention to treatment,  
19 Sanofi transforms scientific innovation into healthcare solutions in human vaccines,  
20 rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes  
21 and cardiovascular, consumer healthcare, established prescription products and  
22 generics. More than 100,000 people at Sanofi are dedicated to making a difference in  
23 patients' daily lives, wherever they live, and enabling them to enjoy a healthier life.  
24  
25  
26  
27  
28

1           3.     Headquartered in Bridgewater, New Jersey, Sanofi US employs more  
2 than 15,000 professionals throughout the country including over 35 at a distribution  
3 center in Reno, Nevada. In addition to Diabetes & Cardiovascular and General  
4 Medicines, our other businesses operating in the United States include Sanofi  
5 Genzyme (specialty care), Sanofi Pasteur (vaccines), Winthrop (generics) and  
6 Chattem (consumer healthcare).  
7  
8

9           4.     Sanofi has a rich history of innovation dating back more than 100 years.  
10 We are tremendously proud of our heritage, which over the years has combined  
11 steady growth and expansion with an exceptional commitment to research and  
12 development.  
13

14           5.     For example, since the launch of Lantus (insulin glargine injection) 100  
15 units/ml, Sanofi has continued investing to better support clinical decision making for  
16 patients with diabetes through comprehensive research including over 2200 full-text  
17 publications from results of approximately 500 randomized controlled clinical trials,  
18 over 220 real-life patient studies and over 50 meta-analyses.  
19  
20

21           6.     Sanofi holds or has rights to patents protecting prescription drugs  
22 marketed and sold by Sanofi US, including patents protecting Lantus, Apidra,  
23 Toujeo, Soliqua and Adlyxin, which are FDA-approved for the treatment of diabetes.  
24 Lantus, Apidra, Toujeo, Soliqua and Adlyxin are thus likely to be subjected to  
25 Nevada Senate Bill No. 539 ("SB 539" or "the Act") as "essential" to the treatment of  
26 diabetes.  
27  
28

1           7.     Simply because Lantus, Apidra, Toujeo, Soliqua and Adlyxin are  
2     “essential” to the treatment of diabetes, I understand that section 3.8 of the Act  
3  
4     requires Sanofi US to report substantial financial and marketing information related  
5     to Lantus, Apidra, Toujeo, Soliqua and Adlyxin to the Nevada Department of Health  
6     and Human Services (“Department”):

- 7
- 8     •     “[t]he costs of producing the drug”;
  - 9
  - 10    •     “marketing and advertising costs” associated with the drug;
  - 11
  - 12    •     profit “earned from the drug” as a “percentage of . . . total profit”;
  - 13
  - 14    •     the amount spent on “patient prescription assistance programs”;
  - 15
  - 16    •     “[t]he aggregate amount of all rebates” in Nevada; and

17

18    “[a]ny additional information prescribed by regulation . . . for the purpose of  
19    analyzing the cost of prescription drugs . . . on the list.” *Id.* § 3.8.

20

21           8.     The information that Sanofi US must disclose under Section 3.8 is  
22     confidential. Moreover, this information is of substantial independent economic  
23     value to Sanofi US by virtue of being confidential and non-public. Information such  
24     as pricing inputs and rationale is restricted internally, is only shared internally on a  
25     need-to-know basis, and is subject to non-disclosure provisions in Sanofi US’s  
26     employment and other business agreements. Employees are required to maintain the  
27  
28

1 secrecy of this information, and are subject to discipline – up to and including  
2 termination – by Sanofi US for its unauthorized disclosure.

3  
4 9. The Department, however, has no obligation to treat this information as  
5 confidential. The Department may publish it, share it with other public or private  
6 entities, or use it for other purposes, such as negotiating rebates with manufacturers.  
7  
8 In fact, SB 539 expressly eliminates trade secret protection for all information  
9 required to be disclosed to the Department. *Id.* § 9.

10 10. Moreover, I understand that SB 539 imposes additional reporting  
11 requirements if manufacturers raise the price of diabetes drugs more than a specified  
12 benchmark linked to the CPI for Medical Services. For the period from July 2016 to  
13 July 2017, this CPI benchmark was 2.6 percent. Our price changes for Apidra for  
14 that period exceed this threshold.<sup>1</sup> For products that exceed the threshold, Section 4  
15 of SB 539 requires companies to disclose:  
16  
17

- 18 • “[a] list of each factor that has contributed to the increase”;
- 19 • “[t]he percentage of the total increase that is attributable to each factor”;
- 20 • “[a]n explanation of the role of each factor”; and
- 21 • “[a]ny other information prescribed by regulation.” *Id.* § 4.

22  
23  
24 11. Information such as the factors considered in setting and adjusting the  
25 prices of our products and the percentage of our profits that derive from diabetes  
26 drugs are confidential and proprietary. This information is not shared publicly, and  
27

28 <sup>1</sup> We have not taken a price increase on Lantus, Toujeo, Soliqua or Adlyxin during this timeframe.

1 access to it is restricted internally and only shared internally on a need-to-know basis.  
2 It is subject to non-disclosure provisions in Company's employment and other  
3 business agreements. Employees are required to maintain the secrecy of this  
4 information, and are subject to discipline – up to and including termination – by  
5 Sanofi US for its unauthorized disclosure.  
6

7  
8 12. The Department is required to prepare a report analyzing the information  
9 and post it on the Internet, and the Department has no limitations on how it may  
10 disclose or otherwise use this information. In fact, SB 539 expressly revokes the  
11 trade secret protection covering this information.  
12

13 13. Once this information is publicly disclosed in Nevada, it is public  
14 everywhere.  
15

16 14. Our customers and competitors would gain an unfair competitive  
17 advantage over Sanofi US if they were to obtain the financial and marketing  
18 information that Section 3.8 and 4 of the Act require Sanofi US to disclose to the  
19 Department. In particular, our customers would learn how we develop our pricing,  
20 which in turn could be used against us in negotiations with insurers and other  
21 intermediaries in the healthcare system – and ultimately negatively impact patients,  
22 by discouraging innovations that would benefit them.  
23  
24

25 15. Likewise, our competitors would learn how we allocate our resources  
26 and set our prices. This in turn could put Sanofi US at a significant disadvantage,  
27 especially if our competitors do not make a diabetes drug and thus are not subject to  
28

1 SB 539's disclosure requirements. We consider the same or similar factors when  
2 setting prices for other products. Thus, the information disclosed could prejudice  
3 Sanofi US in competition involving non-diabetes products as well.  
4

5 16. These impacts will not just be felt in Nevada, but will be felt nationally.  
6 The prices Sanofi US sets and the methods that it uses to set them are substantially  
7 the same from state-to-state. Thus, the information disclosed under SB 539 would  
8 have implications on our negotiations with customers and our competitive positioning  
9 nationwide.  
10

11 17. For example, many of the other healthcare supply chain stakeholders are  
12 national companies that negotiate national contracts. Healthcare purchasers such as  
13 the Culinary Union #226, which was a major public proponent of SB 539, are  
14 affiliated with Unite Here, a national union with affiliates in 37 states.  
15  
16

17 18. In fact, I understand that if the costs of other medical care (such as  
18 hospitalization) decline, then the CPI could decrease, such that unless Sanofi US  
19 lowers the price of Lantus, Apidra, Toujeo, Soliqua and Adlyxin it will be subject to  
20 SB 539's reporting requirements.  
21

22 19. Sanofi US has a longstanding commitment to research in the diabetes  
23 space and there is much remaining to be done in the diabetes space to ensure better  
24 outcomes for patients. Sanofi invested significant capital in developing Lantus,  
25 Apidra, Toujeo, Soliqua and Adlyxin, despite the substantial risk that this investment  
26 would not bear fruit. Sanofi obtained patents on these products, which gives Sanofi  
27  
28

1 US the exclusive legal right to market Lantus, Apidra, Toujeo, Soliqua and Adlyxin  
2 for the term of those patents. Such patent exclusivity enables Sanofi US to price  
3 Lantus, Apidra, Toujeo, Soliqua and Adlyxin at a level that helps to recoup the  
4 investment in this research and development, given that many experimental products  
5 do not even make it to the submission or approval stages. Now, however, Sanofi  
6 faces the unenviable choice of either forgoing its right under the patent laws to price  
7 the products at this level, or suffering the substantial penalty of disclosure of trade  
8 secret information. The risks of competitive harm will lower the value of existing  
9 and future patents on diabetes products, diminishing the incentive, or creating a  
10 disincentive, to invest in developing and enhancing those drugs. Ultimately, this  
11 could slow or blunt the process of providing better treatments for patients.  
12  
13  
14  
15

16 20. SB 539's focus on diabetes medicines also could have severe unintended  
17 consequences. Given the significant investment required to fund research and  
18 development, such a focus could have a chilling effect on Sanofi's efforts in the  
19 diabetes space. For example, the lack of reporting thresholds in Section 3.8 (other  
20 than the requirement that the drug be "essential" to diabetes treatment) and a very low  
21 threshold for reporting price increases in Section 4 (any price greater than the CPI for  
22 medical products) could result in lower return on the patent rights and other  
23 innovations in the diabetes space than in other disease spaces. Further, Sanofi could  
24 be placed at a competitive disadvantage relative to companies who do NOT  
25 manufacture diabetes medicines, who reap an unexpected benefit by virtue of the SB  
26  
27  
28

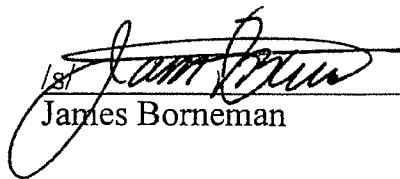
1 539 disclosure requirements. Given that Sanofi US considers the same or similar  
2 factors when setting the prices for other products, the information disclosed could  
3 disadvantage Sanofi US in competition involving non-diabetes products as well.  
4

5 21. Because of these consequences of SB 539's disclosure requirements and  
6 the direct implications they have on products that treat diabetes, SB 539 defeats  
7 Sanofi's legitimate investment expectations regarding its current products, and will  
8 necessitate review of our research and development priorities for diabetes products  
9 going forward. Indeed Sanofi may be forced to consider the costs and risks imposed  
10 by SB 539 in deciding what resources to allocate to enhancing Lantus, Apidra,  
11 Toujeo, Soliqua and Adlyxin and/or to research and development of new diabetes  
12 treatments.  
13  
14  
15

16 22. Given Sanofi's confidence in our researchers and our mission to  
17 continue finding solutions for patients with diabetes – and balancing that with our  
18 duties towards those who invest in Sanofi's lifesaving and life improving treatments  
19 and patients awaiting cures and treatments in other areas – Sanofi may be forced to  
20 weigh the difficult decision of whether to reduce its efforts in continuing to pursue  
21 promising medical advances in the area of diabetes because of these disincentives.  
22  
23  
24  
25  
26  
27  
28

1 I declare under penalty of perjury that the foregoing is true and correct.

2 Executed on September 7, 2017.

3  
4   
5 James Borneman  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 5

# EXHIBIT 5

## ORDER

000638

**EXHIBIT 6**

**EXHIBIT 6**

Pat Lundvall  
Nevada Bar No. 3761  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
plundvall@mcdonaldcarano.com

Robert N. Weiner  
Pending Admission *Pro Hac Vice*  
Jeffrey L. Handwerker  
Pending Admission *Pro Hac Vice*  
R. Stanton Jones  
Pending Admission *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA and  
  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs;

vs.

BRIAN SANDOVAL, in his official capacity  
as Governor of the State of Nevada, and

RICHARD WHITLEY, in his official capacity  
as Director of the Nevada Department for  
Health and Human Services,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

**PLAINTIFFS' MOTION FOR  
TEMPORARY RESTRAINING ORDER  
AND PRELIMINARY INJUNCTION, AND  
SUPPORTING MEMORANDUM OF  
POINTS AND AUTHORITIES**

**EXPEDITED TREATMENT REQUESTED  
(RELIEF NEEDED BY OCTOBER 1, 2017)**

**ORAL ARGUMENT REQUESTED**

**MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY**  
**INJUNCTION**

Plaintiffs Pharmaceutical Research and Manufacturers of America (“PhRMA”) and Biotechnology Innovation Organization (“BIO”) hereby move pursuant to Federal Rule of Civil Procedure 65 for a temporary restraining order requiring Defendants Brian Sandoval, in his official capacity as Governor of the State of Nevada, and Richard Whitley, in his official capacity as Director of the Nevada Department of Health and Human Services (together, “Defendants”), to immediately cease and desist all action implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of Nevada Senate Bill No. 539 (“SB 539” or the “Act”), which will impose irreparable injury on Plaintiffs beginning on October 1, 2017—the date that the challenged provisions of SB 539 go into effect. Such a temporary restraining order will preserve the status quo until the Court can rule on Plaintiffs’ motion for a preliminary injunction. Pursuant to Rule 65(b), sufficient grounds exist to issue a temporary restraining order. Plaintiffs further move for a preliminary injunction barring implementation or enforcement of the Sections of the Act identified above. Should this Court not enter a temporary restraining order, Plaintiffs ask the Court to set a briefing schedule on the motion for a preliminary injunction allowing sufficient time for a ruling before October 1, 2017. Defendants were notified of Plaintiffs’ intent to seek preliminary injunctive relief on August 25, 2017. Through the meet and confer process since then, the parties’ counsel discussed a potential resolution to avoid this motion, but on September 12, 2017, Defendants’ counsel advised that Defendant Sandoval would prefer that Plaintiffs proceed with the filing of a motion.

1 In support of this motion, Plaintiffs respectfully submit the accompanying memorandum of  
2 points and authorities, affidavits, and exhibits detailing the grounds entitling them to relief.

3 Dated this 13th day of September, 2017.

4 McDONALD CARANO LLP

5  
6 By: /s/ Pat Lundvall

7 Pat Lundvall

8 2300 West Sahara Avenue, Suite 1200

9 Las Vegas, NV 89102

10 Telephone: (702) 873-4100

11 Facsimile: (702) 873-9966

12 Robert N. Weiner

13 Jeffrey L. Handwerker

14 R. Stanton Jones

15 ARNOLD & PORTER KAYE SCHOLER LLP

16 601 Massachusetts Avenue, NW

17 Washington, DC 20001

18 Telephone: (202) 942-5000

19 Facsimile: (202) 942-5999

20 *Attorneys for Plaintiffs Pharmaceutical Research*  
21 *and Manufacturers of America and Biotechnology*  
22 *Innovation Organization*  
23  
24  
25  
26  
27  
28

# TABLE OF CONTENTS

	Page
INTRODUCTION .....	1
BACKGROUND .....	3
A.    Plaintiffs' Members Spend Billions Each Year Developing Innovative Diabetes Medicines in Reliance on Patent and Trade-Secret Protections.....	3
B.    History and Overview of Nevada Senate Bill 539 .....	4
C.    SB 539's Harm to Plaintiffs' Members and Innovation of Diabetes Treatments.....	8
ARGUMENT .....	9
I.    PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS .....	10
A.    SB 539 Is Preempted By Federal Patent and Trade-Secret Law.....	10
1.    SB 539 Conflicts with Federal Patent Law .....	11
2.    SB 539 Conflicts with Federal Trade-Secret Law .....	15
B.    SB 539's Uncompensated Abolition of Trade-Secret Protection for Valuable Information Violates the Fifth Amendment Takings Clause.....	17
C.    SB 539 Violates the Commerce Clause by Overriding Every Other State's Laws .....	19
II.    PLAINTIFFS' MEMBERS WILL SUFFER IRREPARABLE HARM ABSENT A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTIVE RELIEF.....	22
III.   THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST SUPPORT A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION .....	22
CONCLUSION.....	23

# TABLE OF AUTHORITIES

	Page(s)
<b>CASES</b>	
<i>Aerodynamics Inc. v. Caesars Entm't Operating Co.</i> , No. 2:15-CV-01344, 2015 WL 5679843 (D. Nev. Sept. 24, 2015).....	16, 22
<i>All. for the Wild Rockies v. Cottrell</i> , 632 F.3d 1127 (9th Cir. 2011).....	9, 20
<i>Amoco Prod. Co. v. Vill. of Gambell</i> , 480 U.S. 531 (1987).....	9
<i>Andrx Pharms., Inc. v. Biovail Corp. Int'l</i> , 256 F.3d 799 (D.C. Cir. 2001).....	12
<i>Ariz. Dream Act Coal. v. Brewer</i> , 757 F.3d 1053 (9th Cir. 2014).....	21
<i>Ashland Mgmt. Inc. v. Janien</i> , 624 N.E.2d 1007 (N.Y. 1993).....	15
<i>Bonito Boats, Inc. v. Thunder Craft Boats, Inc.</i> , 489 U.S. 141 (1989).....	11
<i>Broadcom Corp. v. Qualcomm Inc.</i> , No. SACV 05-468, 2005 WL 5925584 (C.D. Cal. Oct. 19, 2005).....	9
<i>C &amp; A Carbone v. Town of Clarkstown</i> , 511 U.S. 383 (1994).....	21
<i>Excellence Cmty. Mgmt., LLC v. Gilmore</i> , 351 P.3d 720 (Nev. 2015).....	21
<i>Finkel v. Cashman Prof'l, Inc.</i> , 270 P.3d 1259 (Nev. 2012).....	16, 18, 21
<i>Flex-Foot, Inc. v. CRP, Inc.</i> , 238 F.3d 1362 (Fed. Cir. 2001).....	9
<i>Frantz v. Johnson</i> , 999 P.2d 351 (Nev. 2000).....	14, 18
<i>FTC v. Actavis, Inc.</i> , 133 S. Ct. 2223 (2013).....	10
<i>Gade v. Nat'l Solid Wastes Mgmt. Ass'n</i> , 505 U.S. 88 (1992).....	10

1	<i>Healy v. Beer Inst.</i> ,	
2	491 U.S. 324 (1989).....	19, 20, 21
3	<i>Hines v. Davidowitz</i> ,	
4	312 U.S. 52 (1941).....	10, 14, 16
5	<i>Hughes v. Oklahoma</i> ,	
6	441 U.S. 322 (1979).....	19
7	<i>Hydraulic Exch. &amp; Repair, Inc. v. KM Specialty Pumps, Inc.</i> ,	
8	690 N.E.2d 782 (Ind. Ct. App. 1998).....	21
9	<i>Johnson v. Nguyen</i> ,	
10	No. 3:12-CV-00538, 2015 WL 105826 (D. Nev. Jan. 7, 2015).....	9
11	<i>Kewanee Oil Co. v. Bicron Corp.</i> ,	
12	416 U.S. 470 (1974).....	10, 14
13	<i>King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.</i> ,	
14	791 F.3d 388 (3d Cir. 2015).....	10
15	<i>King Instruments Corp. v. Perego</i> ,	
16	65 F.3d 941 (Fed. Cir. 1995).....	11
17	<i>Kuryakyn Holdings, LLC v. Ciro, LLC</i> ,	
18	No. 15-CV-703-JDP, 2017 WL 1026025 (W.D. Wis. Mar. 15, 2017).....	16
19	<i>Lucas v. S.C. Coastal Council</i> ,	
20	505 U.S. 1003 (1992).....	18
21	<i>Mikohn Gaming Corp. v. Acres Gaming, Inc.</i> ,	
22	165 F.3d 891 (Fed. Cir. 1998).....	9
23	<i>of Nashville, Inc. v. Metro. Gov't of Nashville &amp; Davidson Cty.</i> ,	
24	274 F.3d 377 (6th Cir. 2001).....	22
25	<i>Nelson v. NASA</i> ,	
26	530 F.3d 865 (9th Cir. 2008), <i>rev'd on other grounds</i> , 562 U.S. 134 (2011).....	22
27	<i>Peabody v. Norfolk</i> ,	
28	98 Mass. 452 (1868).....	15
	<i>Penn Cent. Transp. Co. v. City of New York</i> ,	
	438 U.S. 104 (1978).....	18
	<i>Perez v. Campbell</i> ,	
	402 U.S. 637 (1971).....	13
	<i>Pharm. Research &amp; Mfrs. of Am. v. District of Columbia (PhRMA)</i> ,	
	406 F. Supp. 2d 56 (D.D.C. 2005), <i>aff'd sub nom. Biotech. Indus. Org. v. District</i> <i>of Columbia (BIO)</i> , 496 F.3d 1362 (Fed. Cir. 2007) .....	10, 19, 20

1	<i>Philip Morris, Inc. v. Reilly</i> ,	
2	312 F.3d 24 (1st Cir. 2002) (en banc) .....	16, 17, 18
3	<i>Pike v. Bruce Church, Inc.</i> ,	
4	397 U.S. 137 (1970) .....	19
5	<i>Preminger v. Principi</i> ,	
6	422 F.3d 815 (9th Cir. 2005) .....	23
7	<i>Prot. Techs., Inc. v. Ribler</i> ,	
8	2017 WL 923912 (D. Nev. Mar. 8, 2017) .....	23
9	<i>Ruckelshaus v. Monsanto Co.</i> ,	
10	467 U.S. 986 (1984) .....	16, 17, 18
11	<i>Saini v. Int'l Game Tech.</i> ,	
12	434 F. Supp. 2d 913 (D. Nev. 2006) .....	21, 22
13	<i>Sears, Roebuck &amp; Co. v. Stiffel Co.</i> ,	
14	376 U.S. 225 (1964) .....	11
15	<i>Sorrell v. IMS Health Inc.</i> ,	
16	564 U.S. 552 (2011) .....	13
17	<i>St. Michael's Convalescent Hosp. v. California</i> ,	
18	643 F.2d 1369 (9th Cir. 1981) .....	17
19	<i>Sw. Voter Registration Educ. Project v. Shelley</i> ,	
20	344 F.3d 882 (9th Cir.), rev'd on other grounds, 344 F.3d 914 (9th Cir. 2003) .....	23
21	<i>United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.</i> ,	
22	550 U.S. 330 (2007) .....	19
23	<i>Wearly v. FTC</i> ,	
24	462 F. Supp. 589 (D.N.J. 1978) .....	17
25	<i>Winter v. Nat. Res. Def. Council, Inc.</i> ,	
26	555 U.S. 7 (2008) .....	9
27	<b>STATUTES</b>	
28	Defend Trade Secrets Act, Pub. L. No. 114-153, 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)) .....	1, 15, 16, 23
	Drug Price Competition and Patent Term Restoration Act of 1984 .....	1, 11
	Nev. Rev. Stat § 600A.030 (1987) .....	7, 18
	Uniform Trade Secrets Act .....	14, 16, 23

## OTHER AUTHORITIES

1	162 Cong. Rec. H2028-01 (Apr. 27, 2016).....	15, 18
2	Andrew Curry, <i>Pathways to a Type 1 Vaccine</i> , Diabetes Forecast (July 2016),	
3	<a href="http://www.diabetesforecast.org/2016/jul-aug/vaccines.html">http://www.diabetesforecast.org/2016/jul-aug/vaccines.html</a> .....	4
4	Ashish Jha et al., <i>Greater Adherence to Diabetes Drugs Is Linked to Less Hospital</i>	
5	<i>Use and Could Save Nearly \$5 Billion Annually</i> , 31 Health Aff. 1836 (2012).....	3
6	<i>Diabetes: Past Treatments and New Discoveries</i> , Med. News Today (May 2017),	
7	<a href="http://www.medicalnewstoday.com/articles/317484.php">http://www.medicalnewstoday.com/articles/317484.php</a> .....	3
8	Diabetes Que., <i>Treating Diabetes: 1921 to the Present Day</i> (Nov. 2016),	
9	<a href="https://tinyurl.com/yaqs7q7s">https://tinyurl.com/yaqs7q7s</a> .....	3
10	<i>Diabetes</i> , WebMD, <a href="http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes">http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes</a> .....	6
11	Genia Long, Analysis Grp., <i>The Biopharmaceutical Pipeline: Innovative Therapies</i>	
12	<i>in Clinical Development</i> (July 2017) .....	3
13	H.R. Rep. No. 114-529 (2016).....	14, 15, 16
14	H.R. Rep. No. 98-857(I) (1984).....	11
15	<i>Hearing on S.B. 265 Before the Sen. Comm. on Health &amp; Human Servs.</i> , 2017 Leg.,	
16	79th Sess. (Nev. May 26, 2017).....	5
17	<i>Hearing on S.B. 265 Before the Sen. Comm. on Health &amp; Human Servs.</i> , 2017 Leg.,	
18	79th Sess. (Nev. Mar. 29, 2017) .....	4
19	<i>Hearing on S.B. 265 Before the Sen. Comm. on Health &amp; Human Servs.</i> , 2017 Leg.,	
20	79th Sess. (Nev. May 3, 2017).....	4
21	Matthew Herper, <i>The Cost of Creating A New Drug Now \$5 Billion, Pushing Big</i>	
22	<i>Pharma To Change</i> , Forbes.com (Aug. 11, 2013).....	11
23	<i>Medicines in Development for Diabetes: A Report on Diabetes and Related</i>	
24	<i>Conditions</i> , PhRMA (2016), <a href="https://tinyurl.com/ydfnrqx7">https://tinyurl.com/ydfnrqx7</a> .....	3
25	Nevada Senate Bill No. 539.....	1, 2
26	Presidential Statement on Signing S. 1538 Into Law, 20 Weekly Comp. Pres. Doc.	
27	1359 (Sept. 24, 1984).....	12, 13
28	<i>Recent Developments Which May Impact Consumer Access to, and Demand for,</i>	
	<i>Pharmaceuticals: Hearing Before the Subcomm. on Health of the House Comm.</i>	
	<i>on Energy and Commerce</i> , 107th Cong. (June 13, 2001) (statement of Rep.	
	Barbara Cubin).....	12

1	Rick Mullin, <i>Tufts Study Finds Big Rise In Cost Of Drug Development</i> , Chem. &	
2	Eng'g News (Nov. 20, 2014) .....	11
3	S. Rep. No. 114-220 (2016) .....	15, 16
4	Senate Bill No. 265 .....	4
5	U.S. Const., amend. V .....	17
6	U.S. Const., amend. XIV .....	17
7	U.S. Const. art. I, § 8, cl. 3 .....	19
8	U.S. Const. art. I, § 8, cl. 8 .....	10
9	U.S. Const. art. VI, § 1, cl. 2 .....	10

**MEMORANDUM OF POINTS AND AUTHORITIES**

**INTRODUCTION**

Plaintiffs bring this action to prevent Nevada Senate Bill No. 539 (“SB 539” or the “Act,” attached as Ex. A) from inflicting serious, nationwide injuries. This unprecedented, overreaching, and unconstitutional statute undermines federal law, devalues intellectual property, and dictates patent and trade secret protection to the entire nation. The challenged provisions of SB 539 will irreparably harm Plaintiffs’ members who invent and manufacture diabetes drugs. Plaintiffs therefore seek a temporary restraining order and preliminary injunction barring implementation or enforcement of those provisions.

SB 539, signed on June 15, 2017, is novel in scope, ambition, and nationwide effect. As a penalty for exercising rights protected under the U.S. patent laws, SB 539 strips pharmaceutical manufacturers of trade secret protection for confidential, competitively sensitive, proprietary information regarding the production, cost, pricing, marketing, and advertising of their patented diabetes medicines. The Act then requires manufacturers to disclose this information to the Nevada Department of Health and Human Services (the “Department”), which must publish some of the information on its website and can disseminate the rest as it sees fit.

SB 539 violates the Constitution in at least four ways. *First*, SB 539 conflicts with federal patent law, including the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”) and is thus invalid under the Supremacy Clause. Federal law allows a patent holder to exclude others from making, using, or selling new inventions. For pharmaceuticals, the Hatch-Waxman Act adapts this system to ensure broad access to affordable medicines while offering innovators economic incentives sufficiently potent to surmount the enormous costs and risks of developing new treatments. SB 539 upsets this legislative balance by burdening a patent holder’s right to set prices reflecting the incentives the federal patent laws provide.

*Second*, SB 539 is also preempted by federal trade-secret law. Recognizing that trade secrets are critical to U.S. businesses, Congress enhanced existing state-law safeguards by enacting the Defend Trade Secrets Act of 2016 (“DTSA”). The DTSA sets a federal baseline for trade-secret

1 protection. SB 539 not only falls below this baseline; it effectively nullifies federal protection for  
2 trade secrets, undermining innovation and competition in the American pharmaceutical industry.

3 *Third*, SB 539 violates the Takings Clause of the Fifth Amendment by depriving affected  
4 manufacturers of trade-secret protection, forcing them to disclose confidential information to the  
5 State, and mandating its dissemination on the Internet. Before SB 539, every state, including  
6 Nevada, treated these materials as trade secrets. They are property, and SB 539 destroys their value  
7 without recompense. It thus takes manufacturers' property "without just compensation."

8 *Fourth*, SB 539 violates the dormant Commerce Clause because the penalty it imposes in  
9 Nevada impairs interstate commerce. By tying penalties to the national benchmark price for a drug,  
10 SB 539 affects drug prices nationwide, even for transactions entirely outside Nevada. The  
11 abrogation of trade-secret protection likewise extends to every state. Rescinding trade-secret  
12 protection, mandating disclosures, and requiring online publication of information destroys its  
13 confidentiality—everywhere. Such disclosures cannot be undone—information cannot be  
14 undisclosed. SB 539 overrides the laws of other states protecting the information as trade secrets,  
15 including states where the affected manufacturers reside, pay taxes, and employ thousands. Only  
16 Congress can override state trade-secret law or impose national economic policies. Nevada cannot.

17 These issues are not only ripe, but urgent. The Department plans to publish its list of  
18 "essential" diabetes drugs on October 15, 2017, stripping away trade-secret protection and raising  
19 the risk of misappropriation. The Act also compels disclosures that will undermine manufacturers'  
20 ability to compete. *See* Veto Letter from Gov. Sandoval to Sen. Maj. Leader Ford (June 2, 2017), at  
21 2-3 ("Veto Letter," attached as Ex. B). The harm to Plaintiffs' members and the public far  
22 outweighs any inconvenience to Defendants from delayed implementation of SB 539. And  
23 maintaining the status quo while this Court considers the constitutional issues is in the public  
24 interest. Plaintiffs therefore ask the Court to temporarily restrain Defendants from implementing or  
25 enforcing the challenged provisions of SB 539 pending resolution of Plaintiffs' motion for a  
26 preliminary injunction, and that the Court enjoin such implementation or enforcement pending  
27 resolution of this action.  
28

## BACKGROUND

### A. Plaintiffs' Members Spend Billions Each Year Developing Innovative Diabetes Medicines in Reliance on Patent and Trade-Secret Protections

More than 30 million Americans live with diabetes. An additional 84 million have pre-diabetes, with blood sugar levels higher than normal, increasing the risk they will develop diabetes. The disease is the seventh leading cause of death in the United States. It is, in short, an epidemic.<sup>1</sup>

Before 1922, a diagnosis of diabetes was a swift death sentence. Even with a strict diet, a patient typically survived “no more than three or four years,” with miserable quality of life.<sup>2</sup> Blood vessel and nerve damage resulted in dizziness and fainting, sexual issues, frequent urination, blindness, kidney failure, and infections leading to amputation. In 1921, two scientists were able to reverse diabetes in dogs by injecting them with insulin from the pancreatic islets of healthy dogs.<sup>3</sup> The following year, Eli Lilly began mass producing early animal-based insulins, which allowed many patients to manage their diabetes.<sup>4</sup>

Since then, pharmaceutical manufacturers have devoted enormous resources to improving insulin treatment and controlling diabetes. They have produced human insulin and developed other ways to treat diabetes and to reduce its risks. They have made diabetes medication easier to use, increasing patients' adherence to their prescribed dosing, thereby reducing emergency room visits and hospitalizations, saving \$8.3 billion a year.<sup>5</sup> Since 2000, FDA has approved 39 diabetes medicines. See Ex. C, Chart of FDA-Approved Diabetes Medicines; Compl. ¶ 24.

Despite these advances, 1.7 million Americans a year receive a new diagnosis of diabetes. Developing innovative new diabetes treatments and improving existing ones requires continuing

<sup>1</sup> See *Medicines in Development for Diabetes: A Report on Diabetes and Related Conditions*, PhRMA (2016) (“PhRMA 2016 Report”), <https://tinyurl.com/ydfnrqx7>.

<sup>2</sup> Diabetes Que., *Treating Diabetes: 1921 to the Present Day* (Nov. 2016), <https://tinyurl.com/yaqsq7s>.

<sup>3</sup> See Brian Wu, *History of Diabetes: Past Treatments and New Discoveries*, Med. News Today (May 2017), <http://www.medicalnewstoday.com/articles/317484.php>.

<sup>4</sup> *Id.*

<sup>5</sup> Ashish Jha et al., *Greater Adherence to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually*, 31 Health Aff. 1836, 1836 (2012).

1 research. In 2016 alone, more than 170 medicines for diabetes and related conditions were in  
 2 development. *See* PhRMA 2016 Report. Most reflect a potential new approach to fighting the  
 3 disease.<sup>6</sup> The development pipeline includes a potential “first-in-class” oral medicine for Types 1  
 4 and 2 diabetes, a fully recombinant monoclonal antibody to treat patients with newly diagnosed  
 5 Type 1 diabetes, and a medicine for nephropathy (kidney damage) from Type 1 or 2 diabetes.

6 Diabetes research and development also focuses on prevention: top universities, hospitals,  
 7 and pharmaceutical companies devote significant time and resources to developing a vaccine that  
 8 could teach the immune system not to attack pancreatic beta cells (which produce insulin), thus  
 9 preventing Type 1 diabetes. In fact, a trial at Massachusetts General Hospital aims not only to  
 10 prevent Type 1 diabetes, but to reverse it in patients who have had the disease under 5 years.<sup>7</sup>

11 The cost of such innovation is staggering. It takes on average 10-15 years and \$2.6 billion to  
 12 develop a new medicine, with low odds of success. From 1988-2014, only 12% of drugs that  
 13 entered clinical trials were approved for use. Manufacturers can invest billions of dollars each year  
 14 in research and development only if they have an appropriate opportunity to recoup that investment  
 15 through sales of the small fraction of products that make it to market.

#### 16 **B. History and Overview of Nevada Senate Bill 539**

17 As in all states, the number of adults in Nevada with diabetes has skyrocketed over the last  
 18 20 years. In 1995, the diabetes rate for adults in Nevada was about 4.7%. Today, it is near 12.4%.  
 19 An additional 787,000 people, 38.5% of Nevada’s adult population, have pre-diabetes. Senate Bill  
 20 No. 265 (“SB 265”), introduced in the Nevada Senate in February 2017, was “intended to address  
 21 the rapidly increasing cost of diabetes care in Nevada.” *Hearing on S.B. 265 Before the Sen. Comm.*  
 22 *on Health & Human Servs.*, 2017 Leg., 79th Sess. 33 (Nev. Mar. 29, 2017) (“Mar. 29 Mins.”). The  
 23 bill’s author “sincerely believe[d] increased transparency leads to decreased costs.” *Hearing on S.B.*  
 24 *265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 5 (Nev. May 3,

25 <sup>6</sup> *See, e.g.,* Genia Long, Analysis Grp., *The Biopharmaceutical Pipeline: Innovative Therapies in*  
 26 *Clinical Development* (July 2017) (69% of diabetes drugs in development were potential first-in-  
 class medicines).

27 <sup>7</sup> *See* Andrew Curry, *Pathways to a Type 1 Vaccine*, Diabetes Forecast (July 2016),  
 28 <http://www.diabetesforecast.org/2016/jul-aug/vaccines.html>.

2017). SB 539 incorporated much of SB 265. As the legislative history of SB 265 shows, the State focused primarily on controlling the list prices of insulin and other patented diabetes medicines. Proponents of the bill complained that “competition has not led to lower [insulin] prices” and asserted that manufacturers would simply “tweak” insulin “to keep it under patent status, so the patent does not expire and become eligible for generic versions.” Mar. 29 Mins. at 36; *see also, e.g., id.* at 33 (noting antitrust allegations against insulin manufacturers); *id.* at 58–60 (discussion of patent protection). Referring to the patented medicines Janumet and Jardiance, one proponent argued that he “should not [have to] depend on [manufacturer] coupons on the Internet to offset the cost of diabetic medications.” *Id.* at 45. Another explained that the bill was designed to “hit directly to the root of the problem” of high diabetes drug prices because “pharma will react accordingly with rebate dollars and trying to unwind what has been done” to “meet the terms of what [SB 265] puts out.” *Id.* at 37 (testimony of managed care pharmacist).

SB 265 sought to control prices by, first, directing the Department to compile a list of prescription drugs “essential” for treating diabetes. SB 265 § 6. Second, it compelled the manufacturer to report to the Department specific cost and pricing information for each essential diabetes drug. *Id.* § 7(1). Third, it excluded this cost and pricing information from Nevada’s definition of “trade secret,” *id.* § 27.5(5), and required the Department to publish a report on the prices and how they affect health care spending in Nevada, *id.* § 7(2). Fourth, it directed manufacturers to provide 90 days’ notice before increasing the national benchmark list price, known as the wholesale acquisition cost or “WAC,” of any essential diabetes drug. *Id.* § 8.

On May 16, 2017, SB 539, also targeting list price increases for diabetes drugs, was introduced. Originally a “complement” to SB 265, *see Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 3 (Nev. May 26, 2017) (“May 26 Mins.”), SB 539 also required that “Pharmacy Benefit Managers” (PBMs)—intermediaries between manufacturers and payers—disclose rebates received from manufacturers the prior calendar year. SB 539’s author justified it as an effort to control prices, as the “retail price [of diabetes drugs] paid by patients is unpredictable and can escalate to unaffordable levels over short periods.” *Id.*

1 On June 2, 2017, Governor Sandoval vetoed SB 265 because it “pose[d] serious risks of  
 2 unintended and potentially detrimental consequences for Nevada’s consumer patients,” including  
 3 the risk “that access to critical care will become more expensive, more restricted, and less  
 4 equitable.” Veto Letter at 2. The bill, he wrote, “could cause more harm than good for Nevada’s  
 5 families.” *Id.* Governor Sandoval concluded that “constitutional and other legal concerns” rendered  
 6 the bill “problematic” and vulnerable to challenges based on “federal preemption, the Fifth  
 7 Amendment’s prohibition on uncompensated takings, and the Dormant Commerce Clause.” *Id.* at 3.

8 On June 5, 2017, the Nevada Senate and State Assembly both passed SB 539, which, as  
 9 amended, largely replicated the drug pricing and reporting provisions of SB 265 that the Governor  
 10 had deemed constitutionally problematic. *See* Veto Letter at 2.<sup>8</sup> Nonetheless, on June 15, 2017,  
 11 three days after his veto, the Governor signed SB 539. Like SB 265, it directs the Department to  
 12 compile, by February 1 of each year, a list of prescription drugs “essential for treating diabetes.” SB  
 13 539 § 3.6(1). While not defining “essential,” the Act requires the list to include “all forms of insulin  
 14 and biguanides” sold in the State. *Id.*<sup>9</sup> In August 2017, the Nevada State Primary Care Office  
 15 distributed a draft list of “essential diabetes drugs” with 46 major drugs, including Afrezza, Byetta,  
 16 Duetact, Farxiga, Humulin, Invokana, Janumet, Januvia, Jardiance, Lantus, Nesina, Novolog,  
 17 PrandiMet, and Trulicity. *See* Ex. D, Draft List of Essential Diabetes Drugs.

18 Upon release of the final list, the Act requires drug manufacturers, by April 1 of each year,  
 19 to submit to the Department a report that includes:

- 20 • “[t]he costs of producing the drug”;
- 21 • “marketing and advertising costs” associated with the drug;
- 22 • profit “earned from the drug” and the amount of “total profit” attributable to it;
- 23 • the amount spent on “patient prescription assistance program[s]”;

24  
 25 <sup>8</sup> The key exception was dropping the 90-day notice provision for increases in the WAC.

26 <sup>9</sup> Insulin and biguanides each lower blood glucose through different physiological mechanisms. *See*  
 27 *Biguanides (Metformin) for Prediabetes and Type 2 Diabetes*, WebMD,  
 28 <http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes>.

- the cost of “coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs”;
- the “wholesale acquisition cost of the drug,” defined as “the manufacturer’s list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing date”;
- “[a] history of any increases in the wholesale acquisition cost of the drug” for the prior five years, “including the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective and any explanation for the increase”;
- “[t]he aggregate amount of all rebates” in Nevada; and
- other “information prescribed by regulation . . . for the purpose of analyzing the cost of prescription drugs . . . on the list.”

SB 539 § 3.8.

Any manufacturer that increases the WAC of an “essential” diabetes drug by more than the “Consumer Price Index, Medical Care Component” (“CPI”) during the preceding year, or by double the percentage increase in the CPI for Medical Care over the previous two years, also must disclose:

- “[a] list of each factor that has contributed to the increase”;
- “[t]he percentage of the total increase that is attributable to each factor”;
- “[a]n explanation of the role of each factor”; and
- “[a]ny other information prescribed by regulation.”

*Id.* §§ 3.6(2), 4.

By tying these disclosures to the CPI for Medical Care, the Act penalizes manufacturers whose diabetes drug prices exceed the index. But the CPI for Medical Care is not based only on drug prices. It also reflects prices for professional and hospital services. Effective diabetes drugs reduce doctor and hospital visits and thereby lower the CPI for Medical Care. Thus, on this measure, the more effective the product, the tighter the constraint on its price.

Once manufacturers have submitted the disclosures required by Sections 3.8 and 4, the Department, by June 1 of each year, must analyze them and “report on the price of the prescription drugs that appear on the most current lists . . . , the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State.” *Id.* § 4.3. The Department must post the report on its website, *id.* § 6(a)(5), organized to provide each

1 manufacturer “its own separate entry,” *id.* § 6(b). SB 539 allows the Department to publish the  
2 information, share it widely, or use it for such purposes as negotiating rebates with manufacturers.

3 What is more, SB 539 expressly eliminates trade-secret protection for all the information  
4 manufacturers must disclose. *Id.* § 4.3. Specifically, the Act narrows the definition of “trade secret”  
5 in NRS 600A.030 to exclude “any information that a manufacturer is required to report pursuant to  
6 section 3.8 or 4 of [the Act], . . . to the extent that such information is required to be disclosed by  
7 [that] section[.]” *Id.* § 9(5)(b). Failure to disclose the required information subjects the manufacturer  
8 to an administrative penalty of up to \$5,000 per day. *Id.* § 8(2).

9 The provisions of SB 539 relevant to this lawsuit are effective immediately “for the purpose  
10 of adopting regulations and performing any other [necessary] administrative tasks . . . and on  
11 October 1, 2017, for all other purposes.” *Id.* § 28(3). The Department intends to publish the first list  
12 of “essential” diabetes drugs on October 15, 2017.

13 **C. SB 539’s Harm to Plaintiffs’ Members and Innovation of Diabetes Treatments**

14 SB 539 would seriously harm Plaintiffs’ members, including the largest U.S. manufacturers  
15 of diabetes medicines. Several members produce drugs on the Department’s draft list of “essential”  
16 diabetes drugs. *Compare* Ex. D, *with* Ex. E, Decl. of Vanessa Broadhurst, at ¶ 4; Ex. F, Decl. of  
17 James Borneman, at ¶ 6; Ex. G, Decl. of Derek L. Asay, ¶ 4; Ex. H, Decl. of Patrick T. Davish, at  
18 ¶ 4; Ex. I, Decl. of Steve Albers, at ¶ 4; Ex. J, Decl. of Christine Marsh, at ¶ 4. None resides in  
19 Nevada. *See, e.g.*, Ex. F ¶ 3; Ex. I ¶ 3; Ex. J ¶ 3.

20 Eliminating trade secret protection allows competitors of affected manufacturers to freely  
21 use the confidential data the Act requires be disclosed showing a manufacturer’s cost structure,  
22 resource allocation, and pricing practices. Such access by competitors could handicap that  
23 manufacturer in the marketplace. Ex. E ¶ 13; Ex. F ¶¶ 15, 20; Ex. G ¶ 13; Ex. H ¶ 13; Ex. I ¶ 13; Ex.  
24 J ¶ 13. Worse, the factors manufacturers consider and the methodologies they deploy in setting  
25 prices are similar from product to product. Thus, this prejudice could spread to competition  
26 involving non-diabetes products. Similarly, information on a manufacturer’s costs and pricing  
27 formulas can prejudice the company’s ability to negotiate with third-party payers, including Nevada  
28

1 itself, regarding purchases and rebates for all the manufacturer's products. Ex. E ¶ 12; Ex. F ¶¶ 14,  
2 17; Ex. G ¶ 12; Ex. H ¶ 12; Ex. I ¶ 12; Ex. J ¶ 12.

3 The economic harm from SB 539 will be nationwide. Because the WAC is a national  
4 benchmark, SB 539's effective cap on a drug's WAC will apply nationwide. Similarly, the  
5 economic value of trade secrets withers in every state—including those where affected  
6 manufacturers reside—once Nevada makes the information public. The competitive harm from SB  
7 539 will undermine the incentives that patents provide for Plaintiffs' members to invest in  
8 developing innovative diabetes medicines. Ex. E ¶¶ 16–18; Ex. F ¶¶ 19–22; Ex. G ¶¶ 16–18; Ex. H  
9 ¶¶ 16–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 16–18. Absent judicial intervention, SB 539 could force  
10 innovators to revise their current and future priorities for diabetes research and development.

### 11 ARGUMENT

12 “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on  
13 the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the  
14 balance of equities tips in his favor, and that an injunction is in the public interest.” *Winter v. Nat.*  
15 *Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also DiTech Financial LLC v. Am. West Vill. II*  
16 *Owners Ass'n*, No. 2:17-CV-2164, 2017 WL 3610559, at \*1 (D. Nev. Aug. 22, 2017) (applying  
17 same standard for temporary restraining order). Under this Circuit's “serious questions” test, a  
18 temporary restraining order and preliminary injunction are also “appropriate when a plaintiff  
19 demonstrates that serious questions going to the merits were raised and the balance of hardships tips  
20 sharply in the plaintiff's favor.” *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134–35 (9th  
21 Cir. 2011); *accord Johnson v. Nguyen*, No. 3:12-CV-00538, 2015 WL 105826, at \*9 (D. Nev. Jan.  
22 7, 2015).<sup>10</sup> The court must balance “competing claims of injury” and “consider the effect on each  
23

24  
25 <sup>10</sup> Although the Federal Circuit would hear any appeal in this case as a result of Plaintiffs' patent  
26 preemption argument, *see, e.g., Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1365 (Fed. Cir. 2001),  
27 Ninth Circuit law governs whether this Court should grant a temporary restraining order and  
28 preliminary injunction. *See Broadcom Corp. v. Qualcomm Inc.*, No. SACV 05-468, 2005 WL  
5925584, at \*2 (C.D. Cal. Oct. 19, 2005); *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d  
891, 894 (Fed. Cir. 1998).

party” of granting or withholding the requested relief. *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 542 (1987).

Plaintiffs’ constitutional challenges to SB 539 will likely succeed on the merits. In stripping trade-secret protection from manufacturers of patented diabetes medicines, the Act conflicts with federal patent and trade-secret law, destroys valuable intellectual property without compensation, and imposes Nevada’s economic policy on every other state. The loss of trade secrets is irreversible and will not only harm the affected manufacturers, but also weaken national competition and undermine incentives to develop diabetes medicines. This harm outweighs any possible inconvenience to Defendants from postponing the Act’s implementation and enforcement.

# **I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS**

## **A. SB 539 Is Preempted By Federal Patent and Trade-Secret Law**

The Supremacy Clause makes “the Laws of the United States . . . the supreme Law of the Land.” U.S. Const. art. VI, § 1, cl. 2. “Thus, where Congress legislates within the scope of its constitutionally granted powers, that legislation may displace state law.” *Pharm. Research & Mfrs. of Am. v. District of Columbia (PhRMA)*, 406 F. Supp. 2d 56, 64 (D.D.C. 2005), *aff’d sub nom. Biotech. Indus. Org. v. District of Columbia (BIO)*, 496 F.3d 1362 (Fed. Cir. 2007). Even where federal legislation does not explicitly preempt state law, “federal courts [must] inquire whether a[n] implied preemption exists.” *Id.* And implied preemption exists, in the form of “conflict preemption,” where compliance with both state and federal regulation is either a “physical impossibility,” *id.* at 65, or “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

To determine whether a state statute poses such an obstacle, courts scrutinize both the legislature’s purpose and the “law’s actual effect.” *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 105 (1992); *accord BIO*, 496 F.3d at 1372 (“Our conflict inquiry is a searching one that ranges beyond the literal text of the statute.”). In purpose and effect, SB 539 obstructs federal patent and trade-secret laws from achieving their goals. It is therefore preempted.

# 1. SB 539 Conflicts with Federal Patent Law

The Constitution delineates Congress’s paramount role in setting national patent policy, vesting Congress with the power to “secur[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. Const. art. I, § 8, cl. 8. The stated objective of this clause is to “promote the Progress of Science and useful Arts.” *Id.*

Federal patent laws “promote . . . progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). Thus, a patent holder may “‘exclude all from the use of the protected process or product’ and charge prices of its choosing, including supracompetitive prices.” *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 400–01 (3d Cir. 2015) (quoting *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013)); *see also Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) (“The grant of a patent is the grant of a statutory monopoly . . .”). Patent laws “suppl[y] a carrot in the form of economic rewards resulting from the right to exclude,” and “the only limitation on the size of the carrot [of exclusivity] should be the dictates of the marketplace.” *King Instruments Corp. v. Perego*, 65 F.3d 941, 950, 960 (Fed. Cir. 1995).

The federal patent system thus “embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). “Congress, as the promulgator of patent policy, is charged with balancing these disparate goals. The present patent system reflects the result of Congress’s deliberations. Congress has decided that patentees’ present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use.” *BIO*, 496 F.3d at 1373.

Patent protection is critical to promote pharmaceutical research and development because discovering a successful new drug is exceedingly difficult, costly, and rare. By one estimate, “95% of the experimental medicines that are studied in humans fail to be both effective and safe. . . . [B]ecause so many drugs fail, large pharmaceutical companies . . . spend \$5 billion per new

1 medicine.”<sup>11</sup> Research and development costs of just the drugs that are ultimately approved are, on  
 2 average, \$2.6 billion, “a 145% increase” over the past decade.<sup>12</sup>

3 To deal with the unique economic challenges of pharmaceutical research and development,  
 4 Congress in the Hatch-Waxman Act, extended the patent term for pharmaceuticals to “create a  
 5 significant, new incentive which would result in increased expenditures for research and  
 6 development, and ultimately in more innovative drugs.” H.R. Rep. No. 98-857(I), at 18 (1984), *as*  
 7 *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 (Committee on Energy and Commerce); *see also BIO*,  
 8 496 F.3d at 1373. Balanced against the need for these incentives to innovate was the goal of  
 9 increasing consumer access to affordable medication. *Andrx Pharms., Inc. v. Biovail Corp. Int’l*,  
 10 256 F.3d 799, 809 (D.C. Cir. 2001). To that end, the Hatch-Waxman Act permits generic versions  
 11 of an innovator’s drug after the patent exclusivity expires. Signing the bill, President Reagan  
 12 reiterated that it “will promote medical breakthroughs and drug innovation by granting drug  
 13 companies up to 5 more years of patent protection for new drugs. And this extension will help  
 14 compensate for the years of patent life lost due to the time-consuming, but essential, testing required  
 15 by the Food and Drug Administration.” Presidential Statement on Signing S. 1538 Into Law, 20  
 16 Weekly Comp. Pres. Doc. 1359 (Sept. 24, 1984).

17 Relying on the incentives in the Hatch-Waxman Act, innovators boosted research and  
 18 development spending from \$3.6 billion in 1984 to more than \$30 billion in 2001.<sup>13</sup> In 2016 alone,  
 19 PhRMA members invested roughly \$65.5 billion in discovering and developing new medicines.<sup>14</sup>  
 20 For example, Novo Nordisk developed NovoLog, a rapid-acting insulin product and one of the most  
 21 widely used diabetes drugs in the United States. Since launching NovoLog, Novo Nordisk has  
 22

23 <sup>11</sup> Matthew Herper, *The Cost of Creating A New Drug Now \$5 Billion, Pushing Big Pharma To*  
 24 *Change*, Forbes.com (Aug. 11, 2013).

25 <sup>12</sup> Rick Mullin, *Tufts Study Finds Big Rise In Cost Of Drug Development*, Chem. & Eng’g News  
 26 (Nov. 20, 2014).

27 <sup>13</sup> *See Recent Developments Which May Impact Consumer Access to, and Demand for,*  
 28 *Pharmaceuticals: Hearing Before the Subcomm. on Health of the House Comm. on Energy and*  
*Commerce*, 107th Cong. (June 13, 2001) (statement of Rep. Barbara Cubin).

<sup>14</sup> Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey  
 (Washington, DC: PhRMA, 2017, forthcoming).

1 continued to invest in improving delivery of the treatment, with patented devices such as a special  
 2 injection syringe, an injection button, and a dose-setting limiter. By enhancing the convenience and  
 3 efficacy of treatment, such innovations reduce nonadherence and help patients control blood sugar.  
 4 The balance struck in the Hatch-Waxman Act has spurred many other innovations in treating  
 5 diabetes. *See* Compl. ¶¶ 23–28 (innovative diabetes products developed by Plaintiffs’ members).

6 In *BIO*, the Federal Circuit found that federal patent law preempted legislation at odds with  
 7 this careful balance. Plaintiffs there challenged a District of Columbia statute prohibiting  
 8 pharmaceutical manufacturers from selling or supplying a “patented prescription drug that results in  
 9 the prescription drug being sold in the District for an excessive price.” *BIO*, 496 F.3d at 1365. The  
 10 court held that the statute was a “clear attempt to restrain . . . excessive [drug] prices, in effect  
 11 diminishing the reward to patentees in order to provide greater benefit to District drug consumers.”  
 12 *Id.* at 1374. Because Congress—and Congress alone—is the “promulgator of patent policy,” federal  
 13 patent law preempted the District’s attempt to “re-balance the statutory framework of rewards and  
 14 incentives insofar as it relates to inventive new drugs.” *Id.* at 1373–74.

15 Like the D.C. law invalidated in *BIO*, SB 539 “attempt[s] to restrain . . . excessive [essential  
 16 diabetes drug] prices, in effect diminishing the reward to patentees in order to provide greater  
 17 benefit to [Nevada] drug consumers.” *Id.* at 1374. The Act punishes manufacturers if “essential”  
 18 diabetes drug prices increase more than the “percentage increase in the [CPI for Medical Services]  
 19 during” the prior year or “[t]wice the percentage increase [in that index]” over the prior two years.  
 20 SB 539 §§ 3.6(2), 4. The punishment is compelled disclosure of additional confidential pricing  
 21 information and loss of trade-secret protection for that information. *See supra*, p. 5. The only way a  
 22 manufacturer can preserve trade-secret protection is by limiting its list price to the *de facto* cap. SB  
 23 539 thus restrains patent holders from exercising their right under federal patent law to set prices.

24 This is precisely why the Federal Circuit in *BIO* struck down the D.C. law, because it  
 25 “shift[ed] the benefits of a patented invention from inventors to consumers.” 496 F.3d at 1374. The  
 26 D.C. law did so by prohibiting manufacturers from selling patented prescription drugs at “excessive  
 27 prices.” Nevada seeks to do so by penalizing manufacturers who, on its measure, excessively raise  
 28 the price of essential diabetes drugs. Both methods of curtailing federal patent rights are

1 unconstitutional. The preemption analysis is the same whether a local law bans excessive prices and  
2 then imposes penalties for violating the ban, as the D.C. law did, or imposes penalties for ostensibly  
3 excessive prices without expressly banning them first. *See Perez v. Campbell*, 402 U.S. 637, 652  
4 (1971) (states may not “nullify . . . unwanted federal legislation by simply . . . articulating some  
5 state interest or policy—other than frustration of the federal objective—that would be tangentially  
6 furthered by the proposed state law”); *cf. Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565–66 (2011)  
7 (“[T]he Government’s content-based burdens [on speech] must satisfy the same rigorous scrutiny as  
8 its content-based bans.”). The dispositive question is whether the law “stands as an obstacle to the  
9 accomplishment and execution of the full purposes and objectives of Congress.” *BIO*, 496 F.3d at  
10 1372 (quoting *Hines*, 312 U.S. at 67). In this respect, the laws in *BIO* and SB 539 are  
11 indistinguishable: both “stand[] as an obstacle to the federal patent law’s balance of objectives as  
12 established by Congress” by “penalizing high prices . . . and thus limiting the full exercise of the  
13 exclusionary power that derives from a patent.” *BIO*, 496 F.3d at 1374.

14 In many ways, SB 539 is even less compatible with Congress’s comprehensive federal  
15 patent scheme than was the law in *BIO*. That law only curbed *future* price increases, barring sales of  
16 patented drugs at “excessive” prices. SB 539 does that *and* punishes manufacturers for *past* price  
17 increases. It singles out a class of private companies—makers of essential diabetes drugs—because  
18 Nevada deems their past prices excessive. *See, e.g.*, Mar. 29 Mins at 33, 36–37, 58–60; May 26  
19 Mins. at 3. The Act requires these companies alone to disclose confidential, competitively critical,  
20 proprietary information detailing costs, pricing factors, advertising plans, and marketing strategies  
21 for their patented diabetes medicines. *See* SB 539 § 3.8. The Act also wipes out trade-secret  
22 protection for this information. *Id.* § 9. Like many retrospective penalties, SB 539 also has a  
23 prospective effect. It deters the enormous investment needed to develop new diabetes medicines,  
24 because when manufacturers seek to recoup their investments by setting prices as federal patent law  
25 contemplates, the State will punish them for doing so. Thus, both retroactively and prospectively,  
26 SB 539 burdens pharmaceutical innovators’ exercise of the right the federal patent laws confer.

## 2. SB 539 Conflicts with Federal Trade-Secret Law

Federal and state trade-secret laws also play an important role in sustaining the American economy. Legal protection for trade secrets “encourage[s] invention in areas where patent law does not reach, and . . . prompt[s] the independent innovator to proceed with the discovery and exploitation of his invention.” *Kewanee Oil*, 416 U.S. at 485. In the end, “[c]ompetition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention.” *Id.*

Every U.S. state protects trade secrets. Forty-eight states, including Nevada, have adopted some form of the Uniform Trade Secrets Act (“UTSA”). *See* H.R. Rep. No. 114-529, at 4 (2016) (Committee on the Judiciary); *Frantz v. Johnson*, 999 P.2d 351, 357–58 (Nev. 2000). The remaining two states—New York and Massachusetts—protect trade secrets under the longstanding common-law tort of misappropriation. *See Ashland Mgmt. Inc. v. Janien*, 624 N.E.2d 1007, 1012 (N.Y. 1993); *Peabody v. Norfolk*, 98 Mass. 452, 457 (1868).

Against this backdrop, Congress passed the Defend Trade Secrets Act (“DTSA”) of 2016, creating a federal private right of action for misappropriation of trade secrets “related to a product or service used in, or intended for use in, interstate or foreign commerce.” Pub. L. No. 114-153, 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)). Congress enacted the DTSA because “trade secrets are increasingly becoming the foundation of businesses across the country, with one estimate placing the value of trade secrets in the United States at \$5 trillion. . . . With so much at stake, it is absolutely vital . . . [to] include strong protections against the theft of trade secrets.” 162 Cong. Rec. H2028-01, H2033 (Apr. 27, 2016) (comments of Rep. Nadler). “By improving trade secret protection,” Congress sought “to incentivize future innovation while protecting and encouraging the creation of American jobs.” S. Rep. No. 114-220, at 3 (2016).

Even though all states protected trade secrets, Congress worried that state trade-secret “laws vary in a number of ways and contain built-in limitations that make them not wholly effective in a national and global economy.” H.R. Rep. No. 114-529, at 4. The DTSA therefore provides U.S. businesses a uniform remedy for misappropriation because “trade secret cases often require swift action by courts across state lines to preserve evidence.” *Id.* “[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist.” 162 Cong. Rec.

1 H2034 (comments of Rep. Jackson Lee). Thus, the DTSA allows businesses “to move quickly to  
 2 Federal court . . . to stop trade secrets from winding up being disseminated and losing their value.”  
 3 H.R. Rep. No. 114-529, at 6; *see also id.* at 13; *accord* S. Rep. No. 114-220, at 3.

4 SB 539 frustrates Congress’s purpose to provide an effective nationwide remedy for  
 5 misappropriation of trade secrets. The Act compels manufacturers to disclose confidential  
 6 information that derives independent value from not being generally known to third-party payers  
 7 and competitors. Ex. E ¶¶ 6, 9; Ex. F ¶¶ 8, 11; Ex. G ¶¶ 6, 9; Ex. H ¶¶ 6, 9; Ex. I ¶¶ 6, 9; Ex. J ¶¶ 6,  
 8 9. This information is a trade secret under the DTSA as well as Nevada law—unless and until SB  
 9 539 takes effect.<sup>15</sup> *See, e.g., Aerodynamics Inc. v. Caesars Entm’t Operating Co.*, No. 2:15-CV-  
 10 01344, 2015 WL 5679843, at \*8 (D. Nev. Sept. 24, 2015) (“confidential pricing information, . . .  
 11 marketing strategies, . . . exact pricing for [certain] bid[s], payment terms, and credits and discounts  
 12 provided” held trade secrets under state law); *Finkel v. Cashman Prof’l, Inc.*, 270 P.3d 1259, 1263  
 13 (Nev. 2012) (“confidential pricing structures and marketing plans” were trade secrets); *see also*  
 14 Compl. ¶ 86 (collecting additional cases). Further, as noted, the Act eliminates trade-secret  
 15 protection for information that a manufacturer is required to report, SB 539 § 9, allows the  
 16 Department to freely use or disseminate the disclosed information, and *directs* the Department to  
 17 post a report matching the information to each manufacturer. *Id.* § 6(a)(5), (b).

18 Once published under the authority of SB 539, a manufacturer’s information loses its trade-  
 19 secret status not just in Nevada, but nationwide. Fundamental to the definition of a trade secret is  
 20 that it remains confidential. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984) (“Because of  
 21 the intangible nature of a trade secret, the extent of the property right therein is defined by the extent  
 22 to which the owner of the secret protects his interest from disclosure to others.”). Thus, information  
 23 broadcast over the Internet has become “public knowledge” and no longer remains a trade secret.

24  
 25 <sup>15</sup> Because Congress modeled the DTSA definition of “trade secret” on the UTSA definition,  
 26 “courts may look to the state UTSA when interpreting the DTSA.” *Kuryakyn Holdings, LLC v.*  
 27 *Ciro, LLC*, No. 15-CV-703-JDP, 2017 WL 1026025, at \*5 (W.D. Wis. Mar. 15, 2017); *see also*  
 28 H.R. Rep. 114-529, at 14 (“[T]he Committee does not intend for the definition of a trade secret to  
 be meaningfully different from . . . [those] States that have adopted the UTSA.”).

1 *Id.*; *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir. 2002) (en banc) (it is “paradigmatic” that  
2 compelled disclosure to a party not required to keep the secret extinguishes the property right).

3 The difference between SB 539 and the DTSA (plus other states’ laws) is not merely a  
4 matter of nuance. SB 539 guts the trade-secret protection afforded by the federal government and  
5 every state for confidential information associated with essential diabetes drugs. This mass  
6 nullification frustrates Congress’s goal in the DTSA to enhance trade-secret protections and thereby  
7 to “incentivize future innovation while protecting and encouraging the creation of American jobs.”  
8 S. Rep. No. 114-220, at 3. SB 539 thus “stands as an obstacle to the accomplishment and execution  
9 of the full purposes and objectives of Congress.” *Hines*, 312 U.S. at 67.

10 **B. SB 539’s Uncompensated Abolition of Trade-Secret Protection for Valuable**  
11 **Information Violates the Fifth Amendment Takings Clause**

12 The Fifth and Fourteenth Amendments forbid the taking of “private property . . . for public  
13 use, without just compensation.” U.S. Const., amend. V, XIV. “Private property” includes  
14 intangible property, such as trade secrets. *Ruckelshaus*, 467 U.S. at 1002–04. A state’s “failure to  
15 provide adequate protection to assure [a trade secret’s] confidentiality, when disclosure is  
16 compelled . . . , can amount to an unconstitutional taking of property by destroying [the trade  
17 secret], or by exposing it to the risk of destruction by public disclosure or by disclosure to  
18 competitors.” *St. Michael’s Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981)  
19 (alteration omitted) (quoting *Wearly v. FTC*, 462 F. Supp. 589, 598 (D.N.J. 1978)).

20 In *Ruckelshaus*, the Supreme Court held that the Environmental Protection Agency (EPA)  
21 impermissibly took property without compensation by disclosing pesticide manufacturers’ trade  
22 secrets collected under EPA’s regulatory authority. 467 U.S. at 1016. A prior version of the statute  
23 had required EPA to keep confidential all information that manufacturers designated as trade  
24 secrets. *Id.* at 990–97. However, the revised statute authorized EPA to disclose this information to  
25 competitors for regulatory purposes so long as they agreed to pay for it and, if necessary, submit to  
26 arbitration over the price. *Id.* The Court held that this revision violated the Takings Clause because  
27 the manufacturer had disclosed the information with the expectation it would remain secret but then  
28

1 found that the information was available to any competitor willing to arbitrate over the price. *Id.* at  
2 1011; *see also Reilly*, 312 F.3d at 41–42; *St. Michael's*, 643 F.2d at 1374.

3 The Supreme Court explained that “[t]he right to exclude others is generally one of the most  
4 essential sticks in the bundle of [property] rights,” and for trade secrets “the right to exclude others  
5 is central to the very definition of the property interest.” *Ruckelshaus*, 467 U.S. at 1011. Under the  
6 revised statute, EPA (like Nevada) was “extinguish[ing]” trade secrets through public disclosure. *Id.*  
7 at 1002. Eliminating confidentiality, the essence of the property right, defeated manufacturers’  
8 investment-backed expectations. *Id.* at 1011–12. The expectations were reasonable because the  
9 information had trade-secret protection when generated. *Id.* at 1013; *Reilly*, 312 F.3d at 41.  
10 Disclosure destroyed its value as a trade secret. *Ruckelshaus*, 467 U.S. at 1012. Although the Court  
11 typically considered “several factors . . . when determining whether a governmental action has gone  
12 beyond ‘regulation’ and effects a ‘taking’”—such as “the character of the governmental action, its  
13 economic impact, and its interference with reasonable investment-backed expectations,” *id.* at  
14 1005—the Court found the depredation of the manufacturers’ investment-backed expectations  
15 dispositive because “the force of this factor [was] so overwhelming,” *id.* In other words, this taking  
16 was “categorical.” *Id.* at 1012; *see also Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992)  
17 (destruction of core property interest is a categorical taking).

18 Like the statute at issue in *Ruckelshaus*, SB 539 extinguishes pharmaceutical manufacturers’  
19 property interest in the confidentiality of their trade secrets and thus works a categorical taking.  
20 Manufacturers investing in diabetes treatments had reasonable “investment-backed expectations”  
21 that their confidential information would remain secret. *See Reilly*, 312 F.3d at 40. For many years  
22 Nevada—like every other state—treated this information as a trade secret, with no diabetes  
23 exception. *See, e.g., Nev. Rev. Stat* § 600A.030 (1987); *Finkel*, 270 P.3d at 1263; *Frantz*, 999 P.2d  
24 at 359. SB 539, however, strips trade-secret protection and *mandates* public disclosure of  
25 confidential information, eradicating trade-secret protection in other states. *See Ruckelshaus*, 467  
26 U.S. at 1011–12; *see also* 162 Cong. Rec. H2034 (“[U]nlike patents, once this information is  
27 disclosed it instantly loses its value and the property right itself ceases to exist.” (comments of Rep.  
28 Jackson Lee)). This is precisely the result that the Supreme Court held unconstitutional.

1 The other two factors in the takings analysis, while cumulative, *see Ruckelshaus*, 467 U.S. at  
 2 1005; *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978), reconfirm that the Act  
 3 is an impermissible taking. First, the “character” of this legislative action weighs heavily against the  
 4 Act. For punishment and coercion, it discloses trade secrets, causing them to “lose all value.” *Reilly*,  
 5 312 F.3d at 41 (citing this aspect of state disclosure statute’s “character” to show a regulatory  
 6 taking). “Therefore, if the [pharmaceutical manufacturers] comply with the requirements of [SB  
 7 539], their property right will be extinguished.” *Id.* at 42. “[T]his is precisely what the Takings  
 8 Clause is designed to prevent.” *Id.* at 43.

9 Second, eliminating trade-secret protection here will have a devastating “economic impact.”  
 10 Manufacturers of essential diabetes drugs, if forced to disclose such information, will be at a severe  
 11 disadvantage vis-à-vis competitors not subject to the Act. *See supra*, p. 8. Affected manufacturers,  
 12 but not manufacturers of non-diabetes drugs, also will be disadvantaged in dealing with third-party  
 13 payers, who have the manufacturer’s playbook in negotiations. *See supra*, p. 8.

14 These adverse effects extend beyond Nevada to the entire Nation. Ex. E ¶¶ 10–14; Ex. F  
 15 ¶¶ 12–17; Ex. G ¶¶ 10–14; Ex. H ¶¶ 10–14; Ex. I ¶¶ 10–13; Ex. J ¶¶ 10–14. As noted, for trade  
 16 secrets, disclosure anywhere is disclosure everywhere. *See supra*, pp. 8–9. A trade secret published  
 17 in Nevada is useable in New York, Ohio, or any other state. This nationwide geographic scope  
 18 amplifies the competitive harm to, and hence the penalty on, Plaintiffs’ members for exercising the  
 19 right federal patent law confers to set prices for their diabetes products. Manufacturers relied on the  
 20 protection that the federal government, Nevada, and every other state afforded trade secrets. These  
 21 companies did not expect Nevada to overturn that protection everywhere. Nor did they expect the  
 22 consequent economic impact: the nationwide erosion of anticipated returns on their investments in  
 23 researching, developing, and marketing their diabetes drugs. Ex. E ¶¶ 15–18; Ex. F ¶¶ 18–21; Ex. G  
 24 ¶¶ 15–18; Ex. H ¶¶ 15–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 15–18.

### 25 C. SB 539 Violates the Commerce Clause by Overriding Every Other State’s Laws

26 The Constitution authorizes Congress “[t]o regulate Commerce . . . among the several  
 27 States.” U.S. Const. art. I, § 8, cl. 3. The Commerce Clause “reflect[s] a central concern of the  
 28 Framers . . . : the conviction that in order to succeed, the new Union would have to avoid the

tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.” *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979). Thus, the Supreme Court has “long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute.” *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This is the “so-called ‘dormant’ aspect of the Commerce Clause.” *Id.*

A state law oversteps these constitutional limits when it imposes a burden on interstate commerce “clearly excessive in relation to the putative local benefits.” *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). The dormant Commerce Clause “prohibits states . . . from regulating interstate commerce and enacting legislation that would ‘offend sister States and exceed the inherent limits of the State’s power.’” *PhRMA*, 406 F. Supp. 2d at 67 (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336 n.13 (1989)). SB 539 violates this principle by imposing sanctions for out-of-state conduct and nullifying rights that all other states grant.

First, SB 539 restrains PhRMA and BIO members’ commerce in other states by penalizing them in Nevada. The Act’s price cap is keyed to the WAC, a *national* benchmark. By affecting a drug’s WAC, SB 539 affects drug prices *nationally*, including for drugs bought and sold outside Nevada. A New York manufacturer of essential diabetes drugs selling to a California purchaser must lower its price to prevent Nevada from negating the company’s trade secrets. The dormant Commerce Clause bars Nevada from imposing such burdens on wholly extraterritorial commerce.

Again, *BIO* is instructive. Besides holding the D.C. law preempted by federal patent law, the district court found that the law’s “impermissible extraterritorial reach” violated the dormant Commerce Clause. *PhRMA*, 406 F. Supp. 2d at 70. The court stressed that Plaintiffs’ members “manufacture patented prescription drugs wholly outside the District of Columbia,” are neither headquartered nor operate warehouses there, and make “the overwhelming majority of [their] sales” outside D.C. to out-of-state wholesalers. *Id.* at 68. “[T]he critical inquiry” was “whether the practical effect of the [law was] to control conduct beyond the boundaries of the State.” *Id.* at 70 (quoting *Healy*, 491 U.S. at 336). It was indeed, as Plaintiffs’ members could not “conduct commerce on their own terms elsewhere, without either scrutiny or control by the District.” *Id.*

1 The same is true of SB 539. By penalizing manufacturers for increasing the WAC of  
 2 diabetes drugs above the CPI for Medical Care, SB 539 prevents them from “conduct[ing]  
 3 commerce on their own terms elsewhere, without either scrutiny or control by [Nevada].” *Id.* Such a  
 4 statute “offend[s] sister States and exceed[s] the inherent limits of [Nevada’s] power.” *Id.* at 67.

5 Second, SB 539 burdens interstate commerce by eviscerating commercial rights other states  
 6 grant, stripping a broad compass of trade-secret protection for *all* manufacturers of essential  
 7 diabetes drugs, whatever the prices they charge. *See* SB 539 §§ 3.8, 9. None of these companies is  
 8 headquartered in Nevada. SB 539 will prevent manufacturers from protecting their trade secrets in  
 9 every state. This imposition will interfere in particular with states that host these manufacturers’  
 10 headquarters or key operations. Those jurisdictions have a legitimate interest—which Nevada  
 11 overrides—in promoting the success of these manufacturers by protecting their trade secrets. *See*  
 12 *Healy*, 491 U.S. at 336–37 (“[T]he Commerce Clause protects against inconsistent legislation  
 13 arising from the projection of one state regulatory regime into the jurisdiction of another State.”).

14 For example, Eli Lilly—one of three major insulin manufacturers—is headquartered in  
 15 Indianapolis, Indiana, with *no* offices or operations in Nevada. Indiana law protects Eli Lilly’s trade  
 16 secrets—including pricing and cost information for its essential diabetes drugs. *See, e.g., Hydraulic*  
 17 *Exch. & Repair, Inc. v. KM Specialty Pumps, Inc.*, 690 N.E.2d 782, 786 (Ind. Ct. App. 1998).  
 18 Indiana has an interest in protecting that confidential information to preserve the company’s  
 19 financial strength, which affects local jobs and economic growth. In compelling the disclosure of  
 20 information that is a trade secret under Indiana law, SB 539 overturns Indiana’s protection. SB 539  
 21 bestows upon Nevada legislators supreme judgment as to the proper balance between the protection  
 22 of trade secrets and the promotion of “transparency” in pricing. The dormant Commerce Clause  
 23 does not tolerate such efforts by one state to foist its regulatory preferences on every other state.

24 These substantial effects on interstate commerce clearly exceed any putative local benefit  
 25 SB 539 may have in Nevada. While the purpose of the Act is to control prices for diabetes drugs,  
 26 neither the Act nor its legislative history explains how gutting manufacturers’ trade-secret  
 27 protection will lower prices—apart, that is, from impermissibly burdening manufacturers’ lawful  
 28 exercise of federal patent rights. *See, e.g., Mar. 29 Mins.* at 33, 36–37, 58–60; *May 26 Mins.* at 3.

1 Nevada's attempt to "extend [its] police power beyond its jurisdictional bounds" offends the  
2 dormant Commerce Clause. *C & A Carbone v. Town of Clarkstown*, 511 U.S. 383, 393 (1994).

3 **II. PLAINTIFFS' MEMBERS WILL SUFFER IRREPARABLE HARM ABSENT A**  
4 **TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTIVE**  
5 **RELIEF**

6 "Irreparable harm is traditionally defined as harm for which there is no adequate legal  
7 remedy, such as an award of damages." *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th  
8 Cir. 2014). It is "presumed where a party misappropriates a trade secret." *Excellence Cmty. Mgmt.,*  
9 *LLC v. Gilmore*, 351 P.3d 720, 724 (Nev. 2015) (presumption where use of stolen trade secret was  
10 ongoing or imminent); *see also Finkel*, 270 P.3d at 1264; *Saini v. Int'l Game Tech.*, 434 F. Supp. 2d  
11 913, 919 (D. Nev. 2006) ("[D]isclosure of confidential information or trade secrets would create  
12 irreparable injury . . ."). "[I]t is axiomatic that unprotected disclosure of a trade secret destroys the  
13 secret." 4 Robert M. Milgrim & Eric E. Bensen, *Milgrim on Trade Secrets* § 15.02[1][c].

14 The challenged provisions of SB 539 become effective on October 1, 2017, and officially  
15 strip affected manufacturers of trade-secret protection for their confidential data as soon as the  
16 Department publishes its list of "essential" diabetes drugs, which Defendants represent will happen  
17 on October 15, 2017—just weeks from now. *See* SB 539 § 28(3). Furthermore, the Act compels  
18 disclosure no later than April 1, 2018. The Department then has free rein to disseminate the  
19 information. Faced with this forced disclosure, Plaintiffs' members must immediately reassess the  
20 risks and returns of their investments in diabetes therapies. *See* Ex. E ¶¶ 16–18; Ex. F ¶¶ 19–22; Ex.  
21 G ¶¶ 16–18; Ex. H ¶¶ 16–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 16–18. "[Such] harms, which are not readily  
22 addressed through payment of economic damages, are sufficient to meet the irreparable injury  
23 requirement for a preliminary injunction." *Saini*, 434 F. Supp. 2d at 919; *accord Aerodynamics*,  
24 2015 WL 5679843, at \*12. Only a temporary restraining order and preliminary injunction can  
25 prevent irreparable harm by protecting trade secrets pending resolution of this litigation.

26 **III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST SUPPORT A**  
27 **TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

28 The balance of hardships decisively favors a temporary restraining order and preliminary  
injunction. Where, as here, a "plaintiff shows a substantial likelihood that the challenged law is

1 unconstitutional, no substantial harm to others can be said to inhere in its enjoinder.” *Déjà vu of*  
 2 *Nashville, Inc. v. Metro. Gov’t of Nashville & Davidson Cty.*, 274 F.3d 377, 400 (6th Cir. 2001);  
 3 *accord Nelson v. NASA*, 530 F.3d 865, 881–82 (9th Cir. 2008) (constitutional violation tips balance  
 4 of hardships “sharply toward” party seeking injunction), *rev’d on other grounds*, 562 U.S. 134  
 5 (2011). Because Plaintiffs have shown a likelihood of success on their constitutional claims, the  
 6 balance of hardships favors them, and the Court need not assess any potential effect on Defendants.

7 In any event, the only arguable “hardship” to Defendants is a possible delay in  
 8 implementation of the Act. Even if publication of the list of “essential” diabetes drugs were  
 9 postponed temporarily, any inconvenience resulting from the delay would pale compared to the  
 10 substantial and irreparable harm that the Act would inflict on Plaintiffs’ members.

11 Finally, the public interest strongly favors a temporary restraining order pending disposition  
 12 of Plaintiffs’ motion for a preliminary injunction, and a preliminary injunction pending resolution of  
 13 this case. “[I]t is always in the public interest to prevent the violation of a party’s constitutional  
 14 rights.” *Sw. Voter Registration Educ. Project v. Shelley*, 344 F.3d 882, 910 (9th Cir.), *rev’d on other*  
 15 *grounds*, 344 F.3d 914 (9th Cir. 2003); *see also Preminger v. Principi*, 422 F.3d 815, 826 (9th Cir.  
 16 2005) (similar). And “there is a strong public interest in protecting trade secrets, as evidenced by the  
 17 existence of the DTSA and UTSA.” *Prot. Techs., Inc. v. Ribler*, 2017 WL 923912, at \*3 (D. Nev.  
 18 Mar. 8, 2017). Allowing SB 539 to take effect could undermine public health by upending  
 19 Congress’s carefully crafted a system of incentives encouraging the development of new medicines.  
 20 It is therefore in the public interest to preserve the *status quo* while the Court considers SB 539’s  
 21 constitutional defects.

## 22 CONCLUSION

23 SB 539 interferes with federal patent and trade-secret laws, deprives manufacturers of  
 24 property rights in their trade secrets, and improperly overrides the regulatory choices of every other  
 25 state. These violations threaten irreparable harm to Plaintiffs’ members, and ultimately, diabetes  
 26 patients. Plaintiffs therefore respectfully ask the Court to temporarily restrain and preliminarily  
 27  
 28

1 enjoin Defendants from implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, and 9 of SB 539,  
2 and all related sections or subsections.

3 Dated: September 13, 2017.

4 McDONALD CARANO LLP

5  
6 By: /s/ Pat Lundvall

7 Pat Lundvall

8 2300 West Sahara Avenue, Suite 1200

9 Las Vegas, NV 89102

10 Telephone: (702) 873-4100

11 Facsimile: (702) 873-9966

12 Robert N. Weiner

13 Jeffrey L. Handwerker

14 R. Stanton Jones

15 ARNOLD & PORTER KAYE SCHOLER LLP

16 601 Massachusetts Avenue, NW

17 Washington, DC 20001

18 Telephone: (202) 942-5000

19 Facsimile: (202) 942-5999

20 *Attorneys for Plaintiffs Pharmaceutical Research and*  
21 *Manufacturers of America and Biotechnology*  
22 *Innovation Organization*  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that I am an employee of McDonald Carano LLP, and that on this 13th day of September, 2017, I caused a true and correct copy of the foregoing **PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION, AND SUPPORTING MEMORANDUM OF POINTS AND AUTHORITIES** to be served via HAND DELIVERY upon the following:

Linda C. Anderson  
Chief Deputy Attorney General  
555 E. Washington, #3900  
Las Vegas, NV 89101  
Phone: (702) 486-3077

*Counsel for Defendants*

/s/ Marianne Carter  
An employee of McDonald Carano LLP

**INDEX OF EXHIBITS**

<b><u>Description</u></b>	<b><u>Exhibit No.</u></b>
Nevada State Senate Bill No. 539	A
June 2, 2017 Letter from Gov. Sandoval to Sen. Majority Leader Ford	B
Chart of FDA-Approved Diabetes Medicines	C
List of Essential Diabetes Drugs	D
Declaration of Vanessa Broadhurst	E
Declaration of James Borneman	F
Declaration of Derek L. Asay	G
Declaration of Patrick T. Davish	H
Declaration of Steve Albers	I
Declaration of Christine Marsh	J

# EXHIBIT 7

# EXHIBIT 7

**McDONALD CARANO**  
2300 WEST SAHARA AVENUE, SUITE 1200 • LAS VEGAS, NEVADA 89102  
PHONE 702.873.4100 • FAX 702.873.9966

Pat Lundvall (NSBN 3761)  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
lundvall@mcdonaldcarano.com

Robert N. Weiner  
Admitted *Pro Hac Vice*  
Jeffrey L. Handwerker  
Admitted *Pro Hac Vice*  
R. Stanton Jones  
Admitted *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA and  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as  
Governor of the State of Nevada; RICHARD  
WHITLEY, in his official capacity as Director of  
the Nevada Department for Health and Human  
Services; and the NEVADA LEGISLATURE,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

**JOINT STATUS REPORT**

Plaintiffs Pharmaceutical Research and Manufacturers of America ("PhRMA") and  
Biotechnology Innovation Organization ("BIO") (together, "Plaintiffs"), and Defendants Brian

1 Sandoval, in his official capacity as Governor of the State of Nevada (the “State”), Richard Whitley,  
 2 in his official capacity as Director of the Nevada Department of Health and Human Services (the  
 3 “Department”), and the Nevada Legislature (the “Legislature”) (together, “Defendants”), by and  
 4 through their respective undersigned counsel, hereby submit this joint status report to apprise the  
 5 Court of their collective views regarding the implications of the now-effective regulation adopted  
 6 by the Department, LCB File No. R042-18 (Joint Status Report Ex. 1), and the State’s subsequent  
 7 actions on this litigation.

8 *First*, as the Court is aware, the Department previously issued a proposed regulation (ECF  
 9 No. 86-1) designed to mitigate the constitutional concerns that Plaintiffs raised with respect to  
 10 Nevada Senate Bill No. 539 (“SB 539”). Plaintiffs argued that the challenged provisions of SB 539,  
 11 including the provision that excludes from the definition of “trade secret” “any information that a  
 12 manufacturer is required to report pursuant to section 3.8 or 4 of [SB 539],” *see* SB 539 § 9, are  
 13 preempted by the federal patent laws and the federal Defend Trade Secrets Act (“DTSA”), and also  
 14 violate the Fifth Amendment Takings Clause and the dormant Commerce Clause. The Department  
 15 argued that Plaintiffs’ claims were not ripe for review because “the Department is not exempt from  
 16 exposure for liability under [the] DTSA if the Department were to disclose a federally defined trade  
 17 secret without consent from the manufacturer who asserted that secrecy. Plaintiffs have a separate,  
 18 stand-alone remedy under [the] DTSA that affords protection for their trade secrets if they need to  
 19 challenge any action of the Department.” Opp’n to Pls.’ Mot. Summ. J. 4, ECF No. 74. Further, the  
 20 Department also argued that “[t]o the extent that the state law fails to set forth a process for protecting  
 21 trade secrets that could be subject to dissemination under SB 539, the void will be filled by  
 22 regulations of the Department.” *Id.* at 4–5.

23 On May 31, 2018, the Department accelerated its anticipated timeline and adopted the  
 24 proposed regulation, which became effective that same date (Joint Status Report Ex. 1 at 1).  
 25 Defendants believe that, as predicted, the now-effective regulation has filled any void and obviated  
 26 Plaintiffs’ alleged facial constitutional claims. Under the now-effective regulation, pharmaceutical  
 27 manufacturers may request that information they submit to the Department pursuant to Sections 3.8  
 28 and 4 of SB 539 be kept confidential as trade secrets under the DTSA. *See* Regulation § 3 (Joint

1 Status Report Ex. 1 at 6-10). To request such confidentiality, the manufacturer must (1) “describe,  
2 with particularity, the information sought to be protected from public disclosure,” *id.* § 3(2)(a); and  
3 (2) “include an explanation of the reasons why public disclosure of the information would constitute  
4 misappropriation of a trade secret for which a court may award relief pursuant to the federal [DTSA],  
5 as amended,” *id.* § 3(2)(b).

6 Under the DTSA, a court may award relief where a trade secret is “misappropriated,” which  
7 the DTSA defines to include “disclosure or use of a trade secret of another without express or implied  
8 consent by a person who . . . at the time of disclosure or use, knew or had reason to know that the  
9 knowledge of the trade secret was . . . acquired under circumstances giving rise to a duty to maintain  
10 the secrecy of the trade secret or limit the use of the trade secret.” 18 U.S.C. § 1839(5)(B)(ii)(II).  
11 The parties agree and acknowledge that, under SB 539, the Department may acquire manufacturer  
12 trade secrets, such as a manufacturer’s costs of production and other internal costs, “under  
13 circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the  
14 trade secret.” *Id.* Thus, the parties agree and acknowledge that, so long as such trade secrets continue  
15 to satisfy the definition of “trade secret” in 18 U.S.C. § 1839, if the Department were to disclose  
16 such trade secrets to any third party or use such trade secrets, such disclosure or use would constitute  
17 “misappropriation” for which a court may award relief pursuant to the DTSA. These protections are  
18 intended to afford an opportunity to manufacturers that submit trade secrets to the Department to  
19 seek to safeguard their interests in the confidentiality of those trade secrets. In Defendants’ view,  
20 the now-effective regulation, as described, resolves the alleged facial constitutional issues with  
21 respect to the challenged provisions of SB 539.

22 *Second*, on June 7, 2018, the Department represented on its website that it would not proceed  
23 with enforcement actions for manufacturer reports submitted on or before January 15, 2019. The  
24 Department has further assured Plaintiffs through email correspondence that it will not bring any  
25 enforcement action against any manufacturer based on the submission of an incomplete report or no  
26 report during this time period, so long as the manufacturer submits a compliant report on or before  
27 January 15, 2019. On the basis of these representations, on June 8, 2018, Plaintiffs withdrew their  
28 renewed motion for a preliminary injunction without prejudice.



/s/ Kevin C. Powers

Kevin C. Powers

Chief Litigation Counsel

Nevada Bar No. 6781

Nevada Legislative Counsel Bureau, Legal Division

401 S. Carson Street

Carson City, Nevada 89701

Telephone: (775) 684-6830

kpowers@lcb.state.nv.us

*Attorney for Defendant Nevada Legislature*

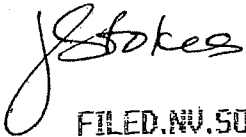
### **CERTIFICATE OF SERVICE**

I certify that I am an employee of McDonald Carano, and that on the 28<sup>th</sup> day of June, 2018, a true and correct copy of the foregoing JOINT STATUS REPORT was electronically filed with the Clerk of the Court by using CM/ECF service which will provide copies to all counsel of record registered to receive CM/ECF notification.

/s/ Beau Nelson

An employee of McDonald Carano LLP

# EXHIBIT 1

SECRETARY OF STATE FILING DATA

FILED.NV.SOS 2018 MAY 31 PM4:42

**Form For Filing  
Administrative Regulations**

**Agency:**  
**Department of Health and Human  
Services**

FOR EMERGENCY REGULATIONS ONLY
Effective date _____
Expiration date _____
_____ Governor's signature

**Classification:**    **PROPOSED** ☒ **ADOPTED BY AGENCY**    **EMERGENCY** ☐

**Brief description of action:**

The adopted regulation outlines how the Department of Health and Human Services will support submission of certain reports by manufacturers of prescription drugs, pharmacy benefit managers and pharmaceutical sales representatives by providing forms online. It describes the process by which a manufacturer or pharmacy benefit manager can submit a request for confidentiality covering certain information. Lastly, it describes procedures the Department will follow when public information requests for information are filed and for which a confidentiality request has been submitted.

**Authority citation other than 233B:**

**Notice date:**    January 30, 2018; April 30, 2018

**Date of Adoption by Agency:** May 31, 2018

**Hearing date:** February 15, 2018; May 31, 2018

**APPROVED REGULATION OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**LCB File No. R042-18**

Effective May 31, 2018

EXPLANATION – Matter in *italics* is new; matter in brackets ~~[omitted material]~~ is material to be omitted.

AUTHORITY: §§1-4, NRS 439.930.

A REGULATION relating to prescription drugs; providing that the Department of Health and Human Services will make available on an Internet website maintained by the Department certain forms that must be used by manufacturers of prescription drugs, pharmacy benefit managers and pharmaceutical sales representatives to submit certain reports to the Department; authorizing a manufacturer or pharmacy benefit manager that submits such a report to request that the Department keep certain information confidential as a trade secret under federal law; establishing procedures for the Department to follow when it receives a request for public records seeking disclosure of information for which a manufacturer or pharmacy benefit manager has submitted a request for confidentiality; prescribing certain requirements for reports compiled by the Department concerning the prices of certain prescription drugs; and providing other matters properly relating thereto.

**Legislative Counsel's Digest:**

Existing law requires the Department of Health and Human Services to compile each year: (1) a list of prescription drugs essential for treating diabetes in this State; and (2) a list of such prescription drugs which have been subject to an increase in wholesale acquisition cost that exceeds a prescribed amount. (Section 3.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4297 (NRS 439B.630)) Existing law also requires the manufacturers of drugs that appear on those lists and pharmacy benefit managers to submit to the Department annual reports containing certain information about the prices of those drugs. (Sections 3.8, 4 and 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 and 439B.645)) Existing law further requires a pharmaceutical sales representative who markets prescription drugs on behalf of a manufacturer in this State to submit to the Department an annual report concerning the provision of compensation and free samples to certain persons. (Section 4.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.660)) **Section 2** of this regulation provides that the Department will make

available on an Internet website maintained by the Department the forms that must be used by the manufacturers, pharmacy benefit managers and pharmaceutical sales representatives to submit such annual reports.

Under existing law, commonly known as the Nevada Public Records Act, when a state or local governmental entity receives a request to disclose information contained in public records within its legal custody or control, the governmental entity must disclose the information, unless the information is confidential under state or federal law. (NRS 239.010; *City of Reno v. Reno Gazette-Journal*, 119 Nev. 55, 58-61 (2003)) Upon receiving such a request for public records, the governmental entity must respond to the requester within five business days by doing one of the following: (1) if the requested information is confidential under state or federal law, the governmental entity must provide the requester with written notice of the denial of the request and a citation to the specific statute or other legal authority that makes the information confidential; (2) if the requested information is not confidential under state or federal law and the governmental entity is able to make the information available within those five business days, the governmental entity must provide the requester with the information; or (3) if the governmental entity is unable to make the information available within those five business days, the governmental entity must provide the requester with written notice of that fact and a date and time after which the information will be made available. (NRS 239.0107)

Under existing federal law, when a state or local governmental entity is exercising its powers and duties under state or local law, the governmental entity must also comply with federal law, which supersedes any conflicting state or local law, because federal law is the supreme law of the land under the Supremacy Clause of the United States Constitution. (U.S. Const. Art. VI, cl. 2; *Alden v. Maine*, 527 U.S. 706, 755 (1999)) For example, if information is provided to state governmental entities and maintained in their databases as part of state regulatory programs and the information has potential commercial value in interstate commerce, Congress may exercise its power under the Commerce Clause of the United States Constitution to prohibit the state governmental entities from disclosing the information, even if such disclosure is authorized by state law. (U.S. Const. Art. I, § 8, cl. 3; *Reno v. Condon*, 528 U.S. 141, 143-51 (2000))

In the context of trade secrets related to products or services used in interstate commerce, Congress has exercised its power under the Commerce Clause to enact the federal Defend Trade Secrets Act of 2016 (DTSA), which authorizes the owner of a trade secret to bring a civil action to prevent the improper disclosure of information that would constitute misappropriation of a trade secret under federal law and, if such information is improperly disclosed, to provide remedies for violations of the federal law. (18 U.S.C. § 1836) In such a civil action brought under the federal DTSA, a court of competent jurisdiction may award legal and equitable relief, including protective orders, injunctive relief, compensatory damages, punitive damages and attorney's fees, to the owner of a trade secret to prevent or remedy violations of the federal law. (18 U.S.C. §§ 1833-1839) In addition to the remedies established by the federal DTSA, federal

law also prohibits certain conduct that constitutes theft of a trade secret and prescribes criminal penalties for such violations. (18 U.S.C. § 1832)

Because information that constitutes a trade secret may be submitted to federal agencies, the federal Trade Secrets Act prohibits federal officers and employees from disclosing such information, unless the disclosure is specifically authorized by federal law. (18 U.S.C. § 1905; *Chrysler Corp. v. Brown*, 441 U.S. 281, 294-319 (1979)) As a result of this federal prohibition, when federal agencies receive requests for public records under the federal Freedom of Information Act (FOIA), the federal agencies cannot disclose information that constitutes a trade secret under the federal Trade Secrets Act, and such information is also exempt from disclosure under the “trade secrets” exemption in FOIA, which is commonly referred to as “Exemption 4.” (5 U.S.C. § 552(b)(4); 18 U.S.C. § 1905; *Canadian Commercial Corp. v. Dep’t of Air Force*, 514 F.3d 37, 39 (D.C. Cir. 2008); *Pac. Architects & Eng’rs v. Dep’t of State*, 906 F.2d 1345, 1346-47 (9th Cir. 1990); *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1286-90 (D.C. Cir. 1983))

To ensure that trade secrets are not improperly disclosed under the federal Trade Secrets Act and FOIA, federal agencies have a duty to adopt regulations establishing specific procedures that the federal agencies must follow when they receive requests for public records under FOIA seeking disclosure of information that may constitute a trade secret or other confidential commercial information. The purpose of such procedures is to ensure that persons who have submitted trade secrets or other confidential commercial information to federal agencies are provided with notice of the potential disclosure of the information under FOIA and an opportunity to respond and protect their interests in the confidentiality of the information before the federal agencies may disclose the information to the public. (*Predisclosure Notification Procedures for Confidential Commercial Information*, Exec. Order No. 12,600, 52 Fed. Reg. 23,781 (June 23, 1987); *OSHA Data/CIH v. Dep’t of Labor*, 220 F.3d 153, 163-64 (3d Cir. 2000); *Venetian Casino Resort v. EEOC*, 530 F.3d 925, 934-35 (D.C. Cir. 2008))

**Section 3** of this regulation establishes specific procedures that the Department will follow when it receives a request for public records under the Nevada Public Records Act seeking disclosure of information which: (1) may constitute a trade secret under the federal DTSA; and (2) is included by a manufacturer or pharmacy benefit manager in an annual report concerning the prices of prescription drugs submitted to the Department under sections 3.8, 4 or 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 or 439B.645). **Section 3** provides that a manufacturer or pharmacy benefit manager which is required to submit such a report may submit to the Department a request to keep information included in the report confidential if the manufacturer or pharmacy benefit manager reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA. If a manufacturer or pharmacy benefit manager submits a request for confidentiality, **section 3** requires the request to: (1) describe, with particularity, the information sought to be protected from public disclosure;

and (2) include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA.

If the Department receives a request for public records under the Nevada Public Records Act seeking disclosure of information for which the manufacturer or pharmacy benefit manager has submitted a request for confidentiality, **section 3** requires the Department, as soon as reasonably practicable after receiving the request, to provide the manufacturer or pharmacy benefit manager with: (1) written notice of the request for public records and the procedures set forth in **section 3**; and (2) a copy of the request for public records and the date on which the Department received the request. **Section 3** also requires the Department to undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA. When the Department undertakes its initial review, **section 3** states that the Department will consider, as persuasive authority, the interpretation and application given to the term “trade secrets” under Exemption 4 of FOIA.

If, after undertaking its initial review, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA, **section 3** provides that the Department will: (1) within the time required by the Nevada Public Records Act, provide the requester of public records with written notice that the Department must deny the request on the basis that the information is confidential under the federal DTSA; and (2) as soon as reasonably practicable after notifying the requester, provide the manufacturer or pharmacy benefit manager with written notice that the Department denied the request and a copy of the written notice provided to the requester and the date on which it was sent to the requester. Under the Nevada Public Records Act, the requester would have the right to bring an action against the Department to challenge the denial of the request for public records. (NRS 239.011; *City of Sparks v. Reno Newspapers*, 133 Nev. Adv. Op. 56, 399 P.3d 352, 354 (2017); *DR Partners v. Bd. of County Comm’rs*, 116 Nev. 616, 620-21 (2000)) If the requester were to bring such an action against the Department, the manufacturer or pharmacy benefit manager could assert a right to intervene in the action to protect its interests in the confidentiality of the information. (*Appleton v. FDA*, 310 F. Supp. 2d 194, 196-97 (D.D.C. 2004); *Yorkshire v. IRS*, 26 F.3d 942, 944-45 (9th Cir. 1994))

If, after undertaking its initial review, the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret under the federal DTSA, **section 3** requires the Department, within the time required by the Nevada Public Records Act, to provide the requester of public records with written notice that the Department intends to disclose the information. However, **section 3** also requires the Department to inform the requester that: (1) the Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and (2) if the manufacturer or pharmacy benefit manager timely commences an action within that 30-day period to enjoin disclosure of the information under the federal DTSA, the Department will not be able to disclose the information, unless the disclosure is permitted after final resolution of the

action, including any appeals. **Section 3** additionally requires the Department, as soon as reasonably practicable after notifying the requester, to provide the manufacturer or pharmacy benefit manager with: (1) written notice that the Department intends to disclose the information; and (2) a copy of the written notice sent to the requester and the date on which it was sent to the requester.

If, within the 30-day period following the date on which the Department sent the written notice to the requester, the manufacturer or pharmacy benefit manager does not commence an action to enjoin the Department from disclosing the information under the federal DTSA, **section 3** requires the Department to disclose the information. However, if such an action is timely commenced within the 30-day period, **section 3** provides that the Department will not disclose the information until final resolution of the action, including any appeals. Following commencement of the action, the requester of the public records could assert a right to intervene in the action to protect its interests in the disclosure of the information. (*Entergy Gulf States La. v. EPA*, 817 F.3d 198, 203-06 (5th Cir. 2016); *LaRouche v. FBI*, 677 F.2d 256, 257-58 (2d Cir. 1982))

After final resolution of the action, including any appeals, if the court enjoins the Department from disclosing the information as a trade secret, **section 3** provides that the Department will not disclose the information so long as the information retains its status as a trade secret. However, if the court does not enjoin the Department from disclosing the information as a trade secret, **section 3** provides that the Department will disclose the information as soon as reasonably practicable after final resolution of the action.

Finally, existing law requires the Department to: (1) analyze the information submitted by manufacturers and pharmacy benefit managers in their annual reports; and (2) compile a report on the prices of the prescription drugs that appear on the most current lists of essential diabetes drugs compiled by the Department. (Section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650)) **Section 4** of this regulation provides that the report compiled by the Department will include only aggregated data that does not disclose the identity of any drug, manufacturer or pharmacy benefit manager. **Section 4** also provides that the Department will include in the report: (1) a description of trends concerning the prices of the prescription drugs that appear on the most current lists of essential diabetes drugs compiled by the Department; and (2) an explanation of how those prices and trends may affect the prevalence and severity of diabetes in this State and the system of health care in this State.

**Section 1.** Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2, 3 and 4 of this regulation.

**Sec. 2. *The Department will make available on an Internet website maintained by the Department the forms on which:***

**1. *A manufacturer is required to submit the reports required by sections 3.8 and 4 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635 and 439B.640).***

**2. *A pharmacy benefit manager is required to submit the report required by section 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4298 (NRS 439B.645).***

**3. *A person included on a list of pharmaceutical sales representatives provided by a manufacturer to the Department pursuant to subsection 1 of section 4.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.660), is required to submit the report required by subsection 4 of that section.***

**Sec. 3. 1. *In complying with section 3.8, 4 or 4.2 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at pages 4297-98 (NRS 439B.635, 439B.640 or 439B.645), if a manufacturer or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the manufacturer or pharmacy benefit manager may submit to the Department a request to keep the information confidential.***

**2. *A request for confidentiality submitted pursuant to subsection 1 must be divided into the following parts, which must be severable from each other:***

**(a) *The first part of the request for confidentiality must describe, with particularity, the information sought to be protected from public disclosure. Upon a request for public records***

*pursuant to NRS 239.010, the Department will not disclose the description set forth in the request for confidentiality or the information sought to be protected from public disclosure, unless the description and information are disclosed pursuant to subsections 5 and 6.*

*(b) The second part of the request for confidentiality must include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended. Upon a request for public records pursuant to NRS 239.010, the Department will disclose the explanation set forth in the request for confidentiality.*

*3. If the Department receives a request for public records pursuant to NRS 239.010 seeking disclosure of any information for which a manufacturer or pharmacy benefit manager has submitted a request for confidentiality pursuant to subsection 1, the Department will:*

*(a) As soon as reasonably practicable after receiving the request for public records, provide the manufacturer or pharmacy benefit manager with:*

*(1) Written notice of the request for public records and the procedures set forth in this section; and*

*(2) A copy of the request for public records and the date on which the Department received the request.*

*(b) Undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016,*

*18 U.S.C. § 1836, as amended. In undertaking its initial review, the Department will consider, as persuasive authority, the interpretation and application given to the term “trade secrets” in Exemption 4 of the federal Freedom of Information Act, 5 U.S.C. § 552(b)(4), as amended.*

*4. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:*

*(a) Within the time prescribed by NRS 239.0107, provide the requester of the public records with written notice pursuant to paragraph (d) of subsection 1 of NRS 239.0107 that the Department must deny the request for public records on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended.*

*(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:*

*(1) Written notice that the Department denied the request for public records; and*

*(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.*

*5. If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will:*

*(a) Within the time prescribed by NRS 239.0107, provide the requester of the public records with written notice pursuant to paragraph (c) of subsection 1 of NRS 239.0107 that the Department intends to disclose the information, except that:*

*(1) The Department will not be able to disclose the information until 30 days have elapsed following the date on which such written notice was sent to the requester; and*

*(2) If the manufacturer or pharmacy benefit manager timely commences an action within the 30-day period as provided in subsection 6, the Department will not be able to disclose the information, unless the disclosure is permitted by that subsection.*

*(b) As soon as reasonably practicable after providing the written notice to the requester pursuant to paragraph (a), provide the manufacturer or pharmacy benefit manager with:*

*(1) Written notice that the Department intends to disclose the information; and*

*(2) A copy of the written notice that the Department provided to the requester pursuant to paragraph (a) and the date on which the Department sent the written notice to the requester.*

*6. If, within the 30-day period following the date on which the Department sent the written notice to the requester of public records pursuant to subsection 5, the manufacturer or pharmacy benefit manager:*

*(a) Does not commence an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended, the Department will disclose the information.*

*(b) Commences an action in a court of competent jurisdiction to enjoin the Department from disclosing the information pursuant to the federal Defend Trade Secrets Act of 2016, 18*

*U.S.C. § 1836, as amended, the Department will not disclose the information until final resolution of the action, including any appeals. After final resolution of the action, if the court:*

*(1) Enjoins the Department from disclosing the information as a trade secret, the Department will not disclose the information so long as the information retains its status as a trade secret.*

*(2) Does not enjoin the Department from disclosing the information as a trade secret, the Department will disclose the information as soon as reasonably practicable after final resolution of the action.*

*Sec. 4. In the report compiled by the Department pursuant to section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650), the Department will include:*

*1. Only aggregated data that does not disclose the identity of any drug, manufacturer or pharmacy benefit manager; and*

*2. In addition to the information required by section 4.3 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4299 (NRS 439B.650), a description of trends concerning the prices of prescription drugs that appear on the most current lists compiled by the Department pursuant to section 3.6 of Senate Bill No. 539, chapter 592, Statutes of Nevada 2017, at page 4297(NRS 439B.630), and an explanation of how those prices and trends may affect:*

*(a) The prevalence and severity of diabetes in this State; and*

*(b) The system of health care in this State.*

# EXHIBIT 8

# EXHIBIT 8

**McDONALD CARANO**  
2300 WEST SAHARA AVENUE, SUITE 1200 • LAS VEGAS, NEVADA 89102  
PHONE 702.873.4100 • FAX 702.873.9966

Pat Lundvall (NSBN 3761)  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
lundvall@mcdonaldcarano.com

Robert N. Weiner  
Admitted *Pro Hac Vice*  
Jeffrey L. Handwerker  
Admitted *Pro Hac Vice*  
R. Stanton Jones  
Admitted *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA and  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as  
Governor of the State of Nevada; RICHARD  
WHITLEY, in his official capacity as Director of  
the Nevada Department for Health and Human  
Services; and the NEVADA LEGISLATURE,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

**PLAINTIFFS' UNOPPOSED MOTION  
FOR VOLUNTARY DISMISSAL  
WITHOUT PREJUDICE**

Pursuant to Federal Rule of Civil Procedure 41(a)(2), Plaintiffs Pharmaceutical Research and  
Manufacturers of America and Biotechnology Innovation Organization (together, "Plaintiffs"), by

1 and through their undersigned counsel, hereby move unopposed for voluntary dismissal of this action  
2 and state as follows:

3 On September 1, 2017, Plaintiffs filed their complaint against Defendants Governor Brian  
4 Sandoval and Nevada Department of Health and Human Services Director Richard Whitley, in their  
5 official capacities, seeking injunctive relief and a declaration that Nevada Senate Bill 539 is  
6 unconstitutional on the grounds that it conflicts with federal patent law and the 2016 Defend Trade  
7 Secrets Act, constitutes an unlawful government taking of trade secrets under the Fifth and  
8 Fourteenth Amendments, and violates the Commerce Clause of Article 1. ECF No. 1.

9 On October 3, 2017, the Court permitted the Nevada Legislature to intervene as a defendant  
10 (collectively with Governor Sandoval and Director Whitley, "Defendants"). ECF No. 43.

11 On October 4, 2017, Governor Sandoval and Director Whitley answered the complaint, ECF  
12 No. 44, and, on October 5, 2017, the Legislature answered, ECF No. 45.

13 Pending before the Court are the parties' cross-motions for summary judgment. *See, e.g.*,  
14 ECF Nos. 46, 66.

15 Plaintiffs have met and conferred with Defendants regarding the filing of this motion.  
16 Plaintiffs have agreed to move for voluntary dismissal without prejudice in light of the  
17 acknowledgements, assurances, changed circumstances, and reservation of rights described in the  
18 parties' June 28, 2018 joint status report. ECF No. 95. Defendants do not oppose.

19 ///

20 ///

21 ///

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

28 ///

1 Plaintiffs therefore respectfully request that the Court dismiss the complaint without  
2 prejudice pursuant to Federal Rule of Civil Procedure 41(a)(2), with each party to bear its own costs.

3 Dated: June 28, 2018.

4 /s/ Pat Lundvall

5 Pat Lundvall (NSBN 3761)  
6 McDONALD CARANO LLP  
7 2300 West Sahara Avenue, Suite 1200  
8 Las Vegas, Nevada 89102  
9 Telephone: (702) 873-4100  
10 lundvall@mcdonaldcarano.com

11 Robert N. Weiner  
12 Jeffrey L. Handwerker  
13 R. Stanton Jones  
14 ARNOLD & PORTER KAYE SCHOLER LLP  
15 601 Massachusetts Avenue, NW  
16 Washington, DC 20001  
17 Telephone: (202) 942-5000

18 *Attorneys for Plaintiffs Pharmaceutical Research  
19 and Manufacturers of America and  
20 Biotechnology Innovation Organization*

21 **CERTIFICATE OF SERVICE**

22 I certify that I am an employee of McDonald Carano, and that on the 28<sup>th</sup> day of June, 2018,  
23 a true and correct copy of the foregoing PLAINTIFFS' UNOPPOSED MOTION FOR  
24 VOLUNTARY DISMISSAL WITHOUT PREJUDICE was electronically filed with the Clerk of  
25 the Court by using CM/ECF service which will provide copies to all counsel of record registered to  
26 receive CM/ECF notification.  
27

28 /s/ Beau Nelson

An employee of McDonald Carano LLP

# Proposed Order

**McDONALD CARANO**  
2300 WEST SAHARA AVENUE, SUITE 1200 • LAS VEGAS, NEVADA 89102  
PHONE 702.873.4100 • FAX 702.873.9966

Pat Lundvall (NSBN 3761)  
McDONALD CARANO LLP  
2300 West Sahara Avenue, Suite 1200  
Las Vegas, NV 89102  
Telephone: (702) 873-4100  
lundvall@mcdonaldcarano.com

Robert N. Weiner  
Admitted *Pro Hac Vice*  
Jeffrey L. Handwerker  
Admitted *Pro Hac Vice*  
R. Stanton Jones  
Admitted *Pro Hac Vice*  
ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Avenue, NW  
Washington, DC 20001  
Telephone: (202) 942-5000  
robert.weiner@apks.com  
jeffrey.handwerker@apks.com  
stanton.jones@apks.com

*Attorneys for Plaintiffs Pharmaceutical  
Research and Manufacturers of America and  
Biotechnology Innovation Organization*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA and  
BIOTECHNOLOGY INNOVATION  
ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as  
Governor of the State of Nevada; RICHARD  
WHITLEY, in his official capacity as Director of  
the Nevada Department for Health and Human  
Services; and the NEVADA LEGISLATURE,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

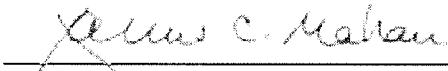
**ORDER GRANTING  
PLAINTIFFS' UNOPPOSED MOTION  
FOR VOLUNTARY DISMISSAL**

1 Having reviewed Plaintiffs Pharmaceutical Research and Manufacturers of America and  
2 Biotechnology Innovation Organization's Unopposed Motion for Voluntary Dismissal Without  
3 Prejudice, and good cause appearing therefor:

4 IT IS HEREBY ORDERED THAT:

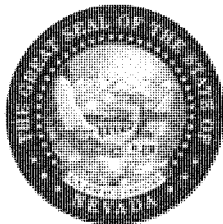
5 Pursuant to Federal Rule of Civil Procedure 41(a)(2), the instant action, *Pharmaceutical*  
6 *Research and Manufacturers of America, et al. v. Sandoval, et al.*, Case No. 2:17-cv-02315-JCM-  
7 CWH, is hereby dismissed without prejudice, each party to bear its own costs.

8 It is SO ORDERED June 28, 2018.

9  
10   
11 \_\_\_\_\_  
12 United States District Judge  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**EXHIBIT 9**

**EXHIBIT 9**



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIRECTOR'S OFFICE  
4126 Technology Way, Suite 100  
Carson City, Nevada 89706  
Telephone (775) 684-4000 • Fax (775) 684-4010  
<http://dhhs.nv.gov>

October 31, 2017

SB539 required the Department of Health and Human Services (DHHS) to develop a list of essential diabetes drugs. To that end, DHHS sought public comment from prescribers in Nevada, analyzed data to determine drugs most often prescribed, and consulted with FDA resources to determine appropriate use as established by the label. Below describes the process for creation of the list:

- An initial list of frequently prescribed drugs used for the treatment of diabetes was created by pharmacists employed by the department.
- The list was then sent to prescribers in the state as a survey to solicit public comment and determine if any drugs needed to be removed/added. DHHS received over 300 responses.
- That list was compared to the Medicaid pharmacy data reported to the Centers for Medicare and Medicaid Services (CMS) and information from the Public Employees Benefit Program on prescribed drugs. This prescriber data accounted for approximately 700,000 Nevadans insured under these public plans and was used to whittle down the list to just those drugs prescribed in Nevada.
- The remaining drugs were checked against the FDA database to ensure that only drugs approved by the FDA for the treatment of diabetes were included on the list. No drugs were included if their treatment of diabetes was considered an "off-label" use.

This process was designed to include the feedback from prescriber stakeholders along with addressing the concerns expressed by industry members regarding appropriate label use. This list does not include any drugs used to treat co-morbidities often present in an individual with diabetes. The list also does not contain every single drug that may be an effective treatment for diabetes or approved for the treatment of diabetes. This list attempts to distill down the numerous treatments to those which are approved for treatment, identified by prescribers as essential, and most frequently prescribed in Nevada (as determined by the publicly available data sources).

As this is the first year DHHS has created this list, we welcome feedback on the process that can be used for the development of the list for 2018. Feedback and questions can be directed to the email: [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov).

Proprietary Name	Non_Proprietary_Name	Class	Labeler
Tanzeum	albiglutide	Glucagon-Like Peptide-1 (GLP-1) Agonists	GlaxoSmithKline, LLC
Byetta	exenatide	Glucagon-Like Peptide-1 (GLP-1) Agonists	Astrazeneca AB; Physicians Total Care, Inc.
Invokana; Invokamet	canagliflozin	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	Jansen Pharmaceuticals, Inc.
Cycloset; Parlodel; Bromocriptine mesylate	bromocriptine mesylate	Ergolines	Paddock Laboratories, LLC; Ranbaxy Pharmaceuticals, Inc.; Sandoz, Inc.; Physicians Total Care, Inc.; Santarus, Inc.; Validus Pharmaceuticals, LLC
Farxiga; Xigduo	DAPAGLIFLOZIN Propanediol	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	AstraZeneca Pharmaceuticals, LP
DiaBeta	glyburide	Sulfonylureas (SUs)	Actavis Elizabeth; Aurobindo Pharma; Dava Pharms, Inc; Epic Pharma LLC; Heritage Pharms, Inc.; Hikma; Impax Labs, Inc; Mylan; Pharmadax, Inc; Sandoz; Sanofi-Aventis U.S., LLC; Teva; Zydus Pharms USA, Inc
Trulicity	Dulaglutide	Glucagon-Like Peptide-1 (GLP-1) Agonists	Eli Lilly and Company
Jardiance Synjardy	Empagliflozin	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.; Cardinal Health
Glyxambi	Empagliflozin and linagliptin	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.
Synjardy	empagliflozin and metformin hydrochloride	Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.
Bydureon Byetta	exenatide	Glucagon-Like Peptide-1 (GLP-1) Agonists	AstraZeneca Pharmaceuticals, LP; Physicians Total Care, Inc.
Fortamet	Metformin hydrochloride	Biguanide	Physicians Total Care, Inc.; Shionogi, Inc.

Proprietary Name	Non_Proprietary_Name	Class	Labeler
Amaryl Glimepiride	Glimepiride	Sulfonylureas (SUs)	<p>Accord Healthcare Inc; Aidarex Pharmaceuticals LLC; American Health Packaging; Aurobindo Pharma Limited; Avera McKennan Hospital; Bionpharma Inc. Blenheim Pharmacal, Inc.; BluePoint Laboratories; Bryant Ranch Prepack; Cardinal Health; Carlsbad Technology, Inc.; Citron Pharma LLC; Dr. Reddy's Laboratories Limited; DIRECT RX; Golden State Medical Supply, Inc.; International Laboratories, LLC; Lake Erie Medical DBA Quality Care Products LLC; Liberty Pharmaceuticals, Inc.; MedVantx, Inc.; Micro Labs Limited; Mylan Institutional Inc.; Mylan Pharmaceuticals Inc.; NCS HealthCare of KY, Inc dba Vanguard Labs; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc. PD-Rx Pharmaceuticals, Inc.;</p> <p>Prasco Laboratories; Preferred Pharmaceuticals Inc.; Physicians Total Care, Inc.; Proficient Rx LP; Qualitest Pharmaceuticals; Rebel Distributors Corp; RedPharm Drug, Inc. REMEDYREPACK INC.; St Marys Medical Park Pharmacy; Sanofi-Aventis U.S., LLC; Solco Healthcare U.S., LLC; STAT Rx USA LLC; Takeda Pharmaceuticals America, Inc.; Teva Pharmaceuticals USA, Inc.; Unit Dose Services; Virtus Pharmaceuticals</p>
Glipizide Glipizide XL Glipizide ER Glucotrol Glucotrol XL	glipizide	Sulfonylureas (SUs)	<p>Accord Healthcare Inc; Actavis Elizabeth LLC; Actavis Pharma, Inc.; Aidarex Pharmaceuticals LLC; Aphena Pharma Solutions - Tennessee, LLC; Apotex Corp.; Apotheca Inc.; Aurobindo Pharma Limited; Avera McKennan Hospital; Bionpharma Inc. Blenheim Pharmacal, Inc.; Bryant Ranch Prepack; Cardinal Health; Carlsbad Technology, Inc.; Clinical Solutions Wholesale; Contract Pharmacy Services-PA; Dr. Reddy's Laboratories Limited; DIRECT RX; Dispensing Solutions, Inc.; Golden State Medical Supply, Inc.; Greenstone LLC; International Laboratories, LLC; H.J. Harkins Company, Inc.; Lake Erie Medical DBA Quality Care Products LLC; Legacy Pharmaceutical Packaging, LLC; Major Pharmaceuticals;</p> <p>MedVantx, Inc.; Mylan Institutional Inc.; Mylan Pharmaceuticals Inc.; NCS HealthCare of KY, Inc dba Vanguard Labs; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc. PD-Rx Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Physicians Total Care, Inc.; Preferred Pharmaceuticals Inc.; Proficient Rx LP; Rebel Distributors Corp; RedPharm Drug, Inc. REMEDYREPACK INC.; Rising Pharmaceuticals, Inc.; St Marys Medical Park Pharmacy; Sandoz Inc; State of Florida DOH Central Pharmacy; STAT Rx USA LLC; Sun Pharmaceutical Industries, Inc.; TYA Pharmaceuticals; Unit Dose Services; Virtus Pharmaceuticals</p>

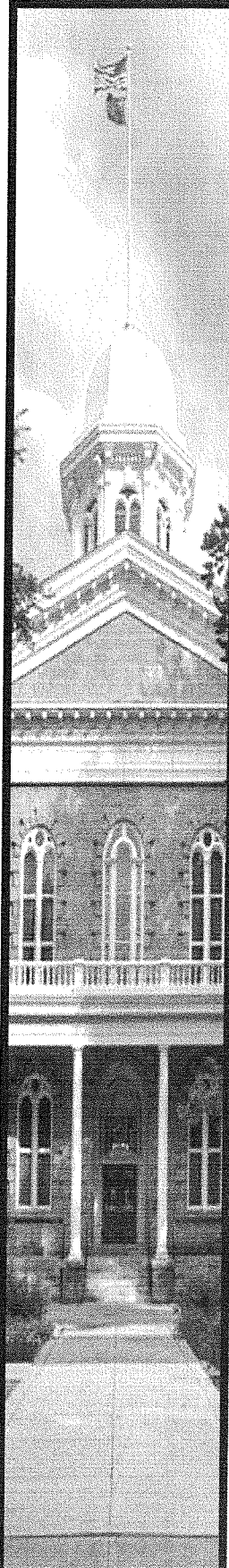
Proprietary Name	Non_Proprietary_Name	Class	Labeler
Glipizide and Metformin Hydrochloride Glipizide and Metformin HCl	Glipizide and Metformin Hydrochloride	Sulfonylureas (SUs)	AvKARE, Inc.; Bryant Ranch Prepack; Cadila Healthcare Limited; Heritage Pharmaceuticals Inc.; KAISER FOUNDATION HOSPITALS; Lake Erie Medical DBA Quality Care Products LLC; Mylan Pharmaceuticals Inc.; Physicians Total Care, Inc.; Rebel Distributors Corp; REMEDYREPACK INC.; St Marys Medical Park Pharmacy; Teva Pharmaceuticals USA, Inc.; Unit Dose Services; Zydus Pharmaceuticals (USA) Inc.
Glucophage	Metformin Hydrochloride	Biguanide	Bristol-Myers Squibb Company; PD-Rx Pharmaceuticals, Inc.
Glumetza	Metformin Hydrochloride	Biguanide	Depomed, Inc.; Santarus, Inc.
Glyset	Miglitol	Alpha-Glucosidase Inhibitors	Pharmacia and Upjohn Company LLC
Novolin	Human Insulin	Short Acting or Regular	Novo Nordisk; Physicians Total Care, Inc.; TYA Pharmaceuticals
Novolog	insulin aspart	Rapid-Acting Insulin	Dispensing Solutions; Novo Nordisk; Physicians Total Care, Inc.; TYA Pharmaceuticals
Tresiba	insulin degludec	insulin	Novo Nordisk
Xultophy	insulin degludec; liraglutide	Glucagon-Like Peptide-1 (GLP-1) Agonists	Novo Nordisk
Levemir	insulin detemir	Long-Acting Insulin	Dispensing Solutions; Novo Nordisk; Physicians Total Care, Inc.
Basaglar Lantus Toujeo	insulin glargine	Long-Acting Insulin	Dispensing Solutions, Inc.; Eli Lilly and Company; Physicians Total Care, Inc.; Sanofi-Aventis U.S. LLC
Soliqua	insulin glargine; Lixisenatide	Insulin	Sanofi-Aventis U.S. LLC
Apidra	insulin glulisine	Rapid-Acting Insulin	Sanofi-Aventis U.S. LLC
Afrezza Humalog 70/30 Humulin Humulin N Humulin R	Insulin human	Intermediate Insulin or Baseline, Basal	Eli Lilly and Company; Mankind Corporation; Physicians Total Care, Inc.
Humalog	Insulin lispro	Rapid-Acting Insulin	Dispensing Solutions, Inc.; Eli Lilly and Company; Physicians Total Care, Inc.
Tradjenta	linagliptin	Dipeptidyl Peptidase 4 Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.; Cardinal Health
Jentadueto Jentadueto XR	linagliptin and metformin hydrochloride	Dipeptidyl Peptidase 4 Inhibitors	Boehringer Ingelheim Pharmaceuticals, Inc.; Bryant Ranch Prepack; Physicians Total Care, Inc.

Proprietary Name	Non_Proprietary_Name	Class	Labeler
Victoza	liraglutide	Glucagon-Like Peptide-1 (GLP-1) Agonists	Novo Nordisk
Metformin HCL	Metformin HCL	Biguanide	Ascend Laboratories, Inc.; Cambridge Therapeutics Technologies, LLC; Time Cap Laboratories, Inc.
Nesina	Alogliptin	Dipeptidyl Peptidase 4 Inhibitors	Takeda Pharmaceuticals America, Inc.
Pioglitazone Actos	Pioglitazone	Thiazolidinediones (TZDs)	Avera McKennan Hospital; Cadila Healthcare Limited; Cardinal Health; Carilion Materials Management; Citron Pharma LLC; Dispensing Solutions, Inc.; International Laboratories, LLC; Lake Erie Medical & Surgical Supply dba Quality Care Products LLC; Macleods Pharmaceuticals Limited; MedVantx, Inc.; Mylan Institutional Inc.; Mylan Pharmaceuticals Inc.; NuCare Pharmaceuticals, Inc.; Physicians Total Care, Inc.; Ranbaxy Pharmaceuticals, Inc.; Rebel Distributors Corp.; Sandoz, Inc.; Takeda Pharmaceuticals America, Inc.; Teva Pharmaceuticals USA, Inc.; Wockhardt Limited; Zydus Pharmaceuticals (USA) Inc.
Prandin	Repaglinide	Meglitinides	Cardinal Health; Carilion Materials Management; Gemini Laboratories, LLC; Lake Erie Medical dba Quality Care Products LLC; Novo Nordisk; Physicians Total Care
Precose	Acarbose	Alpha-Glucosidase Inhibitors	Aphena Pharma Solutions - Tennessee, LLC; Bayer Healthcare Pharmaceuticals, Inc.; Physicians Total Care, Inc.
Riomet	Metformin Hydrochloride	Biguanide	Ranbaxy Laboratories, Inc.
Onglyza	SAXAGLIPTIN	Dipeptidyl Peptidase 4 Inhibitors	AstraZeneca Pharmaceuticals LP; Cardinal Health; Physicians Total Care, Inc.
Kombiglyze	SAXAGLIPTIN AND METFORMIN HYDROCHLORIDE	Metformin +	AstraZeneca Pharmaceuticals LP
Januvia	sitagliptin	Dipeptidyl Peptidase 4 Inhibitors	Avera McKennan Hospital; Cardinal Health; Lake Erie Medical & Surgical Supply dba Quality Care Products LLC; Merck Sharp & Dohme Corp.; Physicians Total Care, Inc.
Janumet	sitagliptin and metformin hydrochloride	Metformin +	Lake Erie Medical & Surgical Supply dba Quality Care Products LLC; Merck Sharp & Dohme Corp
Starlix	Nateglinide	Meglitinides	Novartis Pharmaceuticals Corporation
SymlinPen 60 & 120	Pramlintide	Amylin Agonist	AstraZeneca Pharmaceuticals LP

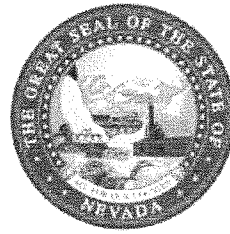
Proprietary Name	Non_Proprietary_Name	Class	Labeler
Welchol	Colesevelam Hydrochloride	Bile Acid Binding Resins	Avera McKennan Hospital; Carillion Materials Management; Daiichi Sankyo, Inc.; Physicians Total Care Inc.; Rebel Distributors

# **EXHIBIT 10**

# **EXHIBIT 10**



**Steve Sisolak**  
Governor



**Richard Whitley, MS**  
Director

**Julie Kotchevar, PhD**  
DPBH Administrator

# **2019 Essential Diabetes Drug List**

*Report Date:*

**February 1, 2019**



**Nevada Department of  
Health and Human Services**

*Prepared by:*

**Primary Care and Health Workforce Development Office, State of Nevada  
Division of Public and Behavioral Health (DPBH)  
4150 Technology Way, Suite 300, Carson City, NV 89706  
Office: (775) 684-4255 Email: [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov)  
[drugtransparency.nv.gov](http://drugtransparency.nv.gov)**

**Helping People. It's who we are and what we do.**

000708

## **Introduction**

During the 79th legislative session, Senate Bill (SB) 539, which supports prescription drug transparency, was approved. SB 539 was codified in Nevada Revised Statutes (NRS) 439B. The law requires in NRS 439B.630 that the Department of Health and Human Services (DHHS) compile a list of prescription drugs essential for treating diabetes in Nevada:

**NRS 439B.630** Department to annually compile lists of certain prescription drugs essential for treating diabetes. On or before February 1 of each year, the Department shall compile:

1. A list of prescription drugs that the Department determines to be essential for treating diabetes in this State and the wholesale acquisition cost of each such drug on the list. The list must include, without limitation, all forms of insulin and biguanides marketed for sale in this State.
2. A list of prescription drugs described in subsection 1 that have been subject to an increase in the wholesale acquisition cost of a percentage equal to or greater than:
  - a.) The percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year; or
  - b.) Twice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years.

(Added to NRS by 2017, 4297)

The first essential diabetes drug list was published on October 31, 2017. The 2019 Essential Diabetes Drug List identifies Nevada's essential diabetes drugs as of the publication date and also indicates if these drugs underwent a significant price increase as defined by NRS 439B.630 (2). To produce the current list, DHHS posted a draft version of the essential diabetes drug list online on January 14, 2019 and received public and other stakeholder comments. All requests were carefully reviewed before finalization of this publication. Manufacturers that produce drugs found on this list are required to submit reports by April 1, 2019 that include information about these drugs as outlined in NRS 439B.635 and NRS 439B.640. Additionally, Pharmacy Benefit Managers (PBMs) are required to provide information to DHHS by April 1, 2019 regarding these drugs as outlined in NRS 439B.645. Data from these reports will be aggregated and published in the DHHS report required by NRS 439B.650 by June 1, 2019.

## **Report Methodology**

To compile the 2019 DHHS Essential Diabetes Drug list, DHHS utilized a methodology that met the requirements of NRS 439B.630. Two versions of the list are published: (1) a summary of the nonproprietary and brand or proprietary drug names found on the essential list [Appendix 1], and (2) a detailed list of all the National Drug Codes (NDCs) indicated by DHHS as essential diabetes drugs and if each drug NDC experienced a significant price increase [Appendix 2]. The summary list [Appendix 1] provides a concise outline of the essential drugs, while the NDC list [Appendix 2] identifies the specific drug NDCs that will be monitored by DHHS and included in the yearly report.

To generate the final list, DHHS compiled an initial list of diabetes drug NDCs that included varying drug packing formulations based on prior and current stakeholder input of essential diabetes drugs. These NDC codes were filtered down to include the drugs for which Nevada Medicaid expended funds in 2017 and/or 2018. Additional NDCs that were of interest to the public and stakeholders were added to this list.

This essential list does not include any drugs used to treat co-morbidities often present in individuals with diabetes. The list does not contain every single drug that may be an effective treatment for diabetes or approved for the treatment of diabetes. This list attempts to refine the numerous treatments to those approved for treatment, identified by prescribers as essential, and most frequently prescribed in Nevada (as determined by publicly available data sources). For this reason, some brand names are excluded while generics or alternative brands are included.

DHHS welcomes feedback regarding this report. DHHS strives to ensure that consumers receive accurate information. Any identified errors, omissions, or feedback can be submitted to the department via email at [drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov).

DHHS invites you to view the Drug Transparency website at [drugtransparency.nv.gov](http://drugtransparency.nv.gov). If you are interested in receiving email notifications for Nevada Drug Transparency information and updates, please subscribe online at <http://drugtransparency.nv.gov> to the DHHS Drug Transparency LISTSERV.

**Appendix 1:**  
**2019 DHHS Essential Diabetes Drug**  
**Summary List**

Essential Non-Proprietary Drug Name	Included Essential Drug Brand Names (Note: some brand names are excluded from this list)
Acarbose	
Albiglutide	Tanzeum
Alogliptin	Nesina
Alogliptin and Metformin HCL	Kazano
Alogliptin and Pioglitazone	Oseni
Bromocriptine Mesylate	Cycloset
Canagliflozin	Invokana
Canagliflozin and Metformin HCL	Invokamet; Invokamet XR
Colesevelam HCL	Welchol
Dapagliflozin	Farxiga
Dapagliflozin and Metformin HCL	Xigduo XR
Dulaglutide	Trulicity
Empagliflozin	Jardiance
Empagliflozin and Linagliptin	Glyxambi
Empagliflozin and Metformin HCL	Synjardy; Synjardy XR
Ertugliflozin	Steglatro
Ertugliflozin and Metformin HCL	Segluromet
Ertugliflozin and Sitagliptin	Steglujan
Exenatide	Bydureon; Bydureon BCise; Byetta
Glimepiride	Amaryl
Glipizide	Glucotrol; Glucotrol XL; Glipizide XL; Glipizide ER
Glipizide and Metformin HCL	
Glucagon	GlucaGen
Glyburide	Glynase
Glyburide and Metformin HCL	
Insulin Aspart	Fiasp; Novolog; Novolog 70/30
Insulin Degludec	Tresiba
Insulin Degludec and Liraglutide	Xultophy 100/3.6
Insulin Detemir	Levemir
Insulin Glargine	Basaglar; Lantus; Toujeo
Insulin Glargine and Lixisenatide	Soliqua 100/33
Insulin Glulisine	Apidra
Insulin Human	Afrezza; Humulin N; Humulin R; Humulin R500; Humulin 70/30; Novolin R; Novolin N; Novolin 70/30
Insulin Lispro	Admelog; Humalog; Humalog 50-50; Humalog 75-25; Humalog Jr
Linagliptin	Tradjenta
Linagliptin and Metformin HCL	Jentadueto; Jentadueto XR
Liraglutide	Victoza
Lixisenatide	Adlyxin
Metformin HCL	Fortamet ER; Glumetza ER; Glucophage; Glucophage XR; Riomet; Metformin ER
Miglitol	Glyset

Essential Non-Proprietary Drug Name	Included Essential Drug Brand Names (Note: some brand names are excluded from this list)
Nateglinide	Starlix
Pioglitazone	Actos
Pioglitazone and Glimepiride	
Pioglitazone and Metformin HCL	Actoplus Met; Actoplus Met XR
Pramlintide Acetate	SymlinPen
Repaglinide	Prandin
Rosiglitazone	Avandia
Saxagliptin	Onglyza
Saxagliptin and Metformin HCL	Kombiglyze XR
Semaglutide	Ozempic
Sitagliptin	Januvia
Sitagliptin and Metformin HCL	Janumet; Janumet XR

**Appendix 2:**  
**2019 Essential Diabetes Drug**  
**NDC List**

Helping People. It's who we are and what we do.

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
16252-0523-01	Acarbose	Actavis Pharma, Inc.	
47781-0340-01	Acarbose	Alvogen, Inc.	
47781-0341-01	Acarbose	Alvogen, Inc.	
47781-0342-01	Acarbose	Alvogen, Inc.	
00115-1152-02	Acarbose	Global Pharmaceuticals	
23155-0149-01	Acarbose	Heritage Pharmaceuticals Inc.	
00378-2821-77	Acarbose	Mylan	
64380-0758-06	Acarbose	Strides Shasun Limited	
64380-0759-06	Acarbose	Strides Shasun Limited	
64380-0760-06	Acarbose	Strides Shasun Limited	
69543-0120-10	Acarbose	Virtus Pharmaceuticals LLC	
69543-0121-10	Acarbose	Virtus Pharmaceuticals LLC	
69543-0122-10	Acarbose	Virtus Pharmaceuticals LLC	
00054-0140-25	Acarbose	West-Ward Pharmaceuticals Corp	
00054-0141-25	Acarbose	West-Ward Pharmaceuticals Corp	
00054-0142-25	Acarbose	West-Ward Pharmaceuticals Corp	
64764-0158-60	Actoplus Met	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0310-30	Actoplus Met XR	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0510-30	Actoplus Met XR	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0151-04	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0151-05	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0301-14	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0301-15	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0451-24	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0451-25	Actos	Takeda Pharmaceuticals U.S.A., Inc.	
00024-5745-02	Adlyxin	Sanofi-Aventis U.S. LLC	Yes
00024-5747-02	Adlyxin	Sanofi-Aventis U.S. LLC	Yes
00024-5924-10	Admelog	Sanofi-Aventis U.S. LLC	
47918-0874-90	Afrezza	Mannkind Corporation	Yes
47918-0878-90	Afrezza	Mannkind Corporation	Yes
47918-0880-18	Afrezza	Mannkind Corporation	Yes
47918-0882-36	Afrezza	Mannkind Corporation	Yes
47918-0884-63	Afrezza	MannKind Corporation	Yes
47918-0891-90	Afrezza	Mannkind Corporation	Yes
47918-0894-63	Afrezza	Mannkind Corporation	Yes
47918-0902-18	Afrezza	Mannkind Corporation	Yes
45802-0169-72	Alogliptin-Metformin	Perrigo New York Inc	
45802-0211-72	Alogliptin-Metformin	Perrigo New York Inc	
00039-0221-10	Amaryl	Sanofi-Aventis U.S. LLC	
00088-2500-33	Apidra	Sanofi-Aventis U.S. LLC	Yes
00088-2502-05	Apidra	Sanofi-Aventis U.S. LLC	Yes
00173-0861-18	Avandia	GlaxoSmithKline LLC	
00002-7715-01	Basaglar	Eli Lilly and Company	
00002-7715-59	Basaglar	Eli Lilly and Company	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
60687-0286-21	Bromocriptine	American Health Packaging	
00378-2042-01	Bromocriptine	Mylan	
00378-7096-01	Bromocriptine	Mylan	
00378-7096-93	Bromocriptine	Mylan	
00574-0106-01	Bromocriptine	Paddock Laboratories, LLC	
00574-0106-03	Bromocriptine	Paddock Laboratories, LLC	
00781-5325-01	Bromocriptine	Sandoz Inc	
00781-5325-31	Bromocriptine	Sandoz Inc	
63304-0962-30	Bromocriptine	Sun Pharmaceutical Industries, Inc.	
68382-0110-06	Bromocriptine	Zydus Pharmaceuticals (USA) Inc.	
00310-6520-04	Bydureon	AstraZeneca Pharmaceuticals LP	
00310-6530-04	Bydureon	AstraZeneca Pharmaceuticals LP	
00310-6540-04	Bydureon BCise	AstraZeneca Pharmaceuticals LP	
00310-6512-01	Byetta	AstraZeneca Pharmaceuticals LP	
00310-6524-01	Byetta	AstraZeneca Pharmaceuticals LP	
51660-0996-28	Colesevelam	Ohm Laboratories, Inc.	
68012-0258-20	Cycloset	Santarus, Inc.	Yes
00003-1428-11	Farxiga	AstraZeneca Pharmaceuticals LP	
00310-6205-30	Farxiga	AstraZeneca Pharmaceuticals LP	Yes
00310-6210-30	Farxiga	AstraZeneca Pharmaceuticals LP	Yes
00169-3201-11	Fiasp	Novo Nordisk	Yes
00169-3204-15	Fiasp	Novo Nordisk	Yes
59630-0574-60	Fortamet ER	Shionogi Inc.	
59630-0575-60	Fortamet ER	Shionogi Inc.	
16729-0001-01	Glimepiride	Accord Healthcare Inc	Yes
16729-0001-16	Glimepiride	Accord Healthcare Inc	Yes
16729-0002-01	Glimepiride	Accord Healthcare Inc	Yes
16729-0002-16	Glimepiride	Accord Healthcare Inc	Yes
16729-0003-01	Glimepiride	Accord Healthcare Inc	Yes
16729-0003-16	Glimepiride	Accord Healthcare Inc	Yes
69452-0128-20	Glimepiride	Bionpharma Inc.	
69452-0128-30	Glimepiride	Bionpharma Inc.	
69452-0129-20	Glimepiride	Bionpharma Inc.	
69452-0130-20	Glimepiride	Bionpharma Inc.	
69452-0130-30	Glimepiride	Bionpharma Inc.	
68001-0177-00	Glimepiride	BluePoint Laboratories	
68001-0178-00	Glimepiride	BluePoint Laboratories	
68001-0178-03	Glimepiride	BluePoint Laboratories	
68001-0179-00	Glimepiride	BluePoint Laboratories	
68001-0179-03	Glimepiride	BluePoint Laboratories	
61442-0115-01	Glimepiride	Carlsbad Technology, Inc.	
61442-0116-01	Glimepiride	Carlsbad Technology, Inc.	
61442-0116-05	Glimepiride	Carlsbad Technology, Inc.	
61442-0117-01	Glimepiride	Carlsbad Technology, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
61442-0117-05	Glimepiride	Carlsbad Technology, Inc.	
55111-0320-01	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0320-05	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0321-01	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0321-05	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0322-01	Glimepiride	Dr. Reddy's Laboratories Limited	
55111-0322-05	Glimepiride	Dr. Reddy's Laboratories Limited	
54458-0966-10	Glimepiride	International Laboratories, LLC	
54458-0966-16	Glimepiride	International Laboratories, LLC	
54458-0967-10	Glimepiride	International Laboratories, LLC	
54458-0967-16	Glimepiride	International Laboratories, LLC	
54458-0968-10	Glimepiride	International Laboratories, LLC	
68645-0572-90	Glimepiride	Legacy Pharmaceutical Packaging, LLC	
68645-0573-90	Glimepiride	Legacy Pharmaceutical Packaging, LLC	
51079-0426-20	Glimepiride	Mylan	
00378-4012-01	Glimepiride	Mylan	
00378-4013-01	Glimepiride	Mylan	
00093-7254-01	Glimepiride	Teva Pharmaceuticals USA, Inc.	
00093-7255-01	Glimepiride	Teva Pharmaceuticals USA, Inc.	
00093-7256-01	Glimepiride	Teva Pharmaceuticals USA, Inc.	
00093-7256-52	Glimepiride	Teva Pharmaceuticals USA, Inc.	
69543-0123-10	Glimepiride	Virtus Pharmaceuticals	
69543-0123-50	Glimepiride	Virtus Pharmaceuticals	
69543-0124-10	Glimepiride	Virtus Pharmaceuticals	
69543-0124-50	Glimepiride	Virtus Pharmaceuticals	
69543-0125-10	Glimepiride	Virtus Pharmaceuticals	
69543-0125-50	Glimepiride	Virtus Pharmaceuticals	
16729-0139-00	Glipizide	Accord Healthcare Inc.	
16729-0139-16	Glipizide	Accord Healthcare Inc.	
16729-0140-00	Glipizide	Accord Healthcare Inc.	
16729-0140-16	Glipizide	Accord Healthcare Inc.	
00591-0460-01	Glipizide	Actavis Pharma, Inc.	
00591-0460-05	Glipizide	Actavis Pharma, Inc.	
00591-0460-10	Glipizide	Actavis Pharma, Inc.	
00591-0461-01	Glipizide	Actavis Pharma, Inc.	
00591-0461-05	Glipizide	Actavis Pharma, Inc.	
00591-0461-10	Glipizide	Actavis Pharma, Inc.	
60505-0141-00	Glipizide	Apotex Corp.	
60505-0141-01	Glipizide	Apotex Corp.	
60505-0141-02	Glipizide	Apotex Corp.	
60505-0142-00	Glipizide	Apotex Corp.	
60505-0142-01	Glipizide	Apotex Corp.	
60505-0142-02	Glipizide	Apotex Corp.	
60505-0142-04	Glipizide	Apotex Corp.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
68645-0150-54	Glipizide	Legacy Pharmaceutical Packaging, LLC	
68645-0151-59	Glipizide	Legacy Pharmaceutical Packaging, LLC	
51079-0810-20	Glipizide	Mylan	
51079-0811-20	Glipizide	Mylan	
00378-1105-01	Glipizide	Mylan	
00378-1105-05	Glipizide	Mylan	
00378-1110-01	Glipizide	Mylan	
00378-1110-05	Glipizide	Mylan	
00781-1452-01	Glipizide	Sandoz Inc	
00781-1452-10	Glipizide	Sandoz Inc	
00781-1453-01	Glipizide	Sandoz Inc	
00781-1453-10	Glipizide	Sandoz Inc	
57664-0398-13	Glipizide	Sun Pharmaceutical Industries, Inc.	
00591-0844-01	Glipizide ER	Actavis Pharma, Inc.	
00591-0844-10	Glipizide ER	Actavis Pharma, Inc.	
00591-0844-15	Glipizide ER	Actavis Pharma, Inc.	
00591-0845-01	Glipizide ER	Actavis Pharma, Inc.	
00591-0845-10	Glipizide ER	Actavis Pharma, Inc.	
00591-0845-15	Glipizide ER	Actavis Pharma, Inc.	
00591-0900-30	Glipizide ER	Actavis Pharma, Inc.	
68084-0111-01	Glipizide ER	American Health Packaging	Yes
68084-0112-01	Glipizide ER	American Health Packaging	Yes
68084-0295-21	Glipizide ER	American Health Packaging	Yes
00378-0340-93	Glipizide ER	Mylan	
00378-0342-01	Glipizide ER	Mylan	
00378-0431-01	Glipizide ER	Mylan	
10370-0745-01	Glipizide ER	Par Pharmaceutical, Inc.	
10370-0745-05	Glipizide ER	Par Pharmaceutical, Inc.	
10370-0746-01	Glipizide ER	Par Pharmaceutical, Inc.	
10370-0746-05	Glipizide ER	Par Pharmaceutical, Inc.	
10370-0190-01	Glipizide ER	Par Pharmaceuticals, Inc.	
10370-0190-05	Glipizide ER	Par Pharmaceuticals, Inc.	
10370-0191-01	Glipizide ER	Par Pharmaceuticals, Inc.	
10370-0191-05	Glipizide ER	Par Pharmaceuticals, Inc.	
64980-0279-03	Glipizide ER	Rising Pharmaceuticals, Inc.	
64980-0280-01	Glipizide ER	Rising Pharmaceuticals, Inc.	
64980-0280-05	Glipizide ER	Rising Pharmaceuticals, Inc.	
64980-0281-01	Glipizide ER	Rising Pharmaceuticals, Inc.	
64980-0281-05	Glipizide ER	Rising Pharmaceuticals, Inc.	
59762-0540-01	Glipizide XL	Greenstone LLC	
59762-0541-01	Glipizide XL	Greenstone LLC	
59762-0541-02	Glipizide XL	Greenstone LLC	
59762-0542-01	Glipizide XL	Greenstone LLC	
59762-0542-02	Glipizide XL	Greenstone LLC	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
23155-0116-01	Glipizide-Metformin	Heritage Pharmaceuticals Inc.	
23155-0117-01	Glipizide-Metformin	Heritage Pharmaceuticals Inc.	
00378-3132-01	Glipizide-Metformin	Mylan	
00378-3133-01	Glipizide-Metformin	Mylan	
00093-7455-01	Glipizide-Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7456-01	Glipizide-Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7457-01	Glipizide-Metformin	Teva Pharmaceuticals USA, Inc.	
68382-0185-01	Glipizide-Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0186-01	Glipizide-Metformin	Zydus Pharmaceuticals (USA) Inc.	
00169-7065-15	Glucagen	Novo Nordisk	Yes
00002-8031-01	Glucagon	Eli Lilly and Company	Yes
00087-6060-05	Glucophage	Bristol-Myers Squibb Company	
00087-6071-11	Glucophage	Bristol-Myers Squibb Company	
00087-6064-13	Glucophage XR	Bristol-Myers Squibb Company	
00049-4110-66	Glucotrol	Roerig	Yes
00049-4120-66	Glucotrol	Roerig	Yes
00049-0170-01	Glucotrol XL	Roerig	Yes
00049-0174-02	Glucotrol XL	Roerig	Yes
00049-0174-03	Glucotrol XL	Roerig	Yes
00049-0178-07	Glucotrol XL	Roerig	Yes
00049-0178-08	Glucotrol XL	Roerig	Yes
68012-0002-13	Glumetza ER	Santarus, Inc.	
68012-0003-16	Glumetza ER	Santarus, Inc.	
65862-0028-01	Glyburide	Aurobindo Pharma Limited	
65862-0029-01	Glyburide	Aurobindo Pharma Limited	
65862-0030-01	Glyburide	Aurobindo Pharma Limited	
65862-0030-99	Glyburide	Aurobindo Pharma Limited	
57237-0022-05	Glyburide	Citron Pharma LLC	
23155-0056-01	Glyburide	Heritage Pharmaceuticals Inc.	
23155-0057-01	Glyburide	Heritage Pharmaceuticals Inc.	
23155-0058-01	Glyburide	Heritage Pharmaceuticals Inc.	
23155-0058-10	Glyburide	Heritage Pharmaceuticals Inc.	
63739-0119-10	Glyburide	McKesson Corporation	
51079-0872-20	Glyburide	Mylan	
51079-0873-20	Glyburide	Mylan	
00093-9364-01	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9364-05	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9364-10	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9433-01	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9433-05	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-9477-53	Glyburide	TEVA Pharmaceuticals USA Inc	
00093-8342-01	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8343-01	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8343-05	Glyburide	Teva Pharmaceuticals USA, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00093-8343-10	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8343-98	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8344-01	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8344-05	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8344-10	Glyburide	Teva Pharmaceuticals USA, Inc.	
00093-8344-98	Glyburide	Teva Pharmaceuticals USA, Inc.	
52817-0120-10	Glyburide	TruPharma, LLC	
52817-0121-10	Glyburide	TruPharma, LLC	
52817-0122-00	Glyburide	TruPharma, LLC	
52817-0122-10	Glyburide	TruPharma, LLC	
68382-0657-01	Glyburide	Zydus Pharmaceuticals (USA) Inc.	
68382-0658-10	Glyburide	Zydus Pharmaceuticals (USA) Inc.	
00378-1125-10	Glyburide Micro	Mylan	
00093-8034-01	Glyburide Micro	Teva Pharmaceuticals USA, Inc.	
00093-8035-01	Glyburide Micro	Teva Pharmaceuticals USA, Inc.	
00093-8035-05	Glyburide Micro	Teva Pharmaceuticals USA, Inc.	
00093-8036-01	Glyburide Micro	Teva Pharmaceuticals USA, Inc.	
00143-9918-01	Glyburide Micro	West-Ward Pharmaceuticals Corp	
00143-9919-01	Glyburide Micro	West-Ward Pharmaceuticals Corp	
00143-9920-01	Glyburide Micro	West-Ward Pharmaceuticals Corp	
00143-9920-05	Glyburide Micro	West-Ward Pharmaceuticals Corp	
00228-2752-11	Glyburide-Metformin	Actavis Pharma, Inc.	
00228-2753-11	Glyburide-Metformin	Actavis Pharma, Inc.	
65862-0081-01	Glyburide-Metformin	Aurobindo Pharma Limited	
65862-0082-01	Glyburide-Metformin	Aurobindo Pharma Limited	
65862-0082-05	Glyburide-Metformin	Aurobindo Pharma Limited	
57237-0024-01	Glyburide-Metformin	Rising Health, LLC	
57237-0024-05	Glyburide-Metformin	Rising Health, LLC	
57237-0025-01	Glyburide-Metformin	Rising Health, LLC	
57237-0025-05	Glyburide-Metformin	Rising Health, LLC	
00093-5712-05	Glyburide-Metformin	Teva Pharmaceuticals USA, Inc.	
68382-0654-05	Glyburide-Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0655-05	Glyburide-Metformin	Zydus Pharmaceuticals (USA) Inc.	
65862-0080-01	Glyburid-Metformin	Aurobindo Pharma Limited	
57237-0023-01	Glyburid-Metformin	Rising Health, LLC	
00009-0341-01	Glynase	Pharmacia and Upjohn Company LLC	Yes
00009-5012-01	Glyset	Pharmacia and Upjohn Company LLC	Yes
00009-5013-01	Glyset	Pharmacia and Upjohn Company LLC	Yes
00009-5014-01	Glyset	Pharmacia and Upjohn Company LLC	Yes
54868-4203-00	Glyset	Physicians Total Care, Inc.	
00597-0164-30	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00597-0164-39	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00597-0164-90	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00597-0182-30	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00597-0182-39	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00597-0182-90	Glyxambi	Boehringer Ingelheim Pharmaceuticals, Inc.	
00002-7510-01	Humalog	Eli Lilly and Company	
00002-7510-17	Humalog	Eli Lilly and Company	
00002-7516-59	Humalog	Eli Lilly and Company	
00002-7712-01	Humalog	Eli Lilly and Company	
00002-7712-27	Humalog	Eli Lilly and Company	
00002-8799-01	Humalog	Eli Lilly and Company	
00002-8799-59	Humalog	Eli Lilly and Company	
00002-7512-01	Humalog 50-50	Eli Lilly and Company	
00002-8798-01	Humalog 50-50	Eli Lilly and Company	
00002-8798-59	Humalog 50-50	Eli Lilly and Company	
00002-7511-01	Humalog 75-25	Eli Lilly and Company	
00002-8797-59	Humalog 75-25	Eli Lilly and Company	
00002-7714-59	Humalog Jr	Eli Lilly and Company	
00002-8715-01	Humulin 70/30	Eli Lilly and Company	
00002-8715-17	Humulin 70/30	Eli Lilly and Company	
00002-8803-01	Humulin 70/30	Eli Lilly and Company	
00002-8803-59	Humulin 70/30	Eli Lilly and Company	
00002-8315-01	Humulin N	Eli Lilly and Company	
00002-8315-17	Humulin N	Eli Lilly and Company	
00002-8805-59	Humulin N	Eli Lilly and Company	
00002-8215-01	Humulin R	Eli Lilly and Company	
00002-8215-17	Humulin R	Eli Lilly and Company	
00002-8501-01	Humulin R500	Eli Lilly and Company	
00002-8824-27	Humulin R500	Eli Lilly and Company	
50458-0540-60	Invokamet	Janssen Pharmaceuticals, Inc.	Yes
50458-0541-60	Invokamet	Janssen Pharmaceuticals, Inc.	Yes
50458-0542-60	Invokamet	Janssen Pharmaceuticals, Inc.	Yes
50458-0543-60	Invokamet	Janssen Pharmaceuticals, Inc.	Yes
50458-0940-01	Invokamet XR	Janssen Pharmaceuticals, Inc.	Yes
50458-0941-01	Invokamet XR	Janssen Pharmaceuticals, Inc.	Yes
50458-0942-01	Invokamet XR	Janssen Pharmaceuticals, Inc.	Yes
50458-0943-01	Invokamet XR	Janssen Pharmaceuticals, Inc.	Yes
50458-0140-30	Invokana	Janssen Pharmaceuticals, Inc.	Yes
50458-0140-90	Invokana	Janssen Pharmaceuticals, Inc.	Yes
50458-0141-30	Invokana	Janssen Pharmaceuticals, Inc.	Yes
50458-0141-90	Invokana	Janssen Pharmaceuticals, Inc.	Yes
00006-0575-61	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0575-62	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0575-82	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0577-61	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0577-62	Janumet	Merck Sharp & Dohme Corp.	Yes
00006-0577-82	Janumet	Merck Sharp & Dohme Corp.	Yes

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00006-0078-61	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0078-62	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0080-61	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0080-62	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0080-82	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0081-31	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0081-54	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0081-82	Janumet XR	Merck Sharp & Dohme Corp.	Yes
00006-0112-28	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0112-31	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0112-54	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0221-28	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0221-31	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0221-54	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-01	Januvia	Merck Sharp & Dohme Corp.	
00006-0277-02	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-28	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-31	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-33	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-54	Januvia	Merck Sharp & Dohme Corp.	Yes
00006-0277-82	Januvia	Merck Sharp & Dohme Corp.	Yes
00597-0152-30	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0152-37	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0152-90	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0153-30	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0153-37	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0153-90	Jardiance	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0146-18	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0146-60	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0147-18	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0147-60	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0148-18	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0148-60	Jentadueto	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0270-73	Jentadueto XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0270-94	Jentadueto XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0275-33	Jentadueto XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0275-81	Jentadueto XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
64764-0335-60	Kazano	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0337-60	Kazano	Takeda Pharmaceuticals U.S.A., Inc.	
00310-6125-60	Kombiglyze XR	AstraZeneca Pharmaceuticals LP	
00310-6135-30	Kombiglyze XR	AstraZeneca Pharmaceuticals LP	
00310-6145-30	Kombiglyze XR	AstraZeneca Pharmaceuticals LP	
00088-2219-05	Lantus	sanofi-aventis U.S. LLC	Yes
00088-2220-33	Lantus	sanofi-aventis U.S. LLC	Yes

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00088-5020-05	Lantus	sanofi-aventis U.S. LLC	Yes
00088-5021-01	Lantus	sanofi-aventis U.S. LLC	Yes
00169-3687-12	Levemir	Novo Nordisk	Yes
00169-6438-10	Levemir	Novo Nordisk	Yes
00591-2412-19	Metformin	Actavis Pharma, Inc.	
00591-2719-60	Metformin	Actavis Pharma, Inc.	
62037-0571-01	Metformin	Actavis Pharma, Inc.	
62037-0571-10	Metformin	Actavis Pharma, Inc.	
62037-0577-01	Metformin	Actavis Pharma, Inc.	
60687-0143-01	Metformin	American Health Packaging	Yes
65162-0220-10	Metformin	Amneal Pharmaceuticals LLC	
65162-0220-11	Metformin	Amneal Pharmaceuticals LLC	
65162-0220-50	Metformin	Amneal Pharmaceuticals LLC	
53746-0178-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0178-05	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0178-10	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0178-90	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0179-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0218-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0218-05	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0218-10	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0219-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0219-05	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0219-10	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0220-01	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0220-05	Metformin	Amneal Pharmaceuticals of New York LLC	
53746-0220-10	Metformin	Amneal Pharmaceuticals of New York LLC	
60505-0190-00	Metformin	Apotex Corp.	
60505-0260-01	Metformin	Apotex Corp.	
60505-0260-02	Metformin	Apotex Corp.	
60505-1329-01	Metformin	Apotex Corp.	
67877-0159-01	Metformin	Ascend Laboratories, LLC	
67877-0159-05	Metformin	Ascend Laboratories, LLC	
67877-0159-10	Metformin	Ascend Laboratories, LLC	
67877-0217-05	Metformin	Ascend Laboratories, LLC	
67877-0217-10	Metformin	Ascend Laboratories, LLC	
67877-0221-01	Metformin	Ascend Laboratories, LLC	
67877-0221-05	Metformin	Ascend Laboratories, LLC	
67877-0221-10	Metformin	Ascend Laboratories, LLC	
67877-0561-01	Metformin	Ascend Laboratories, LLC	
67877-0561-05	Metformin	Ascend Laboratories, LLC	
67877-0561-10	Metformin	Ascend Laboratories, LLC	
67877-0562-05	Metformin	Ascend Laboratories, LLC	
67877-0562-10	Metformin	Ascend Laboratories, LLC	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
67877-0563-01	Metformin	Ascend Laboratories, LLC	
67877-0563-05	Metformin	Ascend Laboratories, LLC	
67877-0563-10	Metformin	Ascend Laboratories, LLC	
65862-0008-01	Metformin	Aurobindo Pharma Limited	
65862-0008-05	Metformin	Aurobindo Pharma Limited	
65862-0008-99	Metformin	Aurobindo Pharma Limited	
65862-0009-01	Metformin	Aurobindo Pharma Limited	
65862-0009-05	Metformin	Aurobindo Pharma Limited	
65862-0010-01	Metformin	Aurobindo Pharma Limited	
65862-0010-05	Metformin	Aurobindo Pharma Limited	
65862-0010-99	Metformin	Aurobindo Pharma Limited	
00185-4416-01	Metformin	Eon Labs, Inc.	
42806-0213-05	Metformin	Epic Pharma, LLC	
42806-0213-10	Metformin	Epic Pharma, LLC	
42806-0215-01	Metformin	Epic Pharma, LLC	
42806-0221-05	Metformin	Epic Pharma, LLC	
42806-0313-05	Metformin	Epic Pharma, LLC	
42806-0314-01	Metformin	Epic Pharma, LLC	
42806-0315-05	Metformin	Epic Pharma, LLC	
68462-0159-01	Metformin	Glenmark Pharmaceuticals Inc., USA	
68462-0159-05	Metformin	Glenmark Pharmaceuticals Inc., USA	
68462-0159-10	Metformin	Glenmark Pharmaceuticals Inc., USA	
68462-0160-01	Metformin	Glenmark Pharmaceuticals Inc., USA	
68462-0161-05	Metformin	Glenmark Pharmaceuticals Inc., USA	
23155-0102-01	Metformin	Heritage Pharmaceuticals Inc.	
23155-0102-05	Metformin	Heritage Pharmaceuticals Inc.	
23155-0102-10	Metformin	Heritage Pharmaceuticals Inc.	
23155-0103-01	Metformin	Heritage Pharmaceuticals Inc.	
23155-0103-05	Metformin	Heritage Pharmaceuticals Inc.	
23155-0103-10	Metformin	Heritage Pharmaceuticals Inc.	
23155-0104-01	Metformin	Heritage Pharmaceuticals Inc.	
23155-0104-05	Metformin	Heritage Pharmaceuticals Inc.	
23155-0104-10	Metformin	Heritage Pharmaceuticals Inc.	
50742-0154-01	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0154-05	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0154-10	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0154-90	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0155-01	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0155-05	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0155-10	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0156-05	Metformin	Ingenus Pharmaceuticals, LLC	
50742-0156-10	Metformin	Ingenus Pharmaceuticals, LLC	
68645-0300-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0539-59	Metformin	Legacy Pharmaceutical Packaging, LLC	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
68645-0544-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0545-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0546-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0547-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68645-0549-59	Metformin	Legacy Pharmaceutical Packaging, LLC	
68180-0336-07	Metformin	Lupin Pharmaceuticals, Inc.	
68180-0338-01	Metformin	Lupin Pharmaceuticals, Inc.	
68180-0339-09	Metformin	Lupin Pharmaceuticals, Inc.	
33342-0240-11	Metformin	Macleods Pharmaceuticals Limited	
00904-6326-61	Metformin	Major Pharmaceuticals	
38779-2126-05	Metformin	Medisca, Inc.	
58657-0640-10	Metformin	Method Pharmaceuticals, LLC	
00378-6002-91	Metformin	Mylan	
00378-7185-05	Metformin	Mylan	
00378-7186-05	Metformin	Mylan	
00378-7187-05	Metformin	Mylan	
68682-0017-10	Metformin	Oceanside Pharmaceuticals	
68682-0018-90	Metformin	Oceanside Pharmaceuticals	
51927-3105-00	Metformin	Professional Co.	
00781-5503-01	Metformin	SANDOZ INC.	
43547-0248-50	Metformin	Solco healthcare U.S., LLC	
43547-0249-50	Metformin	Solco healthcare U.S., LLC	
43547-0357-10	Metformin	Solco healthcare U.S., LLC	
43547-0357-11	Metformin	Solco healthcare U.S., LLC	
43547-0357-50	Metformin	Solco healthcare U.S., LLC	
43547-0358-50	Metformin	Solco healthcare U.S., LLC	
43547-0359-10	Metformin	Solco healthcare U.S., LLC	
43547-0359-50	Metformin	Solco healthcare U.S., LLC	
57664-0397-51	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0397-53	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0397-58	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0435-51	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0435-53	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0435-58	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0435-88	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0474-51	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0474-53	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0474-58	Metformin	Sun Pharmaceutical Industries, Inc.	
57664-0474-88	Metformin	Sun Pharmaceutical Industries, Inc.	
62756-0142-01	Metformin	Sun Pharmaceutical Industries, Inc.	
62756-0142-02	Metformin	Sun Pharmaceutical Industries, Inc.	
62756-0143-01	Metformin	Sun Pharmaceutical Industries, Inc.	
51224-0007-50	Metformin	TAGI Pharma, Inc.	
51224-0007-60	Metformin	TAGI Pharma, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
51224-0107-50	Metformin	TAGI Pharma, Inc.	
51224-0107-60	Metformin	TAGI Pharma, Inc.	
00093-1048-01	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-1048-10	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-1049-10	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7212-01	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7214-01	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7214-10	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7267-01	Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7267-10	Metformin	Teva Pharmaceuticals USA, Inc.	
49483-0620-10	Metformin	TIME CAP LABORATORIES, INC	
49483-0621-10	Metformin	TIME CAP LABORATORIES, INC	
49483-0623-01	Metformin	TIME CAP LABORATORIES, INC	Yes
49483-0623-09	Metformin	TIME CAP LABORATORIES, INC	
49483-0623-10	Metformin	TIME CAP LABORATORIES, INC	
49483-0623-50	Metformin	TIME CAP LABORATORIES, INC	Yes
49483-0624-01	Metformin	TIME CAP LABORATORIES, INC	
68382-0028-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0030-01	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0030-05	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0030-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0758-01	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0758-05	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0758-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0759-01	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0759-05	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0759-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0760-01	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0760-05	Metformin	Zydus Pharmaceuticals (USA) Inc.	
68382-0760-10	Metformin	Zydus Pharmaceuticals (USA) Inc.	
00591-2720-60	Metformin ER	Actavis Pharma, Inc.	
68180-0337-07	Metformin ER	Lupin Pharmaceuticals, Inc.	
00378-6001-91	Metformin ER	Mylan	
29033-0032-06	Metformin ER	Nostrum Laboratories, Inc.	
57664-0684-88	Miglitol	Sun Pharmaceutical Industries Ltd.	
57664-0685-88	Miglitol	Sun Pharmaceutical Industries Ltd.	
57664-0686-88	Miglitol	Sun Pharmaceutical Industries Ltd.	
00591-3354-01	Nateglinide	Actavis Pharma, Inc.	
00591-3355-01	Nateglinide	Actavis Pharma, Inc.	
68084-0458-21	Nateglinide	American Health Packaging	
68084-0459-21	Nateglinide	American Health Packaging	
55111-0328-90	Nateglinide	Dr. Reddy's Laboratories Limited	
55111-0329-90	Nateglinide	Dr. Reddy's Laboratories Limited	
49884-0984-01	Nateglinide	Par Pharmaceutical, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
49884-0985-01	Nateglinide	Par Pharmaceutical, Inc.	
68382-0721-16	Nateglinide	Zydus Pharmaceuticals (USA) Inc.	
68382-0722-16	Nateglinide	Zydus Pharmaceuticals (USA) Inc.	
64764-0125-30	Nesina	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0250-30	Nesina	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0625-30	Nesina	Takeda Pharmaceuticals U.S.A., Inc.	
00169-1837-02	Novolin 70-30	Novo Nordisk	
00169-1837-11	Novolin 70-30	Novo Nordisk	
00169-1834-02	Novolin N	Novo Nordisk	
00169-1834-11	Novolin N	Novo Nordisk	
00169-1833-02	Novolin R	Novo Nordisk	
00169-1833-11	Novolin R	Novo Nordisk	
00169-3303-12	Novolog	Novo Nordisk	Yes
00169-6339-10	Novolog	Novo Nordisk	Yes
00169-7501-11	Novolog	Novo Nordisk	Yes
32849-0500-81	Novolog	Novo Nordisk	
00169-3685-12	Novolog 70/30	Novo Nordisk	Yes
00169-3696-19	Novolog 70/30	Novo Nordisk	Yes
00310-6100-30	Onglyza	AstraZeneca Pharmaceuticals LP	
00310-6100-90	Onglyza	AstraZeneca Pharmaceuticals LP	
00310-6105-30	Onglyza	AstraZeneca Pharmaceuticals LP	
00310-6105-50	Onglyza	AstraZeneca Pharmaceuticals LP	
00310-6105-90	Onglyza	AstraZeneca Pharmaceuticals LP	
64764-0121-03	Oseni	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0251-03	Oseni	Takeda Pharmaceuticals U.S.A., Inc.	
64764-0253-03	Oseni	Takeda Pharmaceuticals U.S.A., Inc.	
00169-4132-12	Ozempic	Novo Nordisk	Yes
00169-4136-02	Ozempic	Novo Nordisk	Yes
16729-0020-10	Pioglitazone	Accord Healthcare, Inc.	
16729-0020-15	Pioglitazone	Accord Healthcare, Inc.	
16729-0020-16	Pioglitazone	Accord Healthcare, Inc.	
16729-0021-10	Pioglitazone	Accord Healthcare, Inc.	
16729-0021-15	Pioglitazone	Accord Healthcare, Inc.	
16729-0021-16	Pioglitazone	Accord Healthcare, Inc.	
16729-0022-10	Pioglitazone	Accord Healthcare, Inc.	
16729-0022-15	Pioglitazone	Accord Healthcare, Inc.	
16729-0022-16	Pioglitazone	Accord Healthcare, Inc.	
00591-3205-05	Pioglitazone	Actavis Pharma, Inc.	
00591-3205-19	Pioglitazone	Actavis Pharma, Inc.	
00591-3205-30	Pioglitazone	Actavis Pharma, Inc.	
00591-3206-19	Pioglitazone	Actavis Pharma, Inc.	
00591-3206-30	Pioglitazone	Actavis Pharma, Inc.	
00591-3207-05	Pioglitazone	Actavis Pharma, Inc.	
00591-3207-19	Pioglitazone	Actavis Pharma, Inc.	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00591-3207-30	Pioglitazone	Actavis Pharma, Inc.	
68084-0878-01	Pioglitazone	American Health Packaging	
54458-0864-10	Pioglitazone	International Laboratories, LLC	Yes
54458-0865-10	Pioglitazone	International Laboratories, LLC	Yes
54458-0866-10	Pioglitazone	International Laboratories, LLC	Yes
33342-0054-07	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0054-10	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0054-15	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0055-07	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0055-10	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0055-15	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0056-07	Pioglitazone	Macleods Pharmaceuticals Limited	
33342-0056-10	Pioglitazone	Macleods Pharmaceuticals Limited	
51079-0513-20	Pioglitazone	Mylan	
00378-0048-77	Pioglitazone	Mylan	
00378-0048-93	Pioglitazone	Mylan	
00378-0228-77	Pioglitazone	Mylan	
00378-0228-93	Pioglitazone	Mylan	
00378-0318-93	Pioglitazone	Mylan	
63304-0313-30	Pioglitazone	Ranbaxy Pharmaceuticals Inc.	
00781-5420-31	Pioglitazone	Sandoz Inc	
00781-5420-92	Pioglitazone	Sandoz Inc	
00781-5421-31	Pioglitazone	Sandoz Inc	
00781-5421-92	Pioglitazone	Sandoz Inc	
00781-5422-31	Pioglitazone	Sandoz Inc	
00781-5422-92	Pioglitazone	Sandoz Inc	
00093-2046-98	Pioglitazone	Teva Pharmaceuticals USA Inc	
00093-2047-98	Pioglitazone	Teva Pharmaceuticals USA Inc	
00093-7271-56	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7271-98	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7272-56	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7272-98	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7273-56	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
00093-7273-98	Pioglitazone	Teva Pharmaceuticals USA, Inc.	
13668-0119-05	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0119-30	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0119-90	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0120-05	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0120-30	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0120-90	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0140-30	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
13668-0140-90	Pioglitazone	TORRENT PHARMACEUTICALS LIMITED	
66993-0821-30	Pioglitazone-Glimepiride	Prasco Laboratories	
66993-0822-30	Pioglitazone-Glimepiride	Prasco Laboratories	

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00781-5634-31	Pioglitazone-Glimepiride	Sandoz Inc	
00781-5635-31	Pioglitazone-Glimepiride	Sandoz Inc	
65862-0525-60	Pioglitazone-Metformin	Aurobindo Pharma Limited	
65862-0526-18	Pioglitazone-Metformin	Aurobindo Pharma Limited	
65862-0526-60	Pioglitazone-Metformin	Aurobindo Pharma Limited	
33342-0177-09	Pioglitazone-Metformin	Macleods Pharmaceuticals Limited	
00378-1550-91	Pioglitazone-Metformin	Mylan	
00378-1575-91	Pioglitazone-Metformin	Mylan	
57237-0218-60	Pioglitazone-Metformin	Rising Health, LLC	
00781-5626-60	Pioglitazone-Metformin	Sandoz Inc	
00781-5627-60	Pioglitazone-Metformin	Sandoz Inc	
00093-7677-06	Pioglitazone-Metformin	Teva Pharmaceuticals USA, Inc.	
00093-7678-06	Pioglitazone-Metformin	Teva Pharmaceuticals USA, Inc.	
13668-0280-60	Pioglitazone-Metformin	TORRENT PHARMACEUTICALS LIMITED	
13668-0281-60	Pioglitazone-Metformin	TORRENT PHARMACEUTICALS LIMITED	
60846-0882-01	Prandin	Gemini Laboratories, LLC	Yes
60846-0884-01	Prandin	Gemini Laboratories, LLC	Yes
10631-0206-01	Riomet	Sun Pharmaceutical Industries, Inc.	Yes
10631-0206-02	Riomet	Sun Pharmaceutical Industries, Inc.	Yes
10631-0238-01	Riomet	Sun Pharmaceutical Industries, Inc.	Yes
10631-0238-02	Riomet	Sun Pharmaceutical Industries, Inc.	Yes
00006-5369-03	Segluromet	Merck Sharp & Dohme Corp.	
00006-5369-06	Segluromet	Merck Sharp & Dohme Corp.	
00006-5370-03	Segluromet	Merck Sharp & Dohme Corp.	
00006-5370-06	Segluromet	Merck Sharp & Dohme Corp.	
00006-5373-03	Segluromet	Merck Sharp & Dohme Corp.	
00006-5373-06	Segluromet	Merck Sharp & Dohme Corp.	
00006-5374-03	Segluromet	Merck Sharp & Dohme Corp.	
00006-5374-06	Segluromet	Merck Sharp & Dohme Corp.	
00024-5761-05	Soliqua 100/33	Sanofi-Aventis U.S. LLC	Yes
00078-0351-05	Starlix	Novartis Pharmaceuticals Corporation	Yes
00078-0352-05	Starlix	Novartis Pharmaceuticals Corporation	Yes
00006-5364-03	Steglatro	Merck Sharp & Dohme Corp.	
00006-5364-06	Steglatro	Merck Sharp & Dohme Corp.	
00006-5367-03	Steglujan	Merck Sharp & Dohme Corp.	
00006-5367-06	Steglujan	Merck Sharp & Dohme Corp.	
00006-5368-03	Steglujan	Merck Sharp & Dohme Corp.	
00006-5368-06	Steglujan	Merck Sharp & Dohme Corp.	
00310-6615-02	Symlinpen	AstraZeneca Pharmaceuticals LP	
00310-6627-02	Symlinpen	AstraZeneca Pharmaceuticals LP	
00597-0159-18	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0159-60	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0168-18	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0168-60	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes

NDC	Essential Diabetes Drug Name	Labeler	Significant Price Increase
00597-0175-18	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0175-60	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0180-18	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0180-60	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0280-90	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0290-74	Synjardy	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0280-73	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0290-59	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0295-78	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0295-88	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0300-45	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0300-93	Synjardy XR	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00173-0866-01	Tanzeum	GlaxoSmithKline LLC	
00173-0866-35	Tanzeum	GlaxoSmithKline LLC	
00173-0867-35	Tanzeum	GlaxoSmithKline LLC	
00024-5869-03	Toujeo	Sanofi-Aventis U.S. LLC	Yes
00024-5871-02	Toujeo	Sanofi-Aventis U.S. LLC	Yes
00597-0140-30	Tradjenta	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0140-61	Tradjenta	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00597-0140-90	Tradjenta	Boehringer Ingelheim Pharmaceuticals, Inc.	Yes
00169-2550-13	Tresiba	Novo Nordisk	Yes
00169-2660-15	Tresiba	Novo Nordisk	Yes
00002-1433-01	Trulicity	Eli Lilly and Company	
00002-1433-80	Trulicity	Eli Lilly and Company	Yes
00002-1434-01	Trulicity	Eli Lilly and Company	
00002-1434-80	Trulicity	Eli Lilly and Company	Yes
00169-4060-12	Victoza	Novo Nordisk	Yes
00169-4060-13	Victoza	Novo Nordisk	Yes
65597-0701-18	Welchol	Daiichi Sankyo Inc.	Yes
65597-0902-30	Welchol	Daiichi Sankyo Inc.	Yes
00310-6250-30	Xigduo XR	AstraZeneca Pharmaceuticals LP	Yes
00310-6260-60	Xigduo XR	AstraZeneca Pharmaceuticals LP	Yes
00310-6270-30	Xigduo XR	AstraZeneca Pharmaceuticals LP	Yes
00310-6280-30	Xigduo XR	AstraZeneca Pharmaceuticals LP	Yes
00169-2911-15	Xultophy 100/3.6	Novo Nordisk	Yes

# EXHIBIT 11

# EXHIBIT 11



**BY E-MAIL**

Nevada Department of Health and Human Services  
4150 Technology Way, Suite 300  
Carson City, NV 89703  
[drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov)

January 15, 2019

**Re: Sanofi US Trade Secret/Confidentiality Request Pursuant to Nevada SB 539**

To Whom It May Concern:

In accordance with Section 3(1) of approved regulation R042-18, which implements Senate Bill No. 539 ("SB 539"), Sanofi US hereby submits this request for confidentiality relating to certain confidential and proprietary information and data as specified below (the "Sanofi Confidential Information") submitted to the Nevada Department of Health and Human Services (the "Department") as required by Section 3.8 of SB 539 (NRS 439B.635). Sanofi US reasonably believes that public disclosure of the Sanofi Confidential Information to any person or entity outside of the Department including to state legislators, would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended (the "DTSA"). In addition, Sanofi submits this request in reliance upon the Joint Status Report filed on June 28, 2018 in the matter of Pharmaceutical Research and Manufacturers of America v. Sandoval, et. al., United States District Court, District of Nevada, Case No.: 2:17-cv-023150JCM-CWH, in which the State of Nevada and the Department agreed that if the Department were to disclose trade secrets of Sanofi to any third party or use such trade secrets, such disclosure or use would constitute misappropriation for which a court may award relief to Sanofi pursuant to the DTSA.

As specified by Section 3(2) of the regulation, this request for confidentiality is divided into two parts.

In preparing this request, Sanofi US has exercised reasonable diligence to ensure that the Sanofi Confidential Information has in fact been kept secret and has not previously been disclosed, whether intentionally or unintentionally. To the extent the information has inadvertently been disclosed publicly, such inadvertent disclosure does not constitute a waiver of trade secret status.

**Part 1: Description of Sanofi Confidential Information**

Sanofi US seeks to protect from public disclosure the following Sanofi Confidential Information that is required to be submitted to the Department pursuant to Section 3.8 of SB 539 for certain of its diabetes drugs:

1. The costs of producing the drug (Section 3.8(1));
2. The total administrative expenditures relating to the drug, including marketing and advertising costs (Section 3.8(2));
3. The profit that Sanofi US has earned from the drug and the percentage of Sanofi US's total profit that is attributable to the drug (Section 3.8(3));
4. The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program (Section 3.8(4));



5. The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs (Section 3.8(5)); and
6. The aggregate amount of all rebates that Sanofi US has provided to pharmacy benefit managers for sales of the drug within the State of Nevada (Section 3.8(8)).

#### Part 2: Rationale for Trade Secret Protection Under the DTSA.

The Sanofi Confidential Information is confidential and proprietary information of Sanofi US and falls within the definition of a "trade secret" under the DTSA because it is of substantial independent value to Sanofi US by virtue of it being confidential and non-public. Any public disclosure of such Sanofi Confidential Information would cause significant harm to Sanofi US.

In satisfaction of 18 U.S.C. § 1839(3)(A), which requires that "the owner [of a trade secret] has taken reasonable measures to keep such information secret," the Sanofi Confidential Information is not shared publicly, and access to it is restricted internally and only shared internally on a need-to-know basis. It is subject to non-disclosure requirements in Sanofi US's employment and other business agreements. Employees of Sanofi US are required to maintain the secrecy of the Sanofi Confidential Information, and are subject to discipline—up to and including termination—by Sanofi US for its unauthorized disclosure.

In satisfaction of 18 U.S. § 1839(3)(B), which requires that a trade secret be "information [which] derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information," the Sanofi Confidential Information is valuable precisely because it is confidential, and it would lose value upon disclosure. The customers and competitors of Sanofi US would gain an unfair competitive advantage if they were to obtain the Sanofi Confidential Information through a public records request pursuant to NRS 239.010. In particular, Sanofi US's competitors and customers would receive the details of our cost structure, marketing and advertising costs, rebate strategies and profit information, which in turn provides insight into our pricing. This information could be used against us in negotiations with insurers and other intermediaries in the healthcare system. This could put Sanofi US at a significant disadvantage, especially if our competitors do not make a diabetes drug and thus are not subject to SB 539's disclosure requirements. Disclosure of the Sanofi Confidential Information could prejudice Sanofi US in competition involving non-diabetes products as well, given that Sanofi US considers the same or similar factors when establishing pricing, advertising and rebate strategies for its other therapeutic products. Such far-reaching effects on non-diabetes drugs would exceed the intent of the Nevada legislature in enacting this statute.



#### Conclusion

For all of these reasons, the Sanofi Confidential Information qualifies for trade secret protection under the DTSA and public disclosure of the Sanofi Confidential Information by the Department would constitute misappropriation of a trade secret thereunder. Sanofi US therefore requests that the Department keep confidential the information described in Part 1 of this request and not disclose it upon any request for public records under NRS 239.010.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Phillip Ridolfi', with a stylized flourish at the end.

Phillip Ridolfi

Head of Business Operations and Support, Sales Support

# **EXHIBIT 12**

# **EXHIBIT 12**



**BY E-MAIL**

Nevada Department of Health and Human Services  
4150 Technology Way, Suite 300  
Carson City, NV 89703  
[drugtransparency@dhhs.nv.gov](mailto:drugtransparency@dhhs.nv.gov)

April 1, 2019

**Re: Sanofi US Trade Secret/Confidentiality Request Pursuant to Nevada SB 539**

To Whom It May Concern:

In accordance with Section 3(1) of approved regulation R042-18, which implements Senate Bill No. 539 ("SB 539"), Sanofi US hereby submits this request for confidentiality relating to certain confidential and proprietary information and data as specified below (the "Sanofi Confidential Information") for the information reported for 2018 submitted to the Nevada Department of Health and Human Services (the "Department") as required by Section 3.8 of SB 539 (NRS 439B.635). Sanofi US reasonably believes that public disclosure of the Sanofi Confidential Information to any person or entity outside of the Department including to state legislators, would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended (the "DTSA"). In addition, Sanofi submits this request in reliance upon the Joint Status Report filed on June 28, 2018 in the matter of Pharmaceutical Research and Manufacturers of America v. Sandoval, et. al., United States District Court, District of Nevada, Case No.: 2:17-cv-02315JCM-CWH, in which the State of Nevada and the Department agreed that if the Department were to disclose trade secrets of Sanofi to any third party or use such trade secrets, such disclosure or use would constitute misappropriation for which a court may award relief to Sanofi pursuant to the DTSA.

As specified by Section 3(2) of the regulation, this request for confidentiality is divided into two parts.

In preparing this request, Sanofi US has exercised reasonable diligence to ensure that the Sanofi Confidential Information has in fact been kept secret and has not previously been disclosed, whether intentionally or unintentionally. To the extent the information has inadvertently been disclosed publicly, such inadvertent disclosure does not constitute a waiver of trade secret status.

**Part 1: Description of Sanofi Confidential Information**

Sanofi US seeks to protect from public disclosure the following Sanofi Confidential Information reported for 2018 that is required to be submitted to the Department pursuant to Section 3.8 of SB 539 for certain of its diabetes drugs:

1. The costs of producing the drug (Section 3.8(1));
2. The total administrative expenditures relating to the drug, including marketing and advertising costs (Section 3.8(2));
3. The profit that Sanofi US has earned from the drug and the percentage of Sanofi US's total profit that is attributable to the drug (Section 3.8(3));
4. The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program (Section 3.8(4));



5. The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs (Section 3.8(5)); and
6. The aggregate amount of all rebates that Sanofi US has provided to pharmacy benefit managers for sales of the drug within the State of Nevada (Section 3.8(8)).\*

#### Part 2: Rationale for Trade Secret Protection Under the DTSA

The Sanofi Confidential Information is confidential and proprietary information of Sanofi US and falls within the definition of a "trade secret" under the DTSA because it is of substantial independent value to Sanofi US by virtue of it being confidential and non-public. Any public disclosure of such Sanofi Confidential Information would cause significant harm to Sanofi US.

In satisfaction of 18 U.S.C. § 1839(3)(A), which requires that "the owner [of a trade secret] has taken reasonable measures to keep such information secret," the Sanofi Confidential Information is not shared publicly, and access to it is restricted internally and only shared internally on a need-to-know basis. It is subject to non-disclosure requirements in Sanofi US's employment and other business agreements. Employees of Sanofi US are required to maintain the secrecy of the Sanofi Confidential Information, and are subject to discipline—up to and including termination—by Sanofi US for its unauthorized disclosure.

In satisfaction of 18 U.S. § 1839(3)(B), which requires that a trade secret be "information [which] derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information," the Sanofi Confidential Information is valuable precisely because it is confidential, and it would lose value upon disclosure. The customers and competitors of Sanofi US would gain an unfair competitive advantage if they were to obtain the Sanofi Confidential Information through a public records request pursuant to NRS 239.010. In particular, Sanofi US's competitors and customers would receive the details of our cost structure, marketing and advertising costs, rebate strategies and profit information, which in turn provides insight into our pricing. This information could be used against us in negotiations with insurers and other intermediaries in the healthcare system. This could put Sanofi US at a significant disadvantage, especially if our competitors do not make a diabetes drug and thus are not subject to SB 539's disclosure requirements. Disclosure of the Sanofi Confidential Information could prejudice Sanofi US in competition involving non-diabetes products as well, given that Sanofi US considers the same or similar factors when establishing pricing, advertising and rebate strategies for its other therapeutic products. Such far-reaching effects on non-diabetes drugs would exceed the intent of the Nevada legislature in enacting this statute.

\*Information reported is as of September 31, 2018 due to data availability. A revised report with Q4 data included will be submitted when all relevant information necessary for reporting is available, which we anticipate will be prior to August 31, 2019.



## Conclusion

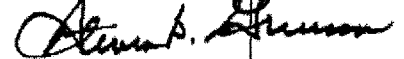
For all of these reasons, the Sanofi Confidential Information qualifies for trade secret protection under the DTSA and public disclosure of the Sanofi Confidential Information by the Department would constitute misappropriation of a trade secret thereunder. Sanofi US therefore requests that the Department keep confidential the information described in Part 1 of this request and not disclose it upon any request for public records under NRS 239.010.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'PR', with a long horizontal flourish extending to the right.

Phillip Ridolfi

Head of Business Operations and Support, Sales Support



1 RPLY

2 MATTHEW J. RASHBROOK  
3 Nevada State Bar No. 12477  
4 ROBERT L. LANGFORD, ESQ.  
5 Nevada State Bar No. 3988  
6 ROBERT L. LANGFORD & ASSOCIATES  
7 616 S. Eighth Street  
8 Las Vegas, NV 89101  
(702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

9 EIGHTH JUDICIAL DISTRICT COURT  
10 LAS VEGAS, NEVADA

11 THE NEVADA INDEPENDENT,

12  
13 Petitioner,

14 vs.

15 RICHARD WHITLEY, in his official  
16 capacity as the Director of the Nevada  
17 Department of Health and Human Services,  
18 and THE STATE OF NEVADA, ex rel. the  
19 NEVADA DEPARTMENT OF HEALTH  
AND HUMAN SERVICES;

20 Respondents,

21 and

22 SANOFI-AVENTIS U.S. LLC,

23 Intervenor.  
24

Case No.: A-19-799939-W

Dept. No.: 14

REPLY TO INTERVENOR'S RESPONSE

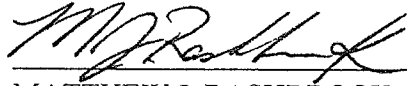
25 COMES NOW Petitioner, The Nevada Independent, and Replies to Sanofi-U.S.  
26 LLC ("Sanofi")'s Response. This Reply is

27 ///

28 ///

1 based on the attached Memorandum of Points and Authorities and further based on the  
2 papers and pleadings already on file in this matter.

3 All of which is respectfully submitted, this 3rd day of January, 2020.

4 

5  
6 MATTHEW J. RASHBROOK  
7 Nevada State Bar No. 12477  
8 ROBERT L. LANGFORD, ESQ.  
9 Nevada State Bar No. 3988  
10 ROBERT L. LANGFORD &  
11 ASSOCIATES  
12 616 S. Eighth Street  
13 Las Vegas, NV 89101  
14 (702) 471-6565  
15 matt@robertlangford.com  
16 robert@robertlangford.com  
17 *Attorneys for Petitioner*  
18 *The Nevada Independent*  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

[illegible]

Therefore, in considering a Petition pursuant to the NPRA, District Courts must consider firstly whether the governmental entity refusing disclosure can prove that a statutory basis exists, under which the records are protected from disclosure. *Public Emples. Ret. Sys. of Nev. v. Nev. Policy Research Inst., Inc.*, 429 P.3d 280, 283 (2018), citing Nev. Rev. Stat. § 239.010. Where there is no specific statutory basis under which to deny the request at issue, the Court must then examine whether Respondents can prove any common-law or other privilege or confidence exists which may exempt the records from disclosure. If such a privilege or confidence exists, the burden lies on the governmental entity seeking to conceal the records to show that their interest in hiding the records “clearly outweighs” the public’s interest in open and democratic government. *Id.*, citing *Public Emples. Ret. Sys. of Nev. v. Reno Newspapers, Inc.*, 129 Nev. 833, 837, 313 P.3d 221, 224 (2013).

As such, the inquiry begins with an examination of whether any law specifically designates the public records at issue as confidential or otherwise protected from disclosure. As discussed below, and throughout, no such law exists. The DTSA provides a

1 federal forum and cause of action in which owners of trade secrets may seek redress for the  
2 misappropriation of such information. It does not create confidentiality or privilege for any  
3 document or piece of information, *Baron v. Dep't of Human Servs.*, 169 A.3d 1268, 1276  
4 n.6 (Pa. Cmwlth. 2017), citing *Ali v. Phila. Planning Comm'n*, 125 A.3d 92 (Pa. Cmwlth.  
5 2015), and it explicitly states that it does not preclude “otherwise lawful activity conducted  
6 by a governmental entity of . . . a State.” 18 U.S.C. § 1833(a)(1).

7 Further, although Respondents state throughout their fear that disclosure of the  
8 public records would constitute a misappropriation under the DTSA, federal courts have  
9 determined this to be a mistaken view – the DTSA by its own terms does not prevent the  
10 State from taking any action, and the Eleventh Amendment protects Respondents from suit  
11 in any event. *See, e.g., Fast enterprises, LLC v. Pollack*, 2018 U.S. Dist. LEXIS 161518,  
12 2018 WL 4539685, U.S. Dist. Mass. 16-cv-12149, Sept. 21, 2018, *Medsense, LLC v. Univ.*  
13 *Sys. of Md.*, U.S. Dist. LEXIS 166730, 2019 WL 4735430, D. Md. GLS-18-3262, Sep. 27,  
14 2019.

15 Nevada trade secret law explicitly and clearly excludes these public records from  
16 enjoying any trade secret protection. NRS § 600A.030(5)(b).

17 Respondents and Intervenor rely on an administrative scheme enacted by  
18 Respondents to further justify their withholding. However, Respondents were not conferred  
19 a specific power by the Legislature to create an “end-run” of the NPRA, and therefore basic  
20 principles of separation of powers require this Court to nullify the regulations at issue  
21 herein, to any extent they conflict with the NPRA.<sup>1</sup> *Clark Cty. Sch. Dist. v. Las Vegas*  
22 *Review-Journal*, 134 Nev. Adv. Rep. 84, 9 – 10, 429 P.3d 313, 317 – 18 (2018) (“Ascribing  
23 a force to such regulations that limits the NPRA would create an opportunity for  
24 government organizations to make an end-run around the NPRA by drafting internal  
25 regulations that render documents confidential by law.”).

---

26  
27  
28 <sup>1</sup> To any extent that the Court determines the regulations are merely applied incorrectly by  
Respondents herein, they may not offend the NPRA, and in that case may survive.

1           Although Intervenor Sanofi contends that the records are kept confidential  
2 internally, and therefore are trade secrets, in fact, Sanofi provided the records to  
3 Respondents with knowledge it had received no guarantee that Respondents could or would  
4 conceal the records from the public, and therefore there can be no confidentiality remaining  
5 to exempt the records from disclosure. In any event, even if Respondents had guaranteed  
6 Sanofi and others confidentiality, Respondents are not entitled to bargain or promise away  
7 the public's access to public records, enshrined by the Legislature in the NPRA. The right  
8 to access public records under the NPRA belongs to the public, not to Respondents, and  
9 therefore is not Respondents to give away – at any price.

10           Lastly, even if this Court finds that some non-statutory privilege or confidence  
11 exists, nonetheless, this Court must decide whether the public's interest is better served by  
12 disclosing the records. *Reno Newspapers, Inc. v. Haley*, 126 Nev. Adv. Rep. 23, 6, 234  
13 P.3d 922, 924 (2010). In this area, the people of this state, through the Legislature, have  
14 made it abundantly clear what their preference is: these records must be disclosed to the  
15 public, in an effort to offer Nevadans some opportunity to beat back the epidemic of  
16 diabetes facing Nevadans today and in the future. The Nevada Supreme Court, along with  
17 numerous others, has stated that in the face of such a clear statement regarding their  
18 preferred policy objectives, it is folly for courts to intervene to support a contrary policy  
19 goal. To this end, the Nevada Supreme Court has indicated that public policy questions are  
20 “better left to the Legislature.” *Renown Health, Inc. v. Vanderford*, 126 Nev. Adv. Rep. 24,  
21 7, 235 P.3d 614, 616 (2010), citing *Nevada Hwy. Patrol v. State, Dep't Mtr. Veh.*, 107 Nev.  
22 547, 550 – 51, 815 P.2d 608, 610 – 11 (1991).<sup>2</sup> This is particularly so in areas in which  
23 “The Legislature has heavily regulated,” because courts can safely assume that the  
24 Legislature would have codified a particular result if they'd intended it. *Renown Health,*  
25 *Inc.*, 126 Nev. Adv. Rep. 24, 7, 235 P.3d at 616.

26  
27 <sup>2</sup> And, see also, *Niece v. Elmview Group Home*, 131 Wn.2d 39, 929 P.2d 420, 428 (Wash.  
28 1997) (“[N]oting that the policy decision to expand the scope of an employer's liability for  
an employee's intentional acts against a person to whom the employer owes a duty of care  
'should be left to the legislature.'”).

1           The NPRA requires the records at issue herein to be disclosed. There is no statute,  
2 federal or state, which exempts the records from disclosure. There is no common-law or  
3 other privilege which exists. Further, in addition to the fact that state law exempts such  
4 information from trade secret status, Sanofi and others similarly situated dissolved any  
5 confidentiality they may otherwise have enjoyed by passing the information to  
6 Respondents without any promise the purported confidentiality would be upheld. Further  
7 still, any such promise would have been ineffective, as Respondents aren't entitled to  
8 ignore or bargain away Nevadans' right to access their government, no matter the  
9 inconvenience. Lastly, even in the event that some common-law privilege was found to  
10 protect such records, nonetheless the Court should order their disclosure, and honor the will  
11 of the citizens of Nevada who have clearly stated their preference that these records be  
12 made publicly available not only by the enactment of the NPRA, but more specifically by  
13 the enactment of S.B. 539.

14                   **a. These Public Records are not made Confidential by any Statute**  
15

16           In seeking to withhold the disputed public records from the view of the public,  
17 Respondents bear the burden of proving to this Court that some statute creates a  
18 confidentiality which exempts these public records from disclosure under the NPRA. As  
19 discussed below, none does – the DTSA does not render anything confidential, rather, it  
20 simply creates a federal forum and cause of action under which to seek redress for  
21 misappropriation of trade secrets, and Nevada statutory law specifically exempts this type  
22 material from protection under its own trade secret legislation, enacted pursuant to S.B.  
23 539.

24           In considering the potential application of statutory confidence or privilege  
25 application, the Nevada Supreme Court endorsed the view of several other state supreme  
26 courts in finding that courts should construe privileges and confidences narrowly:

27                   Thus, this court will presume that all public records are  
28                   open to disclosure unless either (1) the Legislature has  
                    expressly and unequivocally created an exemption or

1 exception by statute, *see Cowles Pub. Co. v. Kootenai*  
2 *County Bd.*, 144 Idaho 259, 159 P.3d 896, 899 (Idaho  
3 2007) (holding that unless public records are “expressly  
4 exempted by statute,” they are presumed to be open to  
5 inspection by the public); *Kroeplin v. DNR*, 2006 WI App  
6 277, 297 Wis. 2d 254, 725 N.W.2d 286, 292 (Wis. Ct. App.  
7 2006) (holding that “exceptions to the open records law are  
8 to be narrowly construed; unless the exception is explicit  
9 and unequivocal, we will not hold it to be an exception”);  
10 or (2) balancing the private or law enforcement interests for  
11 nondisclosure against the general policy in favor of an open  
12 and accessible government requires restricting public  
13 access to government records. *See Donrey of Nevada v.*  
14 *Bradshaw*, 106 Nev. 630, 635 – 36, 798 P.2d 144, 147 – 48  
15 (1990).

16 *Reno Newspapers, Inc. v. Haley*, 234 P.3d at 924 – 25.

17 Consider also the ruling of the Washington Supreme Court in an almost identical  
18 set of circumstances<sup>3</sup>, *Lyft, Inc. v. City of Seattle*, 190 Wn.2d 769, 773, 418 P.3d 102, 104  
19 (Wa. 2018): “We must decide whether records containing trade secrets are categorically  
20 excluded from public disclosure under the Public Records Act (PRA), ch. 42.56 RCW. We  
21 hold that they are not.”

22 Neither the DTSA nor relevant Nevada law renders the type of public records  
23 discussed herein exempt from disclosure under the NPRA. In fact, the relevant Nevada  
24

---

25 <sup>3</sup> In relevant part, Washington’s public records law, *see, generally*, RCW 42.56 *et seq.*, is  
26 similar to Nevada’s, in that it exempts records from public disclosure ““in accordance with  
27 a statute that exempts or prohibits disclosure in whole or in part of specific information or  
28 records.”” *Lyft, Inc. v. City of Seattle*, 190 Wn. 2d at 777, 418 P.3d at 106, quoting  
29 *Progressive Animal Welfare Soc’y v. Univ. of Wash.*, 125 Wn.2d 243, 251 – 52, 884 P.2d  
30 592 (1994) (PAWS), *quoting* former RCW 42.17.340(1) 1992, *recodified as* RCW  
31 42.56.550(1). Further, Washington has codified the Uniform Trade Secrets Act, as 46  
32 other states, including Nevada, and the District of Columbia have, and which is the basis  
33 for the DTSA. In *Lyft, Inc. v. City of Seattle*, the Washington Supreme Court considered  
34 whether Lyft could successfully exclude certain information it considered trade secret from  
35 the view of the public records act by virtue of the categorical statutory exemption quoted  
36 above. The Washington Supreme Court held that it could not, and that it must satisfy the  
37 balancing test – itself similar to Nevada’s: “such records may be enjoined from disclosure  
38 only if disclosure would clearly not be in the public interest, and would substantially and  
39 irreparably damage a person or a vital government interest.” 190 Wn.2d at 773, 418 P.3d at  
40 104.

1 Statue, Nev. Rev. Stat. § 600.030(5)(b) specifically excludes that possibility on its face.  
2 The Nevada Supreme Court and numerous sister courts have previously endorsed this view  
3 in numerous analogous cases, some virtually identical. The conclusion here is inescapable:  
4 no statute puts these public records beyond the reach of the NPRA.

5  
6 i. The DTSA Does not Operate to Render Any Particular Thing  
7 Confidential and Therefore Does not Prevent Disclosure Under the  
8 NPRA

9 The public records at issue in this case are not made confidential by the DTSA.  
10 This is because the DTSA does not make any particular thing confidential, or place  
11 anything outside the reach of a state public records law: “In this context, the DTSA is  
12 comparable to the Copyright Act, 17 U.S.C. §§ 101 – 1332, in that neither federal statute  
13 exempts records from disclosure.” *Baron v. Dep’t of Human Servs.*, 169 A.3d 1268, 1276  
14 n. 6 (Pa. Cmwlth. 2017), citing *Ali v. Phila. Planning Comm’n*, 125 A.3d 92 (Pa. Cmwlth.  
15 2015)<sup>4</sup>. “The DTSA does not expressly provide the rates are confidential or trade secrets;  
16 rather, the statute creates a private right of action to prosecute the improper use of trade  
17 secrets.” *Id.*

18 These decisions comport with the Congressional intent in creating the DTSA:  
19 “Congress went out of its way to make clear that the DTSA does not preempt state trade  
20 secret laws. *Id.* Rather, the DTSA merely provides ‘a complementary Federal remedy if the  
21 jurisdictional threshold for Federal jurisdiction is satisfied.’ *Id.*” *Brand Energy &*  
22 *Infrastructure Servs. v. Irex Contracting Grp.*, 2017 U.S. Dist. LEXIS 43497, 17 n. 17,  
23 E.D. Pa. 16-2499, Mar. 23, 2017, citing H.R. REP. NO. 114-529, at 5.

24  
25  
26 <sup>4</sup> “Based on our review of the Copyright Act and our precedent, we conclude that  
27 Copyright Act is not a federal law that exempts materials from disclosure . . . It neither  
28 expressly makes copyrighted material private or confidential, nor does it expressly preclude  
a government agency, lawfully in possession of the copyrighted material, from disclosing  
that material to the public.” *Ali v. Phila Planning Comm’n*, 125 A.3d 92, 101 – 102 (Pa.  
Cmwlth. 2015).

1 The DTSA provides a federal forum and cause of action for misappropriation of  
2 trade secrets. However, it is incumbent upon a given party to prove that a given thing was  
3 in fact a trade secret. The import for this case then is that the DTSA does not create trade  
4 secret status, and therefore does not exempt the public records at issue from the NPRA.

5 For contrast, consider Nev. Rev. Stat. § 202.3662, examined by the Nevada  
6 Supreme Court in *Reno Newspapers, Inc. v. Haley*, 126 Nev. Adv. Rep. 23, 234 P.3d 922  
7 (2010), which creates confidentiality over certain documents (and the information created  
8 or contained therein) explicitly:

- 9 1. Except as otherwise provided in this section and NRS  
10 202.3665 and 239.0115:
- 11 a. An application for a permit, and all information  
12 contained within that application;
  - 13 b. All information provided to a sheriff or obtained  
14 by a sheriff in the course of the investigation of  
15 an application or permittee;
  - 16 c. The identity of the permittee; and
  - 17 d. Any records regarding the suspension,  
18 restoration or revocation of a permit,  
19 are confidential.

20 The contrast between the statutes enumerated within Nev. Rev. Stat. § 239.010(1),  
21 which specifically declare, e.g., specific items, forms, and applications (as discussed above,  
22 in the case of Nev. Rev. Stat. § 202.3662), and the DTSA is stark: the NPRA contemplates  
23 statutory exemptions which clearly outline specific documents or information contained  
24 within documents (such as personal identifying information) which are exempted from  
25 production, whereas the DTSA describes broad categories of information which a person  
26 may protect as trade secrets by their own conduct. This comports with the view of the  
27 Nevada Supreme Court, and other state supreme courts noted above: to qualify as a  
28 statutory exemption from the NPRA, a statute must be explicit, express, unequivocal in its  
purpose of excluding items from public view. The DTSA is not such a statute.

That the DTSA does not create confidentiality, nor prevent a state from  
complying with its own public records law has been the express finding of federal District

1 Courts examining that question. *Fast Enterprises, LLC v. Pollack*, 2018 U.S. Dist. LEXIS  
2 161518, 2018 WL 4539685, U.S. Dist. Mass. 16-cv-12149, Sept. 21, 2018, *Medsense, LLC*  
3 *v. Univ. Sys. of Md.*, U.S. Dist. LEXIS 166730, 2019 WL 4735430, D. Md. GLS-18-3262,  
4 Sept. 27, 2019.

5 The DTSA does not provide any shelter for Respondents' failure to produce the  
6 public records at issue herein.

7  
8 ii. Nevada Law Specifies the Records at Issue are not Trade Secrets  
9 Under State Law

10 As a part of S.B. 539, the Nevada Legislature amended Nev. Rev. Stat. §  
11 600A.030(5)(b), establishing that the information pharmaceutical manufacturers, pharmacy  
12 benefit managers, or pharmaceutical sales representatives are required to report to  
13 Respondents are not trade secrets. Although Sanofi immediately seeks to engage in an  
14 analysis of the Legislative intent behind the statute, *Response*, 12, the reality is that the  
15 statute is not ambiguous and therefore no inquiry into the Legislative intent is necessary.  
16 That notwithstanding, the entire structure of S.B. 539 exists to put exactly the type of  
17 information at issue in this case into the public domain, and the Legislative intent is  
18 therefore unmistakable: the people of Nevada would like to know why insulin is so  
19 expensive.

20 “Where the language of a statute is plain and unambiguous and its meaning clear  
21 and unmistakable, there is no room for construction and [we] are not permitted to search for  
22 its meaning beyond the statute itself.” *Sandpointe Apts. LLC v. Eighth Jud. Dist. Ct.*, 129  
23 Nev. 813, 822, 313 P.3d 849, 858 *quoting Walters v. Eighth Jud. Dist. Ct.*, 127 Nev. 723,  
24 727, 263 P.3d 231, 234 (2011) (*quoting Madera v. SIIS*, 114 Nev. 253, 257, 956 P.2d 117,  
25 120 (1998)).

26 In this instance, the language of Nev. Rev. Stat. § 600A.030(5)(b) is totally clear,  
27 stating that the term Trade Secret in Nevada:

28 Does not include any information that a manufacturer is

1 required to report pursuant to NRS 439B.635 or 439B.640,  
2 information that a pharmaceutical sales representative is  
3 required to report pursuant to NRS 439B.660 or  
4 information that a pharmacy benefit manager is required to  
report pursuant to NRS 439B.645, to the extent that such  
information is required to be disclosed by those statutes.

5 The meaning of this statute is clear, on its face: under S.B. 539, certain  
6 information must be reported to Respondents, and it is no defense or exemption from the  
7 obligations pharmaceutical manufacturers, PBMs, or pharmaceutical sales representatives  
8 have under S.B. 539 to claim that such information has any protection as a trade secret,  
9 because it is, by definition, not a trade secret.

10 Even if this Court determines the clear language of Nev. Rev. Stat. §  
11 600A.030(5)(b) contains an ambiguity, there is a wealth of legislative history which  
12 indicates the very clear intention of the Legislature to get this very information into the  
13 public domain. *Petition*, 6, n. 4. Further, the Legislative Digest is very clear on this specific  
14 point, describing S.B. 539, in pertinent part as, “AN ACT relating to prescription drugs . . .  
15 providing that certain information *does not constitute a trade secret*[.]” 2017 Statutes of  
16 Nevada, ch. 592, Legislative Counsel’s Digest, at 4295 – 96 (emphasis added).<sup>5</sup>

17 There is no ambiguity in Nev. Rev. Stat. § 600a.030(5)(b), as the language clearly  
18 exempts the public records at issue here from trade secret protection under Nevada law.  
19 Further, and in any event, as discussed above, Nevada’s trade secret laws don’t create a  
20 categorical statutory exemption from the NPRA. Finally, an examination of the Legislative  
21 intent in enacting S.B. 539, and specifically the intent underlying Nev. Rev. Stat. §  
22 600A.030(5)(b), reveals unequivocally that the Nevada Legislature intended that the public  
23 records discussed herein “do not constitute a trade secret.” 2017 Statutes of Nevada, ch.  
24 592, Legislative Counsel’s Digest, at 4295 – 96. There is no statutory exemption from the

25  
26  
27 <sup>5</sup> In its discussion of Legislative intent, Sanofi refers extensively to the relevant NACs  
28 discussed throughout – NAC §§ 439.735 – .740, primarily, *Response*, 13 – 15 – but these  
are agency-created codes – not Legislative acts. Of course, one cannot reasonably inquire  
into Legislative intent by examining the actions of the executive branch.

1 NPRA which springs from Nevada trade secret law.

2  
3 **b. Administrative Codes are Invalid if They Offend the NPRA**

4 Although Respondents and Sanofi both suggest that the administrative codes  
5 established by Respondents have relevance, the Nevada Supreme Court has explained this  
6 is impossible: “A court will not hesitate to declare a regulation invalid when the regulation .  
7 . . conflicts with existing statutory provisions[.]” *Division of Ins. v. State Farm Mutual Ins.*  
8 *Co.*, 116 Nev. 290, 293, 995 P.2d 482, 485 (2000), *citing* NRS § 233B.110, *Clark Co.*  
9 *Social Service Dep’t v. Newkirk*, 106 Nev. 177, 179, 789 P.2d 227, 228 (1990); *Roberts v.*  
10 *State*, 104 Nev. 33, 37, 752 P.2d 221, 223 (1988).

11 If they frustrate the NPRA, the offending administrative codes must be stricken,  
12 because the failure to do so represents an enormous separation of powers problem: to  
13 whatever extent Respondents, or other department or agency heads – unelected members of  
14 the executive branch of government – are entitled to create administrative codes to frustrate  
15 the NPRA or any other Nevada law, they are effectively granted line-item veto over duly  
16 enacted acts of the Legislature. This result cannot stand in a democratic government. So, to  
17 any extent the NAC sections cited by Respondents or Sanofi frustrate the NPRA, they are  
18 invalid, and must be stricken by the Court.

19 If the agency-created administrative codes herein are allowed to exempt records  
20 from the NPRA, the effect will be to allow every twig in the executive branch a line-item  
21 veto over the Legislature. Of course, such a result cannot stand – the same conclusion  
22 reached by the Nevada Supreme Court in more recent cases *Clark Cty. Sch. Dist. v. Las*  
23 *Vegas Review-Journal*, 134 Nev. Adv. Rep. 84, 9 – 10, 429 P.3d 313, 317 – 18 (2018)  
24 (“Ascribing a force to such regulations that limits the NPRA would create an opportunity  
25 for government organizations to make an end-run around the NPRA by drafting internal  
26 regulations that render documents confidential by law.”) and *Comstock Residents Ass’n v.*  
27 *Lyon Cty. Bd. of Comm’rs*, 134 Nev. Adv. Rep. 19, 10, 414 P.3d 318, 322 (2018)  
28 (“Administrative regulations do not limit the reach of the NPRA[.]”).

1  
2 **IN THE SUPREME COURT OF THE STATE OF NEVADA**

3 THE NEVADA INDEPENDENT,

4 Appellant,

No.: 81844

5  
6 vs.

DC No.: A-19-799939-W

7 RICHARD WHITLEY, IN HIS  
8 OFFICIAL CAPACITY AS THE  
9 DIRECTOR OF THE NEVADA  
10 DEPARTMENT OF HEALTH AND  
11 HUMAN SERVICES, THE STATE  
12 OF NEVADA, EX REL. THE  
13 NEVADA DEPARTMENT OF  
14 HEALTH AND HUMAN  
SERVICES, AND SANOFI-  
AVENTIS U.S. LLC,

15 Respondent.

16  
17  
18 **JOINT APPENDIX**  
19 **VOLUME IV**  
20 **PGS. 751-1000**  
21

22 MATTHEW J. RASHBROOK  
Nevada State Bar No. 12477  
23 ROBERT L. LANGFORD, ESQ.  
Nevada State Bar No. 3988  
24 ROBERT L. LANGFORD & ASSOCIATES  
25 616 S. Eighth St.  
Las Vegas, NV 89101  
26 (702) 471-6565  
27 *Attorneys for Appellant*  
*The Nevada Independent*  
28

AARON D. FORD  
Nevada Attorney General  
Nevada State Bar No. 7704  
HEIDI PARRY STERN  
Nevada State Bar No. 8873  
STEVE SHEVORSKI  
Nevada State Bar No. 8256  
Office of the Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101

1 JOHN R. BAILEY  
Nevada State Bar No. 137  
2 DENNIS KENNEDY  
Nevada State Bar No. 1462  
3 SARAH E. HARMON  
Nevada State Bar No. 8106  
4 REBECCA L. CROOKER  
Nevada State Bar No. 15202  
5 BAILEY KENNEDY  
8984 Spanish Ridge Avenue  
6 Las Vegas, NV 89148-1302  
7 (702) 562-8820  
8 *Attorneys for Respondent Sanofi-Aventis U.S.*  
9 *LLC*

(702) 486-3594  
*Attorneys for Respondents Whitley, and  
the State of Nevada ex rel. The Nevada  
Department of Health and Human  
Services*

## **TABLE OF CONTENTS**

<b><u>VOL.</u></b>	<b><u>DOCUMENT</u></b>	<b><u>DATE</u></b>	<b><u>PAGE NUMBERS</u></b>
I	Petition for a Writ of Mandamus	8/8/2019	JA-000001 – JA-000014
I	Appendix to Petition for a Writ of Mandamus	8/8/2019	JA-000015 – JA-000232
I	Order Setting Hearing re Petition for Writ of Mandamus	8/27/2019	JA-000233 – JA-000234
I	Supplemental Brief in Support of Petition for a Writ of Mandamus	10/15/2019	JA-000235 – JA-000246
I	Opposition to The Nevada Independent’s Petition for Writ of Mandamus and Motion to Dismiss	10/17/2019	JA-000247 – JA-000256
II	Motion to Intervene and to Continue Hearing, on Shortened Time	10/21/2019	JA-000257 – JA-000455
II	Petitioner’s Opposition to Sanofi- Aventis U.S. LLC’s Motion to Intervene and to Continue Hearing	10/31/2019	JA-000456 – JA-000465

II	Sanofi-Aventis U.S. LLC's Reply in Support of Motion to Intervene	11/1/2019	JA-000466 – JA-000472
II	Transcript of Proceedings – Motion to Intervene and to Continue Hearing on Shortened Time	11/5/2019	JA-000473 – JA-000491
II	Errata	11/11/2019	JA-000492 – JA-000520
III	Minute Order	11/14/2019	JA-000521 – JA-000522
III	Sanofi-Aventis U.S. LLC's Supplemental Brief in Support of Motion to Intervene	11/21/2019	JA-000523 – JA-000528
III	Supplemental Brief in Opposition to Motion to Intervene and Reply to Proposed Response	12/5/2019	JA-000529 – JA-000544
III	Minute Order	12/16/2019	JA-000545 – JA-000548
III	Order Granting Sanofi-Aventis U.S. LLC's Motion to Intervene	12/23/2019	JA-000549 – JA-000553
III	Intervenor Sanofi-Aventis U.S. LLC's Response to Petitioner's Petition for a Writ of Mandamus	12/23/2019	JA-000554 – JA-000738
III	Reply to Intervenor's Response	1/3/2020	JA-000739 – JA-000758
IV	Petitioner The Nevada Independent's Witness List	1/17/2020	JA-000759 – JA-000761
IV	Sanofi-Aventis U.S. LLC's Disclosure of Witnesses	1/17/2020	JA-000762 – JA-000764
IV	Defendants' Disclosure of Witnesses	1/17/2020	JA-000765 – JA-000766
IV	Reply in Support of Motion to Dismiss	1/23/2020	JA-000767 – JA-000775
IV	Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	1/30/2020	JA-000776 – JA-000815

IV	Sanofi's Opposition to Petitioner's Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	2/3/2020	JA-000816 – JA-000841
IV	Transcript of Proceedings – Motion to Compel Testimony of James Borneman, or in the Alternative, To Strike his Declaration	2/4/2020	JA-000842 – JA-000890
IV	Motion for Leave to File Brief Amicus Curiae	2/13/2010	JA-000891 – JA-000917
IV	Notice of Non-Opposition	2/14/2020	JA-000918 – JA-000920
IV	Minute Order	2/14/2020	JA-000921 – JA-000922
IV	Notice of Non-Opposition to Culinary union's Motion for Leave to file an Amicus Brief	2/14/2010	JA-000923 – JA-000924
IV	Transcript of Proceedings – Petition for Writ of Mandamus	2/21/2020	JA-000925 – JA-000968
IV	Minute Order	4/21/20	JA-000969 – JA-000973
IV	Order Denying Petition for Writ of Mandamus	9/4/2020	JA-000974 – JA-000984
IV	Notice of Entry of Order	9/9/2020	JA-000985 – JA-000998
IV	Notice of Appeal	9/22/2020	JA-000999 – JA-001001
V	Notice of Appeal (cont.)	9/22/2020	JA-001001

1 Sanofi cites, *Supplemental Brief in Support*, 15, *City of Sparks v. Reno*  
2 *Newspapers, Inc.*, 133 Nev. Adv. Rep. 56, 399 P.3d 352 (2017) in support of its suggestion  
3 that administrative codes that offend the NPRA are nonetheless valid. However, this  
4 reliance is misplaced, as the case discusses legislation and associated administrative codes  
5 which have critical differences from those discussed herein and is therefore inapposite.

6 In *City of Sparks v. Reno Newspapers, Inc.*, the Nevada Supreme Court examined  
7 certain legislation and administrative codes surrounding the establishment and regulation of  
8 medical marijuana establishments. “[T]he Legislature may authorize administrative  
9 agencies to make rules and regulations supplementing legislation if the power given is  
10 prescribed in terms sufficiently definite to serve as a guide in exercising that power.” *Id.*, at  
11 356, quoting *Banegas v. State Indus. Ins. Sys.*, 117 Nev. 222, 227, 19 P.3d 245, 248 (2001).  
12 In enacting the laws regarding medical marijuana establishments, the Nevada Legislature  
13 included the following at Nev. Rev. Stat. 453A.370: “The Department shall adopt such  
14 regulations as it determines to be necessary or advisable to carry out the provisions  
15 [concerning the production and distribution of medical marijuana].” *City of Sparks v. Reno*  
16 *Newspapers, Inc.*, 399 P.3d at 355 – 56, quoting NRS 453A.370. Further, “In drafting and  
17 adopting those regulations, under NRS 453A.370(5), the Division “*must . . . [a]s far as*  
18 *possible while maintaining accountability, protect the identity and personal identifying*  
19 *information* of each person who receives, facilitates or delivers services.” *Id.* at 356,  
20 quoting NRS 453A.370(5) (emphasis added in *City of Sparks v. Reno Newspapers, Inc.*).

21 When the Nevada Supreme Court upheld the administrative codes at issue in the  
22 *City of Sparks* case, it was specifically because the Nevada Legislature had authorized the  
23 Department in that case to create administrative codes to protect the “identity and personal  
24 identifying information” as described in the statute, a delegation allowed because it was  
25 “prescribed in terms sufficiently definite to serve as a guide in exercising that power.” *Id.* at  
26 356.

27 However, no provision enabling confidentiality or any NPRA carve-out is found  
28

1 in S.B. 539.<sup>6</sup> The Nevada Legislature did not authorize the Department to enact  
2 administrative codes that would have the function of rendering any particular information  
3 confidential or privileged, and indeed such an authorization would stand in direct conflict  
4 with the portion of S.B. 539 at Nev. Rev. Stat. § 600A.030(5)(b). Therefore, their  
5 enactment represents a usurpation of the power granted by Nevadans to the duly elected  
6 Nevada Legislature, and as discussed *supra*, a very clear separation of powers problem.

7 While it is true that “When determining the validity of an administrative  
8 regulation, courts generally give ‘great deference’ to an agency’s interpretation of a statute  
9 that the agency is charged with enforcing,” still, “even a reasonable agency interpretation  
10 of an ambiguous statute may be stricken by a court when a court determines that the agency  
11 interpretation conflicts with legislative intent.” *Division of Ins. v. State Farm Mutual Ins.*  
12 *Co.*, 116 Nev. at 293, 995 P.2d at 485 (2000), *quoting State v. State Engineer*, 104 Nev.  
13 709, 713, 766 P.2d 263, 266 (1988) (*quoting Clark Co. Sch. Dist. v. Local Gov’t*, 90 Nev.  
14 442, 446, 530 P.2d 114, 117 (1974)), and *quoting Hotel Employees v. State, Gaming*  
15 *Control Bd.*, 103 Nev. 588, 591, 747 P.2d 878, 880 (1987).

16 So, when the Legislature enacts a law which requires pharmaceutical  
17 manufacturers, PBMs, and others to make reports explaining the reason for excessive rises  
18 in certain drug prices, and exempts that information from any trade secret protection, and  
19 when virtually the entirety of the debate centers around the need for transparency in the  
20 marketplace, agency-created regulations which stifle that goal must be stricken.

21 In a democratic system, the Legislature is the body authorized by the people to  
22 create law. Where an arm of the executive branch is allowed to create administrative codes  
23 that have the force of law, but which frustrate an act of the Legislature, it falls to the courts

---

24 <sup>6</sup> There is an enabling provision in Nev. Rev. Stat. § 439B, found at §439B.685, but a close  
25 review reveals that the language substantially predates S.B. 539, and was previously found  
26 at Nev. Rev. Stat. § 439.930 (a section dealing with establishment of an internet site to  
27 publish prices of commonly prescribed drugs), and which still largely deals with that goal.  
28 There is no language in the enabling provision which indicates any desire on the part of the  
legislature to exempt any information from the view of the public via the NPRA, as was  
found necessary in *City of Sparks v. Reno Newspapers, Inc.*, 399 P.3d 352, 355 – 56  
(2017).

1 to invalidate those codes to protect our system of democratic constitutional government.  
2 *Marbury v. Madison*, 5 U.S. 137, 180, 2 L. Ed. 60, (1803).

3 Lastly, even in the event this Court determines that NAC §§ 439.735 and .740 do  
4 not offend the NPRA, nonetheless they do not create a statutory exemption, and therefore  
5 Respondent and Sanofi are still obligated to prove their interest in concealing the records  
6 clearly outweighs the public interest in transparency in order to justify their refusal to  
7 withhold the public records.

8 The NPRA exists “to foster democratic principles,” Nev. Rev. Stat. § 239.001(1),  
9 and to any extent an arm of the executive branch attempts to usurp the Legislature’s power  
10 to escape its reach, courts must invalidate those regulations or codes as they offend the  
11 separation of powers. The NAC sections discussed herein are exactly such codes, as such  
12 are invalid, and must therefore be stricken. If the court finds these NAC sections do not  
13 offend the NPRA, nonetheless they do not present a statutory exemption from it, and  
14 therefore Respondents and Sanofi must satisfy the balancing test in order to withhold on the  
15 basis of the NACs cited.

16 **c. No Other Confidence or Privilege Exempts these Public Records from**  
17 **Disclosure**  
18

19 Neither the DTSA, nor any Nevada statute grants any confidentiality over the  
20 records discussed herein throughout. Although Sanofi asserts that it has gone to lengths to  
21 keep the information confidential, it acknowledges having passed the information to  
22 Respondents without any guarantee from Respondents that the information would be kept  
23 confidential. Thus, no confidentiality can or indeed does exist. Even if some confidentiality  
24 is found to exist, nonetheless, Respondents bear the burden of proving that their interest in  
25 maintaining the confidentiality clearly outweighs the public interest in transparency. *Reno*  
26 *Newspapers, Inc. v. Haley*, 126 Nev. Adv. Rep. 23, 6, 234 P.3d 922, 924 (2010).

27 “It is well settled that privileges, whether creatures of statute or the common law,  
28 should be interpreted and applied narrowly.” *DR Partners v. Board of County Comm’rs*,

1 116 Nev. 616, 621 (2000), *citing Ashokan v. State Dept. of Ins.*, 109 Nev. 662, 668, 856  
2 P.2d 244, 247 (1993) (*citing U.S. v. Nixon*, 418 U.S. 683, 710, 41 L. Ed. 2d 1039, 94 S. Ct.  
3 3090 (1974)).

4         There can be no confidentiality found where, as here, a party passes information  
5 or documents within their exclusive control to another party without any guarantee of  
6 confidentiality. “[I]t is clear that a private party cannot render public records exempt from  
7 disclosure merely by designating information it furnishes a governmental agency  
8 confidential. Neither the desire for nor the expectation of non-disclosure is determinative.”  
9 *Sepero Corp. v. Fla. Dep’t of Envtl. Prot.*, 839 So.2d 781, 784 (Fla. Dist. Ct. App. 2003).

10         Furthermore, even if Respondents had made a promise to keep certain material  
11 collected pursuant to S.B. 539 confidential, nonetheless, Petitioner would prevail:  
12 “[E]ntities doing business with government agencies and submitting records to them in  
13 connection therewith should be aware that regardless of agency promises that documents  
14 will be kept confidential, public record suits can nevertheless be successful. Thus, it is not  
15 safe to assume confidentiality agreements with government agencies will be legally  
16 enforceable.” *Tenn. Valley Printing Co. v. Health Care Auth.*, 61 So. 3d 1027, 1037,  
17 *quoting* Theresa M. Costonis, *What Constitutes Commercial or Financial Information,*  
18 *Exempt from Disclosure Under State Freedom of Information Acts*, 5 A.L.R. 6th 327, § 3  
19 (2005) (footnotes omitted).

20         Indeed, “The right to examine these records is a right belonging to the public; it  
21 cannot be bargained away by a representative of the government.” *Nat’l Collegiate Athletic*  
22 *Ass’n v. Associated Press*, 18 So. 3d 1201, 1208 – 09 (Fla. Dist. Ct. App. 2009).  
23 Notwithstanding Respondents’ apparent desire to put the interests of pharmaceutical  
24 manufacturers ahead of those of the public they serve, the people of the State of Nevada are  
25 entitled, under the NPRA, to examine public records.

26         One of the reasons many prefer to seek a patent or copyright rather than relying  
27 on trade secret status is specifically because trade secret protection is extremely fragile – it  
28 can exist only so long as the holder can totally conceal the information from the entire

1 outside world. So, while Coca-Cola and KFC have managed to maintain the secrecy of  
2 their respective secret recipes, the instant the information is known outside of their  
3 organizations, it loses any protectable secret status. A trade secret can only exist so long as  
4 it stays just that: secret.

5 Where, as here, a party passes information to an entity or person they don't  
6 control, without any guarantee that their claimed confidentiality will be maintained, there  
7 can be no privilege or confidentiality in the disputed material. Sanofi and others were  
8 keenly aware that Respondents would – could – offer no guarantee of confidentiality, as the  
9 relevant NACs indicate only that Respondents would consider claims of confidentiality, not  
10 honor them. So, even putting aside the fact that Respondent is not entitled to give away the  
11 public's right to access its government, Respondent made no guarantee of confidentiality to  
12 Sanofi or others and therefore no confidentiality can exist.

13 **d. The Public's Interest in Transparency Outweighs any Private or**  
14 **Governmental Interest in Opacity**  
15

16 Even if this Court finds that some confidentiality existed, because it is not of a  
17 statutory creation, Respondents and Sanofi would nonetheless be obligated to prove that,  
18 under the balancing test outlined by the Nevada Supreme Court in, *e.g.*, *Reno Newspapers,*  
19 *Inc. v. Haley*, 126 Nev. Adv. Rep. 23, 6, 234 P.3d 922, 924 (2010), the stated government  
20 interest in avoiding some phantom liability under the DTSA, and Sanofi's private interest  
21 in continuing to extract the maximum profit possible from those afflicted with diabetes are  
22 interests that clearly outweigh Nevadans' collective interest in having an open and  
23 democratic government – and of not dying of diabetes, or poverty, or both – in the face of  
24 the clearly stated preference of the Legislature that transparency in this area is necessary for  
25 the health and welfare of Nevadans.

26 Sanofi argues that their knowledge of pricing, supply chain, transportation, and  
27 whatever other factors weigh into their pricing of a particular drug – notably, how much of  
28 a profit they prefer to take – are valuable business information. Given the extraordinarily

1 competitive nature of their business, this is unlikely.<sup>7</sup>

2         Without any exaggeration, hundreds of billions, perhaps even trillions, of dollars  
3 are at stake in the pharmaceutical market, and Sanofi has a litany of competitors who would  
4 all like a larger share of those billions, as Sanofi themselves no doubt would. If one of them  
5 had information that was truly as important as Sanofi claims to have, it seems likely that  
6 they would exploit it more effectively. If Sanofi genuinely possessed knowledge related to  
7 the manufacture, transport, supply, research, development, marketing, or what-have-you of  
8 its products, those advantages would bear themselves out in the market in terms of profit,  
9 market share, and eventually, we would see Sanofi swallowing up or forcing its  
10 competitors into bankruptcy. To the contrary, Sanofi is one of approximately 100  
11 companies who have filed reports under S.B. 539.

12         Sanofi's information is not likely particularly valuable, relative to their  
13 competitors. Each of them, by their very nature, are almost certainly constantly refining  
14 processes, seeking further profit and advantage against each other, and each has a massive  
15 personal, professional, and financial interest at every position and location to ensure that  
16 they achieve a larger advantage than their competitors. If Sanofi had truly discovered  
17 business practices that allowed them a significant advantage over their competitors, it  
18 would present a paradigm shift in one of the largest business markets in the world.

19         Far more likely is that whatever value Sanofi's information may contain is very  
20 likely owed to the bargaining advantage Sanofi thereby enjoys not against other  
21 pharmaceutical manufacturers, but rather, against insurance plans and PBMs it negotiates  
22 against – effectively, against Nevadans with diabetes who need insulin to live. By  
23 maintaining secrecy about how much profit it prefers to make, Sanofi maintains a  
24 bargaining advantage against those who need its drugs to survive.

---

25  
26  
27 <sup>7</sup> Further, it must be noted that this very type of “non-particularized hypothetical concerns”  
28 are not grounds upon which to withhold public records. *DR Partners v. Board of County  
Comm'rs*, 116 Nev. 616, 628, 6 P.3d 465, 473 – 74 (2000). The NRPA is not flummoxed  
by ghost stories.

1 Sanofi does not likely hold the type of information that would correctly be termed  
2 a trade secret. Even if the information was once a trade secret, Sanofi lost that status when  
3 they disclosed the information to Respondents without any guarantee Respondents would  
4 maintain the confidence. Lastly, even in the event this Court determines that Sanofi does  
5 hold some information it derives commercial advantage from, nonetheless the Court should  
6 find, along with the Nevada Legislature, that the public's interest in transparency outweighs  
7 Sanofi's interest in astronomical profits, and order production of the public records.

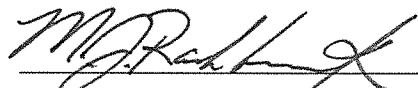
8 **Conclusion**

9 The public records sought by Petitioners herein are not made confidential by any  
10 statute. No other privilege applies, as none was promised before the transfer of the records.

11 Even if this Court finds the public records subject to a non-statutory privilege or  
12 confidence, the public interest in transparency dramatically outweighs the government's  
13 interest in escaping non-existent liability under the DTSA or Sanofi's interest in continued  
14 access to obscene profits at the cost of the lives of Nevadans.

15 The result must be an order mandating that Respondents disclose to Petitioners  
16 the public records they seek in their entirety, together with an order for the reasonable  
17 attorney's fees and costs incurred in the prosecution of this matter.

18 All of which is respectfully submitted, this 3rd day of January, 2020.

19  
20 

21 MATTHEW J. RASHBROOK  
22 Nevada State Bar No. 12477  
23 ROBERT L. LANGFORD, ESQ.  
24 Nevada State Bar No. 3988  
25 ROBERT L. LANGFORD &  
26 ASSOCIATES  
27 616 S. Eighth Street  
28 Las Vegas, NV 89101  
(702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

**CERTIFICATE OF SERVICE**

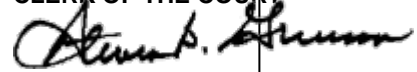
I hereby certify and affirm that on this 3rd day of January, 2020, the foregoing  
**REPLY TO INTERVENOR'S RESPONSE** was served by electronic mail to the following  
counsel of record:

Aaron D. Ford  
Nevada Attorney General  
Nevada Bar No. 7704  
Steve Shevorski  
Chief Deputy Attorney General  
Nevada Bar No. 8256  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
Fax: 702-486-3768  
sshevorski@ag.nv.gov

John R. Bailey  
Nevada Bar No. 0137  
Dennis L. Kennedy  
Nevada Bar No. 1462  
Sarah E. Harmon  
Nevada Bar No. 8106  
Bailey Kennedy  
8984 Spanish Ridge Avenue  
Las Vegas, NV 89148-1302  
Fax: 702-562-8821  
jbailey@baileykennedy.com  
dkennedy@baileykennedy.com  
sharmon@baileykennedy.com

/s/ Matthew J. Rashbrook

An Employee of Robert L. Langford &  
Associates



1 **LTWT**

2 MATTHEW J. RASHBROOK

3 Nevada State Bar No. 12477

4 ROBERT L. LANGFORD, ESQ

5 Nevada State Bar No. 3988

6 ROBERT L. LANGFORD & ASSOCIATES

7 616 South Eighth Street

8 Las Vegas, NV 89101

(702) 471-6565

matt@robertlangford.com

robert@robertlangford.com

*Attorneys for Petitioner*

*The Nevada Independent*

9 **EIGHTH JUDICIAL DISTRICT COURT**

10 **CLARK COUNTY, NEVADA**

11 THE NEVADA INDEPENDENT,

12 Petitioner,

13 vs.

14  
15 RICHARD WHITLEY, in his official  
16 capacity as the Director of the Nevada  
17 Department of Health and Human Services,  
18 and THE STATE OF NEVADA, ex rel. the  
19 NEVADA DEPARTMENT OF HEALTH  
20 AND HUMAN SERVICES;

21 Respondents,

22 and

23 SANOFI-AVENTIS U.S. LLC,

24 Intervenor.

Case No.: A-19-799939-W

Dept. No.: XIV

**PETITIONER THE NEVADA  
INDEPENDENT'S WITNESS LIST**

25 COMES NOW Petitioner, The Nevada Independent, by and through their  
26 undersigned counsel, Matthew J. Rashbrook, and Robert L. Langford, Esq., and hereby  
27 provides the following list of witnesses expected to be called on its behalf

28 ///

1 at the upcoming hearing of this matter:

2 1. Megan Messerly  
3 c/o Robert L. Langford & Associates  
4 616 South 8th St.  
5 Las Vegas, NV 89101

6 Ms. Messerly is expected to testify as to the matters alleged in the Petition,  
7 including, but not limited to, the matters contained in paragraphs 49 – 56.

8 2. James Borneman  
9 c/o Bailey Kennedy  
10 8984 Spanish Ridge Avenue  
11 Las Vegas, Nevada 89148-1302

12 Mr. Borneman may be called to testify as to the matters alleged in Sanofi-Aventis  
13 U.S. LLC's Response, *passim*, including, but not limited to, the purported trade secret status  
14 of the public records at issue in this matter.

15 Additionally, The Nevada Independent reserves its right to amend this witness list  
16 based on cross-examination, to call witnesses not previously listed in its rebuttal case, if any,  
17 and to call any witness listed by any other party.

18 DATED this 17th day of January, 2020.

19 /s/ Matthew J. Rashbrook

20 MATTHEW J. RASHBROOK  
21 Nevada State Bar No. 12477  
22 ROBERT L. LANGFORD, ESQ.  
23 Nevada State Bar No. 3988  
24 ROBERT L. LANGFORD &  
25 ASSOCIATES  
26 616 S. Eighth Street  
27 Las Vegas, NV 89101  
28 (702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

**CERTIFICATE OF SERVICE**

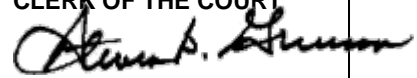
I hereby certify and affirm that on this 17th day of January, 2020, the foregoing  
**PETITIONER THE NEVADA INDEPENDENT'S WITNESS LIST** was served by electronic mail  
to the following counsel of record:

Aaron D. Ford  
Nevada Attorney General  
Nevada Bar No. 7704  
Steve Shevorski  
Chief Deputy Attorney General  
Nevada Bar No. 8256  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
Fax: 702-486-3768  
sshevorski@ag.nv.gov

John R. Bailey  
Nevada Bar No. 0137  
Dennis L. Kennedy  
Nevada Bar No. 1462  
Sarah E. Harmon  
Nevada Bar No. 8106  
Rebecca L. Crooker  
Nevada Bar No. 15202  
Bailey Kennedy  
8984 Spanish Ridge Avenue  
Las Vegas, NV 89148-1302  
Fax: 702-562-8821  
jbailey@baileykennedy.com  
dkennedy@baileykennedy.com  
sharmon@baileykennedy.com  
rcrooker@baileykennedy.com

/s/ Matthew J. Rashbrook

An Employee of Robert L. Langford &  
Associates



**DOW (CIV)**

JOHN R. BAILEY

Nevada Bar No. 0137

DENNIS L. KENNEDY

Nevada Bar No. 1462

SARAH E. HARMON

Nevada Bar No. 8106

**BAILEY ♦ KENNEDY**

8984 Spanish Ridge Avenue

Las Vegas, Nevada 89148-1302

Telephone: 702.562.8820

Facsimile: 702.562.8821

JBailey@BaileyKennedy.com

DKennedy@BaileyKennedy.com

SHarmon@BaileyKennedy.com

*Attorneys for Intervenors*

SANOFI-AVENTIS U.S. LLC

DISTRICT COURT

CLARK COUNTY, NEVADA

THE NEVADA INDEPENDENT,

Petitioner,

vs.

RICHARD WHITLEY, in his official capacity as  
the Director of the Nevada Department of Health  
and Human Services, and THE STATE OF  
NEVADA ex rel. the NEVADA DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

Respondents,

and

SANOFI-AVENTIS U.S. LLC,

Intervenor.

Case No. A-19-799939-W

Dept. No. XIV

**Date of Hearing:** January 31, 2020

**Time of Hearing:** 10:00 a.m.

**SANOFI-AVENTIS U.S. LLC'S DISCLOSURE OF WITNESSES**

Pursuant to the December 23, 2019 Order Granting Sanofi-Aventis U.S. LLC's ("Sanofi")  
Motion to Intervene, Sanofi respectfully submits that it currently does not intend to call any  
affirmative witnesses at the January 31, 2020 evidentiary hearing on Petitioner The Nevada  
Independent's Petition for Writ of Mandamus.

1 Inasmuch as the Petition for Writ of Mandamus primarily presents questions of law (not  
2 fact), to the extent that questions of fact must be resolved, Sanofi intends to rely on the factual  
3 evidence set forth in: (1) the related action, *Pharm. Research & Mfrs. of Am. v. Sandoval*, 2:17-cv-  
4 02315-JCM-CWH, U.S. Dist. Ct. of Nev. (as set forth in Sanofi's Response to Petitioner's Petition  
5 for a Writ of Mandamus and in Exhibits 3 through 8 thereto), of which the Court may take judicial  
6 notice; and (2) the October 17, 2019 Declaration of James Borneman (Vice President and Head of  
7 Diabetes Primary Care Sales for Sanofi US<sup>1</sup>), submitted as Exhibit 2 to Sanofi's Response to  
8 Petitioner's Petition for a Writ of Mandamus.

9 In the event Mr. Borneman's assistance would be helpful to the Court in its decision-making  
10 process regarding the Writ Petition, Sanofi intends to make Mr. Borneman available to the Court at  
11 the January 31, 2020 evidentiary hearing.

12 DATED this 17th day of January, 2020.

13  
14 BAILEY ♦ KENNEDY

15  
16 By: Sarah E. Harmon

17 JOHN R. BAILEY

DENNIS L. KENNEDY

SARAH E. HARMON

18 *Attorneys for Intervenors*

19 SANOFI-AVENTIS U.S. LLC  
20  
21  
22  
23  
24  
25  
26  
27

28 <sup>1</sup> "Sanofi US" is the registered trade name of Sanofi-Aventis U.S. LLC.

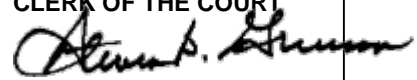
CERTIFICATE OF SERVICE

I certify that I am an employee of BAILEY❖KENNEDY and that on the 17th day of January, 2020, service of the foregoing **SANOFI-AVENTIS U.S. LLC’S DISCLOSURE OF WITNESSES** was made by mandatory electronic service through the Eighth Judicial District Court’s electronic filing system and/or by depositing a true and correct copy in the U.S. Mail, first class postage prepaid, and addressed to the following at their last known addresses:

MATTHEW J. RASHBROOK ROBERT L. LANGFORD <b>ROBERT L. LANGFORD &amp; ASSOCIATES</b> 616 South Eighth Street Las Vegas, Nevada 89101	Email: matt@robertlangford.com robert@robertlangford.com  <i>Attorneys for Petitioner</i> THE NEVADA INDEPENDENT
--	--

AARON D. FORD ATTORNEY GENERAL STEVE SHEVORSKI CHIEF LITIGATION COUNSEL <b>OFFICE OF NEVADA ATTORNEY GENERAL</b> 555 East Washington Avenue, Suite 3900 Las Vegas, Nevada 89101	Email: sshevorski@ag.nv.gov  <i>Attorneys for Respondents</i> RICHARD WHITLEY, in his official capacity as the Director of the Nevada Department of Health and Human Services, and THE STATE OF NEVADA, ex rel. the NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES
---	---

/s/ Samantha T. Kishi  
Employee of BAILEY❖KENNEDY



AARON D. FORD (Bar No. 7704)  
Attorney General  
Steve Shevorski (Bar No. 8256)  
Chief of Civil Litigation  
Office of Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
(702) 486-3783 (phone)  
(702) 486-3773 (facsimile)

*Attorneys for Respondent*

**DISTRICT COURT**  
**CLARK COUNTY, NEVADA**

THE NEVADA INDEPENDENT,  
  
Petitioner,  
  
vs.

Case No. A-19-799939-W  
Dept. No. XIII

RICHARD WHITLEY, in his official capacity  
as the Director of the Nevada Department of  
Health and Human Services, and THE  
STATE OF NEVADA, ex rel. the NEVADA  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES,

Respondents.

**DEFENDANTS' DISCLOSURE OF WITNESSES**

Plaintiff's petition presents pure legal issues. **First**, whether Plaintiff can overcome the presumption that Nevada Administrative Code sections 439.730-740 are valid. **Second**, whether the Defend Trade Secrets Act is a "law" under NRS 239.010(1), which protects trade secret information from disclosure. Because Plaintiff's petition presents questions of law, respondents do not intend to call any witnesses, but reserve the right to cross-examine should the Court allow testimony.

DATED this 17th day of January, 2020.

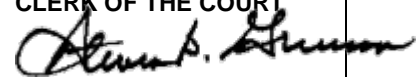
AARON D. FORD  
Attorney General

By: /s/ Steve Shevorski  
Steve Shevorski (Bar No. 8256)  
Chief of Civil Litigation

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

**MATTHEW J. RASHBROOK**  
**ROBERT L. LANGFORD**  
**ROBERT L. LANGFORD & ASSOCIATES**  
616 South Eighth Street  
Las Vegas, Nevada 89101  
Email: matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
**THE NEVADA INDEPENDENT**

/s/ Theresa M. Haar  
Theresa M. Haar, an employee of the  
Office of Attorney General



AARON D. FORD (Bar No. 7704)  
Attorney General  
Steve Shevorski (Bar No. 8256)  
Chief Litigation Counsel  
Office of Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
(702) 486-3783 (phone)  
(702) 486-3773 (facsimile)

*Attorneys for Respondent*

**DISTRICT COURT**  
**CLARK COUNTY, NEVADA**

THE NEVADA INDEPENDENT,  
  
Petitioner,  
  
vs.

Case No. A-19-799939-W  
Dept. No. XIV

RICHARD WHITLEY, in his official capacity  
as the Director of the Nevada Department of  
Health and Human Services, and THE  
STATE OF NEVADA, ex rel. the NEVADA  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES,

Respondents.

**REPLY IN SUPPORT OF MOTION TO DISMISS**

Respondent Richard Whitley, in his official capacity as Director of the Nevada Department of Health and Human Services, and the State of Nevada ex rel. the Nevada Department of Health and Human Services, reply in support of their motion to dismiss.<sup>1</sup>

**MEMORANDUM OF POINTS AND AUTHORITIES**

**I. Introduction**

The Court should grant Respondents' motion to dismiss. **First**, nothing in Senate Bill 539 did, or could, displace the Defend Trade Secrets Act. Tellingly, TNI heavily relies on *Lyft, Inc. v. City of Seattle*, 418 P.3d 102 (Wash. 2018) a case that does not even interpret the Defend Trade Secrets Act (DTSA), and, worse still for TNI, remanded the case for fact

---

<sup>1</sup> TNI has never opposed Respondents' motion to dismiss. To the extent that Petitioner intended that its reply filed on January 3 also serve as an opposition to Respondents' motion to dismiss, this reply addresses TNI's arguments.

1 finding on confidentiality of records requested under Washington state law.<sup>2</sup> **Second**, TNI  
2 concedes that NRS 600A.030(5)(b) does not affect, much less override, the DTSA, while  
3 acknowledging that the DTSA creates a federal forum and a federal cause of action to sue  
4 for misappropriation of trade secrets. **Third**, TNI speculates that Respondents have  
5 nothing to fear from a lawsuit from companies such as Sanofi, but Plaintiff never disputes  
6 that the Respondents may be subject to suit under *Ex Parte Young*, and its progeny, for  
7 prospective injunctive relief to enjoin disclosure of trade secrets.

## 8 **II. Legal argument**

### 9 **A. The “declared by law to be confidential” language of NRS 239.010 is** 10 **broad and includes statutes like the DTSA that protect existing trade** 11 **secrets.**

#### 12 **1. The DTSA, separate and apart from state law, declares that** 13 **trade secrets cannot be misappropriated.**

14 TNI in its brief makes an important concession regarding the DTSA. TNI writes  
15 that “[t]he DTSA provides a federal forum and cause of action for misappropriation of trade  
16 secrets.” Br. 9:1-2. TNI attempts to argue that the DTSA then did not “create trade secret  
17 status.” Br. 9:3-4. The problem for TNI’s argument is that the DTSA codifies, as a separate,  
18 independent federal right, protection for intangible property rights that already exist – the  
19 right to exclude others from using intangible property.

20 It is beyond cavil that if a statute declares a record confidential, then TNI’s  
21 mandamus claim fails. *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 266 P.3d 623,  
22 628 (2011). That is what the DTSA does: The DTSA specifically recognizes that “financial,  
23 business . . . [and] economic” information of the type at issue here can come within trade  
24 secret protection. 18 U.S.C. §1839(3). The DTSA prohibits the disclosure or  
25 misappropriation of trade secrets under federal law, creates a federal cause of action for  
26 misappropriation, and allows aggrieved parties access to a federal forum. *See* 18 U.S.C.  
27 §1836(b).

---

28 <sup>2</sup> *Lyft*, 418 P.3d at 110.

1       The phrase “declared by law to be confidential” does not mean that a statute must  
2 be the creative force for confidentiality. This Court should avoid such an absurd  
3 interpretation. *Allstate Ins. Co. v. Fackett*, 125 Nev. 132, 138, 206 P.3d 572, 576 (2009).  
4 The confidentiality of trade secrets predates any codification of a cause of action against  
5 their misappropriation. For example, our Supreme Court recognized that the  
6 misappropriation cause of action under Nevada’s Uniform Trade Secret Act merely  
7 “codified” that common law right to prevent misappropriation of this intellectual property  
8 right that already existed. *Frantz v. Johnson*, 116 Nev. 455, 465-66, 999 P.2d 351, 357  
9 (2000). The DTSA does the same thing, but under federal statutory law.

10       Prior to the DTSA, the protection of commercial data was dependent on state law.  
11 *See e.g. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003 (1984) (analyzing whether  
12 intellectual property could be the subject of a taking under the Fifth Amendment). The  
13 DTSA changed that. The DTSA provides a federal definition of a trade secret. 18 U.S.C. §  
14 1836(3). And while Congress modeled the DTSA on state trade secret law, the DTSA is in  
15 no way dependent for its existence on state law. *See e.g. Yeiser Research & Dev’t, Teknor*  
16 *Apex Co.*, No. 17-cv-1290-BAS-MSB, 2019 WL 2177658 (S.D. Cal. May 20, 2019) (explaining  
17 history of the DTSA).

18       This principle dooms Petitioner’s theory that in enacting SB 539, Nevada’s  
19 legislature sought to strip companies such as Sanofi of their trade secrets, despite the  
20 presence of the DTSA. While TNI argues that NRS 600A.030(5)(b) is dispositive, nothing  
21 in this section requires disclosure of any record. Section 600A.030(5)(b) simply excludes  
22 from the trade secret definition the information “required” to be reported under the  
23 Reporting Statutes “to the extent that such information is required to be disclosed by those  
24 sections.” NRS 600A.030(5)(b). Importantly, SB 539 is silent on whether the documents  
25 fitting within NRS 600A.030(5)(b) remain confidential under other law, notably federal law  
26 such as the DTSA.

27       TNI appears to argue that for drug price information to “declared by law”  
28 confidential, the DTSA has to specifically delineate drug price information within section

1 1839(3). But, this Court should avoid such an absurd interpretation. *Allstate Ins. Co. v.*  
2 *Fackett*, 125 Nev. 132, 138, 206 P.3d 572, 576 (2009)). It is beyond peradventure that  
3 Congress used broad headings such as “financial, business, and economic information” to  
4 avoid any attempt at cataloguing every conceivable document or record that could be a  
5 trade secret. 18 U.S.C. §1839(3).

## 6 **2. No persuasive authority supporting TNI’s argument**

7 TNI's reliance on *Lyft, Inc. v. City of Seattle, supra*, does not help TNI. TNI writes  
8 the Washington Supreme Court considered a case under “almost identical circumstances.”  
9 Br. at 7:11-12. Importantly, TNI never tells the Court that *Lyft* does not even consider the  
10 DTSA.

11 There, the *Lyft* court concluded that the car-hailing companies' zip code records  
12 "likely meet" the trade secret definition of the UTSA, *Lyft*, 418 P.3d at 106—a conclusion  
13 which TNI fails to mention on page 7 of its Reply. Of course, the zip code records were not  
14 "expressly" defined as trade secrets in the UTSA either. Moreover, the Washington  
15 Supreme Court did not stop there; it remanded the case for a determination of whether the  
16 companies were entitled to an injunction "to prevent the City from disclosing the records  
17 in response to a public records request." *Lyft*, 418 P.3d at 110; *see also id.* at 106 (companies  
18 must show on remand that disclosure of the records was "clearly not in the public interest  
19 and in fact poses substantial and irreparable harm").

20 Here, by contrast, TNI asks the Court to skip that step altogether. TNI mistakenly  
21 seeks to compel Respondents to disclose all information received under the Reporting  
22 Statutes and disregard the separate legal existence of the DTSA.

## 23 **3. Records do not need to be specifically identified to be “declared** 24 **by law to be confidential.”**

25 TNI also mistakenly conflates trade secret status of information with the much  
26 broader category of information declared by law to be confidential. Simply because  
27 information reported to Respondents no longer fits within the definition of a trade secret  
28 under NRS 600A.030(5)(b) does not mean it is not otherwise confidential and proprietary.

1 TNI never explains how information protected by the DTSA as a trade secret or information  
2 that is not a trade secret, but remains confidential due to its economic or proprietary  
3 character simply lost its confidential status after NRS 600A.030(5)(b) was enacted. There  
4 certainly is no language in NRS 600A.030(5)(b) to support such a sweeping attempt to upset  
5 established protections for confidential information.

6 The Nevada Supreme Court frequently consults the exemptions under the Freedom  
7 of Information Act (FOIA)—"the federal analog of the NPRA," *Reno Newspapers, Inc.*, 127  
8 Nev. at 881, 266 P.3d at 628—and federal case law interpreting FOIA to determine whether  
9 a governmental entity was right to withhold a record as confidential under NRS 239.010.  
10 *See, e.g., Donrey of Nev., Inc. v. Bradshaw*, 106 Nev. 630, 644, 798 P.2d 144, 153 (1990)  
11 (consulting "federal authorities interpreting the FOIA" and finding it "apparent that the  
12 investigative report compiled by the Reno Police Department would qualify as exempt  
13 under subsection 7").

14 Under section 552(b)(4) of FOIA, the government is not required to make available  
15 to the public "trade secrets and commercial or financial information obtained from a  
16 person" that are "privileged or confidential." 5 U.S.C. § 552(b)(4) (emphasis added).  
17 Commercial and financial information is "'confidential' for purposes of the [FOIA]  
18 exemption if disclosure of the information is likely . . . to cause substantial harm to the  
19 competitive position of the person from whom the information was obtained." *Nat'l Parks  
20 and Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *see also Food Mktg.  
21 Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) (financial information is  
22 "confidential" and exempt from disclosure where information "is both customarily and  
23 actually treated as private by its owner and provided to the government under an  
24 assurance of privacy . . .").

25 Thus, the fact that the DTSA—unlike NRS 202.3662, which TNI cites as an example,  
26 Reply at 9—does not identify specific records as a trade secret does not mean that the DTSA  
27 fails to "create confidentiality," as TNI contends, let alone preclude a finding of  
28 confidentiality or mandate disclosure of the information, as TNI suggests. Reply at 9-10.

1 See *Lyft*, 418 P.3d at 106, 116 (concluding records qualify as trade secrets under UTSA but  
2 remanding case for "fact-based" inquiry as to whether companies are entitled to injunctive  
3 relief to prevent disclosure).

4 **B. NAC 439.735 strikes a lawful balance between the DTSA and NRS**  
5 **600A.030(5)(b).**

6 TNI does not dispute that regulations such as NAC 439.735 are presumed valid, nor  
7 does it dispute that courts will generally give great deference to the "agency's interpretation  
8 of a statute that the agency is charged with enforcing." *State, Div. of Ins. v. State Farm*,  
9 116 Nev. 290, 293, 995 P.2d 482, 485 (2000). Here, that agency is the Department, which  
10 is uniquely qualified and was specifically charged with adopting "such regulations as it  
11 determines to be **necessary or advisable** to carry out the provisions of NRS 439B.600 to  
12 439B.695 . . . ." NRS 439B.685(1)(emphasis added).

13 Faced with federal and state statutes that touch on the same subject, the  
14 Department was required to give both effect. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S.  
15 470, 479–80 (1974) ("when state law touches upon the area of federal statutes enacted  
16 pursuant to constitutional authority . . . the federal policy may not be set at naught, or its  
17 benefits denied by the state law") (internal quotation marks and citation omitted); see also  
18 *State Farm*, 116 Nev. at 295, 995 P.2d at 486 ("Whenever possible, this court will interpret  
19 a rule or statute in harmony with other rules or statutes") (citing cases).

20 Respondents achieved that goal with NAC 439.735, which accommodates the dueling  
21 policies of NRS 600A.030(5)(b) and NRS 239.010 on the one hand and the DTSA on the  
22 other. NAC 439.735 provides a mechanism for essential diabetes drug manufacturers or  
23 pharmacy benefit managers who reasonably believe that public disclosure of information  
24 they submit to the Department "would constitute misappropriation of a trade secret for  
25 which a court may award relief pursuant to the [DTSA]" to submit "a request to keep the  
26 information confidential." NAC 439.735(1). But the regulation requires a specific showing,  
27 provides safeguards to test the drug manufacturers' or pharmacy benefit managers' DTSA  
28 claims, NAC 439.735(3), and puts the burden on *them* to go to court and prevent disclosure

1 of their information under the NPRA if the Department disagrees with their  
2 misappropriation claims. NAC 439.735(5)-(6). In other words, NAC 439.735 strikes a  
3 careful balance between the private parties' interest in "nondisclosure" and "the public's  
4 interest in access." *PERS*, 129 Nev. at 837, 313 P.3d at 224.

5 Respondents did not enact NAC 439.735 to limit the scope of the NPRA, as in  
6 *Comstock Residents Ass'n v. Lyon Cty. Bd. of Comm'rs*, 134 Nev. 142, 414 P.3d 318, 322 n.1  
7 (2018). Nor is it the intention of the State to "conceal" from the public relevant diabetes  
8 drug pricing information, as TNI contends. NAC 439.735 leaves intact the Department's  
9 obligation to: (1) analyze the information it receives under NRS 439B.635, 439B.640 and  
10 439B.645; (2) "compile a report on the price of the prescription drugs that appear on the  
11 most current lists compiled by the Department pursuant to NRS 439B.630, the reasons for  
12 any increases in those prices and the effect of those prices on overall spending on  
13 prescription drugs in this State"; and (3) ***put the reports it compiles under NRS***  
14 ***439B.650 and 439B.660 on its "Internet website. . ."*** NRS 439B.650, 439B.670(1)(a)(5)  
15 (emphasis added).

16 Thus, the transparency on the pricing of essential diabetes drugs that the Nevada  
17 Legislature aimed to achieve with SB 539 is still accomplished under NRS 439B.670.  
18 There is no legitimate basis to invalidate the regulation.

19 **C. TNI asks this Court to ignore *Ex Parte Young*.**

20 TNI also asks the Court to ignore the DTSA in favor of NRS 600A.030(5)(b), but the  
21 DTSA does not give priority to state law governing trade secrets; it merely leaves state law  
22 remedies for misappropriation of trade secrets intact. See 18 U.S.C. § 1838.

23 TNI's argument that Respondents should not worry about liability because the  
24 DTSA creates no private right of action for "any otherwise lawful activity conducted by . . .  
25 a state," 18 U.S.C. § 1833, not only begs the question but overlooks that neither the Nevada  
26 Supreme Court nor the Ninth Circuit Court of Appeals has interpreted 18 U.S.C. § 1833  
27 (or any other DTSA provision for that matter). Only two United States District Courts did  
28 so, in unpublished decisions in Maryland and Massachusetts. See *MedSense, LLC v. Univ.*

1 *Sys. of Md.*, No. CV GLS-18-3262, 2019 WL 4735430, at \*6 (D. Md. Sept. 27, 2019); *Fast*  
2 *Enters., LLC v. Pollack*, No. 16-CV-12149-ADB, 2018 WL 4539685, at \*2-3 (D. Mass. Sept.  
3 21, 2018). It is not at all established in this jurisdiction that public disclosure of all  
4 information diabetes drug manufacturers and pharmacy benefit managers must provide  
5 under the Reporting Statutes is a "lawful activity"—especially when states do so without  
6 first inquiring whether doing so may pose substantial and irreparable harm to them.

7 Further, although the Eleventh Amendment bars private citizens from suing state  
8 (officials) such as Respondents in federal court, *Edelman v. Jordan*, 415 U.S. 651, 663,  
9 (1974), under *Ex parte Young*, 209 U.S. 123 (1908), there is an exception if such federal  
10 suit seeks prospective injunctive relief to end continuing violations of federal law. *Culinary*  
11 *Workers Union, Local 226 v. Del Papa*, 200 F.3d 614, 619 (9th Cir. 1999). It is therefore  
12 not only possible but likely that diabetes drug manufacturers and pharmacy benefit  
13 managers will bring suit in federal court against Respondents to enjoin them from violating  
14 the DTSA by disclosing the reportable information to the public.

### 15 **III. Conclusion**

16 For these reasons, this Court should dismiss TNI's petition for writ of mandamus.

17 DATED this 23rd day of January, 2020.

18 AARON D. FORD  
19 Attorney General

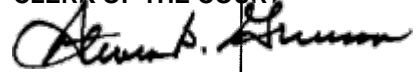
20 By: Steve Shevorski  
21 Steve Shevorski (Bar No. 8256)  
22 Chief Litigation Counsel  
23  
24  
25  
26  
27  
28

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

I certify that the following participants in this case are registered electronic filing systems users and will be served electronically:

John R. Bailey  
Dennis L. Kennedy  
Sarah E. Harmon  
Bailey Kennedy  
8984 Spanish Ridge Ave.  
Las Vegas, NV 89148-1302  
*Attorneys for Intervenors*  
*Sanofi-Aventis U.S. LLC*

/s/ Traci Plotnick  
Traci Plotnick, an employee of the  
Office of the Attorney General



**CONFILE**

MATTHEW J. RASHBROOK  
Nevada State Bar No. 12477  
ROBERT L. LANGFORD, ESQ  
Nevada State Bar No. 3988  
ROBERT L. LANGFORD & ASSOCIATES  
616 South Eighth Street  
Las Vegas, NV 89101  
(702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

**EIGHTH JUDICIAL DISTRICT COURT**

**CLARK COUNTY, NEVADA**

THE NEVADA INDEPENDENT,  
  
Petitioner,

Case No.: A-19-799939-W

Dept. No.: XIV

vs.

RICHARD WHITLEY, in his official  
capacity as the Director of the Nevada  
Department of Health and Human Services,  
and THE STATE OF NEVADA, ex rel. the  
NEVADA DEPARTMENT OF HEALTH  
AND HUMAN SERVICES;

**MOTION TO COMPEL TESTIMONY OF  
JAMES BORNEMAN, OR IN THE  
ALTERNATIVE, TO STRIKE HIS  
DECLARATION**

Respondents,

and

SANOFI-AVENTIS U.S. LLC,

**HEARING REQUESTED**

Intervenor.

COMES NOW Petitioner, The Nevada Independent, by and through their  
undersigned counsel, Matthew J. Rashbrook, and Robert L. Langford, Esq., and hereby  
moves this Court for an Order compelling the testimony of James Borneman, or in the  
alternative an Order striking his Declaration.

1 This Motion is based upon the attached Memorandum of Points and Authorities,  
2 the papers and pleadings on file in this case, and any argument the Court may entertain at  
3 the hearing of the Motion.

4 DATED this 30th day of January, 2020.

6 /s/ Matthew J. Rashbrook

7 MATTHEW J. RASHBROOK  
8 Nevada State Bar No. 12477  
9 ROBERT L. LANGFORD, ESQ.  
10 Nevada State Bar No. 3988  
11 ROBERT L. LANGFORD &  
12 ASSOCIATES  
13 616 S. Eighth Street  
14 Las Vegas, NV 89101  
15 (702) 471-6565  
16 matt@robertlangford.com  
17 robert@robertlangford.com  
18 Attorneys for Petitioner  
19 The Nevada Independent  
20  
21  
22  
23  
24  
25  
26  
27  
28

ROBERT L. LANGFORD & ASSOCIATES  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101  
(702) 471-6565 • FAX (702) 471-6540

NOTICE OF MOTION

TO: ALL INTERESTED PARTIES

PLEASE TAKE NOTICE THAT the foregoing **MOTION TO COMPEL**  
**TESTIMONY OF JAMES BORNEMAN, OR IN THE ALTERNATIVE, TO STRIKE HIS**  
**DECLARATION** will be brought on for hearing before the above-noted Court on the \_\_\_\_  
day of \_\_\_\_\_, 2020, at the hour of \_\_\_\_ o'clock \_\_.m., or as soon thereafter as  
counsel may be heard.



1 information discussed herein – even in the absence of Nev. Rev. Stat. § 600A.030(5) –  
2 could be considered a trade secret.

3 In order to create a full record, and to ensure a fair hearing of the issues herein,  
4 Mr. Borneman must be required to testify. In the alternative, Sanofi must not be allowed to  
5 profit from his defective Declaration, and the Declaration should therefore be stricken.

6 Legal Standard

7 Under E.D.C.R. 2.21, an affidavit “must contain only factual, evidentiary matter,  
8 conform with the requirements of N.R.C.P. 56(e), and avoid mere general conclusions or  
9 argument. Affidavits substantially defective in these respects may be stricken, wholly or in  
10 part.” Under Nev. R. Civ. P. 56(e):

11 If a party fails to properly support an assertion of fact . . .  
the court may:

- 12 1) give an opportunity to properly support or address the  
13 fact;  
14 2) consider the fact undisputed for purposes of the motion;  
15 3) grant summary judgment if the motion and supporting  
16 materials – including the facts considered undisputed –  
show that the movant is entitled to it; or  
17 4) issue any other appropriate order

18 In this instance, the Declaration of Mr. Borneman is defective in numerous  
19 aspects. Mr. Borneman makes numerous legal conclusions, fails to support his broad  
20 factual claims, many of which are contradicted by publicly available material, and makes  
21 extensive argument regarding what are properly policy questions considered by the Nevada  
22 Legislature in enacting S.B. 539, and for this Court to consider in determining the issues  
before it herein.

23 Sanofi and Respondent have both asserted their belief that the Petition raises  
24 purely legal questions. However, Nev. Rev. Stat. § 239.0113 states that when a  
25 governmental entity asserts that a public record is confidential, that entity bears “the burden  
26 of proving by a preponderance of the evidence that the public book or record, or a part  
27 thereof, is confidential.” Sanofi, standing in the place of Respondent, is obligated to prove,  
28

1 by placing competent evidence before this Court, that the records should be held  
2 confidential.

3 Argument

4 Entire sentences – sections, even – of the Declaration appear to have been lifted  
5 from other sources, including the testimony of other Sanofi employees, and Sanofi  
6 corporate materials.

7 For instance, in the second paragraph, Mr. Borneman declares, “From prevention  
8 to treatment, Sanofi transforms scientific innovation into healthcare solutions[,]” which  
9 appears to be an identical copy of the verbiage at Sanofi’s “Inside Sanofi” website: “From  
10 prevention to treatment, Sanofi transforms innovation into healthcare solutions.”<sup>1</sup>

11 Similarly, the opening sentence of paragraph 2 of the Declaration of James  
12 Borneman appears to be lifted from other Sanofi materials as well. The Declaration reads:  
13 “Sanofi US is the U.S. affiliate of Sanofi, a global life sciences company committed to  
14 improving access to healthcare and supporting the people we serve throughout the  
15 continuum of care.” When compared with a job posting at jobs.sanofi.us, one can see the  
16 similarity: “Sanofi is a global life sciences company committed to improving access to  
17 healthcare and supporting the people we serve throughout the continuum of care.”<sup>2</sup>

18 Although the specific number of employees occasionally varies, one finds the last  
19 sentence of paragraph 2 located at several online sites also. Compare the Declaration,  
20 “More than 100,000 people at Sanofi are dedicated to making a difference in patients’ daily  
21 lives, wherever they live, and enabling them to enjoy a healthier life[,]” with  
22

23 <sup>1</sup> “Inside Sanofi – Sanofi U.S.” <https://www.sanofi.us/en/about-us/our-stories/inside-sanofi>,  
24 last visited January 30, 2020. A printout of the quoted portion is attached hereto as Exhibit  
25 (“Ex.”) 1.

26 <sup>2</sup> “Data Scientist: NLP and Deep Learning at Sanofi”  
27 <https://jobs.sanofi.us/job/cambridge/scientist-deep-data-analytics/507/13688120>, last  
28 visited January 30, 2020. Ex. 2. Further examples are available at “Manager, Modeling &  
Simulation, PKDM US at Sanofi” <https://jobs.sanofi.us/job/bridgewater/manager-modeling-and-simulation-pkdm-us/507/14398901>, last visited January 30, 2020. Ex. 3.  
“Sanofi | Science | Business” <https://sciencebusiness.net/networks/sanofi>, last visited  
January 30, 2020. Ex. 4.

1 sciencebusiness.net/networks/sanofi, Ex. 4, “More than 110,000 people at Sanofi are  
2 dedicated to make a difference on patients’ daily life, wherever they live and enable them  
3 to enjoy a healthier life[,]” and About Us – Sanofi U.S., “More than 100,000 people at  
4 Sanofi are dedicated to making a difference in patients’ daily lives, wherever they live, and  
5 enabling them to enjoy a healthier life.”<sup>3</sup>

6 Conveniently, nearly the entirety of paragraph 2 can be found at  
7 sciencebusiness.net/networks/sanofi. Ex. 4

8 Similarly, swaths of paragraph 3 are available online: compare the Declaration,  
9 “Headquartered in Bridgewater, New Jersey, Sanofi US employs approximately 12,500  
10 professionals throughout the country,” with Ex. 5, “Headquartered in Bridgewater, New  
11 Jersey, Sanofi in the United States employs more than 14,000 professionals throughout the  
12 country.”

13 It appears that large portions of the Declaration of James Borneman were also  
14 submitted as testimony to the House Energy and Commerce Subcommittee on Oversight  
15 and Investigations – by Kathleen W. Tregoning, another Sanofi employee. Entire  
16 paragraphs are virtually copied from one document to the other, with only minor changes  
17 reflecting the number of employees (13,000 vs. 12,500). Ex. 6.

18 These cannot, in any meaningful sense, be said to be the words of James  
19 Borneman. The Declaration should be stricken in its entirety, if Petitioner is not offered the  
20 opportunity to examine Mr. Borneman to determine what knowledge he actually personally  
21 possesses.

22 Further, the Declaration is littered with factual statements that are unsupported.  
23 For example, at paragraph 12, Borneman declares: “The Sanofi Reports comprise  
24 information that is of substantial independent economic value to Sanofi US by virtue of  
25 being confidential and non-public.” Throughout their filings, Sanofi has indicated that they  
26 will offer no support for these conclusory statements – demanding instead that this Court,  
27

28 <sup>3</sup> “About Us – Sanofi U.S.” <https://www.sanofi.us/en/about-us>, last visited January 30,  
2020. Ex. 5.

1 along with Petitioner and the people of Nevada, simply accept their statements with no  
2 further inquiry.

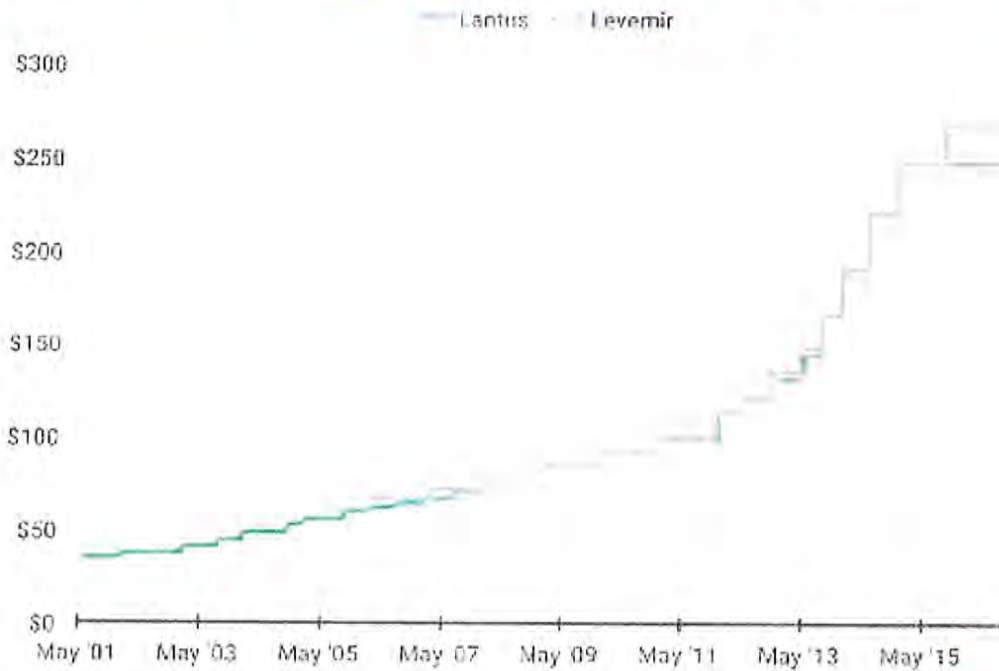
3 Another example of a factual statement without any support can be seen at  
4 paragraph 15, "Disclosure of the Sanofi Reports to The Nevada Independent would  
5 significantly harm Sanofi US." There is no support for this assertion, and the proof of that  
6 statement is absolutely necessary to support Sanofi's argument for confidentiality, whether  
7 proceeding under a theory that the DTSA renders the records confidential, that state law  
8 does, that state regulations do, or under some common-law theory.

9 Further, Mr. Borneman indicates through paragraph 16 and 17 that, if disclosed,  
10 the public records discussed herein would offer Sanofi's customers and competitors "an  
11 unfair competitive advantage over Sanofi," because "our customers would learn how we  
12 develop our pricing," and "our competitors would learn how we allocate resources and set  
13 our prices."

14 These statements are particularly galling, and demand examination. In the case of  
15 the customers for insulin, the suggestion that they could possibly possess an unfair  
16 competitive advantage is absurd – they require insulin to stay alive. Although one may  
17 suggest that a competitive marketplace exists which ensures that Sanofi and its competitors  
18 cannot leverage that fear of death in order to extort their customers, examining the price of  
19 purportedly competitive products from Sanofi and its ilk reveals that to be false – and  
20 makes obvious the truth that neither Sanofi nor its competitors enjoy any competitive  
21 advantage against each other by refusing to disclose this information.

22 As the below chart makes clear, historically, the prices of purportedly competitive  
23 equivalent insulin products have mirrored each other's price increases with virtually no  
24 separation between the times or amounts of increase. "Rising Insulin Prices Track  
25 Competitors Closely – Business Insider" [businessinsider.com/rising-insulin-prices-track-competitors-closely-2016-9](https://www.businessinsider.com/rising-insulin-prices-track-competitors-closely-2016-9), last accessed January 30, 2020. Ex. 7. In fact, this very  
26 behavior has been the subject of federal anti-trust investigation, as well as class action and  
27 other litigation.  
28

## 1 RISING INSULIN PRICES



SOURCE: Insulin Data Analytics

INSULIN DATA ANALYTICS

15 Although Mr. Borneman declares, at paragraph 20, that “Sanofi US has a  
16 longstanding commitment to research in the diabetes space and there is much remaining to  
17 be done in the diabetes space to ensure better outcomes for patients[.]” Indeed, in this  
18 matter, and as a general policy Sanofi asserts that its high prices on diabetes therapies are  
19 necessary to fund research and development of future drugs.

20 However, on December 9, 2019, about 53 days after Mr. Borneman swore the  
21 disputed Declaration, Sanofi (the Paris-based parent company), issued a press release  
22 discussing “new strategy to drive innovation and growth,” which discussed future diabetes  
23 related research: “Sanofi is announcing a discontinuation of research in diabetes[.]” It is  
24 difficult to believe that Mr. Borneman, the head of diabetes for the largest subsidiary of its  
25 parent company, a subsidiary which represents roughly half of the parent’s holdings, was  
26 caught by surprise by this change in direction announced by the parent company. This is an  
27 area of the Declaration which at minimum demands an opportunity for the parties to inquire  
28

1 further of Mr. Borneman, but perhaps more appropriately indicates that Mr. Borneman's  
2 Declaration should be struck in its entirety.

3 Further, at paragraph 21, 22 and 23, Mr. Borneman discusses the potential  
4 consequences of the disclosure of the public records at issue herein is ordered, declaring  
5 that it will "necessitate review of our research and development priorities for diabetes  
6 products going forward[.]" and later threatening that "Sanofi may be forced to weigh the  
7 difficult decision of whether to reduce its efforts in continuing to pursue promising medical  
8 advances in the area of diabetes because of these disincentives." These statements are  
9 rendered meaningless in light of the December 9 press release from the Paris-based Sanofi,  
10 and indicate a significant omission on the part of Mr. Borneman, if indeed he was aware of  
11 the decision to terminate research in the area of diabetes.

12 Even if Mr. Borneman's self-serving statements regarding Sanofi's interest in  
13 diabetes research were not contradicted so obviously, they nonetheless represent  
14 hypotheticals – argument, rather than fact. It is not for Sanofi to decide whether their  
15 preference to hold the lives of diabetics up for ransom in order to fund future research is an  
16 overall positive public policy goal worthy of support. In a larger sense, that decision  
17 belongs to the people of Nevada, who in enacting S.B. 539 have spoken quite clearly. In  
18 this case, it is for the Court to make a determination as to what the preferable policy is. In  
19 any event, Mr. Borneman's assertions in this area present no value to the determination of  
20 this matter, even were they not so clearly contradicted by the Paris-based parent Sanofi.

21 Mr. Borneman's Declaration is littered with statements lifted from a variety of  
22 other sources, baseless factual assertions – many of which are contradicted by publicly  
23 available documents, some of them authored a scant 53 days after his – and legal or policy  
24 arguments which are strictly improper material for an affidavit under both the E.D.C.R. and  
25 Nev. R. Civ. P.

26 The only acceptable remedy is for Petitioner to have the opportunity to question  
27 Mr. Borneman regarding these defects – as Sanofi previously indicated it would facilitate, a  
28 representation Petitioner relied on – or in the alternative, to strike Mr. Borneman's

1 Declaration entirely. Failing to take one of these actions will result in a misleading or  
2 incomplete factual record from which to evaluate the claims raised in the Petition.

3         Given all the foregoing, The Nevada Independent moves this Court either for an  
4 order requiring James Borneman to appear to testify, or for an order striking his  
5 Declaration in its entirety, together with an order for the reasonable attorney's fees and  
6 costs incurred in bringing this motion.

7         DATED this 30th day of January, 2020.

8  
9         /s/ Matthew J. Rashbrook

10         MATTHEW J. RASHBROOK  
11         Nevada State Bar No. 12477  
12         ROBERT L. LANGFORD, ESQ.  
13         Nevada State Bar No. 3988  
14         ROBERT L. LANGFORD &  
15         ASSOCIATES  
16         616 S. Eighth Street  
17         Las Vegas, NV 89101  
18         (702) 471-6565  
19         matt@robertlangford.com  
20         robert@robertlangford.com  
21         Attorneys for Petitioner  
22         The Nevada Independent  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

I hereby certify and affirm that on this 30th day of January, 2020, the foregoing  
**MOTION TO COMPEL TESTIMONY OF JAMES BORNEMAN, OR IN THE ALTERNATIVE, TO  
STRIKE HIS DECLARATION** was served by electronic mail to the following counsel of  
record:

Aaron D. Ford  
Nevada Attorney General  
Nevada Bar No. 7704  
Steve Shevorski  
Chief Deputy Attorney General  
Nevada Bar No. 8256  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
Fax: 702-486-3768  
sshevorski@ag.nv.gov

John R. Bailey  
Nevada Bar No. 0137  
Dennis L. Kennedy  
Nevada Bar No. 1462  
Sarah E. Harmon  
Nevada Bar No. 8106  
Rebecca L. Crooker  
Nevada Bar No. 15202  
Bailey Kennedy  
8984 Spanish Ridge Avenue  
Las Vegas, NV 89148-1302  
Fax: 702-562-8821  
jbailey@baileykennedy.com  
dkennedy@baileykennedy.com  
sharmon@baileykennedy.com  
rcrooker@baileykennedy.com

/s/ Matthew J. Rashbrook

An Employee of Robert L. Langford &  
Associates

# EXHIBIT 1

# EXHIBIT 1

[\(/en\)](#)

Welcome to  
Sanofi U.S.

OPERATE-  
ILITY)

CAREER:

[\(/en/search-results\)](#)

<https://www.sanofi.com/en/directory>

OUR STORIES

# Inside Sanofi

[Home \(/en\)](#)

[About us \(/en/about-us\)](#)

[Our Stories \(/en/about-us/our-stories\)](#)

Inside Sanofi

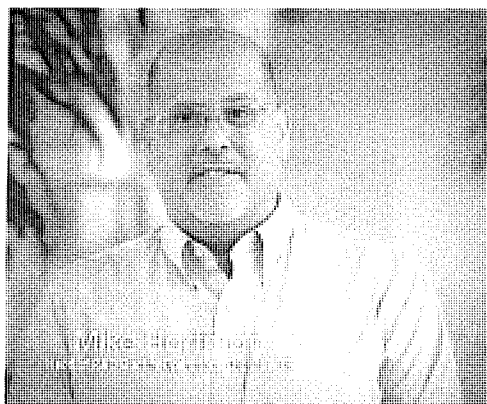
**Meet Sanofi US  
"Working  
Mother of the  
Year" Wendy  
Michelle  
Richard**

000789

## Welcome to Our Stories

From prevention to  
treatment, Sanofi transforms  
scientific innovation into  
healthcare solutions. Our  
more than 15,000 employees  
in the US are dedicated to

making a difference in  
patients' daily lives.



[READ MORE  
\(/EN/ABOUT-  
US/OUR-  
STORIES/INSIDE-  
SANOFI/WELCOME-  
TO-OUR-  
STORIES#READ  
MORE\)](#)

**Follow us**

[\(https://www.facebook.com/sanofi.us\)](#)  
[\(https://www.linkedin.com/company/sanofi-us\)](#)  
[\(https://www.youtube.com/sanofi-us\)](#)

ROBERT L. LANGFORD & ASSOCIATES  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101  
(702) 471-6565 • FAX (702) 471-6540

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 2

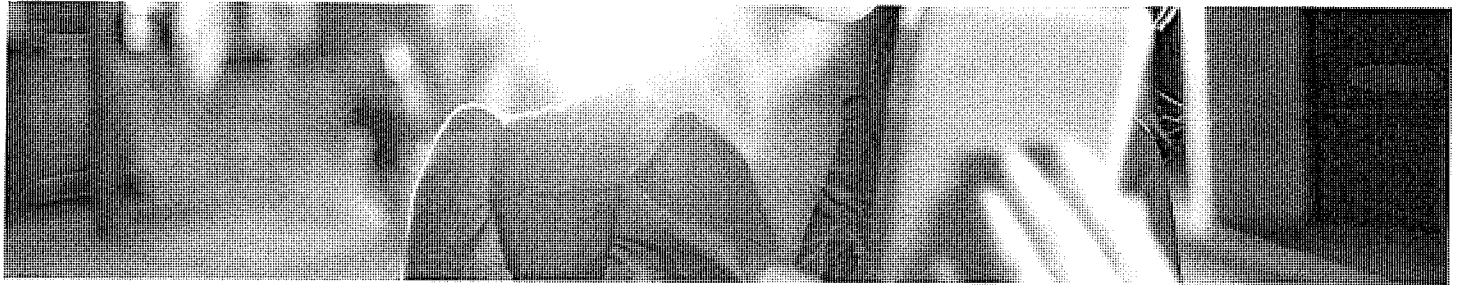
# EXHIBIT 2

## Data Scientist: NLP and Deep Learning

Cambridge, Massachusetts

Full-time

4-6 Months



Sanofi

Job ID: R2517292

Date posted: 10/10/2019

About the Company:

Sanofi is a global life sciences company committed to improving access to healthcare and supporting the people we serve throughout the continuum of care. From prevention to treatment, Sanofi transforms scientific innovation into healthcare solutions, in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes and cardiovascular solutions and consumer healthcare. More than 110,000 people in over 100 countries at Sanofi are dedicated to make a difference on patients' daily life, wherever they live and enable them to enjoy a healthier life. As a company with a global vision of drug development and a highly-regarded corporate culture, Sanofi is recognized as one of the best pharmaceutical companies in the world and is pioneering the application of Artificial Intelligence (AI) in the R&D organization including drug discovery, chemical manufacturing and control, translational research, clinical development, and document intelligence in regulatory affairs. Details of the organization and the company's mission and goals can be found on our website (<http://www.sanofi.us/l/us/en/index.jsp>).

## Overview:

Artificial Intelligence (AI) and Machine Learning (ML) algorithms can significantly speed up drug discovery and shorten the time-to-market for drug development thereby creating better medicines that save lives. AI and Deep Analytics (AIDA) is a critical group in Digital and Data Science (DDS) focused on

000792

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 3

# EXHIBIT 3

## Manager, Modeling & Simulation, PKDM US

Bridgewater, New Jersey

Apply

Save Job



000794

## Manager, Modeling &amp; Simulation, PKDM US

Bridgewater, New Jersey

APPLY

APPLY

Job Summary

Sanofi is a global life sciences company committed to improving access to healthcare and supporting the people we serve throughout the continuum of care. From prevention to treatment, Sanofi transforms scientific innovation into healthcare solutions, in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes and cardiovascular solutions and consumer healthcare.

The Modeling and Simulation (M&S) group in the Pharmacokinetics, Dynamics, and Metabolism (PKDM) department at Sanofi US provides clinical pharmacokinetic/pharmacodynamic analysis and M&S support to enable critical decision making and to accelerate Sanofi ongoing programs in translational medicine, early clinical development, late stage clinical development, and post-marketing across different therapeutic areas including immunology, oncology, hematology, and rare diseases.

The individual in this position will support clinical phase project teams as a M&S expert for the PKDM department in Development at Sanofi

- Conduct population PK and PK/PD analysis, exposure-response analysis, clinical trial simulation, and/or other model-based analysis using different M&S software to characterize the kinetics of drug disposition and to assess the dynamics of drug effect
- Develop and apply state-of-the-art quantitative methodologies (mathematical, physiological or statistical M&S) to support clinical phase projects and execute M&S strategies to inform dose selection and go/no-go decisions
- Develop and review protocols, analysis plans, and study reports for M&S aspects
- Prepare regulatory documents when needed

Knowledge and Skills

1. Develop the following scientific skills:

- Under minimal supervision, perform population PK modeling, mechanistic PK/PD modeling, exposure-response analysis, clinical trial simulation, and/or other model-based analyses such as disease modeling, survival analysis, time to event analysis, and machine learning
- Apply a logical and structured approach to file management
- Develop departmental procedures (SOP's, Protocols, Safety Procedures)
- May train/mentor others

000795

# EXHIBIT 4

# EXHIBIT 4

# Sanofi



*Sanofi is a global integrated healthcare leader focused on patients' needs engaged in the research, development, manufacturing and marketing of innovative therapeutic solutions*

Sanofi is a global life sciences company committed to improving access to healthcare and supporting the people we serve throughout the continuum of care. From prevention to treatment, Sanofi transforms scientific innovation into healthcare solutions, in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes and cardiovascular solutions and consumer healthcare. More than 110,000 people at Sanofi are dedicated to make a difference on patients' daily life, wherever they live and enable them to enjoy a healthier life.

Sanofi has core strengths in healthcare, with 7 growth platforms: diabetessolutions, human vaccines, innovative drugs, consumer healthcare, emergingmarkets, animal health and the new Genzyme.

## Learn more

---

- **Website:** [www.en.sanofi.com](http://www.en.sanofi.com)
  - **Twitter:** @sanofi
  - **Youtube:** <https://www.youtube.com/user/sanofiaventisTVen>
- 

## Sanofi News

Sanofi opens its first digitally-enabled, continuous manufacturing facility

# EXHIBIT 5

# EXHIBIT 5

# About Us

Headquartered in Bridgewater, New Jersey, Sanofi in the United States employs more than 14,000 professionals throughout the country.

Sanofi US is comprised of five business units that focus on human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious diseases, diabetes and cardiovascular solutions, consumer healthcare, established prescription products and generics. More than 100,000 people at Sanofi are dedicated to making a difference in patients' daily lives, wherever they live, and enabling them to enjoy a healthier life.

[\(/en\)](#)

Welcome to  
Sanofi U.S.

FORATE-  
BILITY)

CAREERS(

[\(/en/search-results\)](#)

<https://www.sanofi.com/en/directory>

## ONE PURPOSE

We at Sanofi work passionately,  
every day, to understand  
and solve healthcare needs  
of people across the world.



By 2025, Sanofi is a top 3,  
innovative, global and diversified  
human healthcare company embracing  
transformative technologies and focused  
on its areas of excellence, earning the  
respect and trust of the people and  
the patients we serve.

We are Sanofi, a global biopharmaceutical company committed to healthcare solutions from prevention to treatment. We turn scientific discoveries into medicine to improve human health. Every day we dedicate our most important resource, our people, to support patients and families through their health journey.

## Quick Facts

**14,000+** **\*100,000+** **100+**

in the U.S. workforce

in the global workforce

countries Sanofi is  
currently present in

*\*As of Dec. 31, 2017.*

000800

ROBERT L. LANGFORD & ASSOCIATES  
616 SOUTH EIGHTH STREET  
LAS VEGAS, NEVADA 89101  
(702) 471-6565 • FAX (702) 471-6540

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 6

# EXHIBIT 6



**Testimony of Kathleen W. Tregoning  
Executive Vice President, External Affairs  
Sanofi**

**Before the House Energy and Commerce Subcommittee on  
Oversight and Investigations  
April 10, 2019**

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee, thank you for the opportunity to appear before the House Energy and Commerce Subcommittee on Oversight and Investigations to discuss issues related to pricing, affordability, and patient access to insulin in the United States.

I am Kathleen Tregoning, Executive Vice President, External Affairs, at Sanofi. I am here today to have an open discussion about the current system for pricing and accessing insulin in the U.S., the actions we have taken to improve patient access and affordability to insulin, and our ideas about what more can be done.

At Sanofi, we work passionately every day to understand and address the health care needs of patients around the world. We are dedicated to solving patients' most serious health challenges in numerous therapeutic areas, including diabetes, cardiovascular disease, immunology, oncology, multiple sclerosis (MS), rare diseases, and rare blood disorders. We are also devoted to preventing diseases through the research, development, and delivery of vaccines. And we contribute to improving the health of people around the world through our broad portfolio of consumer health products.

Sanofi has a rich history in the United States dating back over 100 years. We currently employ more than 13,000 professionals across the United States in a broad range of critical roles, including business operations, research and development, and manufacturing. Our most significant U.S. presence is in Massachusetts, where we are the largest employer in the life sciences industry, and New Jersey, home to our U.S. headquarters. We also have major business, manufacturing and R&D operations in Pennsylvania and Tennessee.

Last year, Sanofi spent almost \$7 billion globally on research and development, an increase of approximately 7 percent from 2017, which reflects our commitment to bringing better therapies to patients. Sanofi plans to maintain this level of R&D investment through 2021, and our R&D pipeline now contains 81 projects, including 33 new molecular entities in clinical development, and 35 projects that are in Phase III or have been submitted to regulatory authorities. This investment means that Sanofi potentially will seek approval for nine new

medications in the next three years, primarily in therapeutic areas where Sanofi sees the greatest nexus between our expertise and patient need: diabetes, vaccines, oncology, immunology, rare diseases, and rare blood disorders.

Our work in R&D includes more than a dozen compounds for the treatment of various kinds of cancers, and we are employing cutting-edge approaches in an effort to make significant advances for patients. Our research includes potential treatments to help the body's own immune system fight cancer, and antibody drug conjugates that we believe can deliver cytotoxic drugs to tumors while sparing normal tissue. Just last month we announced successful results with one such candidate in a mid-stage trial in lung cancer, and we intend to initiate a pivotal study later this year.

## I. Evolution of Insulins

Sanofi's innovations in diabetes, and, specifically, for insulin, have been significant.

The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and wake up at night for injections in order to control blood glucose levels. Each such injection of insulin caused a sharp spike in the patient's insulin levels, which could cause symptoms of low blood sugar ranging from shakiness and confusion to, in the extreme, coma or death. Injections also had to be timed before every meal, disrupting patient's lives, sleep times, and ability to eat with friends and family. As such, the consistent goals of insulin therapy over the last century have included reducing the frequency of insulin administration and flattening the post-administration peak of insulin in the bloodstream. Prior attempts to achieve these goals included cumbersome mechanical pumps that had to be worn on the body for constant infusion, and NPH insulin, which had an intermediate duration of action but still caused a pronounced peak in insulin levels.

The discovery and development of glargine changed all of that. Sanofi scientists succeeded in fundamentally altering the human insulin molecule at the amino acid level, changing its pharmacological characteristics to give patients a steady release of insulin with just a single daily administration. Unlike anything that came before it, glargine forms tiny solid crystals upon injection that dissipate over time to provide a flatter, stable, long-lasting effect that mimics the flat profile of insulin release from a healthy pancreas and reduces the risks caused by low blood sugar. The once-daily administration of glargine also provided a significant boon to patient lifestyles. The FDA first approved insulin glargine under the tradename Lantus® in 2000. Since its launch, Lantus has been studied in more than 90 million patient lives. Sanofi went above and beyond the regulatory authorities' approval requirements and conducted the first large Cardiovascular Outcome trial (CVOT - (ORIGIN)), to demonstrate the cardiovascular effects of an antidiabetic drug. Sanofi sponsored over 200 clinical trials, with more than 200,000 patients treated, resulting in over 2000 peer reviewed publications.

Since its discovery of insulin glargine, Sanofi has developed a new glargine formulation and a combination product to meet individual patient needs. While Lantus® provides significant

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

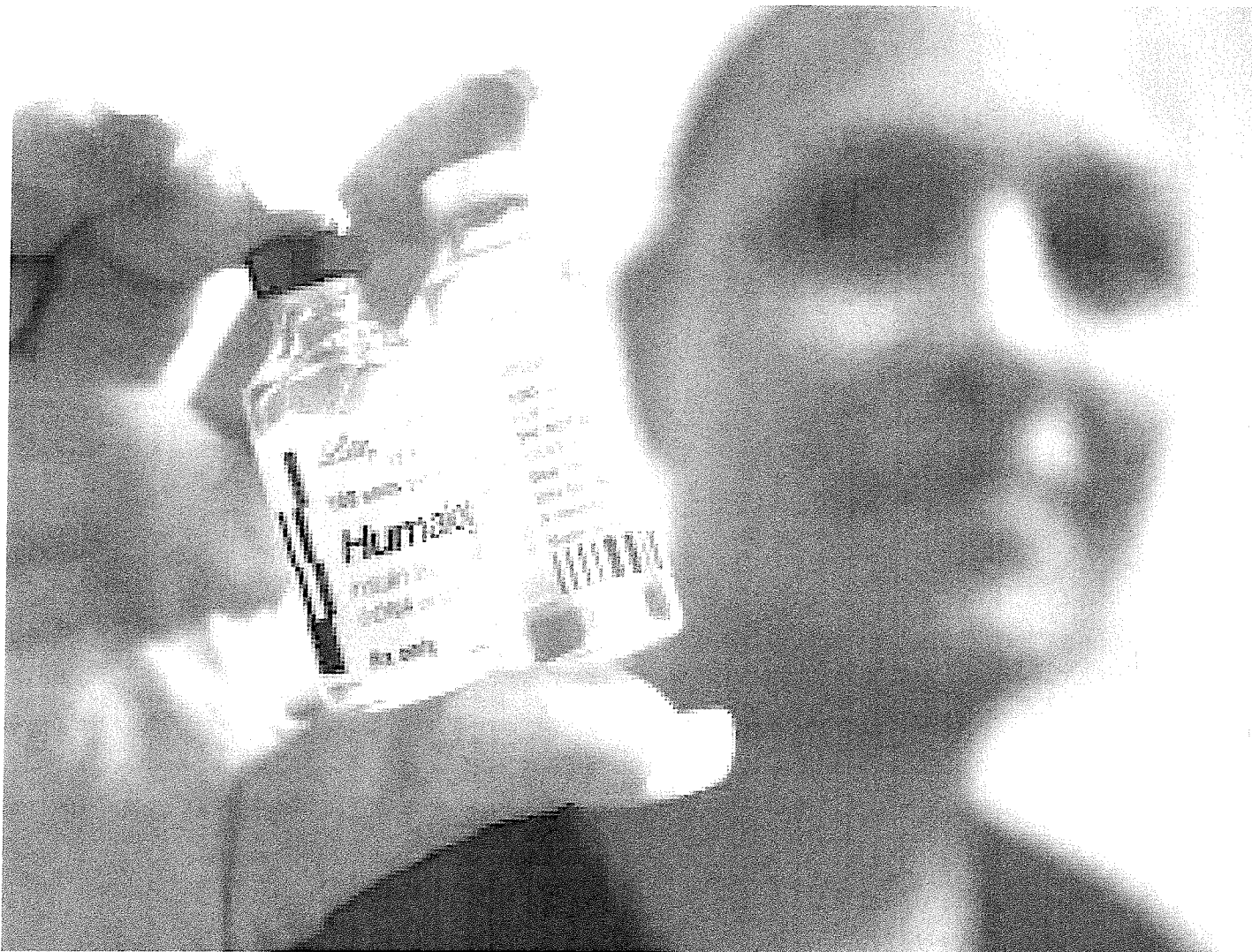
# EXHIBIT 7

# EXHIBIT 7



## There's something odd about the way insulin prices change

Lydia Ramsey Sep 17, 2016, 12:00 PM



A Type 1 diabetes patient holds up bottles of insulin. Reuters/Lucy Nicholson

Insulin prices are rising — increases that mean some people are spending as much on monthly diabetes-related expenses as their mortgage payment.

But what makes the rise in insulin prices different than many other old drugs that have drawn scrutiny over prices, is that there is competition for insulin.

In most industries, competition drives down prices. In this case, the competitors appear to increase prices side-by-side — something that's been referred to as "shadow pricing."



Don't let Todd Munion answer questions about



BUSINESS  
INSIDER

Subscribe

At least three companies — Eli Lilly & Co., Novo Nordisk, and Sanofi Aventis — make and sell insulin.

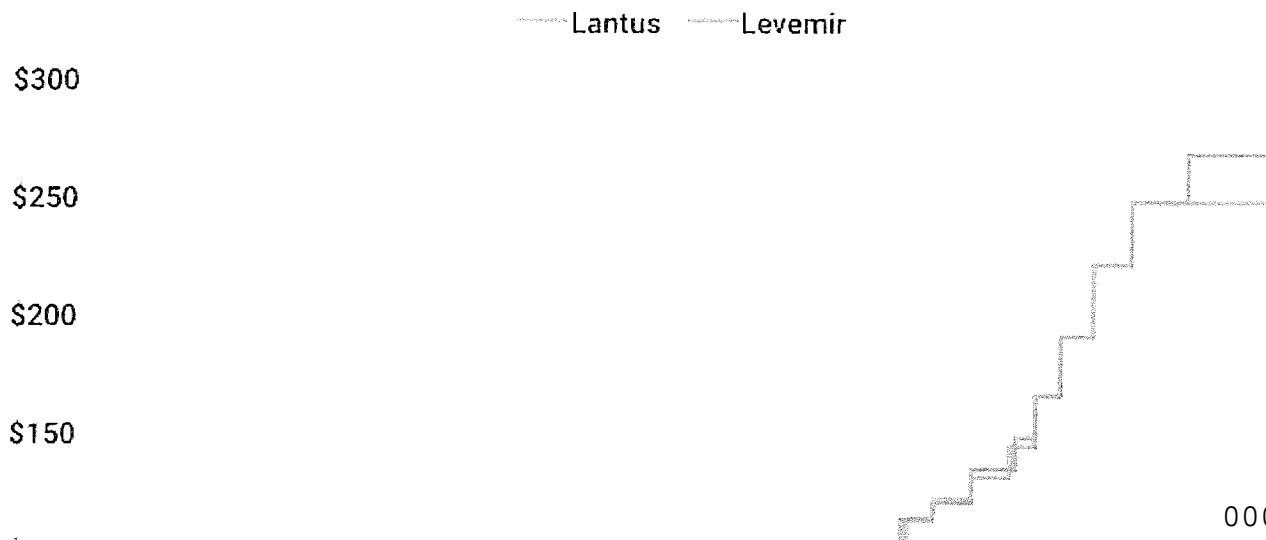
Despite this competition, prices have steadily climbed over the past decade, taking single or double-digit list price increases in a year. A 10 milliliter vial of Sanofi's long-acting insulin, Lantus, first hit the US market at \$34.81 a vial in 2001, according to data from Truven Health Analytics.

Since 2014, the last time Sanofi raised the price, it has been \$248.51.

During the period in which Lantus's price rose 600%, a rival product from Novo Nordisk appeared. In 2006, the new drug, called Levemir, hit the market at \$66.96 (close to what Sanofi's drug cost at the time). These days Levemir costs about \$269.

In other words, the competition seems to have done nothing to push prices down. In fact, when charted side by side, the price increases seem to be in synch.

## RIISING INSULIN PRICES



000806

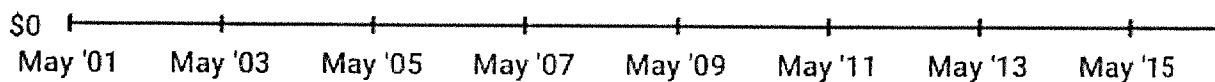


Don't let Todd Munion answer questions about



BUSINESS  
INSIDER

Published



SOURCE: Truven Health Analytics

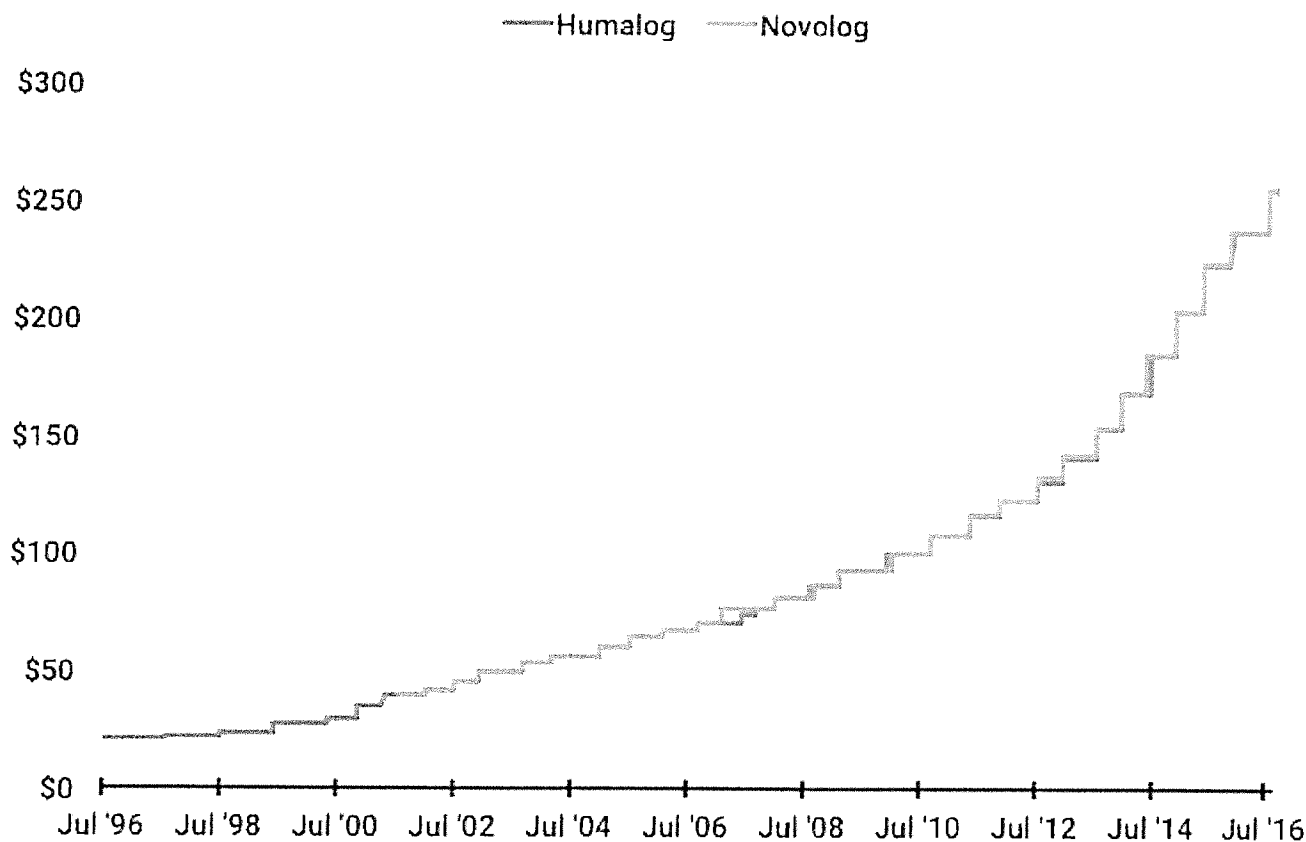
BUSINESS INSIDER

Andy Kiersz/Business Insider

When you look at short-acting analog insulins (the types of insulin that are taken around the time diabetics eat, or what's used in an insulin pump), the prices are in such lockstep that you can't see two lines.

Lilly's Humalog cost \$20.82 in 1996 and now goes for \$255.40, an increase of 1,124% over 20 years. Novo Nordisks's Novolog first hit the market in August 2001 at \$39.75, and as of July 2016, a vial comes with a list price of \$255.40 — exactly the same as Humalog.

## RIISING INSULIN PRICES



SOURCE: Truven Health Analytics

BUSINESS INSIDER

Andy Kiersz/Business Insider

000807



"It is possible to see price changes through a variety of databases, and we have always monitored the market closely, just as other companies do," he said. Sanofi's spokeswoman said that the company sets the prices of its medications independently, and a spokesman for Lilly noted that the companies are all dealing with the same parts of the healthcare system — the pharmacy-benefits managers, the health insurers, etc., that affect pricing decisions.

Even if it seems odd that prices would rise like this in a competitive market, it highlights the hold that drug brands have over doctors who prescribe medicines, and the patients who pay for them.

Bloomberg's Robert Langreth explored the issue last year and spoke to a pharmacist and economist who said that it is proof that branded prescription drugs "are basically not a competitive market," when it comes to prices. This isn't unique to insulin: When there was a viable competitor for EpiPen something similar happened, as with multiple-sclerosis drugs.

As for why the price has gone up so much, regardless of the similarities? The companies offer a number of explanations — including that rebates and other offsets mean that the income to the company is actually declining, and or that they're spending billions to produce and package insulin — making improvements in how the drug is delivered and produced.

**For more about insulin, and the people who depend on it, check out our piece on the rising cost of diabetes care.**



Be at the forefront of the healthcare industry with  
**Digital Health Pro**

[Join Today](#)

**BUSINESS  
INSIDER  
INTELLIGENCE**

#### *Featured Digital Health Articles:*

- *Telehealth Industry: Benefits, Services & Examples*
- *Value-Based Care Model: Pay-for-Performance Healthcare*
- *Senior Care & Assisted Living Market Trends*
- *Smart Medical Devices: Wearable Tech in Healthcare*
- *AI in Healthcare*
- *Remote Patient Monitoring Industry: Devices & Market Trends*

**SEE ALSO: 'People are still getting sick': The lasting health impacts of 9/11, 15 years later »**

**NOW WATCH: 5 'healthy' fast food meals that are worse for you than pizza**



Don't let Todd Munion answer questions about



BUSINESS  
INSIDER

Advertisement

More: [Health](#) [Insulin](#) [Diabetes](#) [Pharmaceuticals](#) ▼

Taboola Feed

#### How To Empty Your Bowels Every Morning - Top Surgeon Explains How

Sponsored by Gundry MD Bio Complete 3 Supplements

#### Celebrity Trainer Unveils New Way to Stay Strong For Aging Americans

Sponsored by Powerlife

#### Support American Fishermen With Wild Caught Seafood Delivery

Sponsored by Wild Alaskan Company

#### The Best Way To Wipe Out Up To \$10,000 Of Debt

Sponsored by NerdWallet

#### How To Make Your Dark Spots Fade (Effortless 2 Minute Routine)

Sponsored by Gundry MD

A family bought a 20,000-square-foot Freemason temple in Indiana for \$89,000, and they're now turning it into their home. Take a look inside.

The outbreaks of both the Wuhan coronavirus and SARS started in Chinese wet markets. Photos show what the markets look like.

000809



Don't let Todd Munion answer questions about



BUSINESS  
INSIDER

Subscribe

**This 40-second video shows what it's like inside a Chinese hospital treating the Wuhan virus**

**Top US Doctor: Sugar is not the problem (This Is)**

Sponsored by Gundry MD Metabolic Advanced Supplements

**2 Savings Accounts Your Bank Doesn't Want You To Know About**

Sponsored by MyFinance

**If you wear Birkenstocks, you'll love this trick**

Sponsored by Wikibuy

**Kobe Bryant accused of dozens of affairs in divorce case — here are the women we know about**

**A \$2 million Porsche-designed RV has a full bedroom and bathroom — see inside**

**A 'cave house' blasted into the side of a mountain in Arizona is on the market for just under \$1 million. Here's a look inside.**

**JCPenney is closing 6 stores. See if your local store is on the list.**

**Interior designers reveal the 9 biggest mistakes people make when decorating a bathroom**

**U.S. Cardiologist: It's Like a Pressure Wash for Your Insides**

Sponsored by Gundry MD Total Restore Supplement

000810



Don't let Todd Munion answer questions about



BUSINESS  
INSIDER

000811

#### Top U.S. Vet Warns: The One Meat All Cats Should Avoid

Sponsored by Dr. Marty Nature's Feast for Cats Supplement

#### The most powerful countries on earth in 2020, ranked

#### 5 Grammys that went to the wrong people this year — sorry

#### I live in an RV year-round with my husband and our 2 dogs. Here's exactly what it's like.

#### Finance PhD Explains Stock Market in Two Words

Sponsored by Stansberry Research

#### See Why These Are The Best Incontinence Products On The Market

Sponsored by Because Market

#### Heart Surgeon: Throw Out Your Olive Oil Now (Here's Why)

Sponsored by Gundry MD Olive Oil

#### A terrifying graph shows how fast the Wuhan coronavirus has spread so far and how close it is to becoming a pandemic

#### Meghan Markle's former LA mansion is still looking for a buyer, and the asking price just dropped — here's a look inside

#### 11 things that waste your time and slow your success, according to Mark Cuban, Tony Hawk, and 9 other business leaders



Don't let Todd Munion answer questions about



BUSINESS  
INSIDER

Subscribe

## How To Pay Off Your House ASAP (It's So Simple)

Sponsored by Fetchrate



\* Copyright © 2020 Insider Inc. All rights reserved. Registration on or use of this site constitutes acceptance of our [Terms of Service](#), [Privacy Policy](#) and [Cookies Policy](#).

[Sitemap](#) | [Disclaimer](#) | [Commerce Policy](#) | [CA Privacy Rights](#) | [Coupons](#) | [Made in NYC](#)

Stock quotes by [finanzen.net](#) | [Reprints & Permissions](#)

International Editions:

[INTL](#) | [DE](#) | [AUS](#) | [FR](#) | [IN](#) | [IT](#) | [JP](#) | [MY](#) | [NL](#) | [SE](#) | [PL](#) | [SG](#) | [ZA](#) | [ES](#)

[CA Do Not Sell My Info](#)

# EXHIBIT 8

# EXHIBIT 8

## Sanofi CEO unveils new strategy to drive innovation and growth

- \* Prioritize key growth drivers – Dupixent® (dupilumab) and vaccines
- \* Accelerate R&D focus on six potentially transformative medicines
- \* Improve operating efficiencies to fund growth and expand business operating income margin<sup>1</sup>
- \* Align to support new strategy with three core businesses and a standalone Consumer Healthcare unit

PARIS – DECEMBER 9, 2019 – At Sanofi's Capital Markets Day tomorrow with the financial community, the company will provide details of a new strategic framework with four key priorities to drive innovation and growth. Sanofi will also discuss the alignment of the organization to support this new strategy.

Sanofi Chief Executive Officer Paul Hudson and Executive Committee members will provide a detailed overview of the company's strategy based on four main priorities – focusing the portfolio, leading with science, accelerating efficiency, and reinventing how the company works.

*"Our new strategy positions Sanofi to achieve breakthroughs with our most promising medicines, addressing significant patient needs. We will anchor our efforts in leading-edge science with clearer priorities and a focus on delivering results," said Hudson. "Sanofi gained leadership and changed the practice of medicine in diabetes and cardiovascular diseases. We are now preparing for our next cycle, with a new round of innovative solutions for patients. I'm confident we will achieve long-term growth and value for shareholders while turning innovation into transformative medicines for patients."*

### Focus on growth

- Dupixent® (dupilumab)<sup>2</sup> – Sanofi expects to deliver strong growth for Dupixent with the ambition of achieving more than €10 billion in peak sales driven by its unique mechanism of action targeting the type 2 inflammation pathway.
- Vaccines – Vaccines are expected to deliver a mid-to-high single-digit net sales CAGR from 2018 to 2025, through differentiated products, market expansion and new launches.
- Pipeline – The company has identified and prioritized six potentially transformative therapies.

Additional core drivers include treatments for oncology, hematology, rare diseases, neurology, and Sanofi's strong presence in China.

### Lead with innovation

Sanofi has six potentially practice changing therapies in areas of high unmet patient need. These investigational therapies are listed as follows in order of planned submission timing:

- Fitusiran is an RNAi therapeutic in development for the treatment of hemophilia A and B with or without inhibitors with the potential to provide once-monthly dosing convenience.
- BIVV001<sup>3</sup> is a factor VIII therapy designed to extend protection from bleeds with prophylaxis dosing of once weekly for people with hemophilia A that seek to enjoy a normalized lifestyle.

- Venglustat is an oral therapy in development for several rare diseases in the category of lysosomal storage disorders (Gaucher type 3, Fabry, Tay-Sachs disease, etc.), and also showing promise for more common disorders including autosomal dominant polycystic kidney disease and some sub-types of Parkinson's disease.
- SERD ('859) is a selective estrogen receptor degrader which aims to be the new standard of care in hormone-receptor-positive breast cancer.
- Nirsevimab<sup>4</sup> is a potentially cost-effective prevention against respiratory syncytial virus, with initial focus on protecting infants.
- BTKi ('168)<sup>5</sup> is an oral medicine for multiple sclerosis with potential to be the first disease-modifying therapy to address inflammation and disability drivers in the brain.

The company also announced plans to acquire Synthorx, Inc. which will bolster its immuno-oncology (IO) pipeline with both a proprietary IO platform synergistic with Sanofi's existing therapeutics platforms, and a lead IO candidate (THOR-707) being explored across multiple solid tumor types both alone and in combination with immune checkpoint inhibitors and other future IO combinations. Additional details can be found here: [press release](#)

Sanofi plans to hold a R&D Day in 2020 to provide a detailed review of its R&D portfolio of candidate medicines, strategy, and specifically productivity.

## Accelerate efficiency

Sanofi expects to expand its business operating income (BOI) margin<sup>1</sup> to 30% by 2022, with an ambition for its BOI margin to exceed 32% by 2025. The company is also announcing efficiency initiatives that are expected to generate €2 billion savings by 2022. These savings will fund investment in its key growth drivers and accelerate priority pipeline projects as well as support the expansion of the BOI margin.

The efficiency savings are expected to result primarily from limiting spend on de-prioritized businesses, from smart spending (procurement) initiatives and from operational excellence in manufacturing and organizational productivity. Regarding de-prioritized businesses, Sanofi is announcing a discontinuation of research in diabetes and cardiovascular (DCV) and will not pursue plans to launch efpeglenatide<sup>6</sup>. The company will also optimize the commercial model for DCV and rheumatoid arthritis, including right-sizing the resources deployed behind Praluent<sup>®</sup> (alirocumab)<sup>2</sup> and Kevzara<sup>®</sup> (sarilumab)<sup>2</sup>.

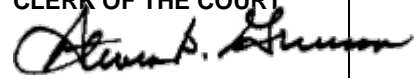
## Reinventing how we work

Sanofi will be structured with three core global business units to support the company's strategy<sup>7</sup> – Specialty Care (immunology, rare diseases, rare blood disorders, neurology and oncology), Vaccines, and General Medicines (diabetes, cardiovascular, and established products). Consumer Healthcare will be a standalone business unit with integrated R&D and manufacturing functions.

*Hudson explained, "Our objective for the Consumer Healthcare business is to unlock value and entrepreneurial energy by growing faster than the market over the mid term. We believe the new standalone structure, coupled with plans to accelerate the over-the-counter switches for Cialis<sup>®</sup> and Tamiflu<sup>®</sup>, will position the business well to accomplish this ambition."*

## Focused capital allocation

Sanofi expects to increase its annual Free Cash Flow by approximately 50% by 2022 compared with an adjusted base of €4.1bn in 2018<sup>8</sup>.



1 **OMCM**

JOHN R. BAILEY

2 Nevada Bar No. 0137

DENNIS L. KENNEDY

3 Nevada Bar No. 1462

SARAH E. HARMON

4 Nevada Bar No. 8106

REBECCA L. CROOKER

5 Nevada Bar No. 15202

**BAILEY ♦ KENNEDY**

6 8984 Spanish Ridge Avenue

Las Vegas, Nevada 89148-1302

7 Telephone: 702.562.8820

Facsimile: 702.562.8821

8 JBailey@BaileyKennedy.com

DKennedy@BaileyKennedy.com

9 SHarmon@BaileyKennedy.com

RCrooker@BaileyKennedy.com

10 *Attorneys for Intervenors*

11 SANOFI-AVENTIS U.S. LLC

12 DISTRICT COURT

13 CLARK COUNTY, NEVADA

14 THE NEVADA INDEPENDENT,

15 Petitioner,

16 vs.

17 RICHARD WHITLEY, in his official capacity as  
18 the Director of the Nevada Department of Health  
and Human Services, and THE STATE OF  
19 NEVADA ex rel. the NEVADA DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

20 Respondents,

21 and

22 SANOFI-AVENTIS U.S. LLC,

23 Intervenor.

Case No. A-19-799939-W  
Dept. No. XIV

**Date of Hearing:** February 4, 2020  
**Time of Hearing:** 1:30 p.m.

24 **SANOFI'S OPPOSITION TO PETITIONER'S**  
25 **MOTION TO COMPEL TESTIMONY OF JAMES BORNEMAN, OR IN THE**  
26 **ALTERNATIVE, TO STRIKE HIS DECLARATION**  
27  
28

**MEMORANDUM OF POINTS AND AUTHORITIES**

The undisputed question before this Court is simple: Does either federal or state law (or both) prohibit Respondents — Richard Whitley and the State of Nevada *ex rel.* the Nevada Department of Health and Human Services (“Respondents”) — from publicly disclosing the confidential information submitted to the Department of Health and Human Services (the “Department”) by Sanofi-Aventis U.S. LLC (“Sanofi”) and other pharmaceutical manufacturers (“Manufacturers”) in their annual reports? In its unauthorized *third* reply brief in support of its Petition for Writ of Mandamus — styled as a so-called “Motion to Compel” (the “Motion”) — Petitioner utterly disregards this question and, instead, introduces legal and factual arguments that were never raised (and, therefore, were waived) in its two prior Replies, and, more importantly, its Writ Petition.<sup>1</sup> Because federal and Nevada law require Respondents to protect the information in the Manufacturers’ annual reports from public disclosure, Petitioner now attempts to distract this Court with *irrelevant and dilatory* challenges to the *undisputed* Borneman Declaration (submitted in support of Sanofi’s Response to the Writ Petition). This is nothing more than a thinly veiled attempt to paint these proceedings into something more sensational than a dispute over a public records request.

It is beyond any reasonable dispute that the Writ Petition — and all subsequent briefs filed by Petitioner — raise, almost exclusively, issues of law. *Petitioner cannot identify to this Court where in its Writ Petition (or any of its other prior submissions) it disputed that the records it seeks from the Department contain trade secrets and would cause the Manufacturers harm if disclosed.* Thus, there is no need for a witness to testify merely to confirm and restate the facts set forth in his wholly uncontested declaration submitted in this action.

Yet now, over three months since submission of the Borneman Declaration (on October 21, 2019), and on the *eve* of the hearing on the Writ Petition, Petitioner raised a series of red herrings revealing its true goal to disparage the pharmaceutical industry to further Petitioner’s agenda as an online newspaper. This Court is not, and cannot be made, a tool to be manipulated for the

---

<sup>1</sup> Petitioner filed its Supplemental Brief in Opposition to Motion to Intervene and Reply to Proposed Response on December 5, 2019, and its Reply to Intervenor’s Response on January 3, 2020.

Petitioner's generation of blog content. Despite Petitioner's attempt to alter the nature of these proceedings, the reality is unchanged: The outcome of this case turns on issues of law, not fact, and as such, this Court should deny Petitioner's Motion and put an end to Petitioner's circus.

## I. STATEMENT OF FACTS

On August 8, 2019, Petitioner filed a Petition for Writ of Mandamus. The only issue raised in the Writ Petition was whether the Department's "Confidentiality Regulations" (NAC 439.735 and NAC 439.740) conflicted with Senate Bill 539 and the NPRA. (Petition, at ¶¶ 65-66.) Thus, Petitioner essentially conceded that the information in the Manufacturers' annual reports submitted to the Department in compliance with Nevada Revised Statute Chapter 439B were confidential and/or trade secrets. Instead, Petitioner chose to assert that the information in the reports was *exempted* from any classification as a trade secret or confidential information. (*Id.* at ¶ 43.)

Petitioner filed a Supplement to its Writ Petition on October 15, 2019. Again, Petitioner failed to raise any issues of fact regarding the classification of the information in the Manufacturers' annual reports as confidential and/or a trade secret. Rather, Petitioner argued that: (1) the Defense Trade Secrets Act ("DTSA") was inapplicable because it allegedly does not preempt state law, create a private right of action, or waive immunity, (Supplement to Petition, at 5:7-7:26); (2) Nevada's trade secret act (NRS 600A.030) allegedly exempted the information in the Manufacturers' annual reports from trade secret protection, (*id.* at 8:1-10:19); and (3) the Department's Confidentiality Regulations were allegedly invalid because they conflicted with Senate Bill 539 and the NPRA, (*id.* at 10:20-12:3). The only factual issue raised in the Supplement to the Writ Petition was whether the government's interest in protecting its records from public disclosure outweighed the public interest in access to government records. (*Id.* at 8:20-10:7.) However, this balancing test is not at issue unless and until the Petitioner can demonstrate the lack of a federal or state statute protecting the information at issue from disclosure. (Suppl. Br. in Opp'n to Mot. to Intervene, at 6:1-4.)

On October 21, 2019, Sanofi moved to intervene in this action. Attached as an exhibit to its moving papers was Sanofi's proposed Response to the Petition for Writ of Mandamus, which included the Borneman Declaration. In Petitioner's *first* Reply to Sanofi's Response to the Writ Petition, filed on December 5, 2019, Petitioner asserted, again, that: (1) the DTSA was not

1 applicable because it allegedly does not preempt state law, (*id.* at 7:11-9:14); (2) Nevada’s trade  
2 secret act allegedly exempted the information in Sanofi’s annual reports to the Department from  
3 trade secret protection, (*id.* at 9:15-10:21); and (3) the Department’s Confidentiality Regulations  
4 were allegedly invalid because they conflicted with the NPRA and Senate Bill 539, (*id.* at 10:22-  
5 12:21.) The only new argument raised by Petitioner was that Sanofi had allegedly waived  
6 confidentiality by voluntarily providing its information to the Department in its reports without any  
7 guarantee of confidentiality. (*Id.* at 13:1-14:19.) Not only is this argument factually inaccurate  
8 because it ignores the Legislature’s participation in drafting and approving the Department’s  
9 Confidentiality Regulations as part of the settlement of the PhRMA action (*see* Sanofi’s Response to  
10 Petition, at 5:17-8:3), but the very nature of this “waiver” argument concedes that the information at  
11 issue has to be confidential or a trade secret to begin with! Petitioner’s concession that the  
12 information in Sanofi’s annual reports is confidential and/or a trade secret is further demonstrated by  
13 Petitioner’s failure to dispute any facts set forth in the Borneman Declaration, including Exhibits 11  
14 and 12 thereto (which comprise Sanofi’s confidentiality statement that accompanied its reports to the  
15 Department pursuant to the Confidentiality Regulations).

16         Petitioner filed a *second* Reply to Sanofi’s Response to the Writ Petition on January 3,  
17 2020. In this second bite at the apple, Petitioner, again, failed to dispute any facts from the  
18 Borneman Declaration, raise any issues of fact regarding Sanofi’s protection of its trade secrets, or  
19 contest the harm Sanofi would suffer from public disclosure of its trade secrets. Rather, Petitioner  
20 restated the same legal arguments it had made in its prior briefs. (Reply to Response to Petition, at  
21 6:14-10:6 (discussing the alleged inapplicability of the DTSA); 10:7-12:1 (discussing the alleged  
22 exemption of the Manufacturers’ annual reports from Nevada’s trade secret act); 12:2-15:15  
23 (discussing the alleged invalidity of the Department’s Confidentiality Regulations); 15:16-17:12  
24 (discussing Sanofi’s alleged waiver of confidentiality by providing the annual reports to the  
25 Department); 17:13-19:7 (discussing the balancing test which is not at issue until the Petitioner can  
26 first meet its burden of proof regarding the lack of federal or state law protecting the records at  
27 issue).

28 ///

1 On December 23, 2019, the Court granted Sanofi’s Motion to Intervene and set a hearing for  
2 the Writ Petition on January 31, 2020. The Court also gave the parties until January 17, 2020, to  
3 disclose any witnesses they wished to present at this hearing. Based on the issues raised in the  
4 Petitioner’s briefs — and the fact that Petitioner did not raise any dispute regarding the content of  
5 the Borneman Declaration — Sanofi’s Disclosure of Witnesses stated that “it currently ***does not***  
6 ***intend to call any affirmative witnesses*** at the January 31, 2020 evidentiary hearing on Petitioner  
7 The Nevada Independent’s Petition for Writ of Mandamus.” (Disclosure of Witnesses, at 1:25-28  
8 (emphasis added).) Sanofi further stated:

9 Inasmuch as the Petition for Writ of Mandamus primarily presents  
10 questions of law (not fact), to the extent that questions of fact must be  
11 resolved, Sanofi intends to rely on the factual evidence set forth in: (1)  
12 the related action, *Pharm. Research & Mfrs. of Am. v. Sandoval*, 2:17-  
13 cv-02315-JCM-CWH, U.S. Dist. Ct. of Nev. (as set forth in Sanofi’s  
14 Response to Petitioner’s Petition for a Writ of Mandamus and in  
15 Exhibits 3 through 8 thereto), of which the Court may take judicial  
16 notice; and (2) the October 17, 2019 Declaration of James Borneman  
17 (Vice President and Head of Diabetes Primary Care Sales for Sanofi  
18 US1), submitted as Exhibit 2 to Sanofi’s Response to Petitioner’s  
19 Petition for a Writ of Mandamus.

20 In the event Mr. Borneman’s assistance would be helpful to the Court  
21 in its decision-making process regarding the Writ Petition, Sanofi  
22 intends to make Mr. Borneman available to the Court at the January  
23 31, 2020 evidentiary hearing.

24 (*Id.* at 2:1-11.) Petitioner ***never objected*** to Sanofi’s notice that it did not intend to call any  
25 witnesses.

26 On January 23, 2020, the Court notified the parties that it needed to continue the hearing and  
27 provided four possible dates on which to reschedule. The only date that all parties were available  
28 was February 4, 2020. However, Mr. Borneman was unavailable on that date. Sanofi informed the  
Court that:

Counsel for Sanofi are available on February 4, 2020, at 1:30 p.m. —  
however, James Borneman, a Sanofi employee who is based in New  
Jersey, is not. Nevertheless, Sanofi would be pleased to proceed on  
February 4th, as Sanofi believes that the issues presented to the Court  
are those requiring the application of law (not fact), and any issues of  
fact have been addressed by Mr. Borneman’s declaration in support of  
Sanofi’s Response to the Writ Petition.

(Ex. 1,<sup>2</sup> at ¶ 3; Ex. 2.<sup>3</sup>) Petitioner *did not dispute* Sanofi's proposal.

On January 28, 2020, Petitioner emailed Sanofi, inquiring whether Mr. Borneman would be participating in the February 4, 2020 hearing by phone. (Ex. 1, at ¶ 4; Ex. 3, at 2.<sup>4</sup>) Consistent with its prior submissions, Sanofi replied that Mr. Borneman would not be testifying and that Sanofi would be relying solely on Mr. Borneman's Declaration. (*Id.*, at ¶ 5; Ex. 3, at 2.)) The following day, Petitioner requested that Sanofi reconsider its position, stating that it had assumed Sanofi would make Mr. Borneman available and would otherwise have utilized a phantom subpoena power to compel Mr. Borneman to travel from New Jersey for the hearing. (*Id.*, at ¶ 6; Ex. 3, at 1-2.)) On January 30, 2020, Sanofi responded:

[Sanofi's] Disclosure of Witnesses explicitly stated that Sanofi did not intend to call any affirmative witnesses at the evidentiary hearing. Sanofi only offered to make Mr. Borneman available to the Court if his assistance would be helpful to the Court in resolving this action.

Mr. Borneman was available to assist the Court at the originally scheduled hearing on January 31st. However, when the Court informed the Parties of the need to continue this hearing, Sanofi informed the Parties that Mr. Borneman was not available on February 4th, but that Sanofi was nevertheless prepared to proceed with the hearing (as the pending motions present issues of law). The Nevada Independent did not object, and the Court did not indicate that it required Mr. Borneman's assistance.

(*Id.*, at ¶ 7; Ex. 3, at 1.) Thirty-four minutes later, Petitioner filed the instant Motion.

## II. ARGUMENT

### A. The Issues Before This Court Are Issues of Law — Not Fact

Petitioner's Writ Petition and subsequent filings almost exclusively raise issues of law. The Court must resolve these issues before the sole issue of fact raised by Petitioner (the balancing test between the public's right of access and the government's need to protect records from disclosure) becomes germane.

---

<sup>2</sup> A true and correct copy of the Declaration of Sarah E. Harmon is attached as Exhibit 1.

<sup>3</sup> A true and correct copy of the January 24, 2020 email chain from Sarah E. Harmon to Diana Powell, Matthew Rashbrook, Robert Langford, Steve Shevovski, Theresa Haar, John R. Bailey, Dennis L. Kennedy, Denise Husted, and Monique Jammer is attached as Exhibit 2. (Ex. 1, at ¶ 3.)

<sup>4</sup> A true and correct copy of the January 30, 2020 email chain from Sarah E. Harmon to Matthew Rashbrook, John R. Bailey, Dennis L. Kennedy, and Robert Langford is attached as Exhibit 3. (Ex. 1, at ¶ 7.)

Specifically, the NPRA specifies that government-generated records are presumed open to the public “unless otherwise declared by law to be confidential.” NRS 239.010. Thus, the threshold question for the Court is whether any law, state or federal, permits the Department to protect the proprietary information in Sanofi’s and the other Manufacturer’s annual reports from public disclosure. *Clark Cty. Sch. Dist. v. Las Vegas Review Journal*, 134 Nev. Adv. Rep. 84, 429 P.3d 313, 317 (2018). Only upon a showing that no such law exists must the Court turn to the next question, which is whether the State’s interest in withholding the records is greater than the public’s interest in disclosure. *Id.* NRS 239.0113. Here, the Court has yet to rule on Petitioner’s objection to the fact that both state and/or federal law — i.e., the DTSA, or SB 539, through NAC 439.735 and 439.740 — protects the records at issue.

Petitioner has never raised an issue as to whether the proprietary information included in Sanofi’s annual reports to the Department is confidential and/or trade secret. Its only arguments have been that the Nevada Legislature exempted the proprietary information from trade secret protection; that the State would not incur any federal liability for the misappropriation of Sanofi’s trade secrets due to immunity and the lack of federal preemption; and the invalidity of the Department’s efforts to protect confidentiality by enacting the Confidentiality Regulations as part of the settlement of the PhRMA litigation. In sum, Petitioner has *conceded that the information at issue is inherently confidential, waived any argument to the contrary*, and has chosen to raise issues of law regarding *exemptions and exceptions* to statutory protections for trade secrets and confidential information.

**B. Sanofi Does Not Bear the Burden of Proof in This Matter**

In a misguided attempt to shift the focus from the issues of law in this action, Petitioner asserts, for the first time, a new and unsupported legal theory that Sanofi, “standing in the place of Respondent, is obligated to prove, by placing competent evidence before this Court, that the records should be held confidential.” (Mot. at 5:23-6:2.) This is a wholly inaccurate misstatement of the law.

When a governmental entity denies a public records request, a Court must *first* consider whether any statutory basis exists to protect the records from disclosure. It is only if the Court finds

no statutory basis that the governmental entity must then demonstrate that the privacy interests at stake outweigh the interests in disclosure. Here, the Court has yet to decide the threshold issue. As the DTSA, NRS 600A, and SB 539, through the creation of NAC 439.735 and 439.740, protect Sanofi's records from disclosure, the inquiry will end once this Court does its analysis.

Additionally, even under the Department's Confidentiality Regulations, Sanofi does not have a burden of proof. NAC 439.735 states that the Manufacturers must make specific showings of confidentiality when submitting their records to the Department. NRS 439.735(1)–(2). After receiving a public records request for the information, the Department decides whether it agrees with the confidentiality determination. NAC 439.735(3). It is only if the Department *disputes* the records' confidentiality that the Manufacturers have a burden to prove the records' confidentiality in a request for injunctive relief. NAC 439.735(6).

Here, the Department agreed that Sanofi's submitted records constituted proprietary and trade secret information. Therefore, it was never Sanofi's burden to go to Court and defend its information. Sanofi chose to do so, out of an abundance of caution, to support the State and ensure that it could provide the Court with answers to any questions it might have. However, Petitioner has raised no issues which would suggest that Sanofi has a burden to meet.

**C. Petitioner's Challenge to the Borneman Declaration Must Be Stricken**

Despite having access to the Borneman Declaration for over three months (since October 21, 2019), Petitioner failed to challenge any facts set forth in the declaration until the eve of the hearing to decide the Writ Petition. As set forth above, Petitioner has filed two Replies to Sanofi's Response to the Petition. Neither Reply disputes the validity or veracity of the Borneman Declaration.

Although Petitioner provides no explanation for its dilatory, eleventh-hour objections, the purpose is obvious. The content of its Motion displays Petitioner's true intent as loudly as a neon sign. Seeing no way to prevail on the legal issues, Petitioner is now trying to distract this Court with a series of indignant accusations that bear no relevance to anything other than to use this Court's scheduled hearing to try and extract fodder for Petitioner's next headline.<sup>5</sup>

<sup>5</sup> See, e.g., Jon Ralston, *As State and Pharma Align, We Will Continue to Pursue Transparency*, THE NEVADA INDEP., Nov. 6, 2019, <https://thenevadaindependent.com/article/as-state-and-pharma-align-we-will-continue-to-pursue-transparency>, attached as Exhibit 4. (See Ex. 1, at ¶ 8.)

1 For example, Petitioner alleges that Mr. Borneman “advances numerous allegations in his  
2 Declaration which are contradicted in whole or in part by publicly available information, giving rise  
3 to serious concerns as to his veracity, and to whether the information discussed . . . could be  
4 considered a trade secret.” (Mot. at 4:25-5:2.) However, Petitioner’s only support for this assertion  
5 is to point to sections of the Borneman Declaration which provide mere background information  
6 about Sanofi as set forth in Sanofi’s website or in other public filings. The fact that the Borneman  
7 Declaration is consistent with other public statements by Sanofi actually undermines Petitioner’s  
8 argument.

9 Petitioner also decrees that Sanofi’s discontinuation of certain research in diabetes is “an area  
10 of the Declaration which at minimum demands an opportunity for the parties to inquire further of  
11 Mr. Borneman.” (*Id.* at 9:20-10:2.) However, as demonstrated by the article upon which the  
12 Petitioner relies, Sanofi’s CEO announced the Company’s new strategic decision almost two months  
13 *after* Mr. Borneman submitted his Declaration.<sup>6</sup> More importantly, Petitioner fails to explain why it  
14 failed to raise this allegedly important issue of fact in its January 3, 2020 Reply to Sanofi’s Response  
15 to the Writ Petition.

16 Petitioner further states that Sanofi’s “galling statements” that its competitors would gain an  
17 unfair advantage should its confidential information be disclosed “demand[s] examination.” (*Id.* at  
18 8:9-14.) Yet, Petitioner never challenged Sanofi’s claims of competitive harm after the October  
19 2019 submission of the Borneman Declaration and cannot do so now. Petitioner chose not to contest  
20 the Borneman Declaration or dispute any facts set forth in the Declaration. Instead, Petitioner  
21 simply argued that as a newspaper, the weight of its interest in publishing Sanofi’s confidential  
22 information should somehow control. Now, after both the State and Sanofi have expressed that they  
23 do not intend to call any witnesses for the evidentiary hearing to address the issues of law, which are  
24 the only questions in dispute in this case, Petitioner raises this dilatory challenge to the Borneman  
25 Declaration in a scramble to create media hype and distract from the actual issues before this Court.

26 ///

27 \_\_\_\_\_  
28 <sup>6</sup> Mr. Borneman, while a valuable Sanofi employee, is not a prophet and, as such, cannot be expected to predict changes in the company’s direction.

Petitioner’s opportunity to raise these issues has long passed, and these arguments should be stricken from the record. This is particularly true given that Petitioner’s alleged objections to the Borneman Declaration are completely irrelevant to the legal issue before this Court.

**III. CONCLUSION**

The law is clear: All owners of trade secrets are entitled to the same protection — non-public disclosure of such trade secrets. Whether owners manufacture pharmaceutical products or Coca-Cola, it makes no difference. Petitioner seems to argue that Sanofi’s status as a pharmaceutical company automatically entitles it to less protection for its proprietary information, but such notion is patently false. Both federal and Nevada law protect the information/records Petitioner desperately seeks to make public, and Petitioner’s attempts to sensationalize the proceedings will not alter reality.

For these reasons, Sanofi respectfully requests that the Court deny the Motion.

DATED this 3rd day of February, 2020.

BAILEY ♦ KENNEDY

By: /s/ John R. Bailey  
JOHN R. BAILEY  
DENNIS L. KENNEDY  
SARAH E. HARMON  
REBECCA L. CROOKER

*Attorneys for Intervenor*  
SANOFI-AVENTIS U.S. LLC

**CERTIFICATE OF SERVICE**

I certify that I am an employee of BAILEY❖KENNEDY and that on the 3rd day of February, 2020, service of the foregoing **SANOFI’S OPPOSITION TO PETITIONER’S MOTION TO COMPEL TESTIMONY OF JAMES BORNEMAN, OR IN THE ALTERNATIVE, TO STRIKE HIS DECLARATION** was made by mandatory electronic service through the Eighth Judicial District Court’s electronic filing system and/or by depositing a true and correct copy in the U.S. Mail, first class postage prepaid, and addressed to the following at their last known address:

MATTHEW J. RASHBROOK ROBERT L. LANGFORD <b>ROBERT L. LANGFORD &amp; ASSOCIATES</b> 616 South Eighth Street Las Vegas, Nevada 89101	Email: matt@robertlangford.com robert@robertlangford.com  <i>Attorneys for Petitioner</i> <b>THE NEVADA INDEPENDENT</b>
--	---

AARON D. FORD ATTORNEY GENERAL STEVE SHEVORSKI CHIEF LITIGATION COUNSEL <b>OFFICE OF NEVADA ATTORNEY GENERAL</b> 555 East Washington Avenue, Suite 3900 Las Vegas, Nevada 89101	Email: sshevorski@ag.nv.gov  <i>Attorneys for Respondents</i> <b>RICHARD WHITLEY</b> , in his official capacity as the Director of the Nevada Department of Health and Human Services, and <b>THE STATE OF NEVADA</b> , ex rel. the <b>NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES</b>
---	--

/s/ Josephine Baltazar  
Employee of BAILEY❖KENNEDY

# EXHIBIT 1

**DECLARATION OF SARAH E. HARMON IN SUPPORT OF SANOFI'S OPPOSITION TO  
PETITIONER'S MOTION TO COMPEL TESTIMONY OF JAMES BORNEMAN, OR IN  
THE ALTERNATIVE, TO STRIKE HIS DECLARATION**

I, Sarah E. Harmon, hereby declare as follows:

1. I am an attorney licensed to practice law in the State of Nevada, and I am a partner of the law firm Bailey ♦ Kennedy, attorneys for Intervenor Sanofi-Aventis U.S. LLC ("Sanofi") in *The Nevada Independent v. Whitley*, No. A-19-799939-W.

2. I have personal knowledge of the facts stated in this declaration unless stated upon information and belief.

3. On January 24, 2020, at 12:07 p.m., I sent an email to Diana Powell, Matthew Rashbrook, Robert Langford, Steve Shevorski, Theresa Haar, John R. Bailey, Dennis L. Kennedy, Denise Husted, and Monique Jammer regarding Sanofi's availability for a continued hearing on Petitioner's Petition for Writ of Mandamus. A true and correct copy of this email chain is attached as Exhibit 2.

4. On January 28, 2020, at 2:52 p.m. I received an email from Matthew Rashbrook, counsel for Petitioner, inquiring whether James Borneman, a Sanofi employee, would be participating by phone in the February 4, 2020 hearing on the Petition for Writ of Mandamus.

5. At 6:29 p.m. that evening, I responded that Mr. Borneman would not be testifying at the hearing and that Sanofi would be relying upon his previously submitted Declaration.

6. The next day, at 4:08 p.m., Mr. Rashbrook sent me an email requesting that I reconsider this position. Mr. Rashbrook stated that Petitioner had assumed Sanofi would make Mr. Borneman available to testify at the hearing and had foregone issuing a subpoena to compel his attendance at the hearing.

7. On January 30, 2020, at 1:43 p.m., I sent an email to Matthew Rashbrook, John R. Bailey, Dennis L. Kennedy, and Robert Langford reiterating the basis for Sanofi's position and confirming that its position remained unchanged. A true and correct copy of this e-mail chain is attached as Exhibit 3.

8. On February 3, 2020, I visited the website of the Nevada Independent and printed a copy of the November 6, 2019 article written by Jon Ralston about this action, titled, *As State and*

1 *Pharma Align, We Will Continue to Pursue Transparency.* The website can be found at  
2 <https://thenevadaindependent.com/article/as-state-and-pharma-align-we-will-continue-to-pursue->  
3 transparency. A true and correct copy of this article, as downloaded, is attached as Exhibit 4.

4 I declare under penalty of perjury under the laws of the State of Nevada that the foregoing is  
5 true and correct.

6 DATED this 3<sup>rd</sup> day of February, 2020.

7   
8 SARAH E. HARMON  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT 2

## Sarah Harmon

---

**From:** Sarah Harmon  
**Sent:** Friday, January 24, 2020 12:07 PM  
**To:** 'Powell, Diana'; Matt@Robertlangford.com;  
'robert@robertlangford.com'; 'sshevorski@ag.nv.gov';  
'thaar@ag.nv.gov'; John Bailey; Dennis Kennedy  
**Cc:** Husted, Denise; Jammer, Monique  
**Subject:** RE: A79939; Nevada Independent v Richard Whitley -Hearing Date Change

Hi Diana –

Counsel for Sanofi are available on February 4, 2020, at 1:30 p.m. – however, James Borneman, a Sanofi employee who is based in New Jersey, is not. Nevertheless, Sanofi would be pleased to proceed on February 4th, as Sanofi believes that the issues presented to the Court are those requiring the application of law (not fact), and any issues of fact have been addressed by Mr. Borneman's declaration in support of Sanofi's Response to the Writ Petition.

Thank you,  
Sarah Harmon

**Sarah E. Harmon**  
Bailey ♦ Kennedy  
8984 Spanish Ridge Avenue  
Las Vegas, NV 89148-1302  
(702) 562-8820 (Main)  
(702) 562-8821 (Fax)  
**(702) 853-0757 (Direct)**  
[SHarmon@baileykennedy.com](mailto:SHarmon@baileykennedy.com)

This e-mail message is a confidential communication from Bailey Kennedy, LLP, and is intended only for the named recipient(s) above and may contain information that is a trade secret, proprietary, privileged or attorney work product. If you have received this message in error, or are not the named or intended recipient(s), please immediately notify the sender at 702-562-8820 and delete this e-mail message and any attachments from your workstation or network mail system

---

**From:** Powell, Diana [mailto:PowellD@clarkcountycourts.us]  
**Sent:** Thursday, January 23, 2020 3:43 PM  
**To:** Matt@Robertlangford.com; 'robert@robertlangford.com' <robert@robertlangford.com>; 'sshevorski@ag.nv.gov' <sshevorski@ag.nv.gov>; 'thaar@ag.nv.gov' <thaar@ag.nv.gov>; John Bailey <JBailey@baileykennedy.com>; Dennis Kennedy <DKennedy@baileykennedy.com>; Sarah Harmon <SHarmon@baileykennedy.com>  
**Cc:** Husted, Denise <HustedD@clarkcountycourts.us>; Jammer, Monique

<Dept14LC@clarkcountycourts.us>

**Subject:** A79939; Nevada Independent v Richard Whitley -Hearing Date Change

Hello Everyone,

We hope you are doing well. Please note that the Court needs to continue the hearing currently scheduled for January 31, 2020 at 9:30 a.m. Please respond and confirm which of the following dates and times would work best for you. If you do not have any restrictions, please let us know that, as well.

- Monday, February 3, 2020 at 1:30 pm
- Tuesday, February 4, 2020 at 1:30 pm
- Wednesday, February 5, 2020 at 1:30 pm
- Thursday, February 6, 2020 at 1:30 pm

Your prompt reply is greatly appreciated. Thank you.

Diana D. Powell  
Judicial Executive Assistant to  
The Honorable Judge Adriana Escobar  
Department 14  
200 Lewis Avenue  
Las Vegas, Nevada 89155  
Direct: 702.671.4419  
Facsimile: 702.671.4418

# EXHIBIT 3

**Sarah Harmon**

---

**From:** Sarah Harmon  
**Sent:** Thursday, January 30, 2020 1:43 PM  
**To:** 'matt@robertlangford.com'  
**Cc:** John Bailey; Dennis Kennedy; Robert Langford  
**Subject:** RE: Nevada Independent v. Whitley et al. - A-19-799939-W

Matthew –

As you will recall, Sanofi's January 17, 2020 Disclosure of Witnesses explicitly stated that Sanofi did not intend to call any affirmative witnesses at the evidentiary hearing. Sanofi only offered to make Mr. Borneman available to the Court if his assistance would be helpful to the Court in resolving this action.

Mr. Borneman was available to assist the Court at the originally scheduled hearing on January 31st. However, when the Court informed the Parties of the need to continue this hearing, Sanofi informed the Parties that Mr. Borneman was not available on February 4th, but that Sanofi was nevertheless prepared to proceed with the hearing (as the pending motions present issues of law). The Nevada Independent did not object, and the Court did not indicate that it required Mr. Borneman's assistance.

Therefore, at this point in time, our position remains unchanged.

Thank you,  
Sarah

**Sarah E. Harmon**  
Bailey ♦ Kennedy  
8984 Spanish Ridge Avenue  
Las Vegas, NV 89148-1302  
(702) 562-8820 (Main)  
(702) 562-8821 (Fax)  
**(702) 853-0757 (Direct)**  
[Sharmon@baileykennedy.com](mailto:Sharmon@baileykennedy.com)

This e-mail message is a confidential communication from Bailey Kennedy, LLP, and is intended only for the named recipient(s) above and may contain information that is a trade secret, proprietary, privileged or attorney work product. If you have received this message in error, or are not the named or intended recipient(s), please immediately notify the sender at 702-562-8820 and delete this e-mail message and any attachments from your workstation or network mail system

**From:** Matthew Rashbrook [mailto:mattthew.rashbrook@gmail.com]  
**Sent:** Wednesday, January 29, 2020 4:08 PM  
**To:** Sarah Harmon <SHarmon@baileykennedy.com>  
**Cc:** John Bailey <JBailey@baileykennedy.com>; Dennis Kennedy <DKennedy@baileykennedy.com>; Robert Langford <robert@robertlangford.com>  
**Subject:** Re: Nevada Independent v. Whitley et al. - A-19-799939-W

Sarah,

As you likely recall, the Court's December 23rd, 2019 Order granting intervention solicited witness lists from the parties. Thereafter, Mr. Borneman was timely noticed as a witness by our client, and it was only in reliance upon your client's representation that he would be made available at the hearing of the Petition that our client did not seek, domesticate, and serve a subpoena on Mr. Borneman to secure his attendance and testimony.

Would your client reconsider its position regarding Mr. Borneman's attendance and testimony, in light of the foregoing? If not, our client will be forced to seek its remedy from the Court, and attorney's fees and costs therewith.

Please let me know your thoughts.

On Tue, Jan 28, 2020 at 6:29 PM Sarah Harmon <[SHarmon@baileykennedy.com](mailto:SHarmon@baileykennedy.com)> wrote:

Hi Matthew -

Mr. Borneman will not be testifying on Feb. 4th. We intend to rely on his declaration (which was previously submitted).

Thank you,  
Sarah

Sent from my iPhone

On Jan 28, 2020, at 2:52 PM, Matthew Rashbrook  
<[matthew.rashbrook@gmail.com](mailto:matthew.rashbrook@gmail.com)> wrote:

Good afternoon all,

I am writing to inquire as to whether you plan to make James Borneman available in person or, in light of the recent email from Ms. Jammer - Judge Escobar's law clerk - whether you intend to have him available to testify via Court Call at the February 4 hearing of the above-noted matter?

All the best,

--

Matthew J. Rashbrook

Robert L. Langford & Associates

616 S. 8th St.  
Las Vegas, NV 89101  
Tel: (702) 471-6565  
Fax: (702) 991-4223

**\*\* DO NOT PRODUCE A COPY OF THIS EMAIL IN DISCOVERY \*\*** If you're a client, the attorney-client privilege protects this email. If you're a lawyer working with us under a joint-defense arrangement, this email is privileged under that arrangement. If you've received this email by mistake, we'd appreciate it if you would reply to let us know, and then delete the email. We don't waive any client's privilege by misdelivered email.

--

Matthew J. Rashbrook

Robert L. Langford & Associates  
616 S. 8th St.  
Las Vegas, NV 89101  
Tel: (702) 471-6565  
Fax: (702) 991-4223

**\*\* DO NOT PRODUCE A COPY OF THIS EMAIL IN DISCOVERY \*\*** If you're a client, the attorney-client privilege protects this email. If you're a lawyer working with us under a joint-defense arrangement, this email is privileged under that arrangement. If you've received this email by mistake, we'd appreciate it if you would reply to let us know, and then delete the email. We don't waive any client's privilege by misdelivered email.

# **EXHIBIT 4**

## AS STATE AND PHARMA ALIGN, WE WILL CONTINUE TO PURSUE TRANSPARENCY



JON RALSTON

NOVEMBER 6TH, 2019 - 9:25AM

When we filed suit against the State of Nevada to enforce a drug transparency law passed by the Legislature in 2017, we knew our fight was not just with Carson City.

We knew at some point that those with the most to lose – the pharmaceutical companies – would try to intervene and protect how they price their products from public view. That has now come to pass, and I want our readers to know we are in this for the long haul.

Sanofi, one of the world's largest drug companies, filed a motion last month to intervene in our lawsuit, which seeks to compel the state to do what the law was intended to do: Make public annual disclosure filings from companies to the state – in this case, diabetes drug producers.

The state has denied these are public records, a move that subverts the intent of the law. Judge Adriana Escobar has delayed a hearing after briefs were filed about three weeks ago by *The Indy* and Attorney General Aaron Ford, who in his filing argued against the intent of a bill he once wholeheartedly supported as a state senator.

Enter Sanofi.

Through its local counsel, Bailey-Kennedy, the company, which is one of the three major insulin manufacturers in the country, filed a motion to intervene in the case at about the time the judge delayed the hearing. But this lawsuit, filed after we were snubbed in our attempt to obtain public records, is between us and the state. So we opposed Sanofi's motion.

(There was a hearing on Sanofi's motion Tuesday, and Escobar is expected to issue a written order.)

Here is the key sentence from our filing:

"The Respondents (the state) have throughout aligned themselves tightly with Sanofi and other pharmaceutical manufacturers and pharmacy benefit managers, and have now filed (a) briefing indicating they will continue to do the same."

And we conclude with what our ultimate challenge is in this case, and why we are so thankful for our pro bono lawyer Matthew Rashbrook:

"Petitioners in (public records) cases are almost universally opposed by government agencies with effectively limitless resources, as *The Nevada Independent* is here. Sanofi, proposing to intervene, concedes that their interests are already adequately represented by the government's limitless resources, but still proposes to bring its own limitless resources to bear, and asks the Court to ignore the extensive prejudice Petitioner has already and will no doubt continue to suffer."

That is, "L'état, c'est Pharma."

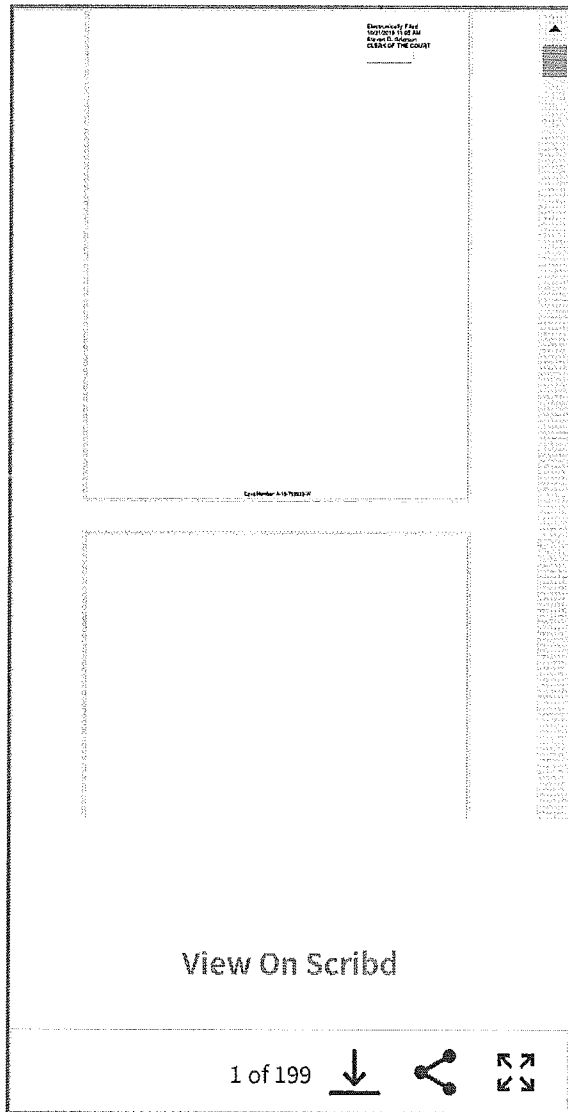
So be it.

We will continue to move forward in what we consider an important effort to ensure the state and Pharma do not subvert the intent of a landmark law.

Sanofi motion to intervene by Jon Ralston on Scribd

2/3/2020

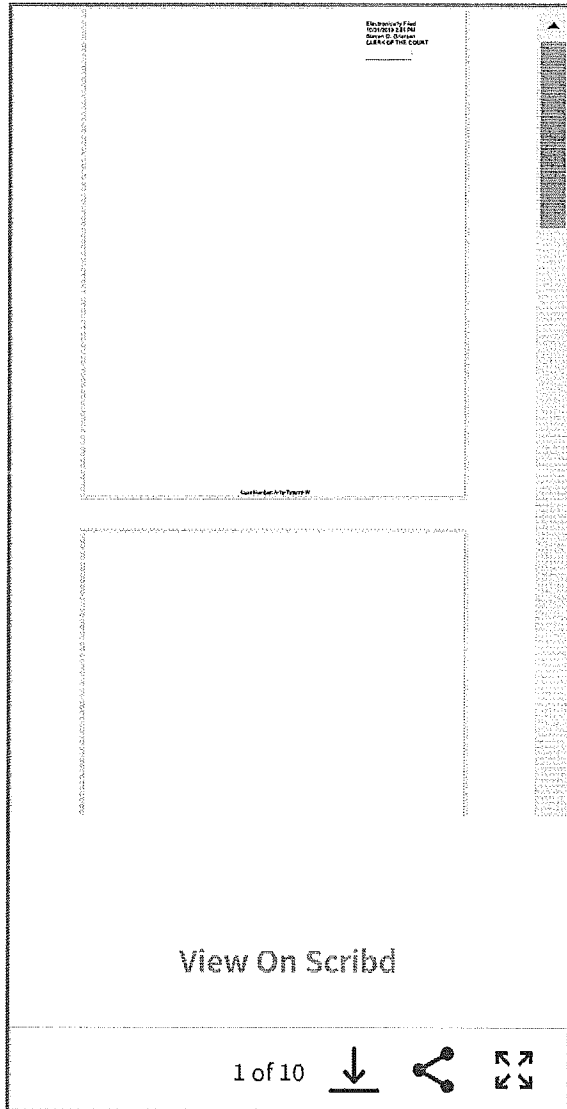
As state and Pharma align, we will continue to pursue transparency



Nevada Independent opposition by Jon Ralston on Scribd

2/3/2020

As state and Pharma align, we will continue to pursue transparency

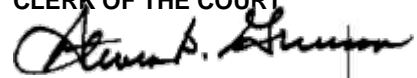


[Privacy Policy](#) [RSS](#) [Contact](#) [Support Our Work](#)

7455 Arroyo Crossing Pkwy Suite 220  
Las Vegas, NV 89113

The Nevada Independent is a project of: Nevada News Bureau, Inc.  
| Federal Tax ID 27-3192716

© 2020 THE NEVADA INDEPENDENT



TRAN

DISTRICT COURT  
CLARK COUNTY, NEVADA  
\* \* \* \* \*

NEVADA INDEPENDENT,	)	CASE NO. A-19-799939-W
	)	
Plaintiff,	)	DEPT NO. XIV
	)	
vs.	)	
	)	
RICHARD WHITLEY, et al,	)	
	)	
Defendants.	)	<b>Transcript of</b>
	)	<b>Proceedings</b>

BEFORE THE HONORABLE ADRIANA ESCOBAR, DISTRICT COURT JUDGE

**PETITION FOR WRIT OF MANDAMUS  
MOTION TO COMPEL TESTIMONY OF JAMES BORNEMAN, OR IN THE  
ALTERNATIVE, TO STRIKE HIS DECLARATION**

TUESDAY, FEBRUARY 4, 2020

APPEARANCES:

FOR THE PLAINTIFF: MATTHEW J. RASHBROOK, ESQ.

FOR THE DEFENDANTS: STEVEN G. SHEVORSKI, ESQ.

FOR THE INTERVENOR: JOHN R. BAILEY, ESQ.  
SARAH E. HARMON, ESQ.  
REBECCA L. CROOKER, ESQ.

RECORDED BY: SANDRA ANDERSON, COURT RECORDER  
TRANSCRIBED BY: JULIE POTTER, TRANSCRIBER

1        LAS VEGAS, NEVADA, TUESDAY, FEBRUARY 4, 2020, 1:44 P.M.

2                    (Court was called to order)

3            THE COURT:    Good afternoon.    Okay.    I'm just going to  
4 call the case.    It's the Nevada Independent versus Richard  
5 Whitley.    Your appearances for the record.

6            MR. RASHBROOK:    Good afternoon, Your Honor.    Matthew  
7 Rashbrook on behalf of the petitioner, the Nevada Independent.

8            THE COURT:    Good afternoon.

9            MR. BAILEY:    Good afternoon, Your Honor.    On behalf --  
10 John Bailey from Bailey Kennedy, along with Sarah Harmon and  
11 Rebecca Crooker on behalf of Sanofi.

12           THE COURT:    Okay.    Good afternoon.

13           MR. SHEVORSKI:    Good afternoon, Your Honor.    Steve  
14 Shevorski of the Attorney General's Office on behalf of the  
15 State.

16           THE COURT:    Very nice to see you all.    Thank you.  
17 Please be seated.    Okay.    This is the petitioner's motion to  
18 compel.    Please go ahead.    I've reviewed your filing and I'd  
19 like to hear from you.

20           MR. RASHBROOK:    Good afternoon, Your Honor.    Under the  
21 Eighth Judicial District Rules and under the Rules of Civil  
22 Procedure there's requirement standards that affidavits of  
23 declarations must meet to be admissible to be considered  
24 relevant to be referred to in a case such as this.

25           The Eighth Judicial Rules require that an affidavit

1 must contain only factual evidentiary matter and has to avoid  
2 making general conclusions or arguments and refers also -- the  
3 rule also refers to Rule 56(e) which deals with summary judgment  
4 motions, and there's a few further requirements there regarding  
5 factual assertions have to be supported.

6           And Rule 56 also indicates that the Court is entitled  
7 to make any order it deems necessary if those requirements are  
8 not met. And under the Eighth Judicial District Rule, the --  
9 the rule indicates that an affidavit which is substantially  
10 defective, the Court may strike whole or in part in that case.

11           I'd like to refer to three sort of primary areas of  
12 concern, and these are outlined in the motion, and there's a few  
13 others that are referred to in the motion. But primarily I  
14 think the largest problems exist with, I believe, paragraphs 20  
15 to 23 of the declaration of Mr. Borneman. There's a couple of  
16 problems with these specific paragraphs.

17           First of all, they are argument, and as such they are  
18 not appropriate matter to be considered in a declaration or an  
19 affidavit. Mr. Borneman outlines his belief in these paragraphs  
20 that should the Court rule in favor of the petitioner and order  
21 that these records be turned over, that one of the possible  
22 outcomes that follows that is that Sanofi will choose later not  
23 to continue to put money and resources into research and  
24 development in the area of diabetes research, and that flowing  
25 from that is the potential consequence that diabetes sufferers,

1 patients, will not benefit from future advances in the area of  
2 these drugs.

3           This is, on its face, a policy argument. It's a  
4 policy argument frequently advanced by Sanofi and others in the  
5 business to auger against further laws, whether they be price  
6 caps at the federal level, whether they be transparency laws,  
7 such as this one, but essentially make the general argument if  
8 you restrict our behavior in this area, one of the perhaps  
9 unintended consequences that flows from that is reduced research  
10 on our part in this area.

11           That is, at its core, that's a policy argument. It is  
12 a -- it's a hypothetical, really. And so because it is an  
13 argument, because it's policy, it is by definition not  
14 appropriate matter for a declaration for an affidavit.

15           The second problem there is it turns out that this  
16 position is entirely undermined by this recent press release  
17 from the parent -- the parent -- the Paris-based Sanofi where  
18 their CEO outlines a vision for the coming years. And one of  
19 the pieces of information critically that's revealed in that  
20 view of the future is that there will be no more diabetes  
21 research.

22           And so there's -- there are these -- these two  
23 reasons, either of which, frankly, demands that these paragraphs  
24 at minimum be struck from the affidavit, or alternatively that  
25 Mr. Borneman be present, whether in person or by phone, but

1 present to answer questions in this regard because these  
2 paragraphs, when compared with the press release, I think it's  
3 very significant questions to be asked.

4           And the Nevada Supreme Court has been very clear in  
5 this area that hypothetical concerns are not enough to -- to  
6 require that records not be disclosed. The consequences have to  
7 be real. They have to be determinative. They have to be  
8 substantial, right. They have to be actual, not dreamt up. And  
9 what these paragraphs refer to is a hypothetical scenario, which  
10 is, I would say, totally undermined by this press release from  
11 the parent company.

12           The next area that I'd like to look at is paragraph 12  
13 and 13 of the declaration, and these are essentially paragraphs  
14 in which Mr. Borneman asserts that -- that the material we're  
15 discussing here are trade secrets, that it -- that it meets the  
16 definition of what is a trade secret. And the point that I  
17 think we really need to look at here is that these are totally  
18 unsupported assertions.

19           And in filings, Sanofi has repeatedly stated that they  
20 will not put any more evidence before the Court. There was --  
21 there was a minute order from the Court in which the Court asked  
22 Sanofi to describe what further evidence they may offer if  
23 allowed to intervene. The response to that was none, frankly.

24           Sanofi has indicated subsequently in witness lists  
25 that it will not call any affirmative witnesses, that it

1 believes there are strictly questions of law or that to whatever  
2 extent there are any questions of fact, those are answered by  
3 the declaration. So I think this -- these paragraphs very  
4 clearly are filled with generalizations with unsupported  
5 allegations of fact, and that does not satisfy either Rule 2.21  
6 or Civil Procedure Rule 56.

7           Further, these paragraphs are alleging, essentially,  
8 that to whatever extent Sanofi is required to reveal the thought  
9 processes, the factors they consider in making determinations  
10 about price, that is critical private information from which  
11 they derive an economic advantage.

12           And I think there is ample evidence to the contrary  
13 when we look at the -- the prices of competitor insulins. And  
14 I'm referring to our motion, page 9. There's a chart. The  
15 article that the chart comes from is an exhibit to the motion.  
16 There is another chart very similar.

17           THE COURT: Which exhibit?

18           MR. RASHBROOK: Pardon me?

19           THE COURT: I have them tabbed, but I can't remember  
20 which exhibit it is.

21           MR. RASHBROOK: That is Exhibit 7.

22           THE COURT: 7. Thank you.

23           MR. RASHBROOK: And the chart that I'm referring to is  
24 at page 9 of our motion.

25           THE COURT: Right.

1 MR. RASHBROOK: I think it's --

2 THE COURT: I have it here.

3 MR. RASHBROOK: Okay.

4 THE COURT: I have both. Okay.

5 MR. RASHBROOK: The reason that I reproduced that  
6 chart in color is because when I printed it in gray, when I  
7 printed it in black and white, it's virtually impossible for  
8 portions of this graph that represent years, it is virtually  
9 impossible to tell in black and white whether there are actually  
10 two lines on the graph. The prices of these competitor products  
11 are pegged so closely to each other.

12 And representatives from Novo, from Eli, from -- from  
13 Sanofi have made public statements to the effect of, yes, we  
14 absolutely look at the pricing of our competitors, and, yes, we  
15 consider that in making our pricing decisions.

16 The suggestion, therefore, that Mr. Borneman makes,  
17 that there is this extraordinary value to this information that  
18 he claims is proprietary I think is significantly undermined,  
19 perhaps entirely undermined by these charts which indicate that  
20 the reality is they just look at each other's price. If one of  
21 them makes a price increase, the others move to match it. I  
22 mean, we're talking about a period, a practice, a pattern of  
23 behavior over the course of decades.

24 And when we look at these -- these insulin products,  
25 Lantus and Levemir are the two that are referred to in this

1 chart, and this chart covers a period of about 15 years. These  
2 are products that have gone from a price in the sort of, you  
3 know, \$30 to \$40 range to now approaching the high 200s, let's  
4 say. And when we look at the list prices, we don't see prices  
5 that are close. We see prices like \$264.71 for these competitor  
6 products.

7 I think it's very difficult to believe that there is a  
8 competitive advantage and that miraculously they come out the  
9 same price to the penny. I think the reality which -- which  
10 these charts give light to is that this is an extremely  
11 competitive business that -- and this is an argument that we  
12 refer to in our -- in our response that essentially there is no  
13 advantage to be had here.

14 These companies are -- these are tens of billions of  
15 dollars worth of companies on either side of the equation. They  
16 employ tens of thousands, or perhaps hundreds of thousands of  
17 people globally. They have, without much exaggeration, an army  
18 of very smart people trying to figure out the accurate price.  
19 It is incredibly unlikely.

20 There is no -- you know, I refer in some of our other  
21 papers to the secret recipe for Coke, you know, the herbs and  
22 spices that go into the Colonel's chicken. We're not talking  
23 about that sort of situation here. And the evidence indicates  
24 that there is no advantage. These -- these prices are pegged to  
25 each other.

1           The next area that I want to discuss is the opening  
2 paragraphs of the declaration. And I think the -- the  
3 declaration and the exhibits sort of speak for themselves. I  
4 mean, these are very obviously not the words of Mr. Borneman.  
5 These are lifted sentence by sentence and paragraph by --

6           THE COURT: Let's go to paragraph 1. So before -- and  
7 then I want to hear the reset of it, but I --

8           MR. RASHBROOK: Sure.

9           THE COURT: It did sound like a person who has held  
10 this type of -- he's played this type of role in this company or  
11 any other company.

12          MR. RASHBROOK: Certainly appears to be.

13          THE COURT: Probably has -- well, he says here,  
14 insights or information that -- I mean, let's just step away  
15 from it for a moment. There would be possibly trade secrets.  
16 Possibly. All right. I'm here completely fair and --

17          MR. RASHBROOK: No, I --

18          THE COURT: -- ready to hear --

19          MR. RASHBROOK: Sure.

20          THE COURT: -- but this first one strikes me as  
21 someone who could have a lot of information that --

22          MR. RASHBROOK: I agree.

23          THE COURT: Right?

24          MR. RASHBROOK: Certainly that's part of -- that's a  
25 large part of why we'd like to call him.

1 THE COURT: Okay. Well, okay, that's another issue.

2 MR. RASHBROOK: Sure.

3 THE COURT: But, I mean --

4 MR. RASHBROOK: No, I really don't quarrel with the  
5 first paragraph at all. I take Mr. Borneman's declaration at  
6 face value --

7 THE COURT: Right.

8 MR. RASHBROOK: -- as to the first paragraph.

9 THE COURT: Okay. I just wanted to make sure we  
10 talked about that because I think that's important.

11 MR. RASHBROOK: I agree.

12 THE COURT: Okay. Go on.

13 MR. RASHBROOK: No, I don't -- no objection, really,  
14 to the first paragraph.

15 THE COURT: Go on.

16 MR. RASHBROOK: The second, third, and fourth  
17 paragraphs, though, are really lifted whole cloth from other  
18 sources. They're submitted and these are from Sanofi's  
19 websites. They're in job postings. They're --

20 THE COURT: I saw them in your exhibits, but please  
21 make a record.

22 MR. RASHBROOK: At one point they're -- they're  
23 submitted as a written testimony of another Sanofi employee.

24 THE COURT: Yes, I saw that, too.

25 MR. RASHBROOK: And so I just sort of -- you know, I

1 think that really kind of gives rise to the question of whether  
2 the declaration can be taken at face value, or whether it  
3 deserves further inquiry. And when we talk about further  
4 inquiry, we're getting at sort of bedrock principles of our  
5 system of law. We operate in an adversarial system. One of the  
6 virtues of the adversarial system is that the opposing parties  
7 test each other's evidence. That's how we find the truth.

8           This is what Justice Scalia in Crawford sort of  
9 famously calls it the crucible of cross-examination, that this  
10 is the paramount way of testing evidence. This is how we make  
11 sure that evidence is reliable and that the decisions that flow  
12 from that evidence are, therefore, themselves reliable. So if  
13 the evidence is not tested, we're prone to end up with evidence  
14 that is not reliable. And results, therefore, that are not  
15 reliable flow from -- from those types of evidence.

16           I'd like to refer for -- for a moment to some of the  
17 suggestions, arguments in Sanofi's brief and opposition.

18           THE COURT: Do you have any other -- I thought you  
19 highlighted some other paragraphs in your --

20           MR. RASHBROOK: I have, Your Honor, but I'm happy with  
21 the briefing on those --

22           THE COURT: Okay.

23           MR. RASHBROOK: -- unless Your Honor --

24           THE COURT: Very good.

25           MR. RASHBROOK: -- wants something specifically.

1 THE COURT: No, I just wanted to give you the  
2 opportunity.

3 MR. RASHBROOK: I appreciate that. Sanofi suggests  
4 sort of a two-pronged argument that on the one hand the  
5 Independent seeks to delay these proceedings. Nothing could be  
6 further from the truth. The Independent has a vested interest  
7 in getting a resolution to these proceedings as quickly as  
8 possible.

9 I mean, a very straightforward way to figure that out  
10 is that the status quo is very bad for us. We're here to try to  
11 get the access to the records. And to the extent that the case  
12 is delayed, we're stuck with the status quo.

13 THE COURT: Right. I did have a question because I  
14 don't remember where I read it but that -- and it may have been  
15 -- it may have been the respondent, but is it correct that  
16 you've had this -- this has been available since December 23,  
17 2019, Mr. Borneman's -- I can't remember all the dates, but --

18 MR. RASHBROOK: Yeah, so December 23rd is the date  
19 that the Court issues the order --

20 THE COURT: Right.

21 MR. RASHBROOK: -- granting Sanofi's motion to  
22 intervene. Yeah.

23 THE COURT: Okay.

24 MR. RASHBROOK: That's correct.

25 THE COURT: Is there a reason why -- why this has

1 taken awhile?

2 MR. RASHBROOK: Well, in the same order the Court  
3 invited witness lists.

4 THE COURT: Correct.

5 MR. RASHBROOK: We noticed Mr. Borneman as a witness  
6 on the 17th.

7 THE COURT: I see.

8 MR. RASHBROOK: And so when Sanofi represents in their  
9 declaration -- I'm sorry, I can't remember if it was styled  
10 declaration, but their corresponding submission.

11 THE COURT: Yes. Yes.

12 MR. RASHBROOK: That they would make him available on  
13 that date.

14 THE COURT: Right.

15 MR. RASHBROOK: And so we relied on that  
16 representation, that Mr. Borneman would be available.  
17 Subsequently, the Court needs to continue the hearing, we confer  
18 over dates that are --

19 THE COURT: I tried to make it as soon as possible.  
20 I'm sorry.

21 MR. RASHBROOK: No, we do appreciate that. And so one  
22 of the things that comes out of that is that there's this  
23 exchange of emails and that goes on between the -- the judicial  
24 executive assistant in Your Honor's chambers and counsel and a  
25 date is --

1 THE COURT: All counsel; right?

2 MR. RASHBROOK: Yes.

3 THE COURT: Okay.

4 MR. RASHBROOK: I certainly think so.

5 THE COURT: That's how we do it here.

6 MR. RASHBROOK: Yep. And a date is agreed upon that  
7 is mutually agreeable for counsel. Counsel for Sanofi indicates  
8 that Mr. Borneman is not going to be available that day, and  
9 then there is an email subsequently from Your Honor's law clerk  
10 indicating that he can attend by Court Call at Sanofi's expense.

11 Following that, we reached out to counsel for Sanofi  
12 to inquire whether he would -- whether he would appear in person  
13 or by phone. And it became clear that the sides had a  
14 misunderstanding about whether his presence was required or not,  
15 and so that was the point at which we filed that motion.

16 THE COURT: Okay. Thank you.

17 MR. RASHBROOK: No problem at all. So -- so as far as  
18 the question of delay, there is no desire for delay --

19 THE COURT: Understood.

20 MR. RASHBROOK: -- on the part of the petitioner.  
21 Further, there is also an allegation or argument, I should say,  
22 that the Independent is seeking to sensationalize these  
23 proceedings, setting aside the fact that if they chose to, that  
24 would be protected activity under the First Amendment. I  
25 believe that the last time my client published anything

1 regarding this case was three months ago, and so I really don't  
2 think that there's any basis in reality for that assertion.

3 If Your Honor has any further questions, I'm happy  
4 to --

5 THE COURT: I don't have any questions yet, but I may.

6 MR. RASHBROOK: Sure.

7 THE COURT: Okay.

8 MR. RASHBROOK: Sure.

9 THE COURT: Is there anything else you'd like to add  
10 at this time?

11 MR. RASHBROOK: No, not at this time, Your Honor.

12 THE COURT: Okay. Thank you.

13 MR. BAILEY: Good afternoon, Your Honor.

14 THE COURT: Good afternoon.

15 MR. BAILEY: Is this -- can I turn this just a little  
16 bit so I can see you better?

17 THE COURT: You can do whatever you need.

18 MR. BAILEY: Thank you.

19 THE COURT: I'm very flexible about my courtroom.

20 Whatever makes -- is easier for all counsel is fine.

21 MR. BAILEY: If you will indulge me for just a moment,  
22 I think it's important to outline what is relevant as it relates  
23 to their motion as opposed to what is not relevant.

24 THE COURT: Okay.

25 MR. BAILEY: As this case comes before this Court, as

1 the saga begins, it begins because the petitioner, which as I  
2 understand it is an online newspaper media source of some time,  
3 the petitioner files or submits a public record request under  
4 NRS 239.010, which is the Nevada Public Records Act. And they  
5 submit that request to a governmental entity, the Nevada  
6 Department of Health and Human Services.

7           And under the Nevada Public Records Act, if a public  
8 person or entity submits a request, they're entitled to  
9 documents that the government generates, except, and this is  
10 straight from the statute, they're not entitled to documents or  
11 information that is declared by law to be confidential. That's  
12 what the statute says. You're entitled to all documents created  
13 by the government, unless those documents or that information is  
14 declared by law to be confidential.

15           So last year, the petitioner submits a couple public  
16 records requests to the Department of Health and Human Services,  
17 and they want a big variety of information. And the Department  
18 responds by saying -- and this is all dealing with  
19 pharmaceutical manufacturers and pharmacy benefit managers  
20 information that entities like my client manufactures are  
21 required under law to provide to the Department. And so they  
22 submit these requests. They have -- they want a large group of  
23 documents.

24           And the Department turns around and says, listen, and  
25 I'm paraphrasing, but this is what happens. The Department says

1 we've done an analysis, and under our analysis, which we're  
2 required to do under state law, Nevada Administrative Code  
3 section, which was promulgated by the Department in Nevada's  
4 legislature, we do this analysis.

5           And under the analysis, if we determine that the  
6 information that you're requesting is confidential, and under  
7 the administrative code it talks about the federal law, the  
8 DTSA --

9           THE COURT: Right.

10           MR. BAILEY: -- Defend Trade Secret Act, if we  
11 determine that the information you're requesting is  
12 confidential, we can't give you that information. If we  
13 determine that it's not confidential, we'll give you that  
14 information.

15           So the Department says to the petitioner, there's a  
16 lot of information we're going to give you because it's not  
17 confidential, but there is some information that is  
18 confidential, it's protected by federal law and state law, the  
19 DTSA. The petitioners are not happy with that determination,  
20 and they have the right to be unhappy.

21           So what they do is on August the 8th of last year,  
22 they file the petition for writ of mandamus. You're the  
23 fortunate judge who ends up getting this case assigned to them,  
24 and they say in that petition only one request for relief. What  
25 they say is that the Nevada Administrative Code, 439.735 through

1 .740 is invalid. They say it's invalid because it conflicts  
2 with Senate Bill 539, which has been codified into state law as  
3 NRS 439B, and they say it conflicts with the Nevada Public  
4 Records Act 239.010.

5           So they come to this Court in their writ petition and  
6 they say, listen, Your Honor, we think that the Administrative  
7 Code 439 is invalid because it conflicts with the Nevada Public  
8 Records Act, another statute, and it conflicts with what is now  
9 NRS 439B.

10           So they want you, this Court, to say this  
11 administrative code conflicts with these statutes and,  
12 therefore, please find it invalid. That's what their writ  
13 petition says to this Court. It's a legal argument. And they  
14 want to be able to argue that it's conflicting, and, of course,  
15 the other side, like my client and manufacturers, along with the  
16 Attorney General's Office, is saying, no, there is no conflict.  
17 You'll hear that argument later on this month, but that's what  
18 their writ petition is about. That's August the 8th.

19           August the 15th they file a supplement to their writ  
20 petition. And they say in addition to our argument that there's  
21 a conflict in the administrative code that needs to be found  
22 invalid, they make two additional arguments. One is that the  
23 federal law, DTSA, is not applicable because it's preempted  
24 under state law. And, two, that Nevada's trade secret law, NRS  
25 600A.030, exempts manufacturers from trade secret protection.

1           So this is their supplement to their writ petition.  
2 They say now in addition to us believing, "us" being the  
3 petitioners, that there's a conflict between the administrative  
4 code and the two statutes, we want to also -- we also want this  
5 Court to look at the federal law, the DTSA, and say it doesn't  
6 apply, and Nevada's trade secret statute, NRS 600A.030 exempts  
7 out manufacturers from trade secret protection.

8           So now they want -- they have all of these statutes  
9 that they want this Court to look at them and say that some  
10 don't apply, some are inapplicable, and another one exempts out  
11 trade secret protection. And they want this legal analysis  
12 done. They will argue in one direction, the other side will  
13 argue in the other direction, and you'll hear that.

14           So that's their argument, that there is this legal  
15 issue where statutes are either inapplicable or invalid. That's  
16 -- that's their argument. That's October 15th. October 21st we  
17 filed our motion to intervene. And as you are required to do,  
18 when we filed our motion to intervene, we attached our proposed  
19 response to the writ petition. We couldn't file it because we  
20 hadn't been granted the right to intervene yet. And attached to  
21 our proposed response, a lot of exhibits -- well, one of the  
22 exhibits is Mr. James Borneman's declaration.

23           THE COURT: Yes.

24           MR. BAILEY: And when you look at his declaration  
25 generally, a couple things kind of stick out. One, he talks

1 about his experience with the company and he talks about  
2 generally the company itself. He then goes on to talk about why  
3 it is that this information, the company's information and how  
4 the company's information is treated. It's treated as a trade  
5 secret.

6           There's very few people who have knowledge of it  
7 within the company. It's on a need to know basis. There's  
8 contractual provisions where people can get fired and terminated  
9 should any of this information leak out. And that's the  
10 information that is generally in his declaration. And I'm not  
11 going to tell the Court how to look at his declaration or what  
12 you think is important or isn't because you can do that, Your  
13 Honor.

14           What you don't see in Mr. Borneman's declaration is  
15 any analysis of Nevada state law and the statutes that have been  
16 framed by the petitioner as being an issue. Mr. Borneman does  
17 not say in his declaration, hey, Judge, I was a legislator when  
18 these statutes were enacted, let me give you my personal  
19 knowledge about what the intent was and whether things conflict  
20 or don't conflict. That's not in his declaration.

21           He can't provide this Court, and you would not want  
22 him to provide and you don't need anybody to help you interpret  
23 these statutes and these regulations and determine whether or  
24 not they're conflicting or not or whether they applicable or  
25 not. Those are pure questions of law that the writ petition, as

1 supplemented, they're asking you to do.

2           So that's October 21st. So they've had Mr. Borneman's  
3 declaration since October 21st of last year. You heard opposing  
4 counsel just say December some time. Misstatement, they've had  
5 it since October 21st.

6           On December the 5th, more than a month later, they  
7 filed their first reply to our response, and they assert  
8 essentially the same arguments that they had asserted in their  
9 writ petition in their first supplement, and they add a new  
10 argument. Their new argument is that Sanofi and the other  
11 manufacturers have waived their right to confidentiality by  
12 providing the Department with information that they are required  
13 to provide under Nevada law.

14           So they made a waiver argument. In addition to  
15 everything else, they're saying we also have this waiver  
16 argument. Of course, you can't waive a right that you don't  
17 have, so their implicitly admitting that we have a  
18 confidentiality right, but they're saying we've waived it  
19 because we complied with Nevada law by giving the Department  
20 information that we're required to give.

21           What they don't do in December of last year, after  
22 having Mr. Borneman's declaration sent two -- two and a half  
23 months earlier is they don't dispute any of the facts or  
24 anything else that's asserted in the declaration. They don't  
25 object to it. They don't dispute it. They don't say, geez, it

1 contains nothing but argument. Nothing.

2           Then we get to a couple days before Christmas,  
3 December 23rd, and that's when you issued your order granting  
4 the motion to intervene. And in that order, as I recall, you  
5 also set a hearing for January the 31st of 2020, and you set a  
6 date to disclose witnesses.

7           And in all candor to the Court, when I got that order  
8 and it said an evidentiary hearing, I honestly believed that  
9 maybe it was a mistake, maybe that's just how you send out your  
10 orders because there is no evidence to help the Court because  
11 it's purely a legal analysis where you're determining the  
12 application of statutes. You don't need -- you don't need  
13 anyone to help you do that. In fact, you would not want anyone  
14 to help you do that.

15           So as we go forward, we go to -- that's December the  
16 23rd. January 3rd they file, "they" being the petitioner, their  
17 second reply to our response to the writ petition. They make  
18 essentially the same arguments that they had previously made.

19           But what's important about that is they do not dispute  
20 any of the facts in Mr. Borneman's declaration. They do not  
21 raise any factual issues with Sanofi's protection of its trade  
22 secrets. They don't contest any of that. And they don't  
23 contest the fact that we will suffer irreparable harm if our  
24 trade secrets are disclosed. Silence. Nothing.

25           So we get to the point of last week. Well, actually,

1 I think it was January 23rd when the Court said I've got a  
2 conflict, I need to move you, whatever happens. And last week,  
3 last Thursday, there's communication between counsel and we say,  
4 listen, this is a pure issue of law, we're not going to offer  
5 any witnesses because it's a pure issue of law, we don't -- we  
6 don't have any affirmative witnesses to cross-examine, it's  
7 really not an evidentiary hearing because it's legal principles.  
8 We file that with the Court. The State files a similar document  
9 saying these are pure issues of law, there's no -- you don't  
10 need witnesses.

11 And, of course, the petitioner identifies a person who  
12 I believe is the individual who initially submitted the public  
13 record request to the Department. What she could possibly  
14 testify to, I have no idea. Is she going to say, you know, I  
15 submitted this? It's not a fact that's in dispute. Everybody  
16 knows she submitted it. What else can she say to help this  
17 Court on a pure issue of law? Is she going to say I understand  
18 these regulations, I was a senator in the legislature when these  
19 regulations were -- and these laws were implemented?

20 So moving forward, last week we get their motion to  
21 compel. And it became very clear to us after reviewing their  
22 motion to compel that their position in all of this, and -- and  
23 I look at it in -- you know, I'm a lawyer who represents a  
24 party, but I look at it as though they've essentially conceded  
25 the fact that they're not going to win on the issue of law.

1 We'll argue that in a few weeks. But I look at it as they  
2 conceded that they're not going to win on the issue of law, so  
3 let's turn to Plan B, which is to try to just go after Sanofi.

4 And when you read it, that's essentially what they're  
5 saying. We want to turn this thing into kind of a circus.  
6 Because there's nothing that Mr. Borneman can do with respect to  
7 the issues of law that this Court will address in a couple of  
8 weeks. There's no testimony he can give that would help you in  
9 any way, assuming you even wanted the help, in making a  
10 determination as to whether statutes conflict or whether they're  
11 applicable.

12 So let me -- let me address what you just heard from  
13 opposing counsel because he said, look, if we look at paragraph  
14 20 to 23 in the Borneman declaration, he says it contains  
15 argument. Now, Your Honor, I -- and he says it should be  
16 stricken because it contains argument. I'm not going to stand  
17 here and try to tell the Court what is argument and what is not  
18 argument.

19 But what I can say with complete confidence is that,  
20 Your Honor, you can read the declaration. You certainly can  
21 tell what you believe to be argument and what is not argument,  
22 what's factual, and you're certainly able and capable of making  
23 that determination and you will make that determination. If you  
24 think it's argument, you will give it the weight that it  
25 deserves, which is nothing. If you believe it's factual, you

1 will give it the weight that it deserves. It does not need to  
2 be stricken. It's part of the record already.

3 Same with paragraph 12 through 13. He says, "he"  
4 being opposing counsel, that those two paragraphs are, and I'll  
5 quote him, unsupported assertions. Well, I'm not going to stand  
6 here and argue about whether it's supported or unsupported.  
7 Judge, you will give it the weight that it deserves, and we're  
8 completely comfortable with you doing that.

9 Then he says that -- that -- well, he goes -- he goes  
10 on and says, and this is not exactly in his brief, but he goes  
11 on to say that we're concerned about competitor pricing and the  
12 price of drugs and so forth. And you know what, you know, you  
13 can be and many of us are concerned about the price of drugs,  
14 but that's an argument for your regulator.

15 That's an argument that you take up with the  
16 legislature. That's an argument that you take up with the  
17 Department. It is not an argument that is before this Court  
18 based on a writ petition that they framed and put the laws that  
19 they want this Court to determine are applicable or not  
20 applicable. It's just not an issue that is before this Court.

21 Finally, they say paragraphs 3, 4, and 5, quoting can  
22 declaration be taken at face value when you look at those three  
23 paragraphs. And my response to that is, Judge, you will make a  
24 determination as to what has weight to it, what does not have  
25 weight to it, if it's argument, disregard it. If it's factual,

1 you will take that into consideration.

2           Based on that, Your Honor, unless you have any  
3 questions, I would ask the Court to do what you are required to  
4 do under writ petition, which is these are issue of law, we will  
5 argue in a few weeks about how these statutes either are  
6 applicable or they're not applicable, whether they exempt  
7 information or don't exempt information, but that's what's  
8 before the Court.

9           It's not Mr. Borneman and his declaration, and to the  
10 extent -- it's in the record to the extent that you want to look  
11 at it and give whatever weight you think is appropriate. That's  
12 what the Court does in almost every instance. So unless you  
13 have any questions, I will sit down and ask you to deny the  
14 motion.

15           THE COURT: I don't have any questions at this time.

16           MR. BAILEY: Thank you, Your Honor.

17           THE COURT: Thank you.

18           MR. RASHBROOK: Your Honor, it appears to me that  
19 Sanofi takes positions as to these questions that are logically  
20 inconsistent. On the one hand they tell you that these are  
21 strictly factual questions. On the other hand -- or, pardon me,  
22 strictly legal questions.

23           On the other hand, they suggest to you that the  
24 appropriate response to our motion is for Your Honor to consider  
25 the weight that should be given to the evidence that's placed

1 before them. Of course, that's not what the Eighth Judicial  
2 Rule refers to or calls for in this circumstance. If the  
3 affidavit or parts of the affidavit are defective, they're to be  
4 stricken from the record, not to be considered and weight given  
5 to them. Beyond that, to the extent that Sanofi thinks that  
6 these are strictly legal questions, I wonder why the affidavit  
7 needs to be in the record at all.

8           Mr. Bailey, when he was at the podium, said that I had  
9 misspoken earlier, that I had had the affidavit on 12/23. I did  
10 not misspeak. The reference to the date December 23rd was the  
11 date that Your Honor granted the intervention and at that point  
12 the Sanofi response becomes a part of the record rather than a  
13 proposed document.

14           THE COURT: I see.

15           MR. RASHBROOK: He's correct that the -- I'm sure he's  
16 correct, I believe it was 10/21 that you said that the motion to  
17 intervene was filed and the proposed response attached along  
18 with it. Beyond that, it's actually the 9th of December before  
19 the press release is issued by the Sanofi CEO and it's at that  
20 point, and not any time before.

21           And so really the passage of time between October and  
22 December I think is really altogether a red herring there. Mr.  
23 Bailey points out that the Independent in its petition only  
24 argues in the first place that the administrative codes are  
25 invalid. And the fact is, at that point, that's all we're

1 confronted with.

2           The only thing that's happened at that point is that  
3 Ms. Meserly (phonetic), on behalf of the Independent, has made a  
4 request for public records. And in response to that request,  
5 the Department of Health and Human Services tells her they're  
6 going to deny the request and that that is the basis upon which  
7 they're going to deny it.

8           Now, as the litigation has progressed, as Sanofi has  
9 joined the litigation and as the Department has fleshed out  
10 their arguments, of course, the petitioner responds to those  
11 arguments in turn. But at the time the petition is filed, the  
12 only thing we're confronted with is the suggestion that the  
13 Department fears that this material is confidential and pursuant  
14 to the act, the Defend Trade Secrets Act, they fear liability  
15 under the Defend Trade Secrets Act. We're not confronted with  
16 any of these factual assertions that Sanofi makes at that time.

17           And so I don't see how the petitioner would have been  
18 in a position to respond to these arguments, which at that point  
19 are entirely hypothetical. Obviously, my client could never  
20 have predicted who would join the litigation or what position  
21 they might take at some future date. Beyond that, Sanofi  
22 suggests that implicit in the argument, the petitioner's  
23 argument, that if they had any trade secret status, they would  
24 have waived it. This is simply an alternative argument to the  
25 -- to the argument that, first of all, in the first place, these

1 are not trade secrets.

2 In the second place, if they ever had been trade  
3 secrets, certainly that status was destroyed, effectively waived  
4 by submitting these records to the department when they had no  
5 guarantee that the confidentiality would be maintained. But  
6 these are arguments that I think perhaps are more appropriate  
7 for the writ petition here. Excuse me.

8 Really, I think that the most significant issue that  
9 should be pointed out is that there's no point at which really  
10 Sanofi meaningfully disputes the points that we make about the  
11 defects in the affidavit. They simply suggest that rather than  
12 striking the affidavit in whole or in part as the rule is made  
13 clear, but instead, Your Honor, allow to continue to be part of  
14 the record and simply assign whatever weight you think fit.  
15 Again, that's a position logically inconsistent with the  
16 alternative, that this is a strictly legal question. And as I  
17 mentioned, not the remedy provided for in the rule.

18 Unless Your Honor has any other questions, those are  
19 my thoughts.

20 THE COURT: What -- so I have some -- just a basic  
21 question for -- as I was reading, I would like to understand,  
22 and it's very basic. Let's -- I know I'm a judge and we're in a  
23 courtroom, but just -- but we also have lives outside.

24 MR. RASHBROOK: Sure.

25 THE COURT: Okay.

1 MR. RASHBROOK: Sure.

2 THE COURT: You know, practical lives.

3 MR. RASHBROOK: We ask juries to bring their common  
4 sense to the --

5 THE COURT: Right. Yes, that is correct. So having  
6 -- having reviewed Mr. Borneman's affidavit or his declaration,  
7 how does a person describe what their trade secrets are without  
8 identifying what the trade secrets are? Do you see my point?

9 MR. RASHBROOK: Absolutely.

10 THE COURT: I mean, honestly, if I had a client --

11 MR. RASHBROOK: Sure.

12 THE COURT: I tried to think about this.

13 MR. RASHBROOK: How much can you describe these things  
14 without giving away what the "it" is?

15 THE COURT: Yes. I mean, how does that happen?

16 MR. RASHBROOK: So I don't pretend to be an expert in  
17 the area, but from the cases that I've looked at in this area,  
18 frequently what happens is an in camera inspection.

19 THE COURT: Yes.

20 MR. RASHBROOK: Occasionally, we have sort of a  
21 counsel's eyes only inspection.

22 THE COURT: This is very interesting because these are  
23 the notes I have question marks on my own without reading  
24 further.

25 MR. RASHBROOK: Yeah, those are --

1 THE COURT: In camera.

2 MR. RASHBROOK: -- those are the procedures that I'm  
3 aware of. At times, a discovery agreement that certain  
4 documents will be counsel's eyes only or alternatively there's  
5 an in camera review and the Judge may make a determination.

6 And our position on that is that it isn't the  
7 petitioner's obligation, the burden of proof. If these -- these  
8 records are not made confidential by statute, and that, of  
9 course, is our position, the only remaining shelter under which  
10 to -- to maintain the -- the Department's position, which is to  
11 withhold the records, would be sort of a common law or a policy  
12 argument in favor.

13 And at that point, the burden, and the case law is  
14 totally point on this point, the burden is on the respondent, or  
15 perhaps in this case the intervenor, to make that showing. The  
16 burden of proof rests on -- rests on them to prove to the Court  
17 that the balance of probabilities weighs in their favor. So my  
18 suggestion on that would be it's not my client's responsibility  
19 to disprove that theory. It's their obligation to prove it.

20 THE COURT: It's just that when I was reading his  
21 declaration, first reading what you filed --

22 MR. RASHBROOK: Absolutely.

23 THE COURT: -- I'm thinking --

24 MR. RASHBROOK: And it's --

25 THE COURT: -- because I've been --

1 MR. RASHBROOK: -- it's a problem.

2 THE COURT: -- a business lawyer, you know, in my  
3 past, and I was thinking how would I prepare this declaration,  
4 just a practical thought, you know.

5 MR. RASHBROOK: Absolutely. And it is -- it is also,  
6 there's a sort of corresponding problem that comes up commonly  
7 in public records cases where the petitioner is in this position  
8 of arguing for access to records without knowing what or how  
9 many or what they may contain.

10 THE COURT: Right.

11 MR. RASHBROOK: And so it can be sort of -- the sort  
12 of famous line from one of the federal cases is a nebulous  
13 position of trying to access something when you're -- you're in  
14 this position of saying it's very important that I have this  
15 thing, notwithstanding the fact that I don't know what the thing  
16 is. But those are the solutions.

17 THE COURT: It's kind of a unique situation.

18 MR. RASHBROOK: Absolutely. Those are the -- those  
19 are the solutions that I've -- that I've seen discussed, are in  
20 camera or counsel's eyes only reviews.

21 THE COURT: Okay. And then I'll address this now,  
22 although we're going to be addressing this very thoroughly, but  
23 I just want food for thought. So with respect to the agency,  
24 okay, if there is a duty to disclose to the agency, right --

25 MR. RASHBROOK: Sure.

1           THE COURT:  -- and that's done, and then the agency --  
2 how -- how is that incompatible with -- with the general  
3 statutes that you're concerned about?  I mean, why would that --  
4 why is there a waiver there?  Because when I was reading about  
5 that, I was very interested in that argument.

6           MR. RASHBROOK:  So --

7           THE COURT:  You know, if I have a duty to disclose  
8 something --

9           MR. RASHBROOK:  Right.

10          THE COURT:  -- and I follow through on that duty,  
11 right --

12          MR. RASHBROOK:  Right.

13          THE COURT:  -- why am I waiving something when it's  
14 something I'm required to do?

15          MR. RASHBROOK:  So two reasons.

16          THE COURT:  It's really simply.  I like to think  
17 really from the beginning and then, you know --

18          MR. RASHBROOK:  It's, yeah, a linear thought.  Right.  
19 There's two reasons.  The first is they're only required to  
20 submit those reports to the extent that they want to raise the  
21 price and want to continue to do business in this state.

22          THE COURT:  I see.

23          MR. RASHBROOK:  The second is because it is -- it is  
24 explicit in these codes that there's no guarantee of  
25 confidentiality.  The Department regulations indicate that

1 they'll undergo a review, a review for confidentiality. So  
2 there's no promise that confidentiality can be maintained.

3         And as a general proposition, privileges and  
4 confidentiality is sort of looked on in general unfavorably,  
5 and certainly in the area of public records where they're  
6 construed as being as small and as fragile as -- as can  
7 reasonably be thought of, right. And so that is why I think  
8 there's a waiver here, which is essentially that they have  
9 alternatives. They could have chosen simply not to submit these  
10 reports, or failing that, they could have chosen not to raise  
11 the prices.

12         But as they've discussed throughout, their  
13 representatives or personally they were involved in the drafting  
14 of these regulations. They were aware of the regulations. They  
15 made an affirmative choice to submit these records complete with  
16 the knowledge that there was no guarantee of confidentiality.  
17 And so, to me, that represents a waiver of the confidentiality  
18 because they gave the records to an entity who had not promised  
19 to keep them confidential.

20         Beyond that, it's the right of the public to access  
21 these records. And so even if there had been a promise, the  
22 promise is ineffective. The public's right to access records is  
23 not the Department's to give away. It's not the legislature's  
24 to give away unless they're going to undue the Public Records  
25 Act. In fact, what we see from the legislature consistently,

1 year by year, session by session, is strengthening the Public  
2 Records Act.

3 THE COURT: Okay. And you -- your client or you  
4 believe that if Mr. Borneman's, if his declaration, you feel is  
5 extremely important to be able to question him?

6 MR. RASHBROOK: Absolutely.

7 THE COURT: I mean, do you feel that you would be  
8 prejudiced if you were unable to do that?

9 MR. RASHBROOK: Absolutely.

10 THE COURT: Why?

11 MR. RASHBROOK: Because this is -- this is sort of --  
12 the -- the quote that I like that I think really captures this  
13 is an old Ben Franklin quote, half the truth is a great lie.  
14 There are assertions of fact in this declaration that are  
15 controverted by publicly available documents. And if the  
16 declaration is allowed to stand on its own without any  
17 examination, I think it creates an extremely misleading record.

18 And although Sanofi and the respondents suggest that  
19 these are strictly questions of law, if they are wrong about  
20 that, what will end up a potential consequence here is that it  
21 may end up in front of the Supreme Court and the Supreme Court  
22 says we don't have an adequate factual record to make a  
23 determination as to whether the district court correctly decided  
24 that the balance of probabilities favored the respondents or the  
25 intervenor or the petitioner.

1           THE COURT: Even if I'm the one that's hearing the  
2 information and I'm the one that's evaluating weight or  
3 everything that's before me?

4           MR. RASHBROOK: I think so, and I think that's why the  
5 rule calls for this type of material to be stricken from the  
6 record in the event that it is defective.

7           THE COURT: Okay. Thank you.

8           MR. RASHBROOK: Thank you.

9           THE COURT: We have time, and if you'd like to say  
10 something else, I will accept it, as long as counsel has the  
11 last say --

12          MR. BAILEY: I --

13          THE COURT: -- since it's his motion.

14          MR. BAILEY: I just have two points, and they're  
15 really based on the questions that you asked.

16          THE COURT: Okay.

17          MR. BAILEY: And so I think they may help you in terms  
18 of -- of your analysis and what you're doing. Let me start with  
19 the last question you asked, which was the conversation about if  
20 a manufacturer submits information that it's required to submit,  
21 how could it be waiving confidentiality as it relates to that  
22 information.

23                 And you heard opposing counsel says, well, they  
24 submitted it, it's -- they waived any -- any right to it, and  
25 that somehow you are supposed to make a determination, "you"

1 being the Court, are supposed to be able to make some  
2 determination with respect to that. And the answer is that's  
3 incorrect. The Department, DHHS, has already made that  
4 determination.

5           And if you look at NAC 439.735, you'll look at the  
6 process that the Department went through. And if the  
7 Department, you know, specifically asked you to look at section,  
8 subsections (4) and (5) of that code, you'll see that once the  
9 Department goes through the information that it has, if it  
10 determines that the information is confidential and it  
11 specifically talks about DTSA, trade -- trade -- trade secret  
12 protection under DTSA, then it will notify the requester who is  
13 requesting the information of the fact that it has made that  
14 determination that that information is confidential, it's trade  
15 secret protected under DTSA.

16           That's what happened in this case. Under Section 5 of  
17 that administrative code, if the Department makes the  
18 determination that it is not trade secret protected or it is  
19 otherwise not confidential, then it has an obligation to wait at  
20 least 30 days, it notifies everyone, and wait 30 days before it  
21 makes any attempt to disclose that information. And the reason  
22 why is so that the person whose information it is can go to  
23 court and get an injunction to stop that disclosure. That's the  
24 answer to your question.

25           The first question you asked was about Mr. Borneman's

1 -- well, you didn't ask about his declaration. You asked the  
2 question how can you describe the trade secret without giving up  
3 the trade secret; right?

4 THE COURT: Perhaps that's too elementary, but  
5 that's --

6 MR. BAILEY: Well --

7 THE COURT: -- a pretty basic thing for me.

8 MR. BAILEY: -- the way you do it is through a  
9 declaration like Mr. Borneman, but more importantly, let me ask  
10 you to look at what is identified as Exhibits 11 and 12 to his  
11 declaration. And what those are, those are the letters that  
12 identify -- those are letters from Sanofi to the Department,  
13 DHHS, and those letters describe in better detail the  
14 confidential information that is being submitted, and the  
15 rationale for the trade secret protection.

16 These are the cover letters that go with the  
17 information where Sanofi is asking the Department to look at  
18 this information, to look at our rationale, to look at the DTSA,  
19 and to make a determination. The Department made that  
20 determination looking at this information and the information  
21 that we were required to provide under Nevada law.

22 And based on that, determined that this information is  
23 subject to DTSA, it is trade secret protected and it's  
24 confidential and, therefore, we can't disclose it. Had they  
25 made a different determination, we would be in federal court or

1 we would be in court seeking an injunction to stop the  
2 Department from disclosing our trade secrets to any third  
3 parties or otherwise disclosing it publicly. But that's the  
4 process, and that's what happened in this case.

5           And as an aside, this statutory scheme was the result  
6 of the Pharma case that we cited in our moving papers where we  
7 resolved a case where we did go to, the Pharma Group, went to  
8 federal court to get an injunction to stop the release. Well,  
9 actually, it was not to stop the release of information. We  
10 didn't want to give the information unless there were  
11 protections in place that once we gave information, that it  
12 wouldn't just be disclosed.

13           We went to court, and that case got resolved by the  
14 Nevada legislature, along with the Department, along with a  
15 group of pharmaceutical manufacturers agreeing that the proper  
16 process needs to be put into state law. And the result of that  
17 is administrative code 749.735. The very same one that they're  
18 saying is inconsistent or conflicting with the Nevada public  
19 records statute and Senate Bill 539.

20           So that's -- that's how all of that came about. But  
21 the determination of this being protected under DTSA and being a  
22 trade secret has already been made by the Department. You can  
23 see the underlying material because it's attached to Mr.  
24 Borneman's declaration. So based on that, Your Honor, if you --  
25 unless you have any other questions, we would ask you to deny

1 the motion.

2 THE COURT: Thank you.

3 MR. RASHBROOK: So, of course, the Department has made  
4 this determination and that's why we're here and this is what  
5 happens in every Public Records Act case. The executive branch  
6 makes a determination, or the legislative branch, but typically  
7 the legislative branch makes the determination that they don't  
8 want to disclose records, and somebody like the petitioner comes  
9 to the court and asks for a review of that decision. The case  
10 is not unusual in that one respect.

11 And so when Sanofi asserts that it is the Department  
12 who makes this determination and, therefore, there's no waiver,  
13 the fact is whether the Department makes that determination and  
14 whether they make a contrary determination that there is no  
15 confidentiality, ultimately the decision is made by a court.  
16 Whether it's made by a Court following the petition or whether  
17 it's made by the Court following Sanofi's motion for an  
18 injunction, ultimately, the decision is made by a court.

19 The Department of Health and Human Services is not  
20 authorized to make this kind of determination about  
21 confidentiality, and so it can't be said to be any guarantee.  
22 They gave this information away not knowing whether the  
23 Department would keep it confidential, and not knowing whether  
24 the Court would allow them to do that ultimately. And so the  
25 suggestion that they had assurances from the Department, this is

1 not how these processes work out.

2 That's all I have to say unless you have further  
3 questions, Your Honor.

4 THE COURT: I'd just like you to explain that again.  
5 It's not that -- it's not that I'm slow, it's just that I'm very  
6 -- I go deep. I go very deep and I think about things over and  
7 over and over again.

8 MR. RASHBROOK: I think one thing we would all agree  
9 upon is the case presents complicated legal questions.

10 THE COURT: Yes.

11 MR. RASHBROOK: So what I'm saying is --

12 THE COURT: It's not that I don't understand. I don't  
13 know if I completely agree with it or not, so I want you to say  
14 it again.

15 MR. RASHBROOK: So --

16 THE COURT: I'm being very frank. That's more on  
17 point.

18 MR. RASHBROOK: So what I'm saying is even in the  
19 event that the regulations that the administrative codes are  
20 found to be appropriate, that they are found not to conflict  
21 with the Public Records Act, which, of course is the --

22 THE COURT: Right.

23 MR. RASHBROOK: -- not the position I would suggest,  
24 but even in the event they are found to be -- they are -- they  
25 are upheld, there are two possible outcomes here. Either the

1 Department says, yes, the material is confidential, we will  
2 withhold it, in which case the petitioner comes to the Court for  
3 review of that decision, right.

4           The other possibility is the Department is confronted  
5 with a public records request and they say we don't think this  
6 information is confidential, in which case somebody like Sanofi  
7 initiates the proceeding, asking either this Court or a federal  
8 district court for an injunction prohibiting the disclosure.

9           But in either case, the end result is that we end up  
10 in court. It is the Court which decides whether these things  
11 are confidential, ultimately, not the Department. The  
12 Department can offer their opinion, but it's not more than that.  
13 It's not determinative. The Court's decision is what's  
14 determinative of whether these records have to be maintained  
15 confidential or not.

16           And so Sanofi has no guarantee, even in the event that  
17 the administrative code is upheld. There's no guarantee that  
18 these records will be maintained confidential, and in those  
19 circumstances there can't be any confidentiality. I can't hand  
20 somebody a record and say promise me you'll keep this  
21 confidential and they say I'll think about it. And I say  
22 there's confidence there. There can't be any privilege in that  
23 circumstance.

24           THE COURT: Isn't there -- it's not they don't think  
25 about it. It's we will analyze it; right?

1 MR. RASHBROOK: Right.

2 THE COURT: And if this criteria is here or not, then

3 we either withhold --

4 MR. RASHBROOK: Sure.

5 THE COURT: Or we -- or we don't withhold.

6 MR. RASHBROOK: Right. The crux of the issue and our

7 position, though, is that because privileges and confidences are

8 construed so narrowly and are so disfavored that a crack in the

9 dam, and the dam bursts. There was no guarantee that these

10 things would be kept confidential. There's no reliability that

11 they will be kept confidential, even in the event that the

12 Department decides that they think they're confidential, we

13 still go through a judicial review to determine that. There

14 can't be any confidence that these things will be maintained

15 privileged, that they'll be kept from the view of the public.

16 THE COURT: So I don't want to jump into our next --

17 our next -- the next time we meet, but the issue with respect to

18 -- that you've mentioned several times concerning the public --

19 is it -- I don't -- not a public service announcement, but the

20 in Paris, the CEO?

21 MR. RASHBROOK: Uh-huh. Uh-huh.

22 THE COURT: Okay.

23 MR. RASHBROOK: Press release I think is --

24 THE COURT: The press release. Thank you.

25 MR. RASHBROOK: Yeah.

1 THE COURT: I'm used to doing a public service  
2 announcement, so it's -- so you're saying that there are two  
3 prongs to that. One --

4 MR. RASHBROOK: Yeah, so the -- the --

5 THE COURT: -- that if a company wants to raise its  
6 prices, and, two, if it wants to continue doing business in  
7 Nevada, that's very relevant. You mentioned that; right?

8 MR. RASHBROOK: I'm sorry.

9 THE COURT: I took copious notes on that.

10 MR. RASHBROOK: I don't make the -- I don't see the  
11 connection between the press release and -- and I don't think I  
12 understood your question.

13 THE COURT: Okay. You discussed the press release.

14 MR. RASHBROOK: Yes.

15 THE COURT: Okay. And you said that -- that normally  
16 that would apply or not apply. I want to be sure. I'm having a  
17 CD made of this so I can review it. But that would only matter,  
18 in other words, if there was an indication that they're not  
19 going to --

20 MR. RASHBROOK: Right. There's a clear statement in  
21 the press release that Sanofi is heading in a new direction.  
22 I'm not sure of the exact language that they used, but  
23 essentially they say we're not doing any more research and  
24 development in the area of diabetes.

25 THE COURT: Oh, that's it. That's it. No more

1 research. I'm sorry to cut you off. And the second?

2 MR. RASHBROOK: And so as far as -- as far as Mr.  
3 Borneman's declaration is concerned --

4 THE COURT: Yes.

5 MR. RASHBROOK: -- that severely undermines the  
6 positions that he outlines in paragraphs 20 to 23, that one of  
7 the, perhaps unintended, but one of the consequences of  
8 revealing these public records is that Sanofi will then be  
9 forced to reevaluate whether diabetes research is profitable for  
10 them and, therefore, whether they will do it in the future and  
11 whether those with diabetes will be -- will miss out on the  
12 benefit of that research and development, which would have  
13 happened in the absence of publication of these records.

14 THE COURT: Okay. Thank you.

15 MR. RASHBROOK: Thank you.

16 MR. BAILEY: Your Honor, very quickly.

17 THE COURT: Only if he gets the last word.

18 MR. BAILEY: He can have the last word.

19 THE COURT: Okay.

20 MR. BAILEY: This is very quickly.

21 THE COURT: I have to be, you know --

22 MR. BAILEY: Here's the flaw.

23 THE COURT: This is the problem. I enjoy hearing both  
24 of your arguments so much that, you know, I have a lot of work,  
25 but this is fascinating.

1 MR. BAILEY: I will make this quick.

2 THE COURT: Okay.

3 MR. BAILEY: Here is the absolute flaw in their  
4 argument. The flaw in their argument is their repetition, their  
5 supplement, does not say that the Department made the wrong  
6 decision with respect to confidentiality and trade secret and,  
7 therefore, we want to go to court and challenge that  
8 determination. That is not their writ petition. It's not their  
9 supplement. Their argument is that the statutes are invalid,  
10 and that the DTSA does not apply.

11 So when you go back and look at what's before the  
12 Court, now it's very clever to try to change horses in  
13 midstream, but when you look at what's before the Court, it's  
14 not that the Department made the wrong decision with respect to  
15 confidentiality in the application of DTSA. That's not their  
16 argument. Their argument is these laws are conflicting and  
17 Nevada's trade secret exempts out manufacturers from trade  
18 secret protection. That's their argument. That's what they're  
19 asking you to rule on.

20 They didn't come here saying, you know, the Department  
21 made the wrong decision, we want you, Your Honor, to go back and  
22 supplement your opinion for the opinion of DHHS. That's not  
23 this case. So for him to stand up here and go, well, geez, this  
24 is -- well, Courts always rule on this kind of stuff. Well, I  
25 don't know if they do or don't, but I can tell you in this case

1 the operative document, the operative pleadings are their writ  
2 petition and their supplements.

3 And none of those documents are questioning the  
4 Department's decision that these documents are trade secret and  
5 otherwise confidential under their authority and their statute.  
6 They're not asking you to second guess what the department has  
7 done. No different, Your Honor, than I know you were at one  
8 point in your career a member of the Nevada Public --

9 THE COURT: Utilities Commission.

10 MR. BAILEY: -- Public Utilities Commission.

11 THE COURT: That was a long time ago. It was a very  
12 different commission.

13 MR. BAILEY: Yes. And when you were on the  
14 commission, when you were on the commission, the people and  
15 entities that you regulated often submitted information to the  
16 commission that was confidential, that they believed was  
17 confidential, and they submitted to the commission and said we  
18 believe our information is confidential. And you guys take it  
19 and you look at it and you go, yeah, it is confidential.

20 Now, what they're saying is the statute that allows  
21 you to make, on the -- on Public Service Commission, to make  
22 that confidential, to make that determination, they're saying  
23 that statute should be invalid. They're not saying that we're  
24 second guessing what you, the Public Service Commission  
25 determines to be confidential or not. So while clever, that

1 argument is completely flawed because that's not the issue  
2 before this Court.

3 THE COURT: And I don't --

4 MR. BAILEY: I tried to be quick, but --

5 THE COURT: I know. I opened the door to this.

6 MR. RASHBROOK: I appreciate Mr. Bailey's endorsement  
7 of my cleverness, but as I said earlier, at the point that we  
8 filed the petition and the initial supplement, we're only  
9 confronted with DHHS's suggestion that they feel liability under  
10 the DTSA. As the litigation has evolved, we've confronted the  
11 other arguments advanced eventually by the Department and by  
12 Sanofi in turn as we're confronted with those arguments in their  
13 subsequent pleadings. So that's all I've got to say on that  
14 score.

15 THE COURT: Okay. Thank you.

16 MR. BAILEY: Thank you, Your Honor.

17 THE COURT: You know I'm going to address this in a  
18 minute order; right?

19 MR. BAILEY: Yes. Yes.

20 THE COURT: Okay. Good.

21 MR. BAILEY: Thank you so much for your time.

22 MR. RASHBROOK: Thank you very much.

23 THE COURT: Of course. Have a great afternoon.

24 (Proceedings concluded at 2:52 p.m.)

25 \* \* \* \* \*

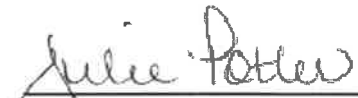
**CERTIFICATION**

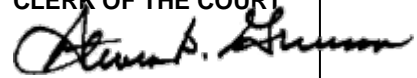
I CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE AUDIO-VISUAL RECORDING OF THE PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

**AFFIRMATION**

I AFFIRM THAT THIS TRANSCRIPT DOES NOT CONTAIN THE SOCIAL SECURITY OR TAX IDENTIFICATION NUMBER OF ANY PERSON OR ENTITY.

**Julie Potter  
Kingman, AZ 86402  
(702) 635-0301**

  
\_\_\_\_\_  
**JULIE POTTER  
TRANSCRIBER**



MLEV  
Paul L. More, SBN 9628  
McCRACKEN, STEMERMAN & HOLSBERRY, LLP  
595 Market Street, Suite 800  
San Francisco, CA 94105  
Tel. No.: (415) 597-7200  
Fax No.: (415) 597-7201  
Email: pmore@msh.law  
  
*Attorneys for Amicus Curie Culinary Workers Union Local 226*

**DISTRICT COURT  
EIGHTH JUDICIAL DISTRICT  
CLARK COUNTY, NEVADA**

THE NEVADA INDEPENDENT

Case No.: A-19-799939-W  
DEPT. NO.: XIV

Petitioner.

vs.

**MOTION FOR LEAVE TO FILE BRIEF  
*AMICUS CURIAE***

RICHARD WHITLEY, in his official  
capacity as the Director of the Nevada  
Department of Health and Human  
Services, and THE STATE OF NEVADA  
ex rel. the DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

Respondents.

SANOFI-AVENTIS U.S. LLC

Intervenor.

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8

Culinary Workers Union Local 226 respectfully requests leave to submit this brief *amicus curiae*, in support of The Nevada Independent’s petition for writ of mandate. As a participant in the Culinary Health Fund, one of the largest health-benefit consumers in the State, and as a proponent of SB 539, the Culinary has a direct interest in this case’s outcome and SB 539’s proper interpretation. Defendant Richard Whitley’s and Intervenor Sanofi-Laventis USA LLC’s positions in this case threaten to blunt SB 539 and rewrite the law of trade secrecy.

## STATEMENT OF INTEREST

Culinary Workers Union Local 226 is a labor organization representing some 60,000 workers in Nevada’s gaming, hospitality, food service, and commercial laundry industries. The Culinary, through its participation in the Culinary Health Fund, is one of the largest healthcare consumers in the state. Culinary Health Fund (“CHF” or the “Fund”) is a multi-employer Taft-Hartley fund that provides medical, dental and vision healthcare benefits to some 143,000 workers and their dependents in Nevada, which makes CHF one of the largest private healthcare-benefit providers in the State.

CHF provides medical benefits to over 12,000 Culinary members and retirees diagnosed with diabetes, and many thousands more who are pre-diabetic. Prescription medications for these diabetic participants are a major and increasing cost for CHF and, ultimately, for the unionized employers and workers who contribute to it. The Fund paid approximately \$26 million for diabetes medications in 2016, which was fully one-quarter of the Fund's total prescription-drug spend. The crisis facing diabetic Culinary members mirrors the crisis faced by diabetics and health-benefit providers nationally.

The amount that the Fund and others pay for key diabetes treatments has increased dramatically and often inexplicably in recent years. The average list price for insulin tripled between 2003 and 2013, and by 15-17% annually between 2012-2016.<sup>1</sup>

<sup>1</sup> “Insulin Access and Affordability Working Group: Conclusions and Recommendations,” 41 DIABETES CARE 1299-1300 (2018), available at: <https://care.diabetesjournals.org/content/41/6/1299> (last visited February 2, 2020).

1 Ultimately, all of the Fund’s participants and contributing employers pay for these price  
2 increases.

3 There is a growing consensus that the lack of transparency in pharmaceutical-  
4 drug pricing is a major factor in the unsustainable rise in prices. This has led to  
5 bipartisan federal and state efforts to mandate drug-pricing disclosure. Legislators in  
6 thirty-three states have passed or introduced bills that would require some form of  
7 pricing disclosure by drug manufacturers.<sup>2</sup> Federal lawmakers have introduced a  
8 number of bills and regulatory changes designed to make drug pricing more  
9 transparent, including the Prescription Drug Price Transparency Act (H.R. 1035).  
10 These laws follow successful state legislation requiring other health-service providers,  
11 such as hospitals and insurers, to publish information about their pricing practices.

12 SB 593 promises to open up the black box of insulin drug pricing. Among other  
13 things, SB 539 requires diabetes-drug manufacturers to disclose basic information  
14 about the pricing of their products to the Nevada Department of Health and Human  
15 Services (“DHS”) and, ultimately, to the public. The Culinary advocated for SB 539  
16 with the expectation that mandated disclosure of this pricing information would lead to  
17 a more transparent market for diabetes medications in Nevada and, ultimately, to lower  
18 negotiated drug prices for the Culinary’s members.

19 DHS’s and Sanofi’s positions in this litigation threaten to close the door that SB  
20 539 pried open. They are based on untenable readings of SB 539, the federal Defend  
21 Trade Secrets Act, and Nevada’s Public Records Act. The Culinary submits this brief  
22 *amicus curiae* to assist the Court in the proper interpretation of these laws.

23 Respectfully submitted,

24 

25 Paul L. More  
26  
27

28 <sup>2</sup> National Academy for State Health Policy, Legislation Tracker, available at:  
<https://nashp.org/rx-legislative-tracker/> (last visited February 1, 2020).

1 MLEV

2 Paul L. More, SBN 9628

3 McCRACKEN, STEMERMAN & HOLSBERRY, LLP

4 595 Market Street, Suite 800

5 San Francisco, CA 94105

6 Tel. No.: (415) 597-7200

7 Fax No.: (415) 597-7201

8 Email: pmore@msh.law

9 *Attorneys for Amicus Curie Culinary Workers Union Local 226*

10 **DISTRICT COURT**  
11 **EIGHTH JUDICIAL DISTRICT**  
12 **CLARK COUNTY, NEVADA**

13  
14 THE NEVADA INDEPENDENT

Case No.: A-19-799939-W

DEPT. NO.: XIV

15  
16 Petitioner.

17 vs.

**[PROPOSED] BRIEF *AMICUS CURIAE***  
**OF CULINARY WORKERS UNION**  
**LOCAL 226**

18 RICHARD WHITLEY, in his official  
19 capacity as the Director of the Nevada  
20 Department of Health and Human  
21 Services, and THE STATE OF NEVADA  
ex rel. the DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

22 Respondents.

23  
24 SANOFI-AVENTIS U.S. LLC

25  
26 Intervenor.

TABLE OF CONTENTS

INTRODUCTION .....	1
BACKGROUND .....	2
The Insulin-Pricing Crisis .....	2
Insulin Pricing: The Need for Transparency .....	4
SB 539 Promises Transparency .....	6
ARGUMENT .....	8
I. The Nevada Public Records Act Requires Disclosure of SB 539 Information Unless the Information is “Otherwise Declared by Law to be Confidential.” .....	8
II. No Law Declares SB 539 Information To Be Confidential. ....	10
A. The DTSA does not apply to documents held by the government.....	10
B. SB 539 information is not confidential under the Nevada Trade Secrets Act. .... .....	14
C. SB 539 information is not confidential under DHS’s regulations. ....	15
CONCLUSION .....	17

## TABLE OF AUTHORITIES

Cases	Page(s)
<i>City of Sparks v. Reno Newspapers, Inc.</i> , 133 Nev. 398, 399 P.3d 352 (2017).....	8, 16
<i>Clark Cty. Sch. Dist. v. Las Vegas Review-Journal</i> , 134 Nev. 700, 429 P.3d 313 (2018).....	16
<i>Comstock Residents Ass’n v. Lyon Cty. Bd. of Commissioners</i> , 134 Nev. 142, 414 P.3d 318 (2018).....	16
<i>Ctr. for Auto Safety v. Nat’l Highway Traffic Safety Admin.</i> , 244 F.3d 144 (D.C. Cir. 2001) .....	9
<i>Fast Enterprises, LLC v. Pollack</i> , No. 16-CV-12149-ADB, 2018 WL 4539685 (D. Mass. Sept. 21, 2018).....	12
<i>Finkel v. U.S. Dep’t of Labor</i> , No. CIV A 05-5525 MLC, 2007 WL 1963163 (D.N.J. June 29, 2007).....	10
<i>Lee v. FDIC</i> , 923 F. Supp. 451 (S.D.N.Y. 1996) .....	10
<i>LVMPD v. Blackjack Bonding</i> , 131 Nev. 80, 343 P.3d 608 (2015).....	8
<i>Nevada State Democratic Party v. Nevada Republican Party</i> , 256 P.3d 1 (Nev. 2011) .....	15
<i>Pub. Employees’ Ret. Sys. of Nevada v. Nevada Policy Research Inst., Inc.</i> , 134 Nev. 669, 429 P.3d 280 (2018).....	9
<i>Reno Newspapers, Inc. v. Gibbons</i> , 127 Nev. 873, 266 P.3d 623 (2011).....	8
<i>Reno Newspapers v. Sheriff</i> , 126 Nev. 211, 234 P.3d 922 (2010).....	16
<i>Uribe v. Howie</i> , 19 Cal.App.3d 194 (1971) .....	13
<b>Federal Statutes</b>	
18 U.S.C. § 1833(a)(1) .....	1, 10, 11, 12, 16

1	18 U.S.C. § 1836.....	2, 15
2	18 U.S.C. § 1838.....	11
3	<b>State Statutes</b>	
4	Cal. Food & Agr. Code § 78925.....	13
5	Cal. Gov't Code § 6254.7(e).....	13
6	Cal. Gov't Code § 6254.26(b).....	13
7	Ind. Code Ann. § 5-14-3-4(a)(5) .....	13
8	Mich. Comp. Law § 15.243(f).....	13
9	NRS 53.045 .....	2
10	NRS 239.010(1) .....	8, 10
11	NRS 239.010(3) .....	8
12	NRS 239.030 .....	8
13	NRS 239B.010(1) .....	1
14	NRS 439B.630(2) .....	6
15	NRS 439B.635.....	<i>passim</i>
16	NRS 439B.640.....	1, 6, 7, 14, 15
17	NRS 439B.645.....	7, 8
18	NRS 439B.650.....	1, 7, 14
19	NRS 439B.660.....	7
20	NRS 439B.670.....	14
21	NRS 439B.670(1)(a)(4).....	1, 7
22	NRS 439B.930.....	17
23	NRS 453A.370(5) .....	16
24	NRS 600A.030.....	2, 15
25		
26		
27		
28		

NRS 600A.030(5)(b) .....	<i>passim</i>
Or. Rev. Stat. § 192.501(2) .....	13

## INTRODUCTION

The Nevada Legislature passed SB 539 in 2017 in order to bring transparency to diabetes-drug pricing and address the ballooning costs facing diabetic Nevadans. SB 539 requires drug manufacturers like Sanofi to report information about their pricing of essential diabetes drugs, and additional information if their list prices increase by a significant amount during a year. NRS 439B.635; NRS 439B.640. It requires DHS to publish the list prices of each essential diabetes drug on its website (NRS 439B.670(1)(a)(4)) and to issue a report annually describing the pricing of the essential diabetes drugs that appear on a DHS-compiled list (NRS 439B.650), including the reasons for price increases. Key to the success of these transparency provisions is NRS 600A.030(5)(b), which excludes information provided by drug manufacturers pursuant to SB 539 from Nevada’s definition of a trade secret.

The Nevada Independent seeks SB 539 information submitted to DHS by various insulin manufacturers, including Sanofi. Under Nevada’s Public Records Act, it is entitled to this information unless a specific statutory exemption applies or the information is “otherwise declared by law to be confidential.” NRS 239B.010(1). Sanofi does not claim that a specific statutory exemption applies, but rather that information about its drug-price increases is “otherwise declared by law to be confidential.” Sanofi Resp. Br., at 4. It identifies three laws that it claims make its SB 539 information confidential. None of these arguments is tenable because none of the laws Sanofi cites applies to the information it submitted under SB 539.

First, Sanofi claims that its SB 539 information is protected by the federal Defend Trade Secrets Act (“DTSA”). Sanofi Resp. Br., at 4. This argument is baseless. The DTSA states explicitly that it does not apply to information lawfully released by a state government: “This chapter does not prohibit or create a private right of action for— . . . any otherwise lawful activity conducted by a governmental entity of the United States, a State, or a political subdivision of a State[.]” 18 U.S.C. § 1833(a)(1). When it passed the DTSA, Congress repeatedly made clear that it did not

1 intend to preempt state law or displace state policy on its citizens’ access to information.  
2 Unsurprisingly, the courts that have addressed Sanofi’s interpretation of the DTSA  
3 have rejected it.

4 Second, Sanofi argues that its SB 539 information is “otherwise declared by law  
5 to be confidential” under NRS 600A.030, Nevada’s Trade Secret Act. But this argument  
6 is backwards. NRS 600A.030 states explicitly that SB 539 information *is not* a trade  
7 secret under Nevada law. NRS 600A.030(5)(b). No amount of grammatical contortion  
8 can reverse the plain meaning of this provision. *Cf.* Sanofi Resp. Br., at 12.

9 Finally, Sanofi points to regulations adopted by DHS. Sanofi Resp. Br., at 4. But  
10 those regulations permit DHS to withhold SB 539 information if public disclosure  
11 “would constitute misappropriation of a trade secret for which a court may award relief  
12 pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as  
13 amended[.]” NAC 439.735. This regulation is inapplicable because the DTSA does not  
14 apply to a government’s release of information it holds and no court may award DTSA  
15 relief against a state government for doing so. Nor is DHS permitted to adopt  
16 regulations that are incompatible with its authorizing legislation, or that disable the  
17 Nevada Public Records Act administratively.

18 The Nevada Independent is entitled to the SB 539 information it has requested  
19 under the Nevada Public Records Act. DHS may not avoid its responsibilities under the  
20 law by misreading SB 539 and relying on a fundamentally baseless view of federal trade  
21 secret law.

## 22 BACKGROUND

### 23 *The Insulin-Pricing Crisis*

24 SB 539 is part of Nevada’s response to the national crisis in diabetes-drug price  
25 increases. The average list price for insulin tripled between 2003 and 2013.<sup>3</sup> Per-

---

27 <sup>3</sup> “Insulin Access and Affordability Working Group: Conclusions and Recommendations,”  
28 41 DIABETES CARE 1299-1300 (2018), available at:  
<https://care.diabetesjournals.org/content/41/6/1299> (last visited February 2, 2020).

1 patient insulin cost nearly *doubled* between 2012 and 2016.<sup>4</sup> The costs of many  
2 individual insulin treatments have risen even faster. The cost of four of the most  
3 popular forms of insulin tripled over the last decade.<sup>5</sup> The cost of Sanofi's Lantus  
4 insulin treatment nearly doubled in the six years from 2013 to 2019, from \$244 to  
5 \$431.<sup>6</sup>

6 These unjustified price increases have resulted in extreme hardship for diabetics,  
7 many of whom are forced to choose between the safe and prescribed method for  
8 controlling their illness and basic necessities like food and rent. As many as *one in four*  
9 *diabetic patients* report reducing their insulin use below prescribed levels because of the  
10 cost of the drug.<sup>7</sup>

11 Drug manufacturers' price increases also take a heavy toll on health-benefit  
12 providers, like the Culinary Health Fund. The large and increasing cost of diabetes  
13 drugs reduces the assets available for other kinds of treatments, increases the burden  
14 on unionized employers, and puts downward pressure on workers' wages. The CHF  
15 paid approximately \$26 million for diabetes medications in 2016, which was fully *one-*  
16 *quarter* of the Fund's total prescription-drug spend. Not even government health-

---

17 <sup>4</sup> Jean Fuglesten Biniek, William Johnson, "Spending on Individuals with Type 1  
18 Diabetes and the Role of Rapidly Increasing Insulin Prices," Health Care Cost Institute  
19 (January 21, 2019), available at: [https://www.healthcostinstitute.org/  
20 research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-  
of-rapidly-increasing-insulin-prices](https://www.healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices) (last visited Feb. 1, 2020).

21 <sup>5</sup> Elisabeth Rosenthal, "When High Prices Mean Needless Death," *JAMA Intern*  
22 *Med.* 179:114-115 (2019), available at: [https://jamanetwork.com/journals/  
23 jamainternalmedicine/article-abstract/2717498](https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717498) (last visited February 2, 2020).

24 <sup>6</sup> Ken Alltucker, "Struggling to stay alive: Rising insulin prices cause diabetics to go to  
25 extremes, USA Today, March 27, 2019, available at: [https://www.usatoday.com/  
26 in-depth/news/50-states/2019/03/21/diabetes-insulin-costs-diabetics-drug-prices-  
increase/3196757002/](https://www.usatoday.com/in-depth/news/50-states/2019/03/21/diabetes-insulin-costs-diabetics-drug-prices-increase/3196757002/) (last visited February 2, 2020).

27 <sup>7</sup> Darby Herkert, Pavithra Vijayakumar, Jing Luo, et al., "Cost-Related Insulin  
28 Underuse Among Patients With Diabetes," *JAMA Intern Med.* 179:112-114 (2019),  
available at: [https://jamanetwork.com/journals/jamainternalmedicine/  
fullarticle/2717499](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2717499) (last visited February 2, 2020).

benefit purchasers are immune. One recent analysis found that from 2007 to 2017, Medicare’s pre-rebate spending on insulin increased 840%, while aggregate annual out-of-pocket spending more than quadrupled.<sup>8</sup>

As the New England Journal of Medicine editorialized, the profit that companies like Sanofi make from diabetic Culinary members is particularly unjust, given that the original patent for insulin dates to the 1920s, and was intended to put public access to the life-saving drug above profit: “As solutions to the insulin-cost crisis are being considered, there is value in remembering that when the patent for insulin was first drafted in 1923, [the discoverers] declined to be named on it. Both felt that insulin belonged to the public. Now, nearly 100 years later, insulin is inaccessible to thousands of Americans because of its high cost.”<sup>9</sup>

### ***Insulin Pricing: The Need for Transparency***

While the causes of diabetes-drug-price increases are complex, experts have pointed to the lack of transparency in pricing decisions as a major contributor. The process by which insulin goes from manufacturer to patient is complex, involving many stakeholders: drug manufacturers, drug wholesalers, pharmacy benefit managers, health plans, and employers. The price ultimately paid by a patient (and their insurer) for insulin results from drug manufacturers’ list prices, together with various rebates and fees remitted and charged by these stakeholders.

Drug manufacturers like Sanofi often publicly stress the rebates that they offer (usually to pharmacy benefit managers in return for formulary placement) and argue that this is a reason to disregard the list prices of their insulin products in favor of the

---

<sup>8</sup> Juliette Cubanski & Tricia Neuman et al., *How much Does Medicare Spend on Insulin?*, Kaiser Family Foundation (Apr. 1, 2019), available at: <https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/> (last visited February 1, 2020).

<sup>9</sup> Michael Fralick & Aaron S. Kesselheim, “The U.S. Insulin Crisis — Rationing a Lifesaving Medication Discovered in the 1920s,” *New England Journal of Medicine*, 381:1793-1795 (2019), available at: <https://www.nejm.org/doi/full/10.1056/NEJMp1909402?query=TOC> (last visited February 2, 2020).

1 “net price” that includes rebates.<sup>10</sup> But there is little evidence that the opaque system  
2 of rebates that insulin manufacturers and PBMs negotiate ultimately reduces patients’  
3 out-of-pocket costs, which continue to rise exponentially. And the rebate system that  
4 drug manufacturers tout does nothing for the uninsured, who have to pay the list price.  
5 Instead, according to the Insulin Access and Affordability Working Group—a team of  
6 academic experts and practitioners convened by the American Diabetes Association to  
7 study the problem—“As list prices increase, the profits of the intermediaries in the  
8 insulin supply chain increase . . . since each may receive a rebate, discount, or fee  
9 calculated as a percentage of the list prices.”<sup>11</sup> The ADA working group concluded that  
10 “[p]eople with diabetes are financially harmed by high list prices and high out-of-pocket  
11 costs. Regardless of the negotiated net price, the cost of insulin for people with diabetes  
12 is greatly influenced by the list price for insulins.”<sup>12</sup>

13 Experts and patient advocates agree that increasing the pricing transparency in  
14 the insulin supply chain, including in the rationale behind list-price increases, is  
15 essential to address skyrocketing drug costs. Doing so is likely to reduce insulin costs to  
16 patients and health-care costs for insurers. For example, researchers at the Brookings  
17 Institute estimated that increasing price transparency in generic drug pricing could  
18 reduce health spending by \$4 billion for every \$1 reduction in average reimbursement to

---

19 <sup>10</sup> Sanofi, “Prescription Medicine Pricing Our Principles and Perspectives” (2019),  
20 available at: [https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-](https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/SanofiUS/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf)  
21 [America/SanofiUS/Home/corporateresponsibility/Prescription\\_Medicine\\_Pricing\\_2019.p](https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/SanofiUS/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf)  
22 [df](https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/SanofiUS/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf) (last visited February 20, 2020). Some insulin manufacturers have also sought to  
23 head off regulatory scrutiny by promising lower cost insulin to segments of diabetes  
24 patients. See Cynthia Koons & Anna Edney, “Drugmakers Discount Insulin, and  
25 Lawmakers Ask What Took So Long,” BLOOMBERG (April 10, 2019), available at:  
26 [https://www.bloomberg.com/news/articles/2019-04-10/sanofi-widens-insulin-discounts-](https://www.bloomberg.com/news/articles/2019-04-10/sanofi-widens-insulin-discounts-ahead-of-congressional-hearing)  
27 [ahead-of-congressional-hearing](https://www.bloomberg.com/news/articles/2019-04-10/sanofi-widens-insulin-discounts-ahead-of-congressional-hearing) (last visited February 2, 2020).

28 <sup>11</sup> William T. Cefalu et al., “Insulin Access and Affordability Working Group:  
Conclusions and Recommendations,” DIABETES CARE 41: 1308 (May 2018), available at:  
<https://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019> (last visited  
February 2, 2020).

<sup>12</sup> *Id.* at 1309.

1 retail and mail-order pharmacies.<sup>13</sup> The American Diabetes Association working group  
2 “identified increase price transparency throughout the insulin supply chain . . . as [an]  
3 important step[] toward developing viable, long-term solutions to improve insulin access  
4 and affordability.”<sup>14</sup>

5 Sanofi itself agrees on the need for transparency in the pricing of its insulin,  
6 notwithstanding its claims of trade secrecy and confidentiality in this lawsuit. One of  
7 Sanofi’s 2019 “Pricing Principles” for its drug products is that if it increases the price of  
8 the drug by more than the growth in National Medical Expenditure (a measure of  
9 healthcare inflation), it pledges to “provide our rationale, highlighting clinical value,  
10 real world evidence, regulatory change, new data, or other circumstances that support  
11 our decision.”<sup>15</sup> This pledge is *essentially the same* as the requirement in SB 539 that  
12 Sanofi disclose basic information about insulin price increases that are greater than the  
13 grown in medical inflation. *See* NRS 439B.630(2), 439B.640. Far from infringing on  
14 Sanofi’s trade secrets, SB 539 merely requires the level of transparency that Sanofi has  
15 already *pledged to the public*.

16 ***SB 539 Promises Transparency***

17 States across the country have adopted legislation requiring transparency in drug  
18 manufacturers’ pricing decisions. Legislators in thirty-three states have passed or  
19 introduced bills that would require some form of pricing disclosure by drug  
20 manufacturers.<sup>16</sup> Federal lawmakers have introduced a number of bills and regulatory  
21 changes designed to make drug pricing more transparent, including the Prescription  
22

---

23 <sup>13</sup> Steven M. Lieberman and Paul B. Ginsburg, “Would Price Transparency For Generic  
24 Drugs Lower Costs For Payers And Patients?” The Brookings Institution (June 2017),  
25 available at: [https://www.brookings.edu/wp-content/uploads/](https://www.brookings.edu/wp-content/uploads/2017/06/es_20170613_genericdrugpricing.pdf)  
2017/06/es\_20170613\_genericdrugpricing.pdf (last visited February 2, 2020).

26 <sup>14</sup> Cefalu et al., at 1299.

27 <sup>15</sup> Sanofi, “Pricing Principles,” at 2.

28 <sup>16</sup> National Academy for State Health Policy, Legislation Tracker, available at:  
<https://nashp.org/rx-legislative-tracker/> (last visited February 1, 2020).

1 Drug Price Transparency Act (H.R. 1035), and have called insulin manufacturers into  
2 hearings to explain skyrocketing prices.<sup>17</sup>

3 Nevada adopted SB 539 to increase insulin-pricing transparency in the State.  
4 The law requires DHS to compile, annually, a list of “essential diabetes drugs.”<sup>18</sup> Each  
5 year, drug manufacturers are required to submit to DHS a report providing certain  
6 information about the essential diabetes drug prices, including the list or wholesale  
7 price, the aggregate amount of rebates provided, and the amount of any co-payment  
8 coupons offered to patients, among other things. NRS 439B.635. Drug manufacturers  
9 that increase the price of essential diabetes drugs by more than a measure of medical-  
10 cost inflation are required to report additional information to DHS, including the factors  
11 that led to the price increase. NRS 439B.640.

12 DHS is required, annually, to compile a report “on the price of the prescription  
13 drugs that appear on the most current lists compiled by the Department[.]” NRS  
14 439B.650. It is also required to display the wholesale (or list) price of each essential  
15 diabetes drug on its website. NRS 439B.670(1)(a)(4). SB 539 says nothing about the  
16 information provided to DHS being “confidential” or protecting it from being released to  
17 the public.

18 To the contrary, the Legislature added an amendment to Nevada’s Trade Secret  
19 Act to ensure that SB 539 information would be *public information*. SB 539 amended  
20 Nevada’s definition to state that a trade secret:

21 Does not include any information that a manufacturer is required to report  
22 pursuant to NRS 439B.635 or 439B.640, information that a pharmaceutical sales  
23 representative is required to report pursuant to NRS 439B.660 or information  
that a pharmacy benefit manager is required to report pursuant to NRS

---

24 <sup>17</sup> Christopher Rowland, “Drug executives grilled in Senate over high prices,”  
25 WASHINGTON POST, February 26, 2019, available at [https://www.washingtonpost](https://www.washingtonpost.com/business/economy/drug-executives-grilled-in-senate-over-high-prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137_story.html)  
26 [.com/business/economy/drug-executives-grilled-in-senate-over-high-](https://www.washingtonpost.com/business/economy/drug-executives-grilled-in-senate-over-high-prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137_story.html)  
27 [prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137\\_story.html](https://www.washingtonpost.com/business/economy/drug-executives-grilled-in-senate-over-high-prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137_story.html) (last visited  
February 2, 2020).

28 <sup>18</sup> In 2019, NRS Chapter 439B was amended to create similar requirements for asthma  
drugs. SB 262 (2019).

1 439B.645, to the extent that such information is required to be disclosed by those  
2 sections.

3 NRS 600A.030(5)(b).

## 4 ARGUMENT

### 5 I. The Nevada Public Records Act Requires Disclosure of SB 539 Information 6 Unless the Information is “Otherwise Declared by Law to be Confidential.”

7 Nevada’s Public Records Act (“NPRA”) gives the public access to “all public books  
8 and public records of a governmental entity” unless an exception to disclosure applies.  
9 NRS 239.010(1). Consistent with the obligation that courts construe the NPRA  
10 “liberally” to promote the public’s access to information, “[a]ny exemption, exception or  
11 balancing of interests which limits or restricts access to public books and records by  
12 members of the public must be construed narrowly[.]” NRS 239.010(3); *Reno*  
13 *Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 877-78, 266 P.3d 623, 626 (2011) (“The  
14 Legislature has declared that the purpose of the NPRA is to further the democratic  
15 ideal of an accountable government by ensuring that public records are broadly  
16 accessible.”).

17 Sanofi suggests that the NPRA only applies to “government-generated records”  
18 and not to records that were originally created by a private entity. Sanofi Resp. Br., at  
19 17. But NRS 239.030 makes no distinction between government records that were  
20 generated by a public official and records that were generated by a non-government  
21 entity and supplied to the government. The NPRA is regularly applied to records that  
22 were not generated by the government, but that are in the government’s possession.  
23 The NPRA applies to emails generated by a private party and sent to a government  
24 official. *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 876, 266 P.3d 623, 625 (2011).  
25 It applies to “telephone calls between private individuals” that are contained in public  
26 records. *LVMPD v. Blackjack Bonding*, 131 Nev. 80, 86, 343 P.3d 608, 612 (2015). And  
27 information supplied by a private entity in “business licenses are public records” and  
28 must be disclosed unless the government proves that an exception applies. *City of*  
*Sparks v. Reno Newspapers, Inc.*, 133 Nev. 398, 401, 399 P.3d 352, 355 (2017) (finding

1 information contained in marijuana outlet licenses to be public records, but finding  
2 them to be confidential under clear Nevada law).

3 Sanofi argues that The Nevada Independent has “failed to cite any authority  
4 demonstrating that the NPRA . . . allows the public to obtain access” to “information  
5 contained in reports prepared by private business entities and submitted to  
6 administrative agencies as required by law.” Sanofi Resp. Br., at 17. But the  
7 information in question was reported to DHS pursuant to a law—SB 539—whose *entire*  
8 *point* was to make insulin pricing decisions transparent. It would be incongruous to  
9 interpret the Nevada Public Records Act not to apply to information that is in the  
10 government’s possession because of a transparency law and that the Legislature  
11 expressly exempted from trade-secrecy protection.

12 In any case, it is Sanofi’s and DHS’s burden to prove that the SB 539 information  
13 is not a public record, not The Nevada Independent’s to prove that it is. *Pub.*  
14 *Employees’ Ret. Sys. of Nevada v. Nevada Policy Research Inst., Inc.*, 134 Nev. 669, 671,  
15 429 P.3d 280, 283 (2018) (“[T]here is a presumption in favor of disclosure, and the  
16 governmental entity in control of the requested information bears the burden of  
17 overcoming this presumption by demonstrating by a preponderance of the evidence that  
18 the requested information is confidential.”). Sanofi cites nothing in the language of the  
19 NPRA that could support the distinction makes between “government-generated”  
20 records and other information in the government’s possession, or limiting public records  
21 to those submitted as part of “bid proposals and license applications.” Sanofi Resp. Br.,  
22 at 17. Nor is there any case law supporting its request to rewrite the NPRA.

23 In fact, the federal Freedom of Information Act (“FOIA”), NPRA’s federal analog,  
24 has always applied both to financial and other information that was “voluntarily”  
25 submitted to the government and to information that the government mandates a  
26 business submit. See, e.g., *Ctr. for Auto Safety v. Nat’l Highway Traffic Safety Admin.*,  
27 244 F.3d 144, 147-48 (D.C. Cir. 2001) (emphasizing that there are two distinct  
28 standards to be used in determining confidentiality under FOIA, depending on whether

1 information is provided on a "mandatory" or a "voluntary" basis); *Lee v. FDIC*, 923 F.  
2 Supp. 451, 454 (S.D.N.Y. 1996) (bank's financial documents that were "required to be  
3 submitted to the Federal Reserve Board" as part of Board's regulatory oversight had to  
4 be disclosed under FOIA, despite confidentiality and trade secret claims); *Finkel v. U.S.*  
5 *Dep't of Labor*, No. CIV A 05-5525 MLC, 2007 WL 1963163, at \*8 (D.N.J. June 29, 2007)  
6 (employer-specific toxins information that had been provided to OSHA by mandate had  
7 to be disclosed under FOIA, despite claims of trade secrecy and commercial  
8 confidentiality).

9       There is no question but that the drug-manufacturer reports mandated by SB 539  
10 are government records subject to the NPRA. Unless DHS and Sanofi can meet their  
11 burden in demonstrating that drug manufacturers' SB 539 reports are exempt from the  
12 NPRA, DHS is required to produce them to The Nevada Independent. As the following  
13 section makes clear, DHS and Sanofi have not met this burden.

## 14       **II. No Law Declares SB 539 Information To Be Confidential.**

15       Sanofi does not claim that its SB 539 reports are barred from disclosure under  
16 any express statutory exemption. *See* NRS 239.010(1); Sanofi Resp. Br., at 4. Instead,  
17 Sanofi argues that this information is "otherwise declared by law to be confidential"  
18 under three laws: (1) the federal Defend Trade Secrets Act ("DTSA"); (2) Nevada's Trade  
19 Secrets Act, NRS chapter 600A; and (3) DHS's regulations codified at NAC 439.735.  
20 None of these laws makes Sanofi's (or any other drug manufacturer's) SB 539 reports to  
21 DHS confidential.

### 22       **A. The DTSA does not apply to documents held by the government.**

23       Sanofi and DHS claim that the DTSA prohibits DHS from releasing the SB 539  
24 reports that drug manufacturers submitted and that DHS would face a DTSA claim for  
25 misappropriating trade secrets if it does so. Sanofi Resp. Br., at 16.

26       Both Sanofi and DHS ignore DTSA's plain language and Congress's repeated  
27 statements that it was not altering state law. 18 U.S.C. § 1833(a)(1) states that "[t]his  
28 chapter does not *prohibit or create a private right of action* for—any *otherwise lawful*

1 *activity conducted by a governmental entity* of the United States, a State, or a political  
2 subdivision of a State.” (Emphasis added). The DTSA does not prohibit DHS from  
3 disclosing information provided to it when that course of action is “otherwise lawful.” In  
4 other words, litigants like Sanofi cannot rely on the DTSA to create a cause of action  
5 against a state government for releasing information in its possession. Disclosing SB  
6 539 reports is an “otherwise lawful activity conducted by a governmental entity of . . . a  
7 State.” 18 U.S.C. § 1833(a)(1). Indeed, SB 539 and the NPRA make clear that such  
8 reports are *required* to be disclosed.

9 Congress did not intend to preempt state law when it enacted the DTSA. This is  
10 clear both from its decision to include an express anti-preemption provision, 18 U.S.C. §  
11 1838,<sup>19</sup> and from Congress’s own description of its actions. Here is how the House  
12 Judiciary Committee described the DTSA:

13 Consistent with the overall intent of the Defense Trade Secret Act and, in  
14 particular, § (2)(f), which provides that the bill does not “preempt any other  
15 provision of law,” the remedies provided in § (3)(A)(i)(1)(I) are intended to coexist  
16 with, and *not to preempt, influence, or modify applicable State law* governing  
when an injunction should issue in a trade secret misappropriation matter.

17 H. Rep. No. 114-529 (2016) (House Judiciary Committee Report), at 11-12; *id.* at 6  
18 (“Carefully balanced to ensure an effective and efficient remedy for trade secret owners  
19 whose intellectual property has been stolen, the legislation is designed to avoid  
20 disruption of legitimate businesses, *without preempting State law.*”); *id.* at 14 (“ . . .  
21 State trade secret laws are not preempted or affected by this Act.”); S. Rep. 114-220  
22 (2016) (Senate Judiciary Committee Report), at 14-15 (“Carefully balanced to ensure an  
23 effective and efficient remedy for trade secret owners whose intellectual property has  
24 been stolen, the legislation is designed to avoid disruption of legitimate business,  
25 *without preempting State law.*”).<sup>20</sup>

26 <sup>19</sup> “[T]his chapter shall not be construed to preempt or displace any other remedies,  
27 whether civil or criminal, provided by United States Federal, State, commonwealth,  
28 possession, or territory law for the misappropriation of a trade secret.” 18 U.S.C. §  
1838.

<sup>20</sup> These House and Senate reports are available, respectively, at: <https://www.congress.gov/114/>

1 DTSA does not apply to otherwise lawful decisions by state governments to  
2 release information to the public and was not intended to override state trade-secrecy  
3 law, including Nevada’s decision to exempt SB 539 reports from state trade-secrecy  
4 protection.

5 Neither DHS nor Sanofi can cite any case interpreting DTSA to apply to  
6 information held and disclosed by a state government. In *Fast Enterprises, LLC v.*  
7 *Pollack*, No. 16-CV-12149-ADB, 2018 WL 4539685, at \*4 (D. Mass. Sept. 21, 2018), a  
8 federal court flatly rejected the argument the DHS and Sanofi make. There, a bidder  
9 for a public contract sought to prevent a television station from obtaining what it  
10 claimed were trade secrets contained in bid documents it had submitted to the  
11 Massachusetts Department of Transportation. The bidder claimed that the information  
12 was protected by the DTSA and should not be subject to the Massachusetts public  
13 records law. But the court flatly rejected this argument as incompatible with the plain  
14 text of 18 U.S.C. § 1833(a)(1): “the exemption [from DTSA] at issue here applies only to  
15 the actions of federal, state, and local government entities and it is entirely reasonable  
16 to read the statute as demonstrating that Congress did not intend for the DTSA to  
17 abrogate state sovereign immunity or to otherwise interfere with lawful policy decisions  
18 made by state legislatures concerning the activities of the state.” *Fast Enterprises,*  
19 *LLC*, No. 16-CV-12149-ADB, 2018 WL 4539685, at \*4.

20 The Court does not need any further reason to reject the position that the DTSA  
21 applies to state governments’ release of information under their public-records laws.  
22 But it is worth recognizing how much state law DHS’s and Sanofi’s interpretation of the  
23 DTSA would override. States frequently make policy choices concerning mandated  
24 disclosure of information that might otherwise be claimed as a trade secret, such as  
25 emissions data supplied by auto manufacturers, Cal. Gov’t Code § 6254.7(e),  
26 agricultural interests’ “information on volume shipments, crop value, and any other  
27 related information that is required for reports to governmental agencies, financial

28 [crpt/hrpt529/CRPT-114hrpt529.pdf](https://www.congress.gov/114/hrpt/529/CRPT-114hrpt529.pdf) and <https://www.congress.gov/114/crpt/srpt220/CRPT-114srpt220.pdf>.

1 reports to the commission, or aggregate sales and inventory information, Cal. Food &  
2 Agr. Code § 78925, and detailed information about the performance and fees of private  
3 equity funds in which state public pensions invest, Cal. Gov’t Code § 6254.26(b).

4       Some states limit trade-secret protection from public disclosure to information  
5 that the government expressly promised to keep confidential and do not prohibit public  
6 disclosure where required by state law. *See, e.g.,* Mass. G. L. c. 4, § 7(26)(g) (protecting  
7 from public disclosure only “trade secrets or commercial or financial information  
8 voluntarily provided to an agency for use in developing governmental policy and upon a  
9 promise of confidentiality; but this subclause shall not apply to information submitted  
10 as required by law[.]”); Ind. Code Ann. § 5-14-3-4(a)(5) (exempting from public  
11 disclosure “[c]onfidential financial information obtained, upon request, from a person,”  
12 but providing that “this does not include information that is filed with or received by a  
13 public agency pursuant to state statute”); Mich. Comp. Law § 15.243(f) (protecting from  
14 public disclosure information that is “voluntarily provided to an agency for use in  
15 developing governmental policy,” but only where the “information is submitted upon a  
16 promise of confidentiality by the public body”). Other states balance the interest in  
17 trade-secrecy protection against the public interest in disclosure. *See, e.g., Uribe v.*  
18 *Howie*, 19 Cal.App.3d 194, 199 (1971) (concluding that public interest in knowing the  
19 location and types of pesticide use outweighed interest in trade secrecy); Or. Rev. Stat. §  
20 192.501(2) (exempting trade secrets from public disclosure “unless the public interest  
21 requires disclosure in the particular instance”). Similar policy choices are made in  
22 Nevada and every other state.

23       But under DHS’s and Sanofi’s view of the DTSA, Congress robbed state citizens  
24 of their right to make these determinations by allowing private businesses to sue state  
25 governments for misappropriating trade secrets through public-records disclosure. That  
26 is not what Congress did or what the DTSA says.<sup>21</sup>

---

27  
28 <sup>21</sup> The fact that Nevada’s previous Attorney General and counsel for the Nevada  
Legislature took the position that the DTSA applied when they settled a different

1           **B.     SB 539 information is not confidential under the Nevada Trade Secrets**  
2           **Act.**

3           Next, Sanofi argues counterintuitively that its SB 539 report is “confidential”  
4 under Nevada’s Trade Secrets Act, NRS chapter 600A. This argument is also  
5 unfounded because NRS 600A.030(5)(b) states expressly that the information that drug  
6 manufacturers provide pursuant to SB 539 is *not* a trade secret. There is no convincing  
7 reason why the Legislature would have expressly exempted drug manufacturers’ SB 539  
8 reports from trade-secrecy protection if it wanted those reports to be confidential under  
9 the same statute. NRS 600A.030(5)(b) states, forthrightly, that a trade secret “[d]oes  
10 not include any information that a manufacturer is required to report pursuant to NRS  
11 439B.635 or 439B.640 . . . to the extent that such information is required to be disclosed  
12 by those sections.”

13           Sanofi tries to avoid this problem by engaging in grammatical contortions and  
14 spraying the provision’s text with italics, bold, and underline. Sanofi Resp. Br., at 12.  
15 According to Sanofi, this provision “remove[s] the trade secret protection only for the  
16 specific information which the manufacturers report to the Department ***and*** which the  
17 Department subsequently reports to the public pursuant to NRS 439B.650 and NRS  
18 439B.670.” *Ibid.*

19           But NRS 600A.030(5)(b) does not say that trade secrecy protection is lifted only  
20 for information that is required to be disclosed “pursuant to NRS 439B.650 and NRS  
21 439B.670” as Sanofi argues. It removes trade secrecy protection for information  
22 required to be reported “pursuant to NRS 439B.635 or 439B.640” to the extent the  
23 information “is required to be disclosed *by those sections*.” Sanofi is trying to rewrite  
24 NRS 600A.030(5)(b) to import into it statutory provisions to which it does not refer.

25  
26 lawsuit is irrelevant. No court has adopted this position, it is contradicted by the  
27 DTSA’s plain language, and has been rejected by the one court that did address it. Cf.  
28 Sanofi Resp. Br., at 14. The federal court’s acceptance of PhRMA’s voluntary dismissal  
of its action in that case did not amount to any endorsement of the parties’ view of the  
DTSA.

1 NRS 600A.030(5)(b)'s language is straightforward. Information in drug  
2 manufacturers' reports to DHS that is required to be disclosed under NRS 439B.635 and  
3 439B.640—wholesale acquisition costs, aggregate amounts of rebates, and the factors  
4 that led to substantial increases in the list prices of diabetes drugs, for example—are  
5 not trade secrets. Of course, if a drug manufacturer includes information in its report to  
6 DHS that is not required to be disclosed to DHS under NRS 439B.635 or 439B.640, but  
7 that the drug manufacturer includes voluntarily, that information retains any trade  
8 secrecy protection it would normally have.

9 “It is well established that, when interpreting a statute, the language of a statute  
10 should be given its plain meaning. Thus, when a statute is facially clear, a court should  
11 not go beyond its language in determining its meaning.” *Nevada State Democratic*  
12 *Party v. Nevada Republican Party*, 256 P.3d 1, 4–5 (Nev. 2011). Sanofi cannot change  
13 NRS 600A.030's plain meaning by adding language that is not in it.

14 **C. SB 539 information is not confidential under DHS's regulations.**

15 Finally, Sanofi and the DHS argue that drug manufacturers' SB 539 information  
16 is confidential under DHS's regulations at NAC 439.735. That regulation states that  
17 when faced with a public-records request, DHS may withhold information reported  
18 pursuant to SB 539 if “the Department reasonably believes that public disclosure of the  
19 information would constitute misappropriation of a trade secret for which a court may  
20 award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. §  
21 1836[.]” NAC 439.735(4). There are three reasons why this regulation does not permit  
22 DHS to withhold drug manufacturers' SB 539 reports.

23 First, as explained, DHS's disclosure of this information could not constitute  
24 misappropriation of a trade secret under the DTSA and could not be the basis for a  
25 court award against DHS because the DTSA does not apply to otherwise lawful actions  
26 by state governments. 18 U.S.C. § 1833(a)(1); *see supra*. Even if NAC 439.735 were a  
27 legitimate interpretation of SB 539 and a permissible restriction of the public's rights  
28 under Nevada's Public Records Act, it does not apply to drug manufacturers' SB 539

1 reports that are in DHS’s possession. There is no legal basis for DHS to conclude that  
2 its disclosure of SB 539 reports is prohibited by the DTSA, much less the “explicit and  
3 unequivocal” evidence of an exception required by the NPRA. *Reno Newspapers v.*  
4 *Sheriff*, 126 Nev. 211, 215, 234 P.3d 922, 925 (2010).

5 But NAC 439.735 is not a legitimate regulation. Nevada’s Public Records Act  
6 does not permit state agencies to create their own exceptions to the NPRA, and the  
7 Legislature made clear in SB 539 that the reports that drug manufacturers make to  
8 DHS are *not* intended to be trade secrets.

9 The Supreme Court has made clear that state agencies may not evade the  
10 NPRA’s requirements by adopting their own exceptions to disclosure. Similarly, Sanofi  
11 may not rely on NAC 439.735 as a basis for its claim that SB 539 reports are  
12 confidential under the law. “Ascribing a force to such regulations that limits the NPRA  
13 would create an opportunity for government organizations to make an end-run around  
14 the NPRA by drafting internal regulations that render documents confidential by law.”  
15 *Clark Cty. Sch. Dist. v. Las Vegas Review-Journal*, 134 Nev. 700, 704, 429 P.3d 313, 318  
16 (2018); *Comstock Residents Ass’n v. Lyon Cty. Bd. of Commissioners*, 134 Nev. 142, 147,  
17 414 P.3d 318, 322 (2018) (administrative regulations are permissible only to the extent  
18 that they “do not limit the reach of the NPRA, but merely establish regulations for good  
19 records management practices”).

20 As The Nevada Independent points out, the case that Sanofi cites as completely  
21 distinguishable. In *City of Sparks v. Reno Newspapers, Inc.*, 133 Nev. 398, 401, 399  
22 P.3d 352, 356 (2017), the statute in question, NRS 453A.370(5), directed that the state  
23 agency “*must ... [a]s far as possible while maintaining accountability, protect the*  
24 *identity and personal identifying information of each person who receives, facilitates or*  
25 *delivers services.*” Thus, the Legislature itself declared that the personal identifying  
26 information of marijuana outlet licensees was to remain confidential. The regulations  
27 adopted by the state agency merely carried out this legislative directive.  
28

1 DHS has no such authority under SB 539. The Legislature was specific about  
2 what DHS's regulations were to include. See NRS 439B.930. SB 539 permits DHS to  
3 adopt regulations setting forth the "form and manner in which manufacturers are to  
4 provide to the Department the information" required by SB 539. But it does give DHS  
5 any authority to make this information confidential.

6 **CONCLUSION**

7 The Nevada Independent's writ petition should be granted. *Amicus* Culinary  
8 Workers Union Local 226 asks the Court to affirm SB 539's plain meaning, so that the  
9 law can deliver the pricing transparency that Nevadans were promised.

10  
11 Dated: February 13, 2020

Respectfully Submitted,

12 

13 \_\_\_\_\_  
14 Paul L. More, SBN 9628  
15 McCRACKEN, STEMERMAN &  
16 HOLSBERRY, LLP  
17 595 Market Street, Suite 800  
18 San Francisco, CA 94105  
Tel. No.: (415) 597-7200  
Fax No.: (415) 597-7201  
Email: pmore@msh.law

19 *Attorneys for Amicus Curie Culinary Workers Union Local 226*  
20  
21  
22  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

I hereby certify that on the 13th day of February, 2020, I served a true and correct copy of the following document: **MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE*** by electronic filing and by placing it in the United States mail, with first-class postage prepaid, addressed to the following:

AARON D. FORD  
Attorney General  
Steve Shevorski  
Chief Litigation Counsel  
Office of Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101

*Attorneys for Respondents*

- And -

Matthew J. Rashbrook  
Robert L. Langford  
Robert L. Langford & Associates  
616 South Eighth Street  
Las Vegas, NV 89101

*Attorneys for Petitioner  
The Nevada Independent*

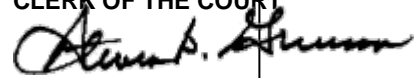
- And -

John R. Bailey  
Dennis L. Kennedy  
Sarah E. Harmon  
Bailey Kennedy  
8984 Spanish Ridge Ave.  
Las Vegas, NV 89148-1302

*Attorneys for Intervenor  
Sanofi-Aventis U.S. LLC*

1 Per NRS 53.045, I declare under penalty of perjury that the foregoing is true and  
2 correct.

3 /s/ Deborah D. Trujillo  
4 DEBORAH TRUJILLO, PP, CLP  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28



**NNOP**

MATTHEW J. RASHBROOK  
Nevada State Bar No. 12477  
ROBERT L. LANGFORD, ESQ  
Nevada State Bar No. 3988  
ROBERT L. LANGFORD & ASSOCIATES  
616 South Eighth St.  
Las Vegas, NV 89101  
(702) 471-6565  
matt@robertlangford.com  
robert@robertlangford.com  
*Attorneys for Petitioner*  
*The Nevada Independent*

**EIGHTH JUDICIAL DISTRICT COURT**

**CLARK COUNTY, NEVADA**

THE NEVADA INDEPENDENT,

Petitioner,

vs.

RICHARD WHITLEY, in his official  
capacity as the Director of the Nevada  
Department of Health and Human Services,  
and THE STATE OF NEVADA, ex rel. the  
NEVADA DEPARTMENT OF HEALTH  
AND HUMAN SERVICES;

Respondents,

and

SANOFI-AVENTIS U.S. LLC,

Intervenor.

Case No.: A-19-799939-W

Dept. No.: XIV

**NOTICE OF NON-OPPOSITION**

COMES NOW Petitioner, The Nevada Independent, by and through their  
undersigned counsel, Matthew J. Rashbrook, and Robert L. Langford, Esq., and hereby

///

1 gives notice of their Non-Opposition to the Culinary Workers Union Local 226's Motion  
2 for Leave to File Amicus Curiae Brief.

3 DATED this 14th day of February, 2020.

4  
5 /s/ Matthew J. Rashbrook

6 MATTHEW J. RASHBROOK  
7 Nevada State Bar No. 12477  
8 ROBERT L. LANGFORD, ESQ.  
9 Nevada State Bar No. 3988  
10 ROBERT L. LANGFORD &  
11 ASSOCIATES  
12 616 S. Eighth St.  
13 Las Vegas, NV 89101  
14 (702) 471-6565  
15 matt@robertlangford.com  
16 robert@robertlangford.com  
17 *Attorneys for Petitioner*  
18 *The Nevada Independent*  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

I hereby certify and affirm that on this 14th day of February, 2020, the foregoing  
**NOTICE OF NON-OPPOSITION** was served by electronic mail to the following counsel of  
record:

Aaron D. Ford  
Nevada Attorney General  
Nevada Bar No. 7704  
Steve Shevorski  
Chief Deputy Attorney General  
Nevada Bar No. 8256  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
Fax: 702-486-3768  
sshevorski@ag.nv.gov

Paul L. More  
Nevada Bar No. 9628  
McCracken, Stemerman  
& Holsberry, LLP  
595 Market St., Ste. 800  
San Francisco, CA 94105  
Fax: 415-597-7201  
pmore@msh.law

John R. Bailey  
Nevada Bar No. 0137  
Dennis L. Kennedy  
Nevada Bar No. 1462  
Sarah E. Harmon  
Nevada Bar No. 8106  
Rebecca L. Crooker  
Nevada Bar No. 15202  
Bailey Kennedy  
8984 Spanish Ridge Ave.  
Las Vegas, NV 89148-1302  
Fax: 702-562-8821  
jbailey@baileykennedy.com  
dkennedy@baileykennedy.com  
sharmon@baileykennedy.com  
rcrooker@baileykennedy.com

/s/ Matthew J. Rashbrook

An Employee of Robert L. Langford &  
Associates

**DISTRICT COURT  
CLARK COUNTY, NEVADA**

**Writ of Mandamus**

**COURT MINUTES**

**February 14, 2020**

---

A-19-799939-W      Nevada Independent, Plaintiff(s)  
vs.  
Richard Whitley, Defendant(s)

---

**February 14, 2020      4:08 PM      Minute Order**

**HEARD BY:** Escobar, Adriana      **COURTROOM:** RJC Courtroom 14C

**COURT CLERK:** Tia Everett

**RECORDER:**

**REPORTER:**

**PARTIES  
PRESENT:**

**JOURNAL ENTRIES**

- Petitioner The Nevada Independent s (Petitioner) Motion to Compel Testimony of James Borneman, or In The Alternative, to Strike His Declaration, which Intervenor Sanofi Aventis U.S. LLC (Sanofi) opposed, came on for hearing on February 4, 2020 before Department XIV of the Eighth Judicial District Court, the Honorable Adriana Escobar presiding, Attorney Matthew J. Rashbrook appeared on behalf of Petitioner. Attorney John R. Bailey, Sarah Harmon, and Rebecca Crooker appeared on behalf of Sanofi. Attorney Steven Shevorski appeared on behalf of Respondent the State of Nevada Department of Health and Human Services (Respondent). After considering the moving papers and arguments of counsel, the Court enters the following order:

As Petitioner cites, Rule 2.21(c) of the Eighth Judicial District Court Rules (EDCR) explains that [a]ffidavits/declarations must contain only factual, evidentiary matter, conform with the requirements of N.R.C.P. 56(e), and avoid mere general conclusions or argument. Affidavits/declarations substantially defective in these respects may be stricken, wholly or in part.

Rule 56(e) of the Nevada Rules of Civil Procedure (NRCP) states as follows:

If a party fails to properly support an assertion of fact or fails to properly address another party s

PRINT DATE: 02/21/2020

Page 1 of 2

Minutes Date: February 14, 2020

assertion of fact as required by Rule 56(c), the court may: (1) give an opportunity to properly support or address the fact; (2) consider the fact undisputed for purposes of the motion; (3) grant summary judgment if the motion and supporting materials including the facts considered undisputed show that the movant is entitled to it; or (4) issue any other appropriate order.

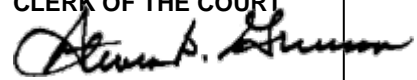
NRCP 56(c) states that [a]n affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated.

Here, the Court concludes Mr. Boreman's declaration is not based solely on his personal knowledge. However, the Court, under the clear discretion allowed under NRCP 56(e), will consider all pleadings and supporting documents in the context of the Petition for Writ of Mandamus (Petition) as a whole. Thus, the entire record will receive the weight of credibility it is due for the Court to decide on the Petition. Moreover, the Court does not find reasonable grounds to compel Mr. Borneman an affiant to Sanofi's Responses to the Petition to testify, as Respondent, rather than Sanofi, bears the burden of proof in the underlying Petition.

Based on the foregoing, the court DENIES Petitioner's Motion. The Court will issue its own order denying the same.

CLERK'S NOTE: The above minute order has been distributed to:

Robert L Langford robert@robertlangford.com  
Matthew J Rashbrook Matt@robertlangford.com  
Mary J. Pizzariello mpizzariello@ag.nv.gov  
Traci A. Plotnick tplotnick@ag.nv.gov  
Katherine Reed KReed@ag.nv.gov  
Steven G. Shevorski sshevorski@ag.nv.gov  
John R. Bailey jbailey@baileykennedy.com  
Sarah E. Harmon sharmon@baileykennedy.com  
Dennis L. Kennedy dkennedy@baileykennedy.com  
Bailey Kennedy, LLP bkfederaldownloads@baileykennedy.com



AARON D. FORD (Bar No. 7704)  
Attorney General  
Steve Shevorski (Bar No. 8256)  
Chief Litigation Counsel  
Office of Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
(702) 486-3783 (phone)  
(702) 486-3773 (facsimile)

*Attorneys for Respondent*

**DISTRICT COURT**  
**CLARK COUNTY, NEVADA**

THE NEVADA INDEPENDENT,  
  
Petitioner,  
  
vs.

Case No. A-19-799939-W  
Dept. No. XIV

RICHARD WHITLEY, in his official capacity  
as the Director of the Nevada Department of  
Health and Human Services, and THE  
STATE OF NEVADA, ex rel. the NEVADA  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES,

Respondents.

**NOTICE OF NON-OPPOSITION TO CULINARY UNION'S MOTION FOR LEAVE  
TO FILE AN AMICUS BRIEF**

Respondent Richard Whitley, in his official capacity as Director of the Nevada  
Department of Health and Human Services, and the State of Nevada ex rel. the Nevada  
Department of Health and Human Services, and files their Notice of Non-Opposition to  
Culinary Union's Motion for Leave to File an Amicus brief.

DATED this 14th day of February, 2020.

AARON D. FORD  
Attorney General

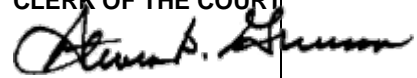
By: /s/ Steve Shevorski  
Steve Shevorski (Bar No. 8256)  
Chief Litigation Counsel

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

I certify that the following participants in this case are registered electronic filing systems users and will be served electronically:

John R. Bailey  
Dennis L. Kennedy  
Sarah E. Harmon  
Bailey Kennedy  
8984 Spanish Ridge Ave.  
Las Vegas, NV 89148-1302  
*Attorneys for Intervenors*  
*Sanofi-Aventis U.S. LLC*

/s/ KC Reed  
KC Reed, an employee of the  
Office of the Attorney General



TRAN

DISTRICT COURT  
CLARK COUNTY, NEVADA

NEVADA INDEPENDENT,

Plaintiff,

vs.

RICHARD WHITLEY,

Defendant.

CASE NO. A-19-799939-W

DEPT. XIV

BEFORE THE HONORABLE ADRIANA ESCOBAR, DISTRICT COURT JUDGE

FRIDAY, FEBRUARY 21, 2020

**TRANSCRIPT OF HEARING**  
PETITION FOR WRIT OF MANDAMUS

APPEARANCES:

For the Plaintiff: MATTHEW J. RASHBROOK, ESQ.

For the Defendant: STEVEN G. SHEVORSKI, ESQ.  
AKKE LEVIN, ESQ.

For the Intervenor: JOHN R. BAILEY, ESQ.  
SARAH E. HARMON, ESQ.  
REBECCA L. CROOKER, ESQ.

RECORDED BY: SANDRA ANDERSON, COURT RECORDER

TRANSCRIBED BY: MANGELSON TRANSCRIBING

1 Las Vegas, Nevada, Friday, February 21, 2020

2  
3 [Case called at 1:48 p.m.]

4 THE COURT: I'm going to call the case. The Nevada  
5 Independent versus Richard Whitley in his official capacity as the  
6 Director of the Nevada Department of Health and Human Services  
7 in the State of Nevada -- the Nevada Department of Health and  
8 Human Services. And I'd like you to state your appearances for the  
9 record, please.

10 MR. RASHBROOK: Good afternoon, Your Honor.  
11 Matthew Rashbrook, Number 12477. On behalf of the Petitioner,  
12 the Nevada Independent.

13 THE COURT: Good afternoon.

14 MR. SHEVORSKI: Good afternoon, Your Honor. Steven  
15 Shevorski of the Office of the Attorney General on behalf of the  
16 Respondents, Bar number 8256.

17 THE COURT: Very good, thank you.

18 MS. LEVIN: Akke Levin on behalf of the same Defendants,  
19 Bar Number 9102.

20 THE COURT: I'm sorry, repeat that, please.

21 MS. LEVIN: Akke Levin, Bar Number 9102, on behalf of  
22 the same Defendants.

23 THE COURT: Okay. Very good, thank you.

24 MR. BAILEY: Good afternoon, Your Honor. John Bailey  
25 from Bailey Kennedy on behalf of the Intervenor Sanofi. Do you

1 want my bar number? It's 187.

2 THE COURT: Okay. Thank you.

3 MS. HARMON: Sarah Harmon, Bar Number 8106. Also  
4 on behalf of the Intervenor Sanofi.

5 THE COURT: Okay. Thank you.

6 Rebecca Crooker, Bar Number 15202. Also on behalf of  
7 Sanofi.

8 THE COURT: Very good. All right. Good afternoon,  
9 Counsel. We should go ahead and get started. Give me one  
10 second.

11 Okay. Very good. Ready to go.

12 MR. RASHBROOK: Good afternoon, Your Honor. As I  
13 know the Court is very well aware, this is a Petition on a Nevada  
14 Public Records Act.

15 THE COURT: Yes.

16 MR. RASHBROOK: And so although we -- although other  
17 areas of law are implicated, other statutes are implicated, we have  
18 to examine the case, and the claims, and defenses through that  
19 lens. And so there's a clearly established rubric under the statute  
20 and following the guidance from the Nevada Supreme Court, the  
21 first step of that inquiry is to look at whether there's a statute that  
22 declares by law that the records sought are confidential.

23 In the absence of such a statute, we turn to a balancing  
24 test -- [the Marshal moves mic]. Thank you. A balancing test and in  
25 that balancing test, we look at whether the Respondents, who bear

1 the burden, can prove that the preponderance of evidence weighs  
2 in their favor and that the policy arguments clearly outweigh --  
3 pardon me, the policy arguments favor in privacy or favor in  
4 confidentiality clearly outweigh the public's interest and access to  
5 an open government.

6 I think it's important to note at the outset, neither the  
7 Respondent nor Sanofi have argued that they can satisfy that  
8 balancing test. Throughout, their position has been that these are  
9 strictly legal questions, whether by operation of law, whether that  
10 be under the administrative code, under the Defend Trade Secrets  
11 Act, or in the case of Sanofi, under Nevada Trade Secrets Act  
12 whether one of those statutes or multiple declare by law that these  
13 records are confidential. And of course our position is that they  
14 don't.

15 But if we arrive at the balancing test, I think it's important  
16 to note that neither the Respondent nor the Intervenor have made  
17 an argument they can satisfy the balancing test. But under the  
18 guidance from the Nevada Supreme Court, we first examine the  
19 question of whether there's a statute which declares by law that  
20 these records are confidential. And the Nevada Supreme Court has  
21 given guidance on what it means for a statute to make a declaration  
22 by law that the records are confidential.

23 Look at the *Haley* case. That's 234 P.3d 922. The Nevada  
24 Supreme Court says: This Court will presume that all public  
25 records are open to disclosure unless either the legislature has

1 expressly and unequivocally created an exemption or exception by  
2 statute.

3           They come back to this in *Gibbons* and the language there  
4 is that it has to be an explicit statement, that under the law certain  
5 records are confidential. And *Haley* involves a question -- an  
6 examination of that type of statute and what we see under those  
7 types of statute is that they are literally defined by the law, they are  
8 stated by the law, this is confidential. It's not to be disclosed. We  
9 don't have that under any of the statutes or administrative codes  
10 that are argued in this case, we don't have such a statement. And  
11 so we don't have a declaration by the law that these records are  
12 confidential.

13           If we look first at the administrative codes, the language of  
14 the administrative code says: If the department reasonably believes  
15 that public disclosure would constitute misappropriation for which  
16 a court may award relief pursuant to the DTSA, then the  
17 Respondents will withhold.

18           That's an if/then statement and what it indicates is that the  
19 Respondent makes a determination. It's not a declaration under  
20 law. If you look closely there, what we have is if the department  
21 reasonably believes. That's not a declaration by the law, that's a  
22 determination by the Respondent.

23           In the alternative, if the administrative code does have the  
24 function of exempting this material from the Nevada Public Records  
25 Act, then it's got to be stricken. And the guidance from the Nevada

1 Supreme Court is clear on that. We have the *Division of Insurance*  
2 *versus State Farm* where the Court states -- this is 116 Nev. 293.

3 A Court will not hesitate to declare a regulation invalid  
4 when the regulation conflicts with existing statutory provisions or  
5 exceeds the statutory authority of the agency.

6 The Nevada Supreme Court's looked at this specific  
7 context of the Nevada Public Records Act in the *Clark County*  
8 *School District* case, *Comstock Residents Association*, the *Nevada*  
9 *Policy Research Institute* and *PERS* cases, and what they  
10 consistently find, in contrast with the *City of Sparks versus Reno*  
11 *Newspapers* case cited by the Intervenor is that there's got to be  
12 specific language. And that's what carries the data in the *City of*  
13 *Sparks* case. The legislating -- the enabling language, the  
14 legislative grant specifically directs in that case, the Respondent to  
15 keep certain material confidential.

16 The enabling language in that case says that the  
17 department must, as far as possible, while maintaining  
18 accountability, protect the identity and personal identifying  
19 information of each person who receives, facilitates, or delivers  
20 such services. Context, there's medical marijuana licensing.

21 So we have there very specific enabling language --  
22 there's a specific grant of authority from the legislature to the  
23 department granting them the authority to exempt stuff, to exempt  
24 that material from the Public Records Acts from the public view.  
25 We contrast that with the *Clark County School District* case,

1 *Comstock Residents Association* where we don't have that specific  
2 language and the Nevada Supreme Court says the Executive  
3 Branch can't be allowed to make an end run of the Public Records  
4 Act.

5           You can't write these administrative codes which have the  
6 function of giving a line-item veto over the Public Records Act  
7 because the rights under the Public Records Act belong to the  
8 public. It's not the Executive Branch's right to give away as they  
9 see fit to.

10           So when we look at the administrative code, we have two  
11 alternatives. Either the administrative code doesn't declare by law  
12 that the material requested herein is confidential because there's  
13 this if/then proposition and it's a determination made by the  
14 Respondents as to whether the material will be held confidential. In  
15 that case, it's not a declaration by the law, it is a declaration by the  
16 Respondents.

17           Alternatively, if the administrative code does offer aid to  
18 exempt this material from the view of the public, it offends the  
19 Nevada Public Records Act and it's got to be stricken on that basis.

20           THE COURT: Can you repeat the last -- your second one,  
21 alternatively.

22           MR. RASHBROOK: Alternatively, if that administrative  
23 code does put this material beyond the reach of the Public Records  
24 Act, it offends the Public Records Act and the Nevada Supreme  
25 Court says that's an overreach, that's a separation of powers

1 problem and the department is not entitled to create regulations  
2 which have the effect of being an end run or a line-item veto over  
3 the Public Records Act. So in that case, if Your Honor finds that the  
4 administrative code has that effect, the administrative code's got to  
5 be stricken.

6           So I'll turn then to the claim that the Defend Trade Secrets  
7 Act can make these records or does have the effect of making these  
8 records confidential. And there's not a ton of law in this area but  
9 there are a couple of cases that are -- although they're not  
10 controlling, I want to acknowledge that I don't think that I have at  
11 any point suggested that they are controlling but to be absolutely  
12 clear, I understand that these are persuasive. But I would suggest  
13 that they're awfully persuasive.

14           When we look at the *Fast Enterprises* case, we have a case  
15 that is just about as close to being on all fours as a case could  
16 possibly be. We have a private entity that submits material to a  
17 governmental agency or governmental employee, that material is  
18 requested under a State Public Records Act and the private entity  
19 goes to the Federal District Court seeking an injunction to prevent  
20 the disclosure of that materials.

21           And the Federal District Court says: Congress specifically  
22 intended to circumscribe the DTSA so that it would not interfere  
23 with the policy choices of state governments in regard to their own  
24 operations. And that's the Federal District Court in Massachusetts  
25 finding that there isn't even a cause of action under the Defend

1 Trade Secrets Act whether for damages or for an injunction.

2 So the Respondents stated concern that they might face  
3 liability, first of all is a hypothetical concern of the kind that the  
4 Nevada Supreme Court has said is an inadequate reason to  
5 withhold records. But second of all, it's a phantom. Federal District  
6 Courts that have looked at this question, State District Courts that  
7 have looked at this question -- and as I say I know these are  
8 persuasive only, but the finding has been universally that there  
9 can't be any liability, whether -- as I say, damages or equitable relief  
10 in the form of an injunction.

11 The Defend Trade Secrets Act doesn't make anything  
12 confidential and there's an easy way to tell that. There were trade  
13 secrets before there was a Trade Secret Act. They're a creature of  
14 common law. Before there was a State Trade Secrets Act, in the  
15 middle 70s and late 70s, they started to get enacted. There were  
16 trade secrets. A trade secret is made by the conduct of the person  
17 who claims to have it. You make a thing a secret by keeping it a  
18 secret.

19 Now, the Defend Trade Secrets Act lists a number of  
20 qualities by which we can identify what a trade secret is, but it  
21 doesn't operate to render a thing a trade secret. We see the  
22 contrast when we look at the statutes the Nevada Supreme Court  
23 has found do make things confidential under the law. Like in *Haley*,  
24 we're looking at in that case, applications for firearms permits  
25 where there's personal identifying information. And the *City of*

1 *Sparks* case, in the medical marijuana context, again, personal  
2 identifying information and the law specifically says, this material  
3 has got to be kept confidential.

4           The Defend Trade Secrets Act -- and this is very clear from  
5 the plain language of the statute, it's clear from the congressional  
6 record and it's clear from federal and state cases that have looked  
7 at this question. The Defend Trade Secrets Act creates a cause of  
8 action and a right to access the federal forum if you can prove that  
9 a person misappropriated your trade secret. If you can get an  
10 injunction, you can get damages. But it doesn't prevent a state  
11 from carrying on its otherwise lawful business.

12           Congress specifically stated they had no intention to stop  
13 a state from making policy choices. We see that in the *Medsense*  
14 *case versus the University of Maryland*, District of Maryland court.  
15 The DTSA does not prohibit or create a private right of action with  
16 regard to any otherwise lawful activity conducted by a  
17 governmental entity of a state. In other words, the State is entitled  
18 to continue to comply with its own Public Records Act.

19           The DTSA doesn't make anything confidential. Only the  
20 entity can keep a thing confidential. That's the nature of a trade  
21 secret. In this way -- and this is the *Baron versus Department of*  
22 *Human Services* case from the Pennsylvania State Court. In this  
23 context, the DTSA's comparable to the copyright act in that neither  
24 of them exempts records from disclosure. And of course there's a  
25 significant difference between copyrighted material and trade

1 secret in the intellectual property arena but --

2 THE COURT: Understood.

3 MR. RASHBROOK: -- the comparison there is that neither  
4 act makes a thing confidential, puts it outside the reach of the  
5 Public Records Act. What those acts do is provide a form, provide a  
6 cause of action to seek redress from the court.

7 So when we compare this with the language in *Haley*,  
8 with the language in *Gibbons*, that the language -- that the statute  
9 has got to be an explicit declaration. It's got to be express,  
10 unequivocal that certain material is to be kept confidential. We  
11 don't see that here. We have no specific reference in the Defend  
12 Trade Secrets Act that this material has got to be kept confidential.

13 In fact, quite the contrary what we have is an express  
14 declaration in the law and in the congressional hearings, the  
15 legislative intent behind the law which explicitly states, the law's  
16 not here to interfere with the State's business. The State continues  
17 to be entitled to make its own policy choices, to comply, and carry  
18 out its otherwise lawful activities. This has been the finding of the  
19 federal courts that have looked at the question. There is not even a  
20 cause of action. Never mind whether it's for damages or injunction,  
21 there is no cause of action.

22 So we can't find any declaration, either in the  
23 administrative code or in the Defend Trade Secrets Act which meets  
24 the kind of language that the Nevada Supreme Court has set as a  
25 requirement; an explicit, unequivocal express indication that certain

1 material has got to be kept confidential.

2 The last statute that's discussed and it's worth noting here  
3 that when I look at the State's reply and support at page 3, lines 18  
4 to 26, it appears to me that the State agrees with the Petitioner's  
5 interpretation of NRS 600A.030(5)(b), which is the portion of the  
6 Nevada Trade Secrets Act which is added to that act by SB539  
7 which is this insulin transparency legislation that is sort of the  
8 underlying law that we're dealing with here.

9 It's Sanofi that argues that the text of 600A.030 sort of can  
10 be contorted into this legal pretzel which gives it the opposite  
11 meaning what -- of what is pretty clear from the text, which is that  
12 this kind of material, by definition, is not a trade secret under the  
13 law of this state.

14 The number one principle, I think, when we're talking  
15 about statutory interpretation is that if a statute is not ambiguous,  
16 we read the statute and we apply. Where the language is not  
17 ambiguous, you look at the text and you say that's what the law  
18 says, and we don't inquire further into legislative intent and I  
19 certainly think that's the case here. We've got a statute which on its  
20 face says, this material is not a trade secret.

21 But if we look at the legislative intent, what we find  
22 overwhelmingly in the hearings, on SB265 which is the sort of  
23 predecessor legislation which at that time dealt only with the  
24 pharmaceutical manufacturers, and it was passed out of both  
25 houses by vetoed by Governor Sandoval. We look at the hearings

1 on that legislation and the hearings on the eventual law that is  
2 passed and signed into law by the Governor, SB539, and there's  
3 extensive quotations in the petition to this effect.

4 But virtually every legislator that gets on the record about  
5 this says the point of this law is to create transparency in this  
6 marketplace which is otherwise so opaque that we cannot tell why  
7 the prices are rising or by whom they are being driven up.

8 We also have the Legislative Counsel's Digest which I  
9 think is just about as clear as you can get. When we look at the  
10 comment or the preamble, this is at 2017 Statutes of Nevada 4295  
11 to 96, refers to SB539 as, and I'm quoting: An act relating to  
12 prescription drugs, providing that certain information does not  
13 constitute a trade secret.

14 I don't think we can be a lot more clearer than that. And  
15 so looking at the administrative code, looking at the Defend Trade  
16 Secrets Act, or looking at the Nevada Trade Secrets Act, there is no  
17 law which declares by law that this material is to be kept  
18 confidential and that it escapes the reach of the Public Records Act.

19 So the only way that it can be kept from the Petitioner,  
20 from the public is if Respondents or the Intervenor can satisfy the  
21 balancing test. There we get into this factual analysis of whether  
22 the preponderance of evidence weighs in favor of the Petitioner or  
23 the Respondent. Throughout, the Respondent and the Intervenor  
24 have taken the position that these are purely legal questions.

25 I don't believe either has made an effort to convince the

1 Court they can satisfy this balancing test and certainly I don't think  
2 that they can. We have direction from the Nevada Supreme Court  
3 that the policy arguments have got to clearly outweigh the public's  
4 interest and access to carry the day.

5 And what we have in this case is the Declaration of James  
6 Borneman which I know the Court's very familiar with the  
7 independency of that declaration. We feel its defective in some  
8 pretty meaningful ways. It's undermined by the parent company's  
9 public position that they are not going to put money into research  
10 and development.

11 When we look at the policy arguments, we have  
12 overwhelming evidence that the will of the people of this state,  
13 expressed by the legislature is for these records, to get into the  
14 public because we need transparency in this marketplace. And this  
15 is -- throughout the legislative hearings this is discussed and it's a  
16 large part of why the bill was vetoed -- why SB265 was vetoed. We  
17 went back and included pharmacy benefit managers in SB539, the  
18 version that's eventually passed because what we see in this debate  
19 is diabetes sufferers or the public generally says why is the cost of  
20 insulin going up so high? Why do we in the United States pay ten  
21 times the amount that a Canadian pays for a vial of insulin that's  
22 made in the United States and trucked across the border to  
23 Canada?

24 And in turn, pharmaceutical manufacturers say, don't  
25 mind the fact that we've raised the price astronomically because

1 we're giving these rebates to pharmacy benefit managers and  
2 they're the bad guys because they're keeping these rebates and  
3 they're not passing them on to their clients, to their customers. The  
4 pharmacy benefit managers in turn say oh no, of course we are.  
5 We're giving all of these rebates away. The problem is that they're  
6 driving the price up. And because non-disclosure agreements and  
7 gag rules are so commonplace in this business, it is impossible for  
8 those of us observers, the public, to have any idea who's telling the  
9 truth or if anyone is about any of it.

10           And so -- and this is discussed in the legislative hearings.  
11 There are lobbyist from both pharmacy benefit manufacturing  
12 manager groups, from pharmaceutical manufacturer lobbying  
13 organizations and they come in front of the Nevada legislature and  
14 they say it's their fault; no, it's their fault. At times they're in the  
15 same hearing.

16           And we see the legislators sort of throwing their hands up  
17 and saying look, we've got to have transparency in this marketplace  
18 with a quarter of the population suffering from diabetes; another  
19 quarter is prediabetic. This was a disease that functionally was  
20 cured 100 years ago but we have people dying of it today because  
21 they're rationing their insulin because they can't afford it. A vial of  
22 insulin costs \$300, \$325, \$275, in that area. Plus or minus, an  
23 average diabetic uses a vial a week. We're talking about a 10, 12, 15  
24 thousand dollar a year insulin problem for an individual.

25           And so the legislature -- and as I said this is quoted

1 extensively in our Petition and it's quoted extensively, I think --  
2 discussed extensively at least in the amicus brief that Culinary  
3 Workers Union 226 has submitted recently, the legislature looks at  
4 the problem and says we've got to get transparency in this  
5 marketplace. We've got to figure out why we have this problem  
6 before we can confront it and do something about it. That's step  
7 one is let's have an honest evaluation of what's provoking this.  
8 Let's get the facts out in the open and let's look at why is this  
9 happening.

10           And the Nevada Supreme Court, along with a number of  
11 other state courts have repeatedly held that where the legislature  
12 speaks so clearly on policy questions like this, it is typically  
13 appropriate for the Court to defer to the legislature on those policy  
14 questions, specifically because legislature is the people's branch of  
15 the government and these are public policy questions so let's  
16 concern ourselves with what the public wants to accomplish.

17           And whether one of us feels that's the appropriate way to  
18 handle it or not, really in general, courts do better to stay out of  
19 those kinds of policy fights where the legislature has spoken so  
20 clearly and specifically. The Nevada Supreme Court has talked  
21 about in areas that are heavily regulated, as this one is -- take also,  
22 you know, for instance medical marijuana insurance, those kind of  
23 areas where there is a lot of regulation, it's clear that a great deal of  
24 legislative thought and angst and agony probably goes into these  
25 decisions. And the Nevada Supreme Court says yeah, best for us to

1 stay out of this kind of questions when we have such clear guidance  
2 from the people's branch as to what their policy reference is.

3 Beyond that, I think there's very significant factual  
4 questions here about whether the material really could be probably  
5 classified as a trade secret. One of the requirements for a trade  
6 secret is that it provide an economic benefit. When we look at the  
7 price of purported competitor products from purported competitors  
8 in this market, what we see is virtually lockstep increases, annually,  
9 biannually, we see increases that come within days/hours of each  
10 other.

11 And over the course of 10, 15, 20 years these, as I say  
12 purported competitors with these purportedly competitive products  
13 in this vicious competitive marketplace, they just peg the price of  
14 the insulin to the next guy on the block and this is so prevalent that  
15 it becomes the object of scrutiny from federal investigators,  
16 antitrust investigations, there's price fixing litigation in this area and  
17 so I think it's at best a dubious claim that this is even the sort of  
18 material that could properly be called a trade secret to begin with  
19 because I don't see how it can reasonably be said that they derive  
20 an economic advantage from any of this when they just fixed the  
21 price to the next guy's price anyway.

22 And I know we discussed this previously, so I'll leave it to  
23 Your Honor if you want to hear more about the --

24 THE COURT: No, I do.

25 MR. RASHBROOK: -- discussion of waiver specifically.

1 THE COURT: I do. I'd like to --

2 MR. RASHBROOK: Okay.

3 THE COURT: -- hear everything --

4 MR. RASHBROOK: So our position --

5 THE COURT: -- that --

6 MR. RASHBROOK: -- in that regard is that there was no  
7 promise of confidentiality from the Respondents to Sanofi or any of  
8 the other pharmaceutical manufacturers or pharmacy benefit  
9 managers. Even if there had been a promise, it would be  
10 ineffective. The right to access open government under the Public  
11 Records Act belongs to the public. It is therefore not for the  
12 Department of Health and Human Services to give it away.

13 So even if there had been a promise, it would be  
14 ineffective, but there was no promise. The clear language of the  
15 administrative code indicates that the department will make a  
16 determination whether it reasonably believes that public disclosure  
17 would constitute a misappropriation. There's no guarantee that the  
18 material will be kept confidential and so there can't be any  
19 confidentiality in that circumstance.

20 This is a quality of virtually every privilege and  
21 confidence but especially so of trade secrets that they are fragile  
22 and we have that guidance in a great deal of juris prudence in the  
23 area of privileges and confidence generally but specifically in the  
24 context of the Public Records Act where the Nevada Supreme Court  
25 says explicitly limitations on the public's right to access documents

1 are to be construed narrowly. And in contrast, the public's right to  
2 access is to be construed broadly because it's a fundamental  
3 principle of our system of government that the government is of  
4 and for and by the people, so we get to look at our own pavers.

5 In contrast, privileges, exceptions, exemptions are to be  
6 construed narrowly. So when we look at the fact that in this case  
7 the Intervenor and others similarly situated have voluntarily handed  
8 this information over with no guarantee that it would be kept  
9 confidential, there can't be any trade secret or other privilege or  
10 confidence that exists at that point, even in the event that it could  
11 be construed that the department's promise was effective.

12 Nonetheless, the ultimate determination is still made by a court.

13 So even if Your Honor could look at the department's  
14 promise and say well, yeah -- or pardon me, the department's  
15 language and say that really is a promise, it is still ineffective  
16 because at the end of the day, we all still wind up in front of a court,  
17 asking for a determination of whether the material will be kept  
18 confidential or not.

19 And whether that's in Your Honor's court in the context of  
20 a public records case or in a federal court if, as the department  
21 apparently fears they face litigation -- although it's been previously  
22 discussed and the guidance we have from the Federal District Court  
23 is that's impossible. But ultimately, we end up in front of the judge  
24 who makes a determination of whether the material will be kept  
25 confidential or not and that's because the right to access public

1 records belongs to the public. It's not for the Respondent to give it  
2 away.

3 And so if there is a promise, it's meaningless. If there's  
4 reliance, it's misplaced. There's abundantly clear law in this area.  
5 You can't enforce a confidence or privilege in this way, by handing  
6 a person a thing and saying I demand that you keep that thing  
7 confidential.

8 Sanofi and other similarly situated handed this material  
9 over voluntarily. They had alternatives. They were not required to  
10 produce these documents. They were only required to produce the  
11 documents if they wanted to do business in Nevada and if they  
12 wanted to increase the price more than the CPI for a healthcare cost  
13 this year. They had a number of alternatives. The state's entitled to  
14 regulate this industry as they are health insurance, medical  
15 marijuana, and so on.

16 So our position is, even in the event that Sanofi or  
17 Respondents could make effectual showing that satisfies it, the  
18 preponderance of evidence lies on their side that this material is  
19 trade secret. Nonetheless, it should be ordered released either or  
20 both because they gave away any trade secret status they may have  
21 enjoyed when they submitted the records to the Department of  
22 Health and Human Services or because the public's interest so  
23 clearly outweighs the private interest in continuing to extract  
24 outrageous profits from a group of people who are going to die if  
25 they don't pay the cost.

1           If Your Honor has any questions, I'd be happy to address  
2 them. And otherwise, I'll turn the floor to them.

3           THE COURT: I don't have any questions at this time.

4           MR. RASHBROOK: Thank you.

5           MR. SHEVORSKI: Good afternoon, again, Your Honor.

6           THE COURT: Good afternoon.

7           MR. SHEVORSKI: Steven Shevorsi for the Respondents.

8           I'd like to start from where my friend from the other side  
9 rather ended which is clear guidance from the legislature. This is a  
10 point we agree on. The clear guidance from the legislature is that is  
11 giving plenary power to the Department of Health and Human  
12 Services to implement regulations for Senate Bill 539. That is  
13 precisely what NRS 439B.685 says.

14           The Department shall adopt such regulations as it  
15 determines to be necessary are advisable to carry out of the  
16 provisions of NRS 439B.600, 439B.695 inclusive. That is plenary  
17 power. It could not be more broad. And I raise that at the start  
18 because correctly understood, this is not a public records case but  
19 an administrative law one.

20           Where my friend comes into this court, seeks  
21 extraordinary relief and asks this Court on Mandamus, you see  
22 where the legislature gave the Department of Health and Human  
23 Services plenary power? I'm striking it down. I'm saying to the  
24 Department of Health and Human Services, your regulation is  
25 invalid, in field where you get the greatest deference. That is what

1 he is asking for. He makes it clear at paragraph 65 and 66 of his  
2 Complaint: To whatever extent the agency created regulations that  
3 issue conflict with statutory law, the regulations are invalid.

4 This is an administrative law case where he is asking for  
5 the most extreme remedy where you have to demonstrate  
6 extraordinary circumstance to get this kind of relief and I submit to  
7 you that that has not been done.

8 We could start on a point where I think we all agree on.  
9 The Nevada Supreme Court has said: The purpose of the Nevada  
10 Public Records Act is to ensure accountability of the government to  
11 the public be facilitating public access to vital information about  
12 government activities.

13 That's from *DR Partners* that I know you're familiar with.

14 The United States Supreme Court has talked about the  
15 importance of an informed electorate, the informed citizenry or the  
16 policist you might know from your philosophy courses. The basic  
17 purpose of FOIA is to ensure an informed citizenry vital to  
18 functioning of a democratic society needed to check against  
19 corruption and to hold the governors accountable to be governed.

20 We agree that is the purpose, but I submit to you that that  
21 purpose is not being served here. It is not being served here. Let  
22 me explain to you essentially four reasons why that is the case and  
23 why we submit that the Court should not agree, and it should deny  
24 the Petitioner's Petition for Mandamus.

25 First, there is nothing in the text of the Senate Bill 539 that

1 says that any of these records are public records. Nothing. My  
2 friend in his petition cites two statutes in particular, 439B.635 and  
3 640. There is nothing in those statutes that says the report you  
4 prepared and submitted to us, it's a public record now. Nothing.  
5 You think they would have mentioned it. They did not. Instead,  
6 they gave the department plenary power to implement regulations.  
7 To create regulations to implement that act which is precisely what  
8 they did.

9           Secondly, touch on this, in Mandamus proceedings you  
10 need a statute that creates a clear and specific duty. No discretion.  
11 I submit to you that that has not been done. We've just seen from  
12 the -- and the statute I quoted Your Honor, there is plenary power to  
13 create these regulations. There is discretion.

14           Thirdly, the cases that my friend cited to you are not on-  
15 point. As someone who has practiced in federal court his entire  
16 career, I'll explain to you why the *Lyft* came out the way it did, why  
17 *Fast Enterprises* came out the way it did, why *Medsense* came out  
18 the way it did. None of those cases is factually or legally similar  
19 here.

20           Finally, the fourth reason is we are being asked to review  
21 an administrative agency's action where it is the expert, where it  
22 gets deference. That is the most difficult standard to overcome.  
23 What the Department of Health and Human Services did here was  
24 take a look at what the legislature has done and attempt to -- and  
25 nowhere in the legislature did they describe these as public records.

1           We were certainly aware of the Defend Trade Secrets Act  
2 and how that is enforced and attempted to come up with a  
3 commonsense solution. And nowhere does my friend say that we  
4 violated our regulations. We followed them to the T. We followed  
5 the statute, we complied with Senate Bill 539, we followed our own  
6 regulations. There are no grounds for a Mandamus here.

7           First let's start with the text of Senate Bill 539. And this  
8 will be important because we're going to look at the cases that my  
9 friend cites to Your Honor, the *Fast Enterprise* and then it says --  
10 and it'll be important to show why those cases are so factually  
11 [indiscernible].

12           Senate Bill 539, nowhere in Section 635 does it say the  
13 report is a public record. And I must disagree -- I think my friend is  
14 quite incorrect to say that somehow Sanofi is voluntary turning  
15 these over. It says shall provide the report. It's not voluntary in any  
16 sense. And that will be important when we look at what happened  
17 in *Fast Enterprises* and in particular, Footnote 1.

18           Nowhere can you construe that language in 635 --  
19 439B.635 as being a voluntary duty. It says you shall do it.  
20 Nowhere in Section 640 does it have any voluntariness whatsoever  
21 which could even construe it as being a voluntary duty. It says you  
22 shall do it. You shall provide a report.

23           Turning again to 600A.030(5), which is our version of  
24 Uniform Trade Secret Act and my friend is quite correct that in the  
25 70s and 80s, the various states, because there is no federal

1 guidance on this have their -- they used to have their own trade  
2 secrets laws and they adopted the Uniform Trade Secrets Act. But  
3 notably in Senate Bill 539, all it does is says that this information is  
4 not a trade secret under the UTSA.

5 One, it never even attempts to address what  
6 confidentiality protections that information has from other sources,  
7 nor could it. The state of Nevada, no matter how great it is cannot  
8 change federal law. And even under state law, just because you  
9 change, you alter, the UTSA that doesn't mean that that information  
10 is not proprietary or confidential for other reasons.

11 Turning to -- my friend started out with the proposition  
12 that the state of Nevada in this instance needs to find a law that  
13 uses the magic words confidential. Respectfully, that is not the  
14 starting place. How different indeed is this case to those typical  
15 cases where a public record is at stake? The definition of a public  
16 record is something that is generated by the government.  
17 Generated. That didn't occur here. And that's from the *Reno*  
18 *Newspapers versus Sheriff* decision 126 Nev. at -- excuse me, 126  
19 Nev. 211 at 214. Generated by the government.

20 My friend may respond with well that wasn't the case in  
21 *Blackjack Bonding*. If you remember, Your Honor, those were the  
22 telephone company's records. It wasn't the case in *Blackjack*. But  
23 what's important there is the state of Nevada went out in the  
24 marketplace for a public purpose and contracted with a private  
25 entity to -- for a public purpose, to generate those records. That is

1 not what happened here.

2           There is no dispute and you will find nothing in my  
3 friend's Petition for Writ of Mandamus that disputes this. These  
4 were entirely privately created. Private funds animated those  
5 entities to create those records. It was a private actor that took the  
6 steps to ensure secrecy. The economic benefit, my friend now  
7 disagrees with this, inures to the private actor and it is dragooned  
8 into submitting that information to the state of Nevada by virtue of  
9 Senate Bill 539. It says you shall do this.

10           My friend says well they don't have to do business in  
11 Nevada, Nevada can just turn the way their markets do. Well, I  
12 think the commerce clause may say something different about that.  
13 That's not at issue here but there's an obvious flaw with that  
14 reasoning. Nevada cannot dictate how drug prices are set. We  
15 wholly dispute that these are public records, I mean, under any  
16 traditional definition of that.

17           Now, turning to the cases that my friend cites, let's talk  
18 about *Fast Enterprises* because he says that's directly on point.  
19 There is a clear reason why that is not the case. The state is that --  
20 is essentially the customer there. It wants a service. It submits an  
21 RFP and says we want to pay you money.

22           And in the RFP at Footnote 1, in capital letters, the Court  
23 points out: All responses to the RFP, including the winning bid  
24 shall become public record as of the date of the contract.

25           So why did that case come out that way because there is

1 the lawful activity; the otherwise lawful activity. The carrot and the  
2 stick. You want to be our customer, what you submit to us as a  
3 condition of that is a public record. That didn't happen here.  
4 There's nothing, number one in the text of Senate Bill 539 that  
5 remotely resembles that RFP.

6 Now let's contrast that with *Medsense*. Why does that  
7 case come out that way? It comes out that way because of  
8 Footnote 4 and where the Court says let me tell you why Ex parte  
9 Young doesn't apply. Because as we all learn in our federalism  
10 classes, you know, if I can even think back that far, Ex parte Young  
11 applies to a perspective threatened violation of federal law that is  
12 going to happen in the future. That is the condition. That's what  
13 gets you around the 11th Amendment.

14 So why couldn't that apply there? It couldn't apply  
15 because the misappropriation had already happened. They had  
16 already breached the agreement. All they had there was  
17 retrospective relief. That will not be the case here.

18 The moment -- I guarantee this will happen the moment --  
19 because it already happened before. The moment Your Honor rules  
20 that these are public records, Sanofi goes to federal court. And not  
21 under the DTSA, under 42 U.S.C. 1983, to enjoin a threatened  
22 violation of federal law. And they won't need the DTSA possibly.

23 They might be arguing the 14th Amendment, separate  
24 and independent. They will be arguing the 14th Amendment to say  
25 you are depriving me of a property interest guaranteed to me by

1 federal law. You are about to -- that's a threatened injury. And I --  
2 and it -- and under *Medsense*, you will see in Footnote 4, if they're  
3 talking about a future injury, *Ex parte Young* applies and there is a  
4 clear threat of that here. That's why they're here. *Medsense* comes  
5 out differently if there is -- if they are seeking prospective relief.  
6 This is not a hypothetical concern.

7           So when my friend talks about cases on all points, I think  
8 it's important to mention the case that he didn't talk about today in  
9 oral argument but another case he said that is on all fours in his  
10 brief, which is the *Lyft* case with the Supreme Court of Washington.  
11 It's important to point out that in *Lyft*, the DTSA isn't even  
12 mentioned. The *Ex parte Young* is not mentioned. The right to go  
13 to federal court to prevent a threatened injury under federal law is  
14 not mentioned. That is clearly available. *Medsense* says so in  
15 Footnote 4, if there had been prospective relief.

16           But moreover, when our friend talks about the copyright  
17 act, it's an act -- I agree with it, it doesn't say anything that -- it  
18 doesn't create -- it doesn't say anything that's confidential -- it  
19 doesn't use those magic words, confidentiality but you better  
20 believe if -- let's use an example, a state university threatens to  
21 misappropriate or misuse a copyright, that owner can go into  
22 federal court to seek injunctive relief to defend its right under the  
23 copyright law. Absolutely.

24           The state is not at liability to ignore federal law. My friend  
25 has provided no authority to you that says that his position is

1 correct. We could merely pass Senate Bill 539 and affect federal  
2 law in any way. They exist parallel to each other, but one is  
3 supreme. It does not matter that 600A.030(5) says this information  
4 is not a trade secret under state law. It does not matter because the  
5 Nevada legislature would not dream of the power that it could  
6 affect in anyway what exists under the DTSA, under the 14th  
7 Amendment, under federal law. Would not dream of that power  
8 and did not say so.

9           Never did the legislature say this material just because we  
10 amended 030(5), oh by the way it's also -- it must be a public record  
11 now. Because what you would have there conversely is the  
12 opposite of the DTSA. What you would have is a simultaneous  
13 destruction of a trade secret under every state's law because it  
14 would be public and there wouldn't be any protection anywhere  
15 else in the country.

16           So far from uniformity, what you would have is the  
17 opposite of that. You would have Nevada being the dictator of  
18 whether or not something was secret because of its Public Records  
19 Act and that -- there's simply no textual evidence in the Public  
20 Records Act, in Senate Bill 539 to support that position.

21           And finally, I'd like to talk about, you know, this is an  
22 administrative law case. We are here at the absolute height of the  
23 power in the administrative body where it had been given by the  
24 legislature plenary power to interpret Senate Bill 539. That's  
25 precisely what it did. It struck a careful balance and followed the

1 administrative regulations to the T. There's no dispute on that.

2 We submit, Your Honor, there is no basis to grant  
3 extraordinary relief. The state of Nevada followed the letter of the  
4 law to the T. We would ask you to deny the Petition.

5 THE COURT: Thank you.

6 MR. BAILEY: Ready?

7 THE COURT: Yes, thank you.

8 MR. BAILEY: Good afternoon, again, Your Honor.

9 First, let me say for the record that Sanofi joins in the  
10 argument and the position of the Department of Health and Human  
11 Services as articulated by Mr. Shevorski just moments ago and in  
12 their moving papers.

13 Let me -- what I'd really like to do is a couple things. One  
14 is emphasize two or three things and then ask if you have any  
15 questions. So I'll try to be short. Famous last words from a lawyer.  
16 But I'll try to be brief to the extent that I want to really get to the  
17 heart of what we're doing here.

18 First, as he has been described as my friend from the  
19 other side, when you listen to the argument, you'd almost be led to  
20 believe that companies like my client, Sanofi and other  
21 pharmaceutical manufacturers are not providing information that's  
22 important to a very important issue in our state and across the  
23 country and that's just not true.

24 The information that is important to our government, our  
25 state government, is being provided. SB539 and how it's been

1 codified in 439(b) I believe requires us to provide that information.  
2 So that information is in the hands of our state government. The  
3 problem that my friend and his client has is that it's not being given  
4 to them. So the whole notion that something is not going right  
5 because information that's vital for our state to have in order to do  
6 its function and protect Nevada citizens, that's just not correct.

7 That information is in the hands of our government, of our  
8 state government, the department itself. The only issue here is they  
9 want information that's been declared by law to be confidential, so  
10 that's the issue. That's -- you know, it's not like we're withholding  
11 information, we're providing information. We're required to  
12 provide the information.

13 The second quick point I want to note, both my friend  
14 from the other side and my friend from this side alluded to the  
15 trade secret definition in NRS 600A.030(5) and subpart (b) of (5).  
16 And what's important about that is I look at that language is it takes  
17 away the term trade secret when you're required to report under  
18 certain statutes, including NRS 439B.635. But then it goes on to say  
19 to the extent that such information is required to be disclosed by  
20 those sections.

21 So what the legislature did was say under SB539, we're  
22 going to require you to provide certain information. And we  
23 understand that that information to you constitutes a trade secret,  
24 it's confidential. You do not want it publicly disclosed. The way we  
25 have to get that information from you is we have to amend NRS

1 600A, so that for the specific purpose of you providing that  
2 information to us, it's not a trade secret. But for any other purpose,  
3 it is a trade secret. That's the importance of that language that my  
4 friend from the other side did not talk about in his presentation to  
5 you is that it's not a trade secret only for that very narrow purpose  
6 of providing it to the department, to the extent that it's required.  
7 And it is required.

8           The last point I want to emphasize is that as we stand here  
9 this afternoon, we stand in a court of law. We're not standing here  
10 in the court of public opinion. We're not standing here in a court of  
11 equity. We're not standing here in a court of let's forget about the  
12 law and just do what feels good or what we think might be correct.  
13 We are here in a court of law.

14           And because of that, and I'm not telling you anything you  
15 don't know, your analysis when you go through this and I know you  
16 will go through it thoroughly, your analysis will begin with NRS  
17 239.010 which is the Nevada Public Records Act because that is the  
18 only basis under which the Petitioner is seeking information that  
19 has been deemed confidential. It's not any other statute, it's this  
20 one statute.

21           And when you look at NRS 239.010, you see quite  
22 appropriately that government-generated documents shall be  
23 disclosed to the public if requested, except there's two buckets  
24 under 239 where you don't get records you may request. The first  
25 bucket is plus or minus a hundred different statutes that are

1 identified -- specifically identified in 239. The second bucket is  
2 documents or information otherwise declared by law to be  
3 confidential. And that's where they're complaining here. That's  
4 where the Petitioner's complaining because the department would  
5 not give them records that have been declared by law to be  
6 confidential.

7 Now I understand they'd like to have confidential  
8 documents; I understand they'd like to have trade secret  
9 documents. But under the law that exists that this court will follow,  
10 you don't get them when they've been declared by law to be  
11 confidential. Does the Petitioner challenge the process that the  
12 department went through to make that determination? The answer  
13 is no. They're not challenging the process that the department  
14 went through.

15 Is the Petitioner saying to this court in their Writ Petition,  
16 gee, something went wrong with the department when they were  
17 doing their analysis under NAC 439.735? No, they don't challenge  
18 that. In fact, when you look at their Writ Petition, they don't  
19 challenge that documents like the ones who -- that came from my  
20 client and others in the industry that were required to be provided  
21 and which have been declared confidential, they don't challenge  
22 that determination. They don't challenge that there are trade  
23 secrets.

24 From looking at the Writ Petition, here's what I  
25 understand -- when you get rid of all the noise, here's what they're

1 saying. They're saying that the regulation NAC 439.735 somehow  
2 conflicts with the Nevada Public Records Act, NRS 239.010. And the  
3 question is how do they conflict because they don't. One says you  
4 get all the government-generated records that you request except  
5 that they fall in one of those two buckets. One bucket being they're  
6 deemed by law to be confidential. There is no conflict there.

7           The other thing they say in their Writ Petition is that NAC  
8 439.735 conflicts with Senate Bill 539. And as you've heard Mr.  
9 Shevorski just tell you and he is absolutely correct, there is no  
10 conflict there. In fact, it really goes beyond that and I'll explain why  
11 in just a minute.

12           The one point I do want to make from reading their Writ  
13 Petition, is they somehow suggest that the regulation that the  
14 department followed in making the determination that certain  
15 records were confidential and others weren't, that somehow that  
16 regulation was entered by the department but somehow without  
17 the authority of the Nevada legislature.

18           That's what I see when I read their Writ Petition, that the  
19 department went rogue and just entered this regulation and then  
20 followed the regulation and here we are. That the Nevada  
21 legislature did not play a part in that process or did not otherwise  
22 condone that and therefore the department exceeded its regulatory  
23 authority because the Nevada legislature was not part of that  
24 process. That's -- when you get rid of the noise, that's kind of what  
25 they're saying when you read their Writ Petition. That's just not

1 correct. That is simply not correct.

2 And what I would ask you to do, Your Honor, is as you go  
3 through your analysis, go back and look at our response to the Writ  
4 Petition. We filed it on December, the 23rd and what you will see,  
5 Exhibit 3 to our response, is the Complaint that was filed by the  
6 Pharmaceutical Research and Manufacturers of America which  
7 we've referred to in this litigation as Pharma and the Biotechnology  
8 Innovation Organization, which we've referred to as Bio, they filed a  
9 federal action September 1st, 2017.

10 So in terms of sequence, you have Senate Bill 539 going  
11 through the legislative session in early 2017. It gets codified into  
12 NRS 439B and before the time that reports were required to be  
13 submitted, Pharma and Bio filed the federal action and we, Sanofi,  
14 my client is a member of Pharma and Bio.

15 So on September 1st, 2017, the federal action is filed, and  
16 you have as Exhibit 3 to our response, the Complaint. And you see  
17 that the Plaintiff was Pharma and Bio, and the Defendants were the  
18 governor at the time, Brian Sandoval and the director of the  
19 Department of Health and Human Services, Mr. Whitley.

20 So you have this federal action where -- and I will  
21 paraphrase essentially what the concern was. You have Pharma on  
22 behalf of all of its members seeking an injunction against having to  
23 comply with SB539 because it would essentially be a process by  
24 which federally protected information, trade secrets, under DTSA,  
25 could potentially be disclosed. So you have this federal action.

1           And what occurs very soon after, and if you look at Exhibit  
2 5, within a month, the legislature files a Motion to Intervene in the  
3 federal action. And Exhibit 5 is the order from the Court granting  
4 that Motion to Intervene. So now the parties to this case are  
5 Pharma, Bio, as Plaintiffs and the Defendants are the governor, the  
6 Department of Health and Human Services, and the legislature.

7           Now the most important document I can ask you to look  
8 at on this point is Exhibit 7 to our Response because Exhibit 7 is a  
9 joint status report filed by all of the parties. And you'll see it is  
10 signed by the lawyer for the governor, the lawyer for the  
11 Department of Health and Human Services, and the lawyer for the  
12 legislature, Mr. Kevin Powers, Chief Litigation Counsel, Nevada  
13 Legislative Counsel Bureau, Legal Division. And it's signed by  
14 Plaintiff's Counsel.

15           And you will see when you read that joint status report  
16 that all of the parties acknowledge that there's a potential risk of  
17 public disclosure of trade secret protected confidential information.  
18 And to solve that problem, the governor's office, the legislature,  
19 and the department enacted Exhibit 1 to that status report; that joint  
20 status report. And Exhibit 1 is what we are now referring to as the  
21 regulation whereby the department goes through a process to  
22 determine what is confidential and protected as a trade secret  
23 under DTSA and what is not.

24           And I would invite you, Your Honor, to look at the  
25 Legislative Counsel Digest on page 1 because it gives you the

1 history and the law of why this was necessary. And so it was only  
2 after this regulation was implemented through the governor's  
3 office, through the legislature, and through the department that  
4 companies like my client were comfortable providing its trade  
5 secret confidential information to the department.

6 So you're probably asking yourself the question where's  
7 the issue. How could the Petitioners be taking the position that  
8 somehow they are nonetheless given this history, given the parties  
9 involved, that they are nonetheless entitled to trade secret  
10 protected confidential information that by the statute they moved  
11 under, the Nevada Public Records Act, is protected? And the  
12 answer to they can't. They simply can't. And that's why their  
13 motion or their Writ of Mandamus has to be denied. It's through  
14 that legal analysis.

15 Unless you have any questions, Your Honor, I will sit  
16 down and not take up any more of your time.

17 THE COURT: I have no questions.

18 MR. BAILEY: Great. Thank you, Your Honor.

19 MR. RASHBROOK: So I'm going to respond to the  
20 arguments of counsel in the turn that they were made and so I'll  
21 respond to the Respondents arguments --

22 THE COURT: Excuse me --

23 MR. RASHBROOK: -- in the first place --

24 THE COURT: -- one second.

25 [Colloquy between the Court and the Clerk]

1 THE COURT: Okay. Very good.

2 MR. RASHBROOK: Shall we continue?

3 THE COURT: Yeah, go ahead.

4 MR. RASHBROOK: Okay.

5 THE COURT: I just wanted to make sure that --

6 MR. RASHBROOK: No, I --

7 THE COURT: Okay.

8 MR. RASHBROOK: We're longwinded, I apologize.

9 THE COURT: No.

10 MR. RASHBROOK: So the Respondents argue that they

11 have a plenary power to make these administrative codes and

12 frame it as though it is an unlimited grant of authority from the

13 legislature. But when we look at the Nevada Supreme Court cases

14 on this point and I'm talking about the *Clark County School District*

15 case, I'm talking about the *Comstock Residents Association*, and to

16 the contrary the *City of Sparks* case. And I have cites for them if

17 you'd like them but I think they're quoted --

18 THE COURT: I have them.

19 MR. RASHBROOK: -- pretty thoroughly in the briefs.

20 So when we look at the cases where the Supreme Court

21 invalidates the regulation, we have these sort of nonspecific grants

22 of the kind we see here which Respondents refer to as a plenary

23 grant of power but which the Nevada Supreme Court has looked at

24 and said these are nonspecific grants, they're not an indication from

25 the legislature that they're giving you a line-item veto over the

1 Public Records Act.

2 To the contrary, we have a really specific grant in the *City*  
3 *of Sparks* case, the medical marijuana regulations case, where the  
4 Nevada Supreme Court looks at that grant and says yeah, this is  
5 clearly the legislature telling you we want you to keep this  
6 information confidential, we're authorizing you to make whatever  
7 regulations, if necessary, to accomplish that.

8 So I've got to disagree with the Respondents framing that  
9 as a plenary power because the Nevada Supreme Court cases are  
10 pretty clear on this, the way that our court looks at that is it's a  
11 nonspecific grant which does not go far enough, is not specific  
12 enough, to make an end run around the Public Records Act.

13 And related to that is the suggestion from the  
14 Respondents that they're entitled to a great deal of deference in that  
15 area. And to some respect that is absolutely true, but the Nevada  
16 Supreme Court has also been clear that when it comes to legislative  
17 intent, a court makes its own determination and does not defer to  
18 the agency. I'm quoting from the *Division of Insurance Versus*  
19 *State Farm*: Even a reasonable agency interpretation of an  
20 ambiguous statute may be stricken by a court when a court  
21 determines that the agency interpretation conflicts with the  
22 legislative intent.

23 The overall legislative intent behind SB539 is absolutely  
24 clear. The Nevada legislature wants the public to have access to  
25 information and to understand why insulin is so expensive here.

1           So to the extent that Respondents argue that their  
2 interpretation has got to preferred, the law from the Nevada  
3 Supreme Court is absolutely clear that that's not the case. Your  
4 Honor is entitled to make your own determination of what the  
5 legislative intent is and you don't owe deference to the  
6 Respondents on that point.

7           Respondents also argue -- and the language that I noted  
8 was I'll guarantee they might argue this. We talked at one point  
9 about 42 U.S.C. 1983 and what I want to note about all those things  
10 is they are hypotheticals, they have not happened, there is no  
11 indication that they will happen. And the Nevada Supreme Court  
12 repeatedly held that hypothetical concerns are not enough to  
13 escape the reach of Public Records Act.

14           The Public Records Act is a powerful tool. The Intervenor  
15 asks how is the Petitioner entitled to overcome his arguments? The  
16 answer is because the Public Records Act is a powerful tool by  
17 design. The Nevada legislature has repeatedly stated, has  
18 amended the Public Records Act repeatedly, the Nevada Supreme  
19 Court has looked at this at least two dozen times and said, the  
20 legislature has made abundantly clear, they want a broad power for  
21 the public to access records of the government.

22           And when we get to this argument that these are not  
23 government-generated records, there's a line of Supreme Court  
24 cases. *Blackjack Bonding* is one, *Don Ray* is one, *DR Partners* is  
25 one, *Haley* is one where we're looking at records that are either

1 made or submitted by members of the public, private people and  
2 once they're in possession of government, they're liable to be  
3 produced under the Public Records Act.

4 *Blackjack Bonding*, we're looking at phone records.  
5 They're only constructively in possession of the government. And  
6 nonetheless, the Nevada Supreme Court says those are public  
7 records, you've got to produce them. So that really truly is a red  
8 herring in my opinion.

9 The Respondent argues at one point that there is no  
10 affirmative grant in SB539 that these records be public. My  
11 response to that is simply that none is necessary. The Nevada  
12 Public Records Act makes abundantly clear that the presumption is  
13 that all records of this state's government are open to the public for  
14 inspection, copy, and review. There is no need for an affirmative  
15 grant. In each statute the legislature enacts that certain records are  
16 made public. Quite the opposite, there's got to be a statute that  
17 renders them confidential or else the presumption is they are all  
18 public.

19 The Respondents try to distinguish the case *Fast*  
20 *Enterprises* at one point by noting that the government in that case  
21 was a customer. I think it's worth pointing out that the state of  
22 Nevada is a pretty big of insulin via Medicaid. The state has  
23 absolutely got an interest in finding out why the price is so high,  
24 and members of the public have got an interest in finding out why  
25 the price is so high because they're not all on Medicaid. That's a

1 point that I think is pretty thoroughly fleshed out at this point but  
2 certainly the Culinary's Brief refers to that extensively.

3 The Intervenor talks about the idea that even if the  
4 information is important, they've submitted it to the government  
5 and essentially -- and this is sort of present throughout the brief and  
6 throughout the arguments really that these are trade secrets, you've  
7 just got to trust us, right? They're trade secrets because we say  
8 they're trade secrets because James Borneman says that they go to  
9 great lengths to keep this information secret and trust me, it's really  
10 really valuable. I'm not going to provide you any other information,  
11 but you can just trust me, it's really, really valuable.

12 And it made me think of, you know, trust, but verify. Well  
13 we'd like to verify. We'd like to have a look at the public records.

14 When we look at the State Trade Secrets Act, Mr. Bailey  
15 talks about the language specifically in there. To the extent that an  
16 entity is required to disclose, it's not trade secret. I think the clear  
17 implication there is if you don't raise the price so high that you're  
18 required to disclose it, then you're good to keep your trade secret  
19 status if you were otherwise entitled to it.

20 And even in the event that Your Honor would agree with  
21 the Intervenor's interpretation of that law -- and again, I want to  
22 point out the Respondent certainly agrees with the Petitioner's  
23 interpretation of that law. But even in the event that Your Honor  
24 was to prefer the Intervenor's interpretation that only gets them to  
25 the balancing test. It is still not in law which declares this material

1 to be confidential.

2 And beyond that, I think that the last point that I'd like to  
3 make to Your Honor is even in the event that Your Honor is satisfied  
4 that the Intervenor has provided adequate evidence, that they've  
5 satisfied the preponderance of evidence, certainly nobody else has.  
6 There's no one else here.

7 And so in the event that Your Honor sees fit to find in the  
8 Intervenor's favor, no other party similarly situated has offered any  
9 indication. The State hasn't offered any indication on their behalf.  
10 We have the declaration of Mr. Borneman. We don't have any  
11 other evidence. So certainly I think at the minimum what has to be  
12 found is that all of those parties' submissions have to be disclosed.

13 The last thing I'll touch on is that under the Public Records  
14 Act, disclosure is presumed. It's the Respondent's burden to  
15 produce the largest portion of what they can. If they need to redact,  
16 they can redact. But it's constantly -- the burden is on the  
17 government to produce the largest amount that they can produce  
18 because it is the public's right to access its government, which is  
19 preserved by the Public Records Act.

20 If Your Honor has any questions?

21 THE COURT: Not at this time.

22 MR. RASHBROOK: Thank you.

23 THE COURT: I'm sure I will though. I may send them to  
24 both parties in writing if I have anything I need to follow-up on.

25 MR. RASHBROOK: Thanks very much.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

THE COURT: Okay.  
Thank you, Your Honor.  
THE COURT: You're very welcome. Have a great  
afternoon, Counsel.

[Proceeding concluded at 3:10 p.m.]

\* \* \* \* \*

ATTEST: I do hereby certify that I have truly and correctly  
transcribed the audio/video proceedings in the above-entitled case  
to the best of my ability.

  
\_\_\_\_\_  
Brittany Mangelson  
Independent Transcriber

**DISTRICT COURT  
CLARK COUNTY, NEVADA**

**Writ of Mandamus**

**COURT MINUTES**

**April 21, 2020**

---

A-19-799939-W	Nevada Independent, Plaintiff(s)
	vs.
	Richard Whitley, Defendant(s)

---

<b>April 21, 2020</b>	<b>7:00 PM</b>	<b>Minute Order</b>
-----------------------	----------------	---------------------

<b>HEARD BY:</b> Escobar, Adriana	<b>COURTROOM:</b> RJC Courtroom 14C
-----------------------------------	-------------------------------------

**COURT CLERK:** Denise Husted

**RECORDER:**

**REPORTER:**

**PARTIES  
PRESENT:**

**JOURNAL ENTRIES**

- Petitioner The Nevada Independent s (Petitioner) Petition for Writ of Mandamus (Petition), was opposed by Respondents Richard Whitley in his official capacity for the Nevada Department of Health and Human Services (the Department) (collectively, Respondents), as well as Intervenor Sanofi Aventis U.S. LLC (Sanofi), came on for hearing on February 21, 2020 before Department XIV of the Eighth Judicial District Court, the Honorable Adriana Escobar presiding, Attorney Matthew J. Rashbrook appeared on behalf of Petitioner, Attorney Steven Shevorski appeared on behalf of Respondents, Attorneys John R. Bailey and Sarah Harmon appeared on behalf of Sanofi. After considering the moving papers and arguments of counsel, the Court enters the following order:

Regulations created by the Department are presumed valid. N RS 233B.090; see also Montage Marketing, LLC v. Washoe County ex rel. Washoe County Bd. of Equalization, 134 Nev. 294, 300 (2018).

To develop procedural avenues to protect information required as disclosures under Nevada Revised Statute (NRS) NRS 439B.635 or 439B.640, the Department developed Nevada Administrative Code 439. If the Department receives a request for public records pursuant to NRS 239.010 seeking disclosure of any information for which a manufacturer or pharmacy benefit manager has submitted

PRINT DATE: 04/21/2020

Page 1 of 5

Minutes Date: April 21, 2020

a request for confidentiality pursuant to subsection 1, the Department will, after notifying the manufacturer or pharmacy benefit manager:

Undertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act (DTSA) of 2016, 18 U.S.C. 1836, as amended. In undertaking its initial review, the Department will consider, as persuasive authority, the interpretation and application given to the term trade secrets in Exemption 4 of the federal Freedom of Information Act, 5 U.S.C. 552(b)(4), as amended.

NAC 439.735(3).

If, after undertaking its initial review pursuant to subsection 3, the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. 1836, as amended, the Department will provide the requester of the public records with written notice that the Department must deny the request for public records on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. 1836, as amended.

NAC 439.735(4).

Pursuant to NRS 600A.030(5), the trade secret definition [d]oes not include any information that a manufacturer is required to report pursuant to NRS 439B.635 or 439B.640, information that a pharmaceutical sales representative is required to report pursuant to NRS 439B.660 or information that a pharmacy benefit manager is required to report pursuant to NRS 439B.645, to the extent that such information is required to be disclosed by those sections.

However, the federal Defend Trade Secrets Act of 2016, 18 U.S.C. 1836 (DTSA), which Nevada Arbitration Code (NAC) 439.735(1) codifies as a Nevada law protection, provides an express protection for information otherwise required to be disclosed under NRS 439B:

In complying with NRS 439B.635, 439B.640 or 439B.645, if a manufacturer or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. 1836, as amended, the manufacturer or pharmacy benefit manager may submit to the Department a request to keep the information confidential.

18 U.S.C. 1839(3) defines trade secrets as:

the term trade secret means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if the owner thereof has taken reasonable measures to keep such information secret; and the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.

If a request for inspection, copying or copies of a public book or record open to inspection and copying is denied, the requester may apply to the district court in the county in which the book or record is located for an order either permitting the requester to inspect or copy the book or record or requiring the person who has legal custody or control of the public book or record to provide a copy to the requester, as applicable. NRS 239.011(1).

The Department bears the burden to prove that its interest in nondisclosure clearly outweighs the public's interest in access. *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880 (2011). When determining the validity of an administrative regulation, courts generally give great deference to an agency's interpretation of a statute that the agency is charged with enforcing. *State, Div. of Ins. v. State Farm Mut. Auto. Ins. Co.*, 116 Nev. 290, 293 (2000)

Here, while Petitioner bears the burden of proving that it is entitled to this remedy, the burden is ultimately on the Department to prove, by a preponderance of the evidence, that the information it declined to provide to Petitioner was confidential. NRS 239.0113.

On April 3, 2019, the Department denied, in part, Petitioner s request for certain annual reports. In said denial, the Department explained as follows:

DHHS is denying disclosure of the fields not included in Appendix 2 on the basis that the information is confidential pursuant to the federal Defend Trade Secrets Act (DTSA) of 2016, 18 U.S.C. 1836, as amended. This determination is based on DHHS s review of the DTSA, and on the information provided by drug manufacturers and PBMs in the completed RFCs submitted to DHHS pursuant to NAC 439.735, Subsection 2. Please note that a copy of this letter will be sent to manufacturers and PBMs that submitted an RFC.

Petition, Exhibit 2-2.

On June 24, 2019, the Department denied, in part, Petitioner s follow-up request for certain annual reports, on the same grounds explained above. Petition, Exhibit 2-4.

On August 8, 2019, Petitioner filed the instant Petition. Petitioner raised several chief arguments in the instant Petition. First, Petitioner argues that to the extent the agency-related regulations at issue conflict with statutory law, the regulations are invalid, that the DTSA explicitly states it does not preempt state law, and thus, NAC 439.730 740 is invalid and must be invalidated. *Division of Ins. v. State Farm Mutual Ins. Co.*, 116 Nev. 290, 293 (2000). Petition, 11:11 15. Petition, 11:1 6.

This Court disagrees. The Department in its broad discretion to implement regulations to foster efficient enforcement of codified legislation developed NAC 439.730 740, respectively, to ensure the NPRA coincided with the DTSA protections. See Case 2:17-cv-02315 at Doc. 1, p. 20. Had the Department failed to carve out these procedural protections, the courts would become inundated with cases in which the compelled disclosing parties claim they did not have the opportunity to protect their trade secrets from mass disclosures.

Moreover, the confidentiality protections are not automatic. The Department notifies the entity with information implicated in the NPRA request and gives said entity 30 days to claim any confidentiality protections. The Department then analyzes the requested information through the DTSA confidentiality and trade-secret lenses to confirm whether said information should be protected. Only after this process does the Department conclude whether the information should be protected. The Court does not find grounds to find that NAC 439.730 740 is unenforceable.

Next, Petitioner argues that the Legislature showed clear intent to allow the public access to these records, and the Department violated the NPRA by denying Petitioner s requests because DTSA does not apply to Petitioner s requests in a manner that would particularly place the requested reports under confidentiality protections. Petition, 12:18 24; Supplement to Petition, 5:8 7:26.

The Court is not persuaded by this argument. The DTSA definition for trade secrets places these reports squarely under confidentiality protections. 18 U.S.C. 1839(3). Specifically, and as both Respondent and Intervenor highlight, these reports derive independent economic value, actual or potential, from not being generally known to, or readily ascertainable by other people who can obtain economic value from its disclosure or use and is subject to reasonable efforts to maintain its secrecy. *Id.* 1839(3). These efforts include significant limitations on who receives said information the Department and high-level employees privatizing the information that is shared, and submitting prompt requests to the Department to exclude said reports from disclosure based on their trade-secret qualities.

Based on the foregoing, the Court concludes that the Department proved, by a preponderance of the evidence, that the denied disclosures have confidentiality protections pursuant to the DTSA. Thus, the Court DENIES Petitioner s Petition.

Counsel for Respondents to prepare an order including findings of fact and conclusions of law, to be

reviewed by counsel for Petitioner as to form and content. The order is to be submitted to Chambers in Microsoft word format by email to dept14lc@clarkcountycourts.us, and to Diana Powell at PowellD@clarkcountycourts.us.

CLERK'S NOTE: Counsel notified via email:

Matthew Rashbrook (matt@nvlitigation.com)  
Steven Sherovski (steven.sherovski@akerman.com)  
John Bailey (jbailey@baileykennedy.com)

1 **ORDR**

2 **DISTRICT COURT**

3 **CLARK COUNTY, NEVADA**

4 **THE NEVADA INDEPENDENT,**

Case No. A-19-799939-W  
Dept. No. XIV

5 **Petitioner,**

6 **vs.**

7 **RICHARD WHITLEY, in his official capacity**  
8 **as the Director of the Nevada Department of**  
9 **Health and Human Services, and THE**  
10 **STATE OF NEVADA, ex rel. the NEVADA**  
11 **DEPARTMENT OF HEALTH AND HUMAN**  
12 **SERVICES,**

13 **Respondents.**

14 **ORDER DENYING PETITION FOR WRIT OF MANDAMUS**

15 The Court heard argument on the Nevada Independent's (the Independent)  
16 Petition for Writ of Mandamus (Petition) on February 21, 2020. Matthew J. Rashbrook  
17 appeared for Petitioner; Steve Shevorski appeared for Richard Whitley as Director of the  
18 Nevada Department of Health and Human Services and State of Nevada ex rel. the  
19 Nevada Department of Health and Human Services (collectively, Respondents); and John  
20 R. Bailey, Sarah E. Harmon, and Rebecca L. Crooker appeared for Intervenor Sanofi-  
21 Aventis U.S. LLC (Sanofi). The Court, after considering the moving papers and  
22 arguments of counsel, denies the Petition and enters the following findings of fact and  
23 conclusions of law:

24 **I. Findings of Fact**

25 1. The Independent submitted a public records request to Respondents on  
26 January 17, 2019. The Independent sought (i) the names of pharmaceutical  
27 manufacturers and pharmacy benefit managers that submitted annual reports pursuant  
28 to Nevada Senate Bill 539<sup>1</sup>, (ii) annual reports submitted by 98 pharmaceutical  
manufacturers, including Sanofi, and 7 pharmacy benefit managers (and any others who

<sup>1</sup> Nevada's legislature passed Nevada Senate Bill 539 in 2017. SB 539 was, in the main, codified as 439B. Relevant here, as explained below, SB 539 also amended NRS 600A.030(5)'s definition of a trade secret under Nevada state law.

submitted reports), and (iii) written opinions (including drafts) by the Nevada Attorney General's Office relating to SB 539's implementation in 2017.

2. Respondents responded in writing on April 3, 2019. Respondents stated that they would disclose the following information, which was contained in Appendix 2 of their letter:

**1) Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635)**

- i) Drug Manufacturer Name
- ii) Nonproprietary Prescription Drug Name
- iii) Proprietary Prescription Drug Name
- iv) National Drug Code (NDC)
- v) Wholesale Acquisition Cost (WAC) Price History
- vi) Increase in WAC Unit Price
- vii) Date of Increase in WAC Price

**2) Drug Manufacturer Essential Diabetes Drug Price Increase Reports (NRS 439B.640)**

- i) Drug Manufacturer Name
- ii) Non-Proprietary Drug Name
- iii) Proprietary Drug Name
- iv) NDC

**3) PBM Essential Diabetes Drug Reports (NRS 439B.645)**

- i) A list of PBMs that submitted reports

(bold in original). Respondents did not disclose the following information from the Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635):

- The Cost of Producing the Drug;
- Total Administrative Expenditures Relating to the Drug;
- Profit Manufacturer Earned from the Drug;
- Percentage of Manufacturer's Total Profit for the Period During Which the Manufacturer Has Marketed the Drug for Sale that Is Attributable to Drug;
- Total Amount of Financial Assistance Provided through Patient Prescription Assistance Programs;
- Cost Associated with Consumer Coupons and for Consumer Copayment Assistance Programs;
- Manufacturer Cost Attributable to Redemption of Consumer Coupons and Use of Consumer Copayment Assistance Program; and
- Aggregate of All Rebates Manufacturers Provided to Pharmacy Benefit Managers for Drug Sales in Nevada.

3. In their written response, Respondents explained that, pursuant to NAC 439.735(4), they had undertaken a review of the material requested to determine whether

Respondents reasonably believed that the disclosure of the material would constitute a misappropriation of a trade secret under the federal Defend Trade Secrets Act of 2016, 18 U.S.C. §1836, as amended (DTSA). Respondents explained that they reasonably believed the requested information was not subject to the Nevada Public Records Act (NPRa) because it was confidential pursuant to the DTSA.

4. The Independent submitted another public records request to Respondents on June 11, 2019. The Independent sought (i) the names of pharmaceutical manufacturers and pharmacy benefit managers that submitted annual reports pursuant to Nevada Senate Bill 539, (ii) annual reports submitted by 72 pharmaceutical manufacturers, including Sanofi, and 7 pharmacy benefit managers (and any others who submitted reports).

5. Respondents responded in writing on June 24, 2019. Respondents stated that they would disclose the following information, which was contained in Appendix 2 of their letter:

**1) Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635)**

- i) Drug Manufacturer Name
- ii) Nonproprietary Prescription Drug Name
- iii) Proprietary Prescription Drug Name
- iv) National Drug Code (NDC)
- v) Wholesale Acquisition Cost (WAC) Price History
- vi) Increase in WAC Unit Price
- vii) Date of Increase in WAC Price

**2) Drug Manufacturer Essential Diabetes Drug Price Increase Reports (NRS 439B.640)**

- i) Drug Manufacturer Name
- ii) Non-Proprietary Drug Name
- iii) Proprietary Drug Name
- iv) NDC

**3) PBM Essential Diabetes Drug Reports (NRS 439B.645)**

- i) A list of PBMs that submitted reports

(bold in original). Respondents did not disclose the following information from the Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635):

- The Cost of Producing the Drug;
- Total Administrative Expenditures Relating to the Drug;
- Profit Manufacturer Earned from the Drug;

Percentage of Manufacturer's Total Profit for the Period During Which the Manufacturer Has Marketed the Drug for Sale that Is Attributable to Drug;

- Total Amount of Financial Assistance Provided through Patient Prescription Assistance Programs;
- Cost Associated with Consumer Coupons and for Consumer Copayment Assistance Programs;
- Manufacturer Cost Attributable to Redemption of Consumer Coupons and Use of Consumer Copayment Assistance Program; and
- Aggregate of All Rebates Manufacturers Provided to Pharmacy Benefit Managers for Drug Sales in Nevada.

6. Similar to their earlier response noted above, Respondents explained again that, pursuant to NAC 439.735(4), they had undertaken a review of the material requested to determine whether Respondents reasonably believed that the disclosure of the material would constitute a misappropriation of a trade secret under the DTSA. Respondents explained that they reasonably believed the requested information was not subject to the NPRA, because it was confidential pursuant to the DTSA.

7. The Independent filed a petition for writ of mandamus on August 8, 2019, and Respondents opposed and moved to dismiss the Petition on October 17, 2019. After being granted leave to intervene, Sanofi opposed the Independent's petition on December 23, 2019. The Independent filed a reply in response to Sanofi's opposition on January 3, 2020. Respondents filed a reply supporting their motion to dismiss on January 23, 2020.

8. The Court set the matter for hearing on February 21, 2020. No party called fact witnesses. Counsel for the Independent, counsel for Respondents, and counsel for Sanofi presented legal argument for the Court's consideration.

## II. Conclusions of Law

### A. Legal Background

1. The Nevada Public Records Act starts with the general rule that "unless otherwise declared by law to be confidential, all public books and public records of a

1 governmental entity must be open at all times during office hours to inspection by any  
2 person. . . .” NRS 239.010(1).

3       2. Nevada Senate Bill 539, now codified in part as Nevada Revised Statutes  
4 439B, institutes certain requirements for the Nevada Department of Health and Human  
5 Services (HHS or the Department), manufacturers of pharmaceuticals, and pharmacy  
6 benefit managers, among others. It has four relevant parts. First, NRS 439B.630 requires  
7 HHS to compile (1) a “list of prescription drugs [including insulin and biguanides] that  
8 the Department determines to be essential for treating diabetes in this State”; and (2) a  
9 “list of prescription drugs described in subsection 1 that have been subject to [a  
10 significant price] increase in the wholesale acquisition.” Second, NRS 439B.635 requires  
11 the manufacturer of a drug included on the list described by NRS 439B.630 (1)-(2), to  
12 submit to HHS an annual report that contains certain information about the cost of the  
13 drug. Third, NRS 439B.640 requires the manufacturer to submit a report to HHS  
14 concerning the reasons for the cost increase, if any. Fourth, NRS 439B.645 requires  
15 pharmacy benefit managers to report to HHS detailed information relating to the rebates  
16 that they negotiated and provided.

17       3. SB 539 also amended NRS 600A.030, as follows:

18       ‘Trade secret’ . . .

19       Does not include any information that a manufacturer is  
20       required to report pursuant to NRS 439B.635 or 439B.640,  
21       information that a pharmaceutical sales representative is  
22       required to report pursuant to NRS 439B.660 or information  
23       that a pharmacy benefit manager is required to report  
24       pursuant to NRS 439B.645, to the extent that such information  
25       is required to be disclosed by those sections.

26 NRS 600A.030 (5)(a).

27       4. After SB 539’s passage, and as a result of the resolution in *Pharm. Research*  
28       & *Mfrs. of Am. v. Sandoval*, 2:17-cv-02315-JCM-CWH, U.S. Dist. Ct. Dist. of Nev., which  
29       concerned a challenge to the constitutionality of SB 539’s requirement of disclosure of  
30       trade secrets to HHS, Respondents promulgated corresponding regulations, found in  
31       Section 439 of the Nevada Administrative Code (NAC).

5. Pursuant to NAC 439.735, “[i]n complying with NRS 439B.635, 439B.640 or 439B.645, if a manufacturer or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836 (DTSA), as amended, the manufacturer or pharmacy benefit manager may submit to the Department a request to keep the information confidential.” NAC 439.735(1). If the Department is faced with a public records request, it then must determine if it agrees with this assessment. NAC 439.735(3). If it agrees that the information requested is confidential, it must deny the public records request. NAC 439.735(4). If the Department does not agree, then it provides the affected entity at least 30-days’ notice and allows the entity to go to court to defend its alleged trade secrets. NAC 439.735(5).

The Defend Trade Secrets Act, 18 U.S.C. 1839(3) defines “trade secrets” as:

all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if the owner thereof has taken reasonable measures to keep such information secret; and the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.

6. Thus, while public policy calls for transparency under NRS 239.010(1), the legislature made clear that the Nevada law was not designed to circumvent the protections enumerated under federal law.

#### **B. Petitioner’s Request for Mandamus is Denied**

7. Mandamus is an extraordinary remedy to compel the performance of an act that the law requires as a duty resulting from an office, trust or station. *State v. Dist. Ct. (Armstrong)*, 127 Nev. 927, 929, 267 P.3d 777, 779 (2011). Petitioner bears the burden to demonstrate that a writ of mandamus is warranted. *Am. Home Assurance Co. v. Dist.*

1 *Ct.*, 122 Nev. 1229, 1234, 147 P.3d 1120, 1124 (2006). Mandamus is the appropriate  
2 procedural remedy to compel production of the public records sought in this case. *See*,  
3 *e.g.*, *Donrey of Nevada v. Bradshaw*, 106 Nev. 630, 798 P.2d 144 (1990).

4 8. Nevada courts initially presume that “all government-generated records are  
5 open to disclosure.” *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 266 P.3d 623,  
6 628 (2011). The state entity bears the burden of overcoming this presumption by proving,  
7 by a preponderance of the evidence, that the requested records are confidential. NRS  
8 239.0113; *DR Partners v. Bd. of Cnty. Comm.*, 116 Nev. 616, 621, 6 P.3d 465, 468 (2000).  
9 Without a statutory provision that explicitly declares a record to be confidential, any  
10 limitations on disclosure must be based upon a broad balancing of the interests involved,  
11 *DR Partners*, 116 Nev. at 622, 6 P.3d at 468. In that circumstance the state entity has the  
12 burden to prove that its interest in nondisclosure outweighs the public's interest in access  
13 *Gibbons*, 127 Nev. at 880, 266 P.3d at 628. The state entity cannot meet that burden  
14 with a non-particularized showing, or by expressing hypothetical concerns. *Id.* (citations  
15 omitted).

16 9. Regulations created by a state agency are presumed valid. NRS 233B.090;  
17 *see also Montage Marketing, LLC v. Washoe County ex rel. Washoe County Bd. of*  
18 *Equalization*, 134 Nev. 294, 300 (2018).

19 10. The Independent argues that NAC.439.730 and 740 are invalid. The Court  
20 disagrees. The Court defers to the Respondents’ reasonable interpretation of a statute  
21 they are charged with enforcing. *State, Div. of Insurance v. State Farm*, 116 Nev. 290,  
22 293, 995 P.2d 482, 485 (2000). The Independent’s lawsuit can only succeed by finding a  
23 direct conflict between the unambiguous language of the statute and the agency’s  
24 regulation. *Clark Co. Social Service Dep’t v. Newkirk*, 106 Nev. 177, 179, 789 P.2d 227,  
25 228 (1990).

26 11. HHS, in its broad discretion to implement regulations to foster efficient  
27 enforcement of codified legislation, developed NAC 439.730 and 740 to ensure the Nevada  
28 Public Records Act complied with the DTSA protections. Had the Respondents failed to

1 carve out these procedural protections, the courts would become inundated with cases in  
2 which the compelled disclosing parties claim they did not have the opportunity to protect  
3 their trade secrets from mass disclosures.

4 12. The confidentiality protections are not automatic. Respondents notify the  
5 entity with information implicated in the NPRA request. The targeted entity then has 30  
6 days to claim any confidentiality protections. Respondents then analyze the requested  
7 information through the DTSA confidentiality and trade-secret requirements to confirm  
8 whether the allegedly confidential information should be protected. Only after this  
9 process has been completed do Respondents reach a conclusion as to protection of the  
10 information.

11 13. The Independent next argues that the records it seeks are not declared by  
12 law to be confidential, and that Respondents violated the NPRA by denying the  
13 Independent's requests because the DTSA does not apply in a manner that would place  
14 the requested reports under confidentiality protections. Again, the Court is not persuaded  
15 by the Independent's argument. The DTSA's definition for trade secrets places these  
16 reports squarely under confidentiality protections. 18 U.S.C. 1839(3). Specifically, and as  
17 both Respondents and Sanofi highlight, these reports derive independent economic value,  
18 actual or potential, from not being generally known to, or readily ascertainable by, other  
19 people who can obtain economic value from their disclosure or use and are subject to  
20 reasonable efforts to maintain their secrecy. *Id.* 1839(3). These efforts include  
21 Respondents placing significant limitations on who receives said information,  
22 Respondents and high-level employees privatizing the information that is shared, and the  
23 affected entity submitting prompt requests to Respondents to exclude said reports from  
24 disclosure based on their status as confidential data or information that derives economic  
25 value from not being generally known, and thus protected, trade secrets under the DTSA.

26 ///

27 ///

28 ///

III. Order

IT IS HEREBY ORDERED that Petitioners' petitioner for writ of mandamus is denied.

Dated this 4th day of September, 2020



HONORABLE ADRIANA ESCOBAR  
DISTRICT COURT JUDGE

05A D9E A945 2F08  
Adriana Escobar  
District Court Judge

1 **CSERV**

2  
3 DISTRICT COURT  
4 CLARK COUNTY, NEVADA

5  
6 Nevada Independent, Plaintiff(s) | CASE NO: A-19-799939-W  
7 vs. | DEPT. NO. Department 14  
8 Richard Whitley, Defendant(s)  
9

10 **AUTOMATED CERTIFICATE OF SERVICE**

11 This automated certificate of service was generated by the Eighth Judicial District  
12 Court. The foregoing Order Denying was served via the court's electronic eFile system to all  
13 recipients registered for e-Service on the above entitled case as listed below:

14 Service Date: 9/4/2020

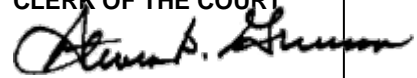
15 Sarah Harmon	sharmon@baileykennedy.com
16 Dennis Kennedy	dkennedy@baileykennedy.com
17 John Bailey	jbailey@baileykennedy.com
18 Bailey Kennedy, LLP	bkfederaldownloads@baileykennedy.com
19 Traci Plotnick	tplotnick@ag.nv.gov
20 Steven Shevorski	sshevorski@ag.nv.gov
21 Mary Pizzariello	mpizzariello@ag.nv.gov
22 Robert Langford	robert@robertlangford.com
23 Matthew Rashbrook	Matt@robertlangford.com
24 Eddie Rueda	erueda@ag.nv.gov

25  
26  
27  
28

1 If indicated below, a copy of the above mentioned filings were also served by mail  
2 via United States Postal Service, postage prepaid, to the parties listed below at their last  
3 known addresses on 9/8/2020

4 Aaron Ford State of Nevada - Attorney General  
5 Attn: Aaron D. Ford  
6 100 N. Carson Street  
7 Carson City, NV, 89701-4717

8 Paul More McCracken Stemerman & Holsberry  
9 Attn: Paul L. More  
10 1630 South Commerce Street - Suite A-1  
11 Las Vegas, NV, 89102  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28



AARON D. FORD  
Attorney General  
Steve Shevorsi (Bar No. 8256)  
Chief Litigation Counsel  
Office of the Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
(702) 486-3420 (phone)  
(702) 486-3773 (facsimile)

*Attorneys for Respondents*

**DISTRICT COURT**

**CLARK COUNTY, NEVADA**

THE NEVADA INDEPENDENT,

Petitioner,

vs.

RICHARD WHITLEY, in his official capacity  
as the Director of the Nevada Department of  
Health and Human Services, and THE  
STATE OF NEVADA, ex rel. the NEVADA  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES,

Respondents.

Case No. A-19-799939-W  
Dept. No. XIV

**NOTICE OF ENTRY OF ORDER**

PLEASE TAKE NOTICE that an Order Denying Petition for Writ Mandamus was  
entered on the 4th day of September, 2020, a copy of which is attached hereto as Exhibit  
“A”.

DATED this 9th day of September, 2020.

AARON D. FORD  
Attorney General

By: /s/ Steve Shevorsi  
Steve Shevorsi (Bar No. 8256)  
Chief Litigation Counsel

*Attorneys for Respondents*

1 **CERTIFICATE OF SERVICE**

2 I hereby certify that I electronically filed the foregoing document with the Clerk of  
3 the Court by using the electronic filing system on the 9th day of September, 2020, and e-  
4 served the same on all parties listed on the Court's Master Service List.

5  
6 /s/ Eddie Rueda  
Eddie Rueda, an employee of the  
7 Office of the Attorney General  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# EXHIBIT A

# EXHIBIT A

1 **ORDR**

2 **DISTRICT COURT**

3 **CLARK COUNTY, NEVADA**

4 **THE NEVADA INDEPENDENT,**

Case No. A-19-799939-W

Dept. No. XIV

5 **Petitioner,**

6 **vs.**

7 **RICHARD WHITLEY, in his official capacity**  
8 **as the Director of the Nevada Department of**  
9 **Health and Human Services, and THE**  
10 **STATE OF NEVADA, ex rel. the NEVADA**  
11 **DEPARTMENT OF HEALTH AND HUMAN**  
12 **SERVICES,**

13 **Respondents.**

14 **ORDER DENYING PETITION FOR WRIT OF MANDAMUS**

15 The Court heard argument on the Nevada Independent's (the Independent)  
16 Petition for Writ of Mandamus (Petition) on February 21, 2020. Matthew J. Rashbrook  
17 appeared for Petitioner; Steve Shevorski appeared for Richard Whitley as Director of the  
18 Nevada Department of Health and Human Services and State of Nevada ex rel. the  
19 Nevada Department of Health and Human Services (collectively, Respondents); and John  
20 R. Bailey, Sarah E. Harmon, and Rebecca L. Crooker appeared for Intervenor Sanofi-  
21 Aventis U.S. LLC (Sanofi). The Court, after considering the moving papers and  
22 arguments of counsel, denies the Petition and enters the following findings of fact and  
23 conclusions of law:

24 **I. Findings of Fact**

25 1. The Independent submitted a public records request to Respondents on  
26 January 17, 2019. The Independent sought (i) the names of pharmaceutical  
27 manufacturers and pharmacy benefit managers that submitted annual reports pursuant  
28 to Nevada Senate Bill 539<sup>1</sup>, (ii) annual reports submitted by 98 pharmaceutical  
manufacturers, including Sanofi, and 7 pharmacy benefit managers (and any others who

<sup>1</sup> Nevada's legislature passed Nevada Senate Bill 539 in 2017. SB 539 was, in the main, codified as 439B. Relevant here, as explained below, SB 539 also amended NRS 600A.030(5)'s definition of a trade secret under Nevada state law.

submitted reports), and (iii) written opinions (including drafts) by the Nevada Attorney General's Office relating to SB 539's implementation in 2017.

2. Respondents responded in writing on April 3, 2019. Respondents stated that they would disclose the following information, which was contained in Appendix 2 of their letter:

**1) Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635)**

- i) Drug Manufacturer Name
- ii) Nonproprietary Prescription Drug Name
- iii) Proprietary Prescription Drug Name
- iv) National Drug Code (NDC)
- v) Wholesale Acquisition Cost (WAC) Price History
- vi) Increase in WAC Unit Price
- vii) Date of Increase in WAC Price

**2) Drug Manufacturer Essential Diabetes Drug Price Increase Reports (NRS 439B.640)**

- i) Drug Manufacturer Name
- ii) Non-Proprietary Drug Name
- iii) Proprietary Drug Name
- iv) NDC

**3) PBM Essential Diabetes Drug Reports (NRS 439B.645)**

- i) A list of PBMs that submitted reports

(bold in original). Respondents did not disclose the following information from the Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635):

- The Cost of Producing the Drug;
- Total Administrative Expenditures Relating to the Drug;
- Profit Manufacturer Earned from the Drug;
- Percentage of Manufacturer's Total Profit for the Period During Which the Manufacturer Has Marketed the Drug for Sale that Is Attributable to Drug;
- Total Amount of Financial Assistance Provided through Patient Prescription Assistance Programs;
- Cost Associated with Consumer Coupons and for Consumer Copayment Assistance Programs;
- Manufacturer Cost Attributable to Redemption of Consumer Coupons and Use of Consumer Copayment Assistance Program; and
- Aggregate of All Rebates Manufacturers Provided to Pharmacy Benefit Managers for Drug Sales in Nevada.

3. In their written response, Respondents explained that, pursuant to NAC 439.735(4), they had undertaken a review of the material requested to determine whether

Respondents reasonably believed that the disclosure of the material would constitute a misappropriation of a trade secret under the federal Defend Trade Secrets Act of 2016, 18 U.S.C. §1836, as amended (DTSA). Respondents explained that they reasonably believed the requested information was not subject to the Nevada Public Records Act (NPRa) because it was confidential pursuant to the DTSA.

4. The Independent submitted another public records request to Respondents on June 11, 2019. The Independent sought (i) the names of pharmaceutical manufacturers and pharmacy benefit managers that submitted annual reports pursuant to Nevada Senate Bill 539, (ii) annual reports submitted by 72 pharmaceutical manufacturers, including Sanofi, and 7 pharmacy benefit managers (and any others who submitted reports).

5. Respondents responded in writing on June 24, 2019. Respondents stated that they would disclose the following information, which was contained in Appendix 2 of their letter:

**1) Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635)**

- i) Drug Manufacturer Name
- ii) Nonproprietary Prescription Drug Name
- iii) Proprietary Prescription Drug Name
- iv) National Drug Code (NDC)
- v) Wholesale Acquisition Cost (WAC) Price History
- vi) Increase in WAC Unit Price
- vii) Date of Increase in WAC Price

**2) Drug Manufacturer Essential Diabetes Drug Price Increase Reports (NRS 439B.640)**

- i) Drug Manufacturer Name
- ii) Non-Proprietary Drug Name
- iii) Proprietary Drug Name
- iv) NDC

**3) PBM Essential Diabetes Drug Reports (NRS 439B.645)**

- i) A list of PBMs that submitted reports

(bold in original). Respondents did not disclose the following information from the Drug Manufacturer Essential Diabetes Drug Reports (NRS 439B.635):

- The Cost of Producing the Drug;
- Total Administrative Expenditures Relating to the Drug;
- Profit Manufacturer Earned from the Drug;

Percentage of Manufacturer's Total Profit for the Period During Which the Manufacturer Has Marketed the Drug for Sale that Is Attributable to Drug;

- Total Amount of Financial Assistance Provided through Patient Prescription Assistance Programs;
- Cost Associated with Consumer Coupons and for Consumer Copayment Assistance Programs;
- Manufacturer Cost Attributable to Redemption of Consumer Coupons and Use of Consumer Copayment Assistance Program; and
- Aggregate of All Rebates Manufacturers Provided to Pharmacy Benefit Managers for Drug Sales in Nevada.

6. Similar to their earlier response noted above, Respondents explained again that, pursuant to NAC 439.735(4), they had undertaken a review of the material requested to determine whether Respondents reasonably believed that the disclosure of the material would constitute a misappropriation of a trade secret under the DTSA. Respondents explained that they reasonably believed the requested information was not subject to the NPRA, because it was confidential pursuant to the DTSA.

7. The Independent filed a petition for writ of mandamus on August 8, 2019, and Respondents opposed and moved to dismiss the Petition on October 17, 2019. After being granted leave to intervene, Sanofi opposed the Independent's petition on December 23, 2019. The Independent filed a reply in response to Sanofi's opposition on January 3, 2020. Respondents filed a reply supporting their motion to dismiss on January 23, 2020.

8. The Court set the matter for hearing on February 21, 2020. No party called fact witnesses. Counsel for the Independent, counsel for Respondents, and counsel for Sanofi presented legal argument for the Court's consideration.

## II. Conclusions of Law

### A. Legal Background

1. The Nevada Public Records Act starts with the general rule that "unless otherwise declared by law to be confidential, all public books and public records of a

1 governmental entity must be open at all times during office hours to inspection by any  
2 person. . . .” NRS 239.010(1).

3       2. Nevada Senate Bill 539, now codified in part as Nevada Revised Statutes  
4 439B, institutes certain requirements for the Nevada Department of Health and Human  
5 Services (HHS or the Department), manufacturers of pharmaceuticals, and pharmacy  
6 benefit managers, among others. It has four relevant parts. First, NRS 439B.630 requires  
7 HHS to compile (1) a “list of prescription drugs [including insulin and biguanides] that  
8 the Department determines to be essential for treating diabetes in this State”; and (2) a  
9 “list of prescription drugs described in subsection 1 that have been subject to [a  
10 significant price] increase in the wholesale acquisition.” Second, NRS 439B.635 requires  
11 the manufacturer of a drug included on the list described by NRS 439B.630 (1)-(2), to  
12 submit to HHS an annual report that contains certain information about the cost of the  
13 drug. Third, NRS 439B.640 requires the manufacturer to submit a report to HHS  
14 concerning the reasons for the cost increase, if any. Fourth, NRS 439B.645 requires  
15 pharmacy benefit managers to report to HHS detailed information relating to the rebates  
16 that they negotiated and provided.

17       3. SB 539 also amended NRS 600A.030, as follows:

18       ‘Trade secret’ . . .

19       Does not include any information that a manufacturer is  
20       required to report pursuant to NRS 439B.635 or 439B.640,  
21       information that a pharmaceutical sales representative is  
22       required to report pursuant to NRS 439B.660 or information  
23       that a pharmacy benefit manager is required to report  
24       pursuant to NRS 439B.645, to the extent that such information  
25       is required to be disclosed by those sections.

26 NRS 600A.030 (5)(a).

27       4. After SB 539’s passage, and as a result of the resolution in *Pharm. Research*  
28       & *Mfrs. of Am. v. Sandoval*, 2:17-cv-02315-JCM-CWH, U.S. Dist. Ct. Dist. of Nev., which  
29       concerned a challenge to the constitutionality of SB 539’s requirement of disclosure of  
30       trade secrets to HHS, Respondents promulgated corresponding regulations, found in  
31       Section 439 of the Nevada Administrative Code (NAC).

5. Pursuant to NAC 439.735, “[i]n complying with NRS 439B.635, 439B.640 or 439B.645, if a manufacturer or pharmacy benefit manager reasonably believes that public disclosure of information that it submits to the Department would constitute misappropriation of a trade secret for which a court may award relief pursuant to the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836 (DTSA), as amended, the manufacturer or pharmacy benefit manager may submit to the Department a request to keep the information confidential.” NAC 439.735(1). If the Department is faced with a public records request, it then must determine if it agrees with this assessment. NAC 439.735(3). If it agrees that the information requested is confidential, it must deny the public records request. NAC 439.735(4). If the Department does not agree, then it provides the affected entity at least 30-days’ notice and allows the entity to go to court to defend its alleged trade secrets. NAC 439.735(5).

The Defend Trade Secrets Act, 18 U.S.C. 1839(3) defines “trade secrets” as:

all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if the owner thereof has taken reasonable measures to keep such information secret; and the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.

6. Thus, while public policy calls for transparency under NRS 239.010(1), the legislature made clear that the Nevada law was not designed to circumvent the protections enumerated under federal law.

#### **B. Petitioner’s Request for Mandamus is Denied**

7. Mandamus is an extraordinary remedy to compel the performance of an act that the law requires as a duty resulting from an office, trust or station. *State v. Dist. Ct. (Armstrong)*, 127 Nev. 927, 929, 267 P.3d 777, 779 (2011). Petitioner bears the burden to demonstrate that a writ of mandamus is warranted. *Am. Home Assurance Co. v. Dist.*

1 *Ct.*, 122 Nev. 1229, 1234, 147 P.3d 1120, 1124 (2006). Mandamus is the appropriate  
2 procedural remedy to compel production of the public records sought in this case. *See*,  
3 *e.g.*, *Donrey of Nevada v. Bradshaw*, 106 Nev. 630, 798 P.2d 144 (1990).

4 8. Nevada courts initially presume that “all government-generated records are  
5 open to disclosure.” *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 266 P.3d 623,  
6 628 (2011). The state entity bears the burden of overcoming this presumption by proving,  
7 by a preponderance of the evidence, that the requested records are confidential. NRS  
8 239.0113; *DR Partners v. Bd. of Cnty. Comm.*, 116 Nev. 616, 621, 6 P.3d 465, 468 (2000).  
9 Without a statutory provision that explicitly declares a record to be confidential, any  
10 limitations on disclosure must be based upon a broad balancing of the interests involved,  
11 *DR Partners*, 116 Nev. at 622, 6 P.3d at 468. In that circumstance the state entity has the  
12 burden to prove that its interest in nondisclosure outweighs the public's interest in access  
13 *Gibbons*, 127 Nev. at 880, 266 P.3d at 628. The state entity cannot meet that burden  
14 with a non-particularized showing, or by expressing hypothetical concerns. *Id.* (citations  
15 omitted).

16 9. Regulations created by a state agency are presumed valid. NRS 233B.090;  
17 *see also Montage Marketing, LLC v. Washoe County ex rel. Washoe County Bd. of*  
18 *Equalization*, 134 Nev. 294, 300 (2018).

19 10. The Independent argues that NAC.439.730 and 740 are invalid. The Court  
20 disagrees. The Court defers to the Respondents’ reasonable interpretation of a statute  
21 they are charged with enforcing. *State, Div. of Insurance v. State Farm*, 116 Nev. 290,  
22 293, 995 P.2d 482, 485 (2000). The Independent’s lawsuit can only succeed by finding a  
23 direct conflict between the unambiguous language of the statute and the agency’s  
24 regulation. *Clark Co. Social Service Dep’t v. Newkirk*, 106 Nev. 177, 179, 789 P.2d 227,  
25 228 (1990).

26 11. HHS, in its broad discretion to implement regulations to foster efficient  
27 enforcement of codified legislation, developed NAC 439.730 and 740 to ensure the Nevada  
28 Public Records Act complied with the DTSA protections. Had the Respondents failed to

1 carve out these procedural protections, the courts would become inundated with cases in  
2 which the compelled disclosing parties claim they did not have the opportunity to protect  
3 their trade secrets from mass disclosures.

4 12. The confidentiality protections are not automatic. Respondents notify the  
5 entity with information implicated in the NPRA request. The targeted entity then has 30  
6 days to claim any confidentiality protections. Respondents then analyze the requested  
7 information through the DTSA confidentiality and trade-secret requirements to confirm  
8 whether the allegedly confidential information should be protected. Only after this  
9 process has been completed do Respondents reach a conclusion as to protection of the  
10 information.

11 13. The Independent next argues that the records it seeks are not declared by  
12 law to be confidential, and that Respondents violated the NPRA by denying the  
13 Independent's requests because the DTSA does not apply in a manner that would place  
14 the requested reports under confidentiality protections. Again, the Court is not persuaded  
15 by the Independent's argument. The DTSA's definition for trade secrets places these  
16 reports squarely under confidentiality protections. 18 U.S.C. 1839(3). Specifically, and as  
17 both Respondents and Sanofi highlight, these reports derive independent economic value,  
18 actual or potential, from not being generally known to, or readily ascertainable by, other  
19 people who can obtain economic value from their disclosure or use and are subject to  
20 reasonable efforts to maintain their secrecy. *Id.* 1839(3). These efforts include  
21 Respondents placing significant limitations on who receives said information,  
22 Respondents and high-level employees privatizing the information that is shared, and the  
23 affected entity submitting prompt requests to Respondents to exclude said reports from  
24 disclosure based on their status as confidential data or information that derives economic  
25 value from not being generally known, and thus protected, trade secrets under the DTSA.

26 ///

27 ///

28 ///

III. Order

IT IS HEREBY ORDERED that Petitioners' petitioner for writ of mandamus is denied.

Dated this 4th day of September, 2020



HONORABLE ADRIANA ESCOBAR  
DISTRICT COURT JUDGE

05A D9E A945 2F08  
Adriana Escobar  
District Court Judge

1 **CSERV**

2  
3 DISTRICT COURT  
4 CLARK COUNTY, NEVADA

5  
6 Nevada Independent, Plaintiff(s) | CASE NO: A-19-799939-W  
7 vs. | DEPT. NO. Department 14  
8 Richard Whitley, Defendant(s)  
9

10 **AUTOMATED CERTIFICATE OF SERVICE**

11 This automated certificate of service was generated by the Eighth Judicial District  
12 Court. The foregoing Order Denying was served via the court's electronic eFile system to all  
13 recipients registered for e-Service on the above entitled case as listed below:

14 Service Date: 9/4/2020

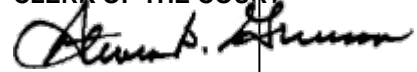
15 Sarah Harmon	sharmon@baileykennedy.com
16 Dennis Kennedy	dkennedy@baileykennedy.com
17 John Bailey	jbailey@baileykennedy.com
18 Bailey Kennedy, LLP	bkfederaldownloads@baileykennedy.com
19 Traci Plotnick	tplotnick@ag.nv.gov
20 Steven Shevorski	sshevorski@ag.nv.gov
21 Mary Pizzariello	mpizzariello@ag.nv.gov
22 Robert Langford	robert@robertlangford.com
23 Matthew Rashbrook	Matt@robertlangford.com
24 Eddie Rueda	erueda@ag.nv.gov

25  
26  
27  
28

1 If indicated below, a copy of the above mentioned filings were also served by mail  
2 via United States Postal Service, postage prepaid, to the parties listed below at their last  
3 known addresses on 9/8/2020

4 Aaron Ford State of Nevada - Attorney General  
5 Attn: Aaron D. Ford  
6 100 N. Carson Street  
7 Carson City, NV, 89701-4717

8 Paul More McCracken Stemerman & Holsberry  
9 Attn: Paul L. More  
10 1630 South Commerce Street - Suite A-1  
11 Las Vegas, NV, 89102  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28



1 **NOAS**

2 MATTHEW J. RASHBROOK

3 Nevada State Bar No. 12477

4 ROBERT L. LANGFORD, ESQ.

5 Nevada State Bar No. 3988

6 ROBERT L. LANGFORD & ASSOCIATES

7 616 S. Eighth Street

8 Las Vegas, NV 89101

(702) 471-6565

9 matt@robertlangford.com

10 robert@robertlangford.com

11 *Attorneys for Petitioner*

12 *The Nevada Independent*

13 **EIGHTH JUDICIAL DISTRICT COURT**

14 **LAS VEGAS, NEVADA**

15 THE NEVADA INDEPENDENT,

Case No.: A-19-799939-W

16 Petitioner,

Dept. No.: XIV

17 vs.

18 RICHARD WHITLEY, in his official  
19 capacity as the Director of the Nevada  
20 Department of Health and Human Services,  
21 and THE STATE OF NEVADA, ex rel. the  
22 NEVADA DEPARTMENT OF HEALTH  
23 AND HUMAN SERVICES;

**NOTICE OF APPEAL**

24 Respondents.

25 Notice is hereby given that The Nevada Independent, Petitioner above-named,  
26 hereby appeals to the Supreme Court of Nevada from the final judgment entered in this

27 ///

28 ///

///

///

1 action on the 4th day of September, 2020.

2 DATED this 22nd day of September, 2020.

3  
4 /s/ Matthew J. Rashbrook

5 MATTHEW J. RASHBROOK

6 Nevada State Bar No. 12477

7 ROBERT L. LANGFORD, ESQ.

8 Nevada State Bar No. 3988

9 ROBERT L. LANGFORD &

10 ASSOCIATES

11 616 S. Eighth Street

12 Las Vegas, NV 89101

13 (702) 471-6565

14 matt@robertlangford.com

15 robert@robertlangford.com

16 *Attorneys for Petitioner*

17 *The Nevada Independent*

1  
2 **IN THE SUPREME COURT OF THE STATE OF NEVADA**

3 THE NEVADA INDEPENDENT,

4 Appellant,

No.: 81844

5  
6 vs.

DC No.: A-19-799939-W

7 RICHARD WHITLEY, IN HIS  
8 OFFICIAL CAPACITY AS THE  
9 DIRECTOR OF THE NEVADA  
10 DEPARTMENT OF HEALTH AND  
11 HUMAN SERVICES, THE STATE  
12 OF NEVADA, EX REL. THE  
13 NEVADA DEPARTMENT OF  
14 HEALTH AND HUMAN  
SERVICES, AND SANOFI-  
AVENTIS U.S. LLC,

15 Respondent.

16  
17  
18 **JOINT APPENDIX**  
19 **VOLUME V**  
20 **PG. 1001**  
21

22 MATTHEW J. RASHBROOK  
Nevada State Bar No. 12477  
23 ROBERT L. LANGFORD, ESQ.  
Nevada State Bar No. 3988  
24 ROBERT L. LANGFORD & ASSOCIATES  
25 616 S. Eighth St.  
Las Vegas, NV 89101  
26 (702) 471-6565  
27 *Attorneys for Appellant*  
*The Nevada Independent*  
28

AARON D. FORD  
Nevada Attorney General  
Nevada State Bar No. 7704  
HEIDI PARRY STERN  
Nevada State Bar No. 8873  
STEVE SHEVORSKI  
Nevada State Bar No. 8256  
Office of the Nevada Attorney General  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101

1 JOHN R. BAILEY  
 Nevada State Bar No. 137  
 2 DENNIS KENNEDY  
 Nevada State Bar No. 1462  
 3 SARAH E. HARMON  
 Nevada State Bar No. 8106  
 4 REBECCA L. CROOKER  
 Nevada State Bar No. 15202  
 5 BAILEY KENNEDY  
 8984 Spanish Ridge Avenue  
 7 Las Vegas, NV 89148-1302  
 (702) 562-8820  
 8 *Attorneys for Respondent Sanofi-Aventis U.S.*  
 9 *LLC*

(702) 486-3594  
*Attorneys for Respondents Whitley, and  
 the State of Nevada ex rel. The Nevada  
 Department of Health and Human  
 Services*

## TABLE OF CONTENTS

<u><b>VOL.</b></u>	<u><b>DOCUMENT</b></u>	<u><b>DATE</b></u>	<u><b>PAGE NUMBERS</b></u>
I	Petition for a Writ of Mandamus	8/8/2019	JA-000001 – JA-000014
I	Appendix to Petition for a Writ of Mandamus	8/8/2019	JA-000015 – JA-000232
I	Order Setting Hearing re Petition for Writ of Mandamus	8/27/2019	JA-000233 – JA-000234
I	Supplemental Brief in Support of Petition for a Writ of Mandamus	10/15/2019	JA-000235 – JA-000246
I	Opposition to The Nevada Independent’s Petition for Writ of Mandamus and Motion to Dismiss	10/17/2019	JA-000247 – JA-000256
II	Motion to Intervene and to Continue Hearing, on Shortened Time	10/21/2019	JA-000257 – JA-000455
II	Petitioner’s Opposition to Sanofi- Aventis U.S. LLC’s Motion to Intervene and to Continue Hearing	10/31/2019	JA-000456 – JA-000465

II	Sanofi-Aventis U.S. LLC's Reply in Support of Motion to Intervene	11/1/2019	JA-000466 – JA-000472
II	Transcript of Proceedings – Motion to Intervene and to Continue Hearing on Shortened Time	11/5/2019	JA-000473 – JA-000491
II	Errata	11/11/2019	JA-000492 – JA-000520
III	Minute Order	11/14/2019	JA-000521 – JA-000522
III	Sanofi-Aventis U.S. LLC's Supplemental Brief in Support of Motion to Intervene	11/21/2019	JA-000523 – JA-000528
III	Supplemental Brief in Opposition to Motion to Intervene and Reply to Proposed Response	12/5/2019	JA-000529 – JA-000544
III	Minute Order	12/16/2019	JA-000545 – JA-000548
III	Order Granting Sanofi-Aventis U.S. LLC's Motion to Intervene	12/23/2019	JA-000549 – JA-000553
III	Intervenor Sanofi-Aventis U.S. LLC's Response to Petitioner's Petition for a Writ of Mandamus	12/23/2019	JA-000554 – JA-000738
III	Reply to Intervenor's Response	1/3/2020	JA-000739 – JA-000758
IV	Petitioner The Nevada Independent's Witness List	1/17/2020	JA-000759 – JA-000761
IV	Sanofi-Aventis U.S. LLC's Disclosure of Witnesses	1/17/2020	JA-000762 – JA-000764
IV	Defendants' Disclosure of Witnesses	1/17/2020	JA-000765 – JA-000766
IV	Reply in Support of Motion to Dismiss	1/23/2020	JA-000767 – JA-000775
IV	Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	1/30/2020	JA-000776 – JA-000815

IV	Sanofi's Opposition to Petitioner's Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike his Declaration	2/3/2020	JA-000816 – JA-000841
IV	Transcript of Proceedings – Motion to Compel Testimony of James Borneman, or in the Alternative, To Strike his Declaration	2/4/2020	JA-000842 – JA-000890
IV	Motion for Leave to File Brief Amicus Curiae	2/13/2010	JA-000891 – JA-000917
IV	Notice of Non-Opposition	2/14/2020	JA-000918 – JA-000920
IV	Minute Order	2/14/2020	JA-000921 – JA-000922
IV	Notice of Non-Opposition to Culinary union's Motion for Leave to file an Amicus Brief	2/14/2010	JA-000923 – JA-000924
IV	Transcript of Proceedings – Petition for Writ of Mandamus	2/21/2020	JA-000925 – JA-000968
IV	Minute Order	4/21/20	JA-000969 – JA-000973
IV	Order Denying Petition for Writ of Mandamus	9/4/2020	JA-000974 – JA-000984
IV	Notice of Entry of Order	9/9/2020	JA-000985 – JA-000998
IV	Notice of Appeal	9/22/2020	JA-000999 – JA-001001
V	Notice of Appeal (cont.)	9/22/2020	JA-001001

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8

Aaron D. Ford  
Nevada Attorney General  
Nevada Bar No. 7704  
Steve Shevorsi  
Chief Deputy Attorney General  
Nevada Bar No. 8256  
555 E. Washington Ave., Ste. 3900  
Las Vegas, NV 89101  
Fax: 702-486-3768  
sshevorsi@ag.nv.gov

John R. Bailey  
Nevada Bar No. 0137  
Dennis L. Kennedy  
Nevada Bar No. 1462  
Sarah E. Harmon  
Nevada Bar No. 8106  
Rebecca L. Crooker  
Nevada Bar No. 15202  
Bailey Kennedy  
8984 Spanish Ridge Ave.  
Las Vegas, NV 89148-1302  
Fax: 702-562-8821  
jbbailey@baileykennedy.com  
dkennedy@baileykennedy.com  
sharmon@baileykennedy.com  
rcrooker@baileykennedy.com

3