Case No. 81844

IN THE SUPREME COURT OF NEVADA

THE NEVADA INDEPENDENT,
Appellant,

vs.

RICHARD WHITLEY, IN HIS OFFICIAL CAPACITY AS THE DIRECTOR OF THE NEVADA DEPARTMENT OF HEALTH AND HUMAN SERVICES; THE STATE OF NEVADA, EX REL. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and SANOFI-AVENTIS U.S. LLC,
Respondents.

District Court Case No. A-19-799939-W, Department XIV

RESPONDENT SANOFI-AVENTIS U.S. LLC'S SUPPLEMENT TO JOINT APPENDIX VOLUME 1 OF 2

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April 26, 2021

RESPONDENT SANOFI-AVENTIS U.S. LLC'S
SUPPLEMENT TO THE JOINT APPENDIX - VOLUME 1 OF 2

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TAB 1

TAB 1

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IN THE 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

OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

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COMES NOW, Defendants GOVERNOR BRIAN SANDOVAL and RICHARD WHITLEY, (hereinafter referred to collectively as "the State" or if only referring to Richard Whitley as "the Department") through their counsel ADAM PAUL LAXALT, Attorney General through LINDA C. ANDERSON, Chief Deputy Attorney General and file this opposition to the Motion for Preliminary Injunction (#27) filed September 13, 2017. This Opposition is based upon the following memorandum of points and authorities, and all other papers and pleadings on file in this matter.

Dated this 25th day of September, 2017.

ADAM PAUL LAXALT
Attorney General

By: */s/ Linda C. Anderson*
Linda C. Anderson,
Chief Deputy Attorney General

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MEMORANDUM OF POINTS AND AUTHORITIES

A preliminary injunction is an "extraordinary and drastic remedy" that is "never awarded as of right." *Munaf v. Geren,* 553 U.S. 674, 689–90 (2008) (citations omitted). Instead, in every case, the court "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Winter v. Natural Resources Defense Council, Inc.,* 555 U.S. 7, 24 (2008) (internal quotation marks and citation omitted). The claim of injury of Plaintiffs revolve around trade secrets. Plaintiffs argue that recent state legislation conflicts with federal patent law; is preempted by Defend Trade Secrets Act (DTSA); results in a taking under the Fifth Amendment; and violates the dormant Commerce Clause because the law compels disclosure of trade secrets which will not be protected by state law. However, Plaintiffs cannot establish a likelihood of success on the merits because their claim that the Department will disclose their trade secrets is not yet ripe until the Department has not completed the public rule-making process to implement the new law. In addition, Plaintiffs' claims for a preliminary injunction is premature because Plaintiffs will not suffer any imminent harm. If this Court finds that injunctive relief is warranted at this early stage of the proceedings, the State submits that any preliminary injunction should be narrowly tailored to enjoin the enforcement and implementation of the specific parts of the state legislation which this Court finds will result in irreparable harm related to the trade secrets of Plaintiffs.

I. PROPOSED PRELIMINARY INJUNCTION DOES NOT SERVE PUBLIC INTEREST

The State shares the perspective of the Plaintiffs that prescription drugs to treat diabetes are essential to public welfare. The Nevada Legislature passed Senate Bill 539 (SB 539) to enhance the access of Nevadans to this critical treatment by making comprehensive pricing information from manufacturers, pharmacy benefit managers, and nonprofit organizations available to consumers on an existing state website. *See,* Exhibit 1 for SB 539. Therefore, the public interest to be considered by this Court encompasses both the implementation of state law intended to serve the needs of Nevadans with diabetes as well as to ensure that the State complies with federal law as argued by the Plaintiffs. Public interest demands that any injunction should be tailored to prevent constitutional violations and protect legitimate property interests while allowing lawful action of the State to proceed. The State requests this Court to limit the scope of its review and intervention to maximize the public benefit of the state

legislation which was manifestly intended to promote the health of Nevadans by providing transparency on the pricing of prescription drugs for the treatment of diabetes.

II. PLAINTIFFS WILL NOT SUFFER IRREPARABLE HARM ABSENT THE PRELIMINARY INJUNCTION AS REQUESTED BY PLAINTIFFS.

In their motion, Plaintiffs argue that misappropriation of trade secrets is presumed to constitute irreparable harm but they do not clearly identify why their proposed preliminary injunction of specific sections of SB 539 would avert that harm. In other words, Plaintiffs do not establish why this Court should preliminarily enjoin the implementation of all aspects of SB 539 which apply to the manufacturers of prescriptions drugs when many of those sections do not pose an immediate and direct threat to the trade secrets of the Plaintiffs at this time. An examination of each section of SB 539 which the Plaintiffs request to enjoin demonstrates that Plaintiffs' request for a preliminary injunction of sections 3.6, 3.8, 4, 4.3, 6, 7, 8 and 9 of the bill is too broad and over-reaching. Unless Plaintiffs articulate how these provisions of state law specifically impact a manufacturer's trade secrets, there is not reach to conclude that they pose an immediate threat of irreparable harm to Plaintiffs.

A. PRELIMINARY INJUNCTION OF SECTIONS 3.6 AND 7 SHOULD BE DENIED.

Sections 3.6 will become effective October 1, 2017 according to Section 28 of SB 539. Section 3.6(1) of the bill requires the Department to compile a list of the prescription drugs that the Department determines to be essential for the treatment of diabetes in Nevada. Section 3.6(2) requires the Department to compile a list of those prescription drugs described in Section 3.6(1) that have been subject to a significant price increase within the last 2 years. According to Section 26.9 of SB 539, the Department shall place these lists on the Internet website maintained by the Department on or before November 1, 2017. The compilation of these lists by the Department does not directly involve either the reporting of trade secrets or any potential for disclosure by the State.

Plaintiffs argue that once the list is published, the manufacturers who are required to report to the Department will be identified and their information will no longer be a "trade secret" under Nevada law. *See,* Exhibit 1 for section 9 of SB 539 which provides that "any information that a manufacturer is required to report pursuant to section 3.8 or 4" is not included in the definition of a "trade secret" in NRS 660A.030. In addition to the remedies afforded by federal law which are discussed more fully

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below, Plaintiffs cannot assert any immediate threat to their trade secrets because no manufacturer currently operates in Nevada. Therefore, the compilation of these lists has no impact on the trade secrets of the Plaintiffs. Delay in the compilation of these lists would prevent the implementation of other sections of SB 539 which have not been challenged in this litigation. The lists are necessary for the parties and this Court to determine the applicable manufacturers of prescription drugs impacted before determining the full scope of the proposed injunction in the Complaint. Therefore, the State asks this Court to deny the motion for preliminary injunction as to Section 3.6 of SB 539.

Plaintiffs have requested this Court to enjoin the State from implementing Section 7 of SB 539 as part of their relief. Section 7 of the bill modifies NRS 439.930 to require the Department to adopt any necessary regulations concerning "the form and manner in which manufacturers provide information" and other issues in the implementation of the bill. The rule-making authority of the Department has no direct impact on the trade secrets of Plaintiffs and is necessary for the implementation of the other parts of SB539 which are not the subject of this lawsuit. More importantly, the public workshop and regulation hearing will allow the manufacturers and the Department to work cooperatively to adopt regulations that may address the concerns about trade secrets and ultimately render them moot. Therefore, the State asks this Court to deny the motion for preliminary injunction as to Section 7 of SB 539 and allow the public rule-making to proceed under Nevada's Administrative Procedures Act.

B. REQUEST TO ENJOIN OTHER SECTIONS OF SB 539 IS PREMATURE

Section 3.8 of SB 539 requires the manufacturers of prescription drugs included on the list described in Section 3.6(1) to submit to the Department an annual report containing certain information concerning the costs of those drugs. In addition, section 4 requires some of the listed manufacturers whose drug increase by a certain cost to submit a report to the Department concerning the reasons for the increase in cost. Section 4.3 of SB 539 requires the Department to analyze the information submitted by the manufacturers and compile a report concerning the reasons for and effect of the pricing of the essential diabetes prescription drugs.

Section 6 of SB 539 amends NRS 439.915, in part, to require the Department to place its reports and the "wholesale acquisition cost" of each prescription drug with an entry for each manufacturer on the Internet website of the Department. The Department has discretion to detail in its regulations the

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contents of its reports and the information which will be posted. Section 8 of SB 539 authorizes the Department to impose an administrative penalty against a manufacturer who fails to provide the required information to the Department. The Department has discretion concerning the imposition of any penalty and the parameters of this discretion may be outlined in regulations.

As this Court has recognized in the Order (#28) denying the temporary restraining order, Section 26.9 requires the manufacturers to submit these initial reports on or before July 1, 2018. The Department is unable to place any information, create any reports, or impose any penalties until after that deadline of July 1, 2018 when the manufacturers must report. Therefore, any harm to trade secret that may be disclosed in these reports is not imminent. Because the Department has the authority to adopt regulations in Section 7 of SB 539, the process for the submission of these reports is not complete, such that this Court cannot determine the extent to which trade secrets may be exposed or jeopardized by the reporting process. The regulations adopted by the Department may provide sufficient protection for trade secrets as defined by federal law as discussed more fully below.

III. PLAINTIFFS ARE UNABLE TO DEMONSTRATE SUCCESS ON THE MERITS.

In Section 9, the Nevada Legislature amended NRS 600A.030 to alter the definition of trade secret for purposes of state law protection. Because the term "trade secret" no longer includes "any information that a manufacturer is required to report pursuant to section 3.8 or 4", Nevada's state trade secret law will no longer apply to that information as of October 1, 2017. The Department does not implement or enforce Chapter 600A. Therefore, SB 539 did not require the State to take any specific action to be enjoined when the law becomes effective. More importantly, Nevada's state law protection appears to be redundant to the federal law that remains in place regardless of the action of the Nevada Legislature.

Prior to 2016, civil trade secret claims were governed entirely by state law even when the matter was brought in federal court. However, the passage of Defend Trade Secrets Act of 2016 (hereinafter "DTSA") by Congress provided a federal equivalent to state law. *See, Henry Schien, Inc. v Cook,* 191 F.Supp.3d 1072 (2016) (Temporary restraining order sought under both DTSA and the California Uniform Trade Secrets Act). In their motion, Plaintiffs fail to explain why the federal DTSA is

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insufficient to protect their interests now that the Nevada Legislature has rendered the state trade secrets law inapplicable to the information that they are required to report to the Department.

DTSA creates a private right of action for the "owner of a trade secret that is misappropriated." 18 U.S.C.A. § 1836(b)(1). The term "trade secret" is defined for the purpose of the federal law 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--
> (A) the owner thereof has taken reasonable measures to keep such information secret; and
> (B) 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;

18 U.S.C.A. § 1839(3). DTSA does not reference or rely on any state definition of "trade secrets" so the change in Nevada law has no impact on the federal definition. The definition of "misappropriation" includes "disclosure or use of a trade secret of another without express or implied consent by a person who at the time of the 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.A. § 1839(5)(B)(ii)(II). DTSA 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 political subdivision of a State." 18 U.S.C.A. § 1833(a)(1). This provision of DTSA underscores that the federal law is not related to any state law definition of a trade secret.

Plaintiffs are unable to identify the specific trade secrets at issue or that the Department is unable to implement the law without harming the trade secrets of the Plaintiffs. The Department cannot alter the state statute which defines "trade secret" by regulation. However, the Department must adopt regulations to establish the "form and manner" in which manufacturers provide information to the Department in Section 7 of SB 539 and may be able to ensure a process to protect trade secrets as defined by DTSA. Plaintiffs cannot yet show the likelihood of the success of their claims that the Department will be unable to protect trade secrets of the Plaintiffs. Therefore, the claims of the Plaintiffs are not yet ripe and the State asks this Court to give the Department the opportunity to adopt

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regulations to address the protection of trade secrets under DTSA before ruling on whether the Department should be subject to a preliminary injunction.

CONCLUSION

The State respectfully requests this Court to deny the motion for preliminary injunction as to Sections 3.6 and 7 of Senate Bill 539 and defer ruling on the remaining provisions until the Department has had opportunity to adopt regulations. This Court could schedule further briefing to address the preliminary injunction before any reports are due from the manufacturers in July of 2018 which Plaintiffs argue would result in the irreparable harm of the improper exposure of their trade secrets. If this Court were to issue a preliminary injunction concerning sections 3.8, 4, 4.3, 6 and 8, the injunction should be tailored to prohibit the dissemination of information identified as trade secret under federal law until this matter is resolved.

DATED this 25th day of September, 2017.

ADAM PAUL LAXALT
Attorney General

By: */s/Linda C. Anderson*
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CERTIFICATE OF SERVICE

I hereby certify that I am an employee of the Office of the Attorney General and that on the 25th day of September, 2017, I served a copy of the foregoing *OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION* to the United States District Court—District of Nevada who will notify the following parties:

Patricia K Lundvall, Esq.
McDONALD CARANO LLP
2300 West Sahara Avenue, Suite 1200
Las Vegas, NV 89102

I further certify that the following parties have been served a copy of the aforementioned *OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION* via U.S. Mail, first class, postage pre-paid at the address listed below:

Jeffrey L. Handwerker, Esq.
R. Stanton Jones. Esq.
Robert N. Weiner, Esq.
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, NW
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/s/ *Linda Aouste*
Linda Aouste
An Employee of the Attorney General's Office

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EXHIBIT 1

EXHIBIT A - NEVADA SENATE BILL NO. 539

EXHIBIT A - NEVADA SENATE BILL NO. 539

(Reprinted with amendments adopted on June 5, 2017)

FIRST REPRINT **S.B. 539**

EMERGENCY REQUEST OF SENATE MINORITY LEADER

SENATE BILL NO. 539–SENATORS ROBERSON, GANSERT, KIECKHEFER, HARRIS, HARDY; GOICOECHEA, GUSTAVSON, HAMMOND, SETTELMEYER, ATKINSON, CANCELA, CANNIZZARO, DENIS, FARLEY, FORD, MANENDO, PARKS, RATTI, SEGERBLOM, SPEARMAN AND WOODHOUSE

MAY 16, 2017

Referred to Committee on Health and Human Services

SUMMARY—Revises provisions relating to prescription drugs. (BDR 40-1217)

FISCAL NOTE: Effect on Local Government: Increases or Newly Provides for Term of Imprisonment in County or City Jail or Detention Facility.
Effect on the State: Yes.

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EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets **[**~~omitted material~~**]** is material to be omitted.

AN ACT relating to prescription drugs; requiring the Department of Health and Human Services to compile certain lists of certain prescription drugs that are used to treat diabetes; requiring the manufacturer of a drug included on such lists and a pharmacy benefit manager to provide certain information to the Department; requiring the Department to compile a report based on such information; requiring a manufacturer of prescription drugs to submit a list of each pharmaceutical sales representative who markets prescription drugs to certain persons in this State; prohibiting a pharmaceutical sales representative who is not included on such a list from marketing prescription drugs on behalf of a manufacturer; requiring each pharmaceutical sales representative included on such a list to report certain information to the Department; requiring certain nonprofit organizations to report to the Department certain information concerning certain contributions and benefits received from drug manufacturers, insurers and pharmacy benefit managers or trade and advocacy groups for such entities; requiring the Department to place certain information on its Internet website; authorizing the Department to impose an administrative penalty in certain circumstances; providing that certain information does not constitute a trade secret; imposing certain requirements on a pharmacy benefit manager; requiring a private school to allow a pupil to keep and self-administer certain drugs; requiring certain insurers to provide certain notice to insureds; providing penalties; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the organization with the largest membership in this State which represents the interests of retail merchants to prepare a list of not less than 100 prescription drugs most commonly prescribed to residents of this State. (NRS 439.905) Existing law also requires the Department of Health and Human Services to place on the Internet website maintained by the Department certain information reported by pharmacies concerning the prices charged by the pharmacies for drugs that appear on that list. (NRS 439.915) **Section 3.6** of this bill requires the Department to compile: (1) a list of prescription drugs that the Department determines to be essential for treating diabetes in this State; and (2) a list of such prescription drugs that have been subject to a significant price increase within the immediately preceding 2 calendar years. **Section 3.8** of this bill requires the manufacturer of a prescription drug included on the list of essential diabetes drugs to submit to the Department an annual report that contains certain information concerning the cost of the drug. **Section 4** of this bill requires the manufacturer of a drug included on the list of essential diabetes drugs that have undergone a substantial cost increase to submit to the Department a report concerning the reasons for the cost increase. **Section 4.2** of this bill requires a pharmacy benefit manager to report certain information concerning essential diabetes drugs to the Department. **Section 9** of this bill provides that any information that a manufacturer of an essential diabetes drug, a pharmacy benefit manager or a pharmaceutical sales representative is required to report is not a trade secret. **Section 4.3** of this bill requires the Department to analyze the information submitted by such manufacturers and compile a report concerning the reasons for and effect of the pricing of essential diabetes drugs.

Section 4.9 of this bill requires a nonprofit organization that advocates for patients or funds medical research in this State to post on its Internet website or, if the nonprofit organization does not maintain an Internet website, submit to the Department certain information concerning payments, donations and anything else of value that the organization receives from manufacturers of prescription drugs, certain third parties or pharmacy benefit managers or trade or advocacy groups for such entities. **Section 6** of this bill requires the Department to place on the Internet website maintained by the Department: (1) the information and lists compiled by the Department pursuant to **sections 3.6, 4.3 and 4.6**; and (2) the information submitted to the Department pursuant to **sections 3.8 and 4.9**. **Section 6.5** of this bill provides that the Department is not liable for any act, omission, error or technical problem that results in the failure to provide information or the provision of any incorrect information placed on the Internet website of the Department. **Section 7** of this bill requires the Department to adopt any necessary regulations concerning the reporting of information by manufacturers and nonprofit organizations for inclusion on the Internet website of the Department. **Section 26.3** of this bill requires an insurer that offers or issues a policy of individual health insurance and uses a formulary to provide, during each open enrollment period, a notice of any drugs on the list of essential diabetes drugs that have been removed from the formulary or will be removed from the formulary during the current plan year or the next plan year.

Section 4.6 of this bill requires a manufacturer to provide to the Department a list of each pharmaceutical sales representative who markets prescription drugs to providers of health care, pharmacies, medical facilities and insurers in this State on behalf of the manufacturer. **Section 4.6** also prohibits a person who is not included on such a list from marketing prescription drugs on behalf of a manufacturer to providers of health care, pharmacies, medical facilities and insurers. Additionally, **section 4.6** requires each pharmaceutical sales representative who is included on such a list to submit an annual report to the Department. Finally, **section 4.6** requires the Department to compile an annual report based on the information

submitted by pharmaceutical sales representatives. **Section 8** of this bill authorizes the Department to impose an administrative penalty against a manufacturer, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative who fails to provide the information required by **sections 3.8, 4, 4.2, 4.6 and 4.9**.

Upon the submission of a written request, existing law requires a public school to allow a pupil who has asthma, anaphylaxis or diabetes to carry and self-administer medication to treat his or her disorder while the pupil is on the grounds of a public school, participating in an activity sponsored by a public school or on a school bus. (NRS 392.425) Willful failure to carry out this requirement is grounds to suspend, demote, dismiss or refuse to reemploy a teacher or administrator. (NRS 391.750) **Section 8.6** of this bill: (1) imposes similar requirements for private schools; and (2) makes a willful violation of those requirements a misdemeanor. **Section 19** of this bill provides that a pharmacy benefit manager has a fiduciary duty to an insurer with which the pharmacy benefit manager has entered into a contract to manage prescription drug coverage.

Section 20 of this bill prohibits a pharmacy benefit manager from engaging in certain trade practices.

Federal law prohibits states from regulating an employee benefit plan established under the Employee Retirement Income Security Act of 1974. (29 U.S.C. § 1144) **Section 17** of this bill provides that the requirements that this bill imposes upon pharmacy benefit managers and insurers do not apply to the management or provision of prescription drug benefits included in such a plan unless the plan requires compliance with those provisions.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 439 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 4.9, inclusive, of this act.

Sec. 2. ***"Manufacturer" has the meaning ascribed to it in NRS 639.009.***

Sec. 3. ***"Pharmacy" means every store or shop licensed by the State Board of Pharmacy where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed. The term does not include an institutional pharmacy as defined in NRS 639.0085.***

Sec. 3.2. ***"Pharmacy benefit manager" has the meaning ascribed to it in section 14.5 of this act.***

Sec. 3.4. ***"Wholesale acquisition cost" means 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 data.***

Sec. 3.6. ***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.

Sec. 3.8. *On or before April 1 of each year, the manufacturer of a prescription drug that appears on the most current list compiled by the Department pursuant to subsection 1 of section 3.6 of this act shall prepare and submit to the Department, in the form prescribed by the Department, a report which must include:*

1. The costs of producing the drug;

2. The total administrative expenditures relating to the drug, including marketing and advertising costs;

3. 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;

4. The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;

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;

6. The wholesale acquisition cost of the drug;

7. 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 and any explanation for the increase;

8. The aggregate amount of all rebates that the manufacturer has provided to pharmacy benefit managers for sales of the drug within this State; and

9. Any additional information prescribed by regulation of the Department for the purpose of analyzing the cost of prescription

drugs that appear on the list compiled pursuant to subsection 1 of section 3.6 of this act, trends in those costs and rebates available for such drugs.

Sec. 4. *On or before April 1 of a year in which a drug is included on the list compiled pursuant to subsection 2 of section 3.6 of this act, the manufacturer of the drug shall submit to the Department a report describing the reasons for the increase in the wholesale acquisition cost of the drug described in that subsection. The report must include, without limitation:*

1. A list of each factor that has contributed to the increase;

2. The percentage of the total increase that is attributable to each factor;

3. An explanation of the role of each factor in the increase; and

4. Any other information prescribed by regulation by the Department.

Sec. 4.2. *1. Except as otherwise provided in subsection 2, on or before April 1 of each year, a pharmacy benefit manager shall submit to the Department a report which includes:*

(a) The total amount of all rebates that the pharmacy benefit manager negotiated with manufacturers during the immediately preceding calendar year for prescription drugs included on the list compiled by the Department pursuant to subsection 1 of section 3.6 of this act;

(b) The total amount of all rebates described in paragraph (a) that were retained by the pharmacy benefit manager; and

(c) The total amount of all rebates described in paragraph (a) that were negotiated for purchases of such drugs for use by:

(1) Recipients of Medicare;

(2) Recipients of Medicaid;

(3) Persons covered by third parties that are governmental entities which are not described in subparagraph (1) or (2);

(4) Persons covered by third parties that are not governmental entities; and

(5) Persons covered by a plan described in subsection 2 to the extent required by a contract entered into pursuant to subsection 3.

2. Except as otherwise provided in subsection 3, the requirements of this section do not apply to the coverage of prescription drugs under a plan that is subject to the Employee Retirement Income Security Act of 1974 or any information relating to such coverage.

3. A plan described in subsection 2 may, by contract, require a pharmacy benefit manager that manages the coverage of

prescription drugs under the plan to comply with the requirements of this section.

Sec. 4.3. *On or before June 1 of each year, the Department shall analyze the information submitted pursuant to sections 3.8, 4 and 4.2 of this act and compile a report on the price of the prescription drugs that appear on the most current lists compiled by the Department pursuant to section 3.6 of this act, the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State. The report may include, without limitation, opportunities for persons and entities in this State to lower the cost of drugs for the treatment of diabetes while maintaining access to such drugs.*

Sec. 4.6. *1. A manufacturer of a prescription drug shall provide to the Department a list of each pharmaceutical sales representative who markets prescription drugs on behalf of the manufacturer to providers of health care licensed, certified or registered in this State, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified under the provisions of title 57 of NRS and update the list at least annually.*

2. The Department shall provide electronic access to the most recent list provided by each manufacturer pursuant to subsection 1 to each provider of health care licensed, certified or registered in this State, operator of a pharmacy, operator of a medical facility or person licensed or certified under the provisions of title 57 for the purposes of ensuring compliance with the requirements of subsection 3. This subsection must not be construed to impose any duty on a provider of health care, operator of a pharmacy, operator of a medical facility or person licensed or certified under the provisions of title 57 to ensure such compliance.

3. A person who is not included on a current list submitted pursuant to subsection 1 shall not market prescription drugs on behalf of a manufacturer:

(a) To any provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of NRS; or

(b) For sale to any resident of this State.

4. On or before March 1 of each year, each person who was included on a list of pharmaceutical sales representatives submitted pursuant to subsection 1 at any time during the immediately preceding calendar year shall submit to the Department a report, which must include, for the immediately preceding calendar year:

(a) A list of providers of health care licensed, certified or registered in this State, pharmacies and employees thereof, operators and employees of medical facilities and persons licensed or certified under the provisions of title 57 of NRS to whom the pharmaceutical sales representative provided:

(1) Any type of compensation with a value that exceeds $10; or

(2) Total compensation with a value that exceeds $100 in aggregate; and

(b) The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of NRS and the name of each such person to whom a free sample was provided.

5. The Department shall analyze annually the information submitted pursuant to subsection 4 and compile a report on the activities of pharmaceutical sales representatives in this State. Any information contained in such a report that is derived from a list provided pursuant to subsection 1 or a report submitted pursuant to subsection 3 must be reported in aggregate and in a manner that does not reveal the identity of any person or entity. On or before June 1 of each year, the Department shall:

(a) Post the report on the Internet website maintained by the Department; and

(b) Submit the report to the Governor and the Director of the Legislative Counsel Bureau for transmittal to the Legislative Committee on Health Care and, in even-numbered years, the next regular session of the Legislature.

6. As used in this section:

(a) "Medical facility" has the meaning ascribed to it in NRS 629.026.

(b) "Pharmaceutical sales representative" means a person who markets prescription drugs to providers of health care licensed, certified or registered in this State, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified under the provisions of title 57 of NRS.

(c) "Provider of health care" has the meaning ascribed to it in NRS 629.031.

Sec. 4.9. *1. On or before February 1 of each year, a nonprofit organization that advocates on behalf of patients or funds medical research in this State and has received a payment, donation, subsidy or anything else of value from a manufacturer, third party or pharmacy benefit manager or a trade or advocacy*

group for manufacturers, third parties or pharmacy benefit managers during the immediately preceding calendar year shall:

(a) Compile a report which includes:

(1) For each such contribution, the amount of the contribution and the manufacturer, third party or pharmacy benefit manager or group that provided the payment, donation, subsidy or other contribution; and

(2) The percentage of the total gross income of the organization during the immediately preceding calendar year attributable to payments, donations, subsidies or other contributions from each manufacturer, third party, pharmacy benefit manager or group; and

(b) Except as otherwise provided in this paragraph, post the report on an Internet website that is maintained by the nonprofit organization and accessible to the public. If the nonprofit organization does not maintain an Internet website that is accessible to the public, the nonprofit organization shall submit the report compiled pursuant to paragraph (a) to the Department.

2. As used in this section, "third party" means:

(a) An insurer, as that term is defined in NRS 679B.540;

(b) A health benefit plan, as that term is defined in NRS 689A.540, for employees which provides coverage for prescription drugs;

(c) A participating public agency, as that term is defined in NRS 287.04052, and any other local governmental agency of the State of Nevada which provides a system of health insurance for the benefit of its officers and employees, and the dependents of officers and employees, pursuant to chapter 287 of NRS; or

(d) Any other insurer or organization that provides health coverage or benefits in accordance with state or federal law.

➥ The term does not include an insurer that provides coverage under a policy of casualty or property insurance.

Sec. 5. NRS 439.900 is hereby amended to read as follows:

439.900 As used in NRS 439.900 to 439.940, inclusive, *and sections 2 to 4.9, inclusive, of this act,* unless the context otherwise requires, ~~["pharmacy" means every store or shop licensed by the State Board of Pharmacy where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed. The term does not include an institutional pharmacy as defined in NRS 639.0085.]~~ *the words and terms defined in sections 2 to 3.4, inclusive, of this act have the meanings ascribed to them in those sections.*

Sec. 6. NRS 439.915 is hereby amended to read as follows:

439.915 1. Except as otherwise provided in subsection 2 ~~[,]~~ *and subsection 3 of section 4.6 of this act,* the Department shall:

(a) Place or cause to be placed on the Internet website maintained by the Department ~~[the]~~ *:*

(1) The information provided by each pharmacy pursuant to NRS 439.910;

(2) The information compiled by a nonprofit organization pursuant to section 4.9 of this act if such a report is submitted pursuant to paragraph (b) of subsection 1 of that section;

(3) The lists of prescription drugs compiled by the Department pursuant to section 3.6 of this act;

(4) The wholesale acquisition cost of each prescription drug reported pursuant to section 3.8 of this act; and

(5) The reports compiled by the Department pursuant to sections 4.3 and 4.6 of this act.

(b) Ensure that the information ~~[provided by each pharmacy pursuant to NRS 439.910 and]~~ placed on the Internet website maintained by the Department *pursuant to paragraph (a)* is organized so that each individual pharmacy *, manufacturer and nonprofit organization* has its own separate entry on that website; and

(c) Ensure that the usual and customary price that each pharmacy charges for each prescription drug that is on the list prepared pursuant to NRS 439.905 and that is stocked by the pharmacy:

(1) Is presented on the Internet website maintained by the Department in a manner which complies with the requirements of NRS 439.920; and

(2) Is updated not less frequently than once each calendar quarter.

➥ Nothing in this subsection prohibits the Department from determining the usual and customary price that a pharmacy charges for a prescription drug by extracting or otherwise obtaining such information from claims reported by pharmacies to the Medicaid program.

2. If a pharmacy is part of a larger company or corporation or a chain of pharmacies or retail stores, the Department may present the pricing information pertaining to such a pharmacy in such a manner that the pricing information is combined with the pricing information relative to other pharmacies that are part of the same company, corporation or chain, to the extent that the pricing information does not differ among those pharmacies.

3. The Department may establish additional or alternative procedures by which a consumer who is unable to access the

Internet or is otherwise unable to receive the information described in subsection 1 in the manner in which it is presented by the Department may obtain that information:

(a) In the form of paper records;

(b) Through the use of a telephonic system; or

(c) Using other methods or technologies designed specifically to assist consumers who are hearing impaired or visually impaired.

4. As used in this section, "usual and customary price" means the usual and customary charges that a ~~[provider]~~ ***pharmacy*** charges to the general public for a drug, as described in 42 C.F.R. § ~~[447.331.]~~ ***447.512.***

Sec. 6.5. NRS 439.925 is hereby amended to read as follows:

439.925 The Department and its members, officers and employees are not liable civilly or criminally for any act, omission, error or technical problem that results in:

1. The failure to provide to consumers information regarding a pharmacy, ***prescription drug or nonprofit organization,*** including, without limitation, the ~~[prices charged by the pharmacy for the prescription drugs and generic equivalents that are on the list prepared pursuant to NRS 439.905; or]~~ ***information made available on the Department's Internet website pursuant to NRS 439.915; or***

2. The providing to consumers of incorrect information regarding a pharmacy, ***prescription drug or nonprofit organization,*** including, without limitation, the ~~[prices charged by the pharmacy for the prescription drugs and generic equivalents that are on the list prepared pursuant to NRS 439.905.]~~ ***information made available on the Department's Internet website pursuant to NRS 439.915.***

Sec. 7. NRS 439.930 is hereby amended to read as follows:

439.930 The Department shall adopt such regulations as it determines to be necessary or advisable to carry out the provisions of NRS 439.900 to 439.940, inclusive ~~[.]~~ ***, and sections 2 to 4.9, inclusive, of this act.*** Such regulations must provide for, without limitation:

1. Notice to consumers stating that:

(a) Although the Department will strive to ensure that consumers receive accurate information regarding pharmacies, ***prescription drugs and nonprofit organizations*** including, without limitation, the ~~[prices charged by those pharmacies for the prescription drugs and generic equivalents that are on the list prepared pursuant to NRS 439.905,]~~ ***information made available on the Department's Internet website pursuant to NRS 439.915,*** the Department is unable to guarantee the accuracy of such information;

(b) If a consumer follows an Internet link from the Internet website maintained by the Department to an Internet website ***not*** maintained by ~~[a pharmacy,]~~ ***the Department,*** the Department is

unable to guarantee the accuracy of any information made available on ~~[the]~~ *that* Internet website *;* ~~[maintained by the pharmacy;]~~ and

(c) The Department advises consumers to contact a pharmacy *, manufacturer or nonprofit organization* directly to verify the accuracy of any information regarding the pharmacy *, a prescription drug manufactured by the manufacturer or the nonprofit organization, as applicable,* which is made available to consumers pursuant to NRS 439.900 to 439.940, inclusive ~~[;]~~ *, and sections 2 to 4.9, inclusive, of this act;*

2. Procedures adopted to direct consumers who have questions regarding the program described in NRS 439.900 to 439.940, inclusive, *and sections 2 to 4.9, inclusive, of this act* to contact the Office for Consumer Health Assistance of the Department;

3. Provisions in accordance with which the Department will allow an Internet link to the information ~~[provided by each pharmacy pursuant to NRS 439.910 and]~~ made available on the Department's Internet website *pursuant to NRS 439.915* to be placed on other Internet websites managed or maintained by other persons and entities, including, without limitation, Internet websites managed or maintained by:

(a) Other governmental entities, including, without limitation, the State Board of Pharmacy and the Office of the Governor; and

(b) Nonprofit organizations and advocacy groups;

4. Procedures pursuant to which consumers *,* ~~[and]~~ pharmacies *, manufacturers and nonprofit organizations* may report to the Department that information made available to consumers pursuant to NRS 439.900 to 439.940, inclusive, *and sections 2 to 4.9, inclusive, of this act* is inaccurate;

5. The form and manner in which pharmacies are to provide to the Department the information described in NRS 439.910; and

6. The form and manner in which manufacturers are to provide to the Department the information described in sections 3.8, 4 and 4.6 of this act;

7. The form and manner in which pharmacy benefit managers are to provide to the Department the information described in section 4.2 of this act;

8. The form and manner in which pharmaceutical sales representatives are to provide to the Department the information described in section 4.6 of this act;

9. The form and manner in which nonprofit organizations are to provide to the Department the information described in section 4.9 of this act, if required; and

10. Standards and criteria pursuant to which the Department may remove from its Internet website information regarding a pharmacy or an Internet link to the Internet website maintained by a

pharmacy, or both, if the Department determines that the pharmacy has:

(a) Ceased to be licensed and in good standing pursuant to chapter 639 of NRS; or

(b) Engaged in a pattern of providing to consumers information that is false or would be misleading to reasonably informed persons.

Sec. 7.5. NRS 439.935 is hereby amended to read as follows:

439.935 1. On or before July 1 of each odd-numbered year, the Department shall make a determination of whether sufficient money is available and authorized for expenditure to fund one or more components of the programs and other duties of the Department relating to NRS 439.900 to 439.940, inclusive ~~[.]~~ , *and sections 2 to 4.9, inclusive, of this act.*

2. The Department shall temporarily suspend any components of the program or duties of the Department for which it determines pursuant to subsection 1 that sufficient money is not available.

3. The Department may apply for and accept any available grants and may accept any bequests, devises, donations or gifts from any public or private source to carry out the provisions of NRS 439.900 to 439.940, inclusive ~~[.]~~ , *and sections 2 to 4.9, inclusive, of this act.*

Sec. 8. NRS 439.940 is hereby amended to read as follows:

439.940 *1.* If a pharmacy that is licensed under the provisions of chapter 639 of NRS and is located within the State of Nevada fails to provide to the Department the information required to be provided pursuant to NRS 439.910 or fails to provide such information on a timely basis, and the failure was not caused by excusable neglect, technical problems or other extenuating circumstances, the Department may impose against the pharmacy an administrative penalty of not more than $500 for each day of such failure.

2. If a manufacturer fails to provide to the Department the information required by section 3.8, 4 or 4.6 of this act, a pharmacy benefit manager fails to provide to the Department the information required by section 4.2 of this act, a nonprofit organization fails to post or provide to the Department, as applicable, the information required by section 4.9 of this act or a manufacturer, pharmacy benefit manager or nonprofit organization fails to post or provide, as applicable, such information on a timely basis, and the failure was not caused by excusable neglect, technical problems or other extenuating circumstances, the Department may impose against the manufacturer, pharmacy benefit manager or nonprofit organization, as applicable, an administrative penalty of not more than $5,000 for each day of such failure.

3. If a pharmaceutical sales representative fails to comply with the requirements of section 4.6 of this act, the Department may impose against the pharmaceutical sales representative an administrative penalty of not more than $500 for each day of such failure.

4. Any money collected as administrative penalties pursuant to this section must be accounted for separately and used by the Department to establish and carry out programs to provide education concerning diabetes and prevent diabetes.

Sec. 8.6. Chapter 394 of NRS is hereby amended by adding thereto a new section to read as follows:

1. The parent or legal guardian of a pupil who has asthma, anaphylaxis or diabetes may submit a written request to the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled to allow the pupil to self-administer medication for the treatment of the pupil's asthma, anaphylaxis or diabetes while the pupil is on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus.

2. A private school shall establish protocols for containing blood-borne pathogens and the handling and disposal of needles, medical devices and other medical waste and provide a copy of these protocols and procedures to the parent or guardian of a pupil who requests permission for the pupil to self-administer medication pursuant to subsection 1.

3. A written request made pursuant to subsection 1 must include:

(a) A signed statement of a physician indicating that the pupil has asthma, anaphylaxis or diabetes and is capable of self-administration of the medication while the pupil is on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus;

(b) A written treatment plan prepared by the physician pursuant to which the pupil will manage his or her asthma, anaphylaxis or diabetes if the pupil experiences an asthmatic attack, anaphylactic shock or diabetic episode while on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus; and

(c) A signed statement of the parent or legal guardian:

(1) Indicating that the parent or legal guardian grants permission for the pupil to self-administer the medication while the pupil is on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus;

(2) Acknowledging that the parent or legal guardian is aware of and understands the provisions of subsections 4 and 5;

(3) Acknowledging the receipt of the protocols provided pursuant to subsection 2;

(4) Acknowledging that the protocols established pursuant to subsection 2 have been explained to the pupil who will self-administer the medication and that he or she has agreed to comply with the protocols; and

(5) Acknowledging that authorization to self-administer medication pursuant to this section may be revoked if the pupil fails to comply with the protocols established pursuant to subsection 2.

4. The provisions of this section do not create a duty for the private school in which the pupil is enrolled, or an employee or agent thereof, that is in addition to those duties otherwise required in the course of service or employment.

5. If a pupil is granted authorization pursuant to this section to self-administer medication, the governing body of the private school in which the pupil is enrolled, the private school and any employee or agent thereof, are immune from liability for the injury to or death of:

(a) The pupil as a result of self-administration of a medication pursuant to this section or the failure of the pupil to self-administer such a medication; and

(b) Any other person as a result of exposure to or injury caused by needles, medical devices or other medical waste from the self-administration of medication by a pupil pursuant to this section.

6. Upon receipt of a request that complies with subsection 3, the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled shall provide written authorization for the pupil to carry and self-administer medication to treat his or her asthma, anaphylaxis or diabetes while the pupil is on the grounds of the private school, participating in an activity sponsored by the private school or on a school bus. The written authorization must be filed with the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled and must include:

(a) The name and purpose of the medication which the pupil is authorized to self-administer;

(b) The prescribed dosage and the duration of the prescription;

(c) The times or circumstances, or both, during which the medication is required or recommended for self-administration;

(d) The side effects that may occur from an administration of the medication;

(e) The name and telephone number of the pupil's physician and the name and telephone number of the person to contact in the case of a medical emergency concerning the pupil; and

(f) The procedures for the handling and disposal of needles, medical devices and other medical waste.

7. The written authorization provided pursuant to subsection 6 is valid for 1 school year. If a parent or legal guardian submits a written request that complies with subsection 3, the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled shall renew and, if necessary, revise the written authorization.

8. If a parent or legal guardian of a pupil who is authorized pursuant to this section to carry medication on his or her person provides to the principal or, if applicable, the school nurse of the private school in which the pupil is enrolled doses of the medication in addition to the dosage that the pupil carries on his or her person, the principal or, if applicable, the school nurse shall ensure that the additional medication is:

(a) Stored on the premises of the private school in a location that is secure; and

(b) Readily available if the pupil experiences an asthmatic attack, anaphylactic shock or diabetic episode during school hours.

9. An employee of a private school who willfully violates any provision of this section is guilty of a misdemeanor.

10. As used in this section:

(a) "Medication" has the meaning ascribed to it in NRS 392.425.

(b) "Physician" has the meaning ascribed to it in NRS 392.425.

(c) "Self-administer" has the meaning ascribed to it in NRS 392.425.

Sec. 9. NRS 600A.030 is hereby amended to read as follows:

600A.030 As used in this chapter, unless the context otherwise requires:

1. "Improper means" includes, without limitation:

(a) Theft;

(b) Bribery;

(c) Misrepresentation;

(d) Willful breach or willful inducement of a breach of a duty to maintain secrecy;

(e) Willful breach or willful inducement of a breach of a duty imposed by common law, statute, contract, license, protective order or other court or administrative order; and

(f) Espionage through electronic or other means.

2. "Misappropriation" means:

(a) Acquisition of the trade secret of another by a person by improper means;

(b) Acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or

(c) Disclosure or use of a trade secret of another without express or implied consent by a person who:

(1) Used improper means to acquire knowledge of the trade secret;

(2) At the time of disclosure or use, knew or had reason to know that his or her knowledge of the trade secret was:

(I) Derived from or through a person who had used improper means to acquire it;

(II) Acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or

(III) Derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or

(3) Before a material change of his or her position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake.

3. "Owner" means the person who holds legal or equitable title to a trade secret.

4. "Person" means a natural person, corporation, business trust, estate, trust, partnership, association, joint venture, government, governmental subdivision or agency, or any other legal or commercial entity.

5. "Trade secret" ~~[means]~~ *:*

(a) Means information, including, without limitation, a formula, pattern, compilation, program, device, method, technique, product, system, process, design, prototype, procedure, computer programming instruction or code that:

~~[(a)]~~ *(1)* Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by the public or any other persons who can obtain commercial or economic value from its disclosure or use; and

~~[(b)]~~ *(2)* Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

(b) Does not include any information that a manufacturer is required to report pursuant to section 3.8 or 4 of this act, information that a pharmaceutical sales representative is 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.

Sec. 10. Chapter 683A of NRS is hereby amended by adding thereto the provisions set forth as sections 11 to 21, inclusive, of this act.

Sec. 11. (Deleted by amendment.)

Sec. 12. *As used in sections 12 to 21, inclusive, of this act, unless the context otherwise requires, the words and terms defined in sections 13 to 16, inclusive, of this act have the meanings ascribed to them in those sections.*

Sec. 13. *"Covered person" means a person who is covered by a pharmacy benefits plan.*

Sec. 14. *"Pharmacy" has the meaning ascribed to it in NRS 639.012.*

Sec. 14.5. *"Pharmacy benefit manager" means an entity that contracts with or is employed by a third party and manages the pharmacy benefits plan provided by the third party.*

Sec. 15. *"Pharmacy benefits plan" means coverage of prescription drugs provided by a third party.*

Sec. 16. *"Third party" means:*

1. An insurer, as that term is defined in NRS 679B.540;

2. A health benefit plan, as that term is defined in NRS 689A.540, for employees which provides a pharmacy benefits plan;

3. A participating public agency, as that term is defined in NRS 287.04052, and any other local governmental agency of the State of Nevada which provides a system of health insurance for the benefit of its officers and employees, and the dependents of officers and employees, pursuant to chapter 287 of NRS; or

4. Any other insurer or organization that provides health coverage or benefits or coverage of prescription drugs as part of workers' compensation insurance in accordance with state or federal law.

➥ *The term does not include an insurer that provides coverage under a policy of casualty or property insurance.*

Sec. 17. *1. Except as otherwise provided in subsection 2, the requirements of sections 12 to 21, inclusive, of this act and any regulations adopted by the Commissioner pursuant thereto do not apply to the coverage of prescription drugs under a plan that is subject to the Employee Retirement Income Security Act of 1974 or any information relating to such coverage.*

2. A plan described in subsection 1 may, by contract, require a pharmacy benefit manager that manages the coverage of prescription drugs under the plan to comply with the requirements

of sections 12 to 21, inclusive, of this act and any regulations adopted by the Commissioner pursuant thereto.

Sec. 18. (Deleted by amendment.)

Sec. 19. *A pharmacy benefit manager has a fiduciary duty to a third party with which the pharmacy benefit manager has entered into a contract to manage the pharmacy benefits plan of the third party and shall notify the third party in writing of any activity, policy or practice of the pharmacy benefit manager that presents a conflict of interest that interferes with the ability of the pharmacy benefit manager to discharge that fiduciary duty.*

Sec. 20. *1. A pharmacy benefit manager shall not:*

(a) Prohibit a pharmacist or pharmacy from providing information to a covered person concerning the amount of any copayment or coinsurance for a prescription drug or informing a covered person concerning the clinical efficacy of a less expensive alternative drug;

(b) Penalize a pharmacist or pharmacy for providing the information described in paragraph (a) or selling a less expensive alternative drug to a covered person;

(c) Prohibit a pharmacy from offering or providing delivery services directly to a covered person as an ancillary service of the pharmacy; or

(d) If the pharmacy benefit manager manages a pharmacy benefits plan that provides coverage through a network plan, charge a copayment or coinsurance for a prescription drug in an amount that is greater than the total amount paid to a pharmacy that is in the network of providers under contract with the third party.

2. As used in this section, "network plan" means a health benefit plan offered by a health carrier under which the financing and delivery of medical care is provided, in whole or in part, through a defined set of providers under contract with the carrier. The term does not include an arrangement for the financing of premiums.

Sec. 21. (Deleted by amendment.)

Sec. 22. (Deleted by amendment.)

Sec. 23. (Deleted by amendment.)

Sec. 24. (Deleted by amendment.)

Sec. 25. (Deleted by amendment.)

Sec. 26. (Deleted by amendment.)

Sec. 26.3. NRS 689A.405 is hereby amended to read as follows:

689A.405 1. An insurer that offers or issues a policy of health insurance which provides coverage for prescription drugs shall include with any summary, certificate or evidence of that

coverage provided to an insured, notice of whether a formulary is used and, if so, of the opportunity to secure information regarding the formulary from the insurer pursuant to subsection 2. The notice required by this subsection must:

(a) Be in a language that is easily understood and in a format that is easy to understand;

(b) Include an explanation of what a formulary is; and

(c) If a formulary is used, include:

(1) An explanation of:

(I) How often the contents of the formulary are reviewed; and

(II) The procedure and criteria for determining which prescription drugs are included in and excluded from the formulary; and

(2) The telephone number of the insurer for making a request for information regarding the formulary pursuant to subsection 2.

2. If an insurer offers or issues a policy of health insurance which provides coverage for prescription drugs and a formulary is used, the insurer shall:

(a) Provide to any insured or participating provider of health care, upon request:

(1) Information regarding whether a specific drug is included in the formulary.

(2) Access to the most current list of prescription drugs in the formulary, organized by major therapeutic category, with an indication of whether any listed drugs are preferred over other listed drugs. If more than one formulary is maintained, the insurer shall notify the requester that a choice of formulary lists is available.

(b) Notify each person who requests information regarding the formulary, that the inclusion of a drug in the formulary does not guarantee that a provider of health care will prescribe that drug for a particular medical condition.

(c) During each period for open enrollment, publish on an Internet website that is operated by the insurer and accessible to the public or include in any enrollment materials distributed by the insurer a notice of all prescription drugs that:

(1) Are included on the most recent list of drugs that are essential for treating diabetes in this State compiled by the Department of Health and Human Services pursuant to subsection 1 of section 3.6 of this act; and

(2) Have been removed or will be removed from the formulary during the current plan year or the next plan year.

(d) Update the notice required by paragraph (c) throughout the period for open enrollment.

Sec. 26.6. The provisions of subsection 1 of NRS 218D.380 do not apply to any provision of this act which adds or revises a requirement to submit a report to the Legislature.

Sec. 26.9. 1. Notwithstanding any other provision of this act to the contrary:

(a) On or before November 1, 2017, the Department of Health and Human Services shall place on the Internet website maintained by the Department the information prescribed by section 3.6 of this act.

(b) On or before July 1, 2018:

(1) The manufacturer of a drug included on the list:

(I) Described in subsection 1 of section 3.6 of this act shall submit to the Department a report which includes the information prescribed by section 3.8 of this act.

(II) Described in subsection 2 of section 3.6 of this act shall submit to the Department a report which includes the information prescribed by section 4 of this act.

(2) A pharmacy benefit manager shall submit to the Department a report which includes the information prescribed by section 4.2 of this act.

(c) On or before September 1, 2018, the Department shall analyze the reports submitted pursuant to paragraph (b) and compile and post on the Internet website maintained by the Department the initial report required by section 4.3 of this act.

2. As used in this section:

(a) "Manufacturer" has the meaning ascribed to it in section 2 of this act.

(b) "Pharmacy benefit manager" has the meaning ascribed to it in section 14.5 of this act.

Sec. 27. 1. The provisions of sections 19 and 20 of this act do not apply to any contract existing on January 1, 2018, for the pharmacy benefit manager to manage a pharmacy benefits plan for a third party until the contract is renewed.

2. As used in this section:

(a) "Pharmacy benefit manager" has the meaning ascribed to it in section 14.5 of this act.

(b) "Pharmacy benefits plan" has the meaning ascribed to it in section 15 of this act.

(c) "Third party" has the meaning ascribed to it in section 16 of this act.

Sec. 28. 1. This section and section 26.9 of this act become effective upon passage and approval.

2. Section 8.6 of this act becomes effective on July 1, 2017.

3. Sections 1 to 6.5, inclusive, 7.5, 8, 9 and 26.6 of this act become effective upon passage and approval for the purpose of

adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on October 1, 2017, for all other purposes.

4. Sections 10 to 26.3, inclusive, and 27 of this act become effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on January 1, 2018, for all other purposes.

5. Section 7 of this act becomes effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on May 1, 2018, for all other purposes.

TAB 2

TAB 2

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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; and BIOTECHNOLOGY INNOVATION ORGANIZATION, 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** **NEVADA LEGISLATURE'S MOTION TO INTERVENE AS DEFENDANT TO DEFEND CONSTITUTIONALITY OF SENATE BILL NO. 539 (2017)**

MOTION

Proposed Intervenor-Defendant Nevada Legislature (Legislature), by and through its counsel the Legal Division of the Legislative Counsel Bureau (LCB), hereby files this motion to intervene as a defendant to defend the constitutionality of Senate Bill No. 539 (SB 539), 2017 Nev. Stat., ch. 592, at 4295, which the Legislature enacted during the 2017 legislative session. The Legislature's motion is made under FRCP 24 and NRS 218F.720[1] and is based upon the following Memorandum of Points and Authorities, all pleadings, documents and exhibits on file in this case and any oral arguments the Court

[1] Nevada Revised Statutes (NRS) 218F.720 is reproduced in the Addendum following the Memorandum of Points and Authorities.

may allow. As required by FRCP 24(c), this motion is accompanied by the Legislature's proposed answer to the complaint for declaratory and injunctive relief, which is attached as Exhibit 1.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

In this case, Plaintiffs attack the facial validity of several provisions of SB 539 (hereafter the "challenged provisions"). SB 539, 2017 Nev. Stat., ch. 592, §§ 3.6, 3.8, 4, 4.3, 6, 7, 8 & 9, at 4297-4307. Even though SB 539 was enacted into law on June 15, 2017, Plaintiffs did not file their complaint until September 1, 2017 (ECF No. 1), and they did not serve the summons and complaint on the Nevada Attorney General's office until September 13, 2017 (ECF Nos. 29 & 30).

On the same day that they served the summons and complaint on the Nevada Attorney General's office, Plaintiffs filed and served their motion for preliminary injunction (ECF No. 27). In their motion, Plaintiffs raise several complex constitutional claims attacking the facial validity of the challenged provisions. Id. at 10-22. Plaintiffs allege that the challenged provisions: (1) are preempted by federal patent laws and federal trade-secret laws under the Supremacy Clause of the Federal Constitution; (2) constitute an unconstitutional taking of private property under the Takings Clause of the Federal Constitution; and (3) impose unreasonable burdens on interstate commerce under the dormant Commerce Clause of the Federal Constitution. Id.

On September 14, 2017, the Court entered an order directing Defendants—who are Nevada state officers being sued in their official capacity—to file their opposition to Plaintiffs' motion on or before Wednesday, September 27, 2017. (ECF No. 28 at 4.) The order also provided that Plaintiffs have 14 days thereafter to file a reply in support of their motion. Id. Finally, the order set a hearing on Plaintiffs' motion for Tuesday, October 17, 2017, at 11:00 a.m. Id.

On Monday, September 25, 2017, Defendants filed their opposition to Plaintiffs' motion for preliminary injunction (ECF No. 37). The next day on Tuesday, September 26, 2017, the Legislature

filed its motion to intervene to defend the constitutionality of the challenged provisions because the Legislature has an independent "legal interest in defending the constitutionality of [its] laws" that is separate and distinct from the interests of the Nevada state officers who are being sued in their official capacity. Ne. Ohio Coal. for Homeless v. Blackwell, 467 F.3d 999, 1007-08 (6th Cir. 2006) (granting intervention to Ohio Legislature in constitutional action brought against state officers sued in their official capacity because the Legislature had "an independent interest in defending the validity of Ohio laws and ensuring that those laws are enforced."); People's Legislature v. Miller, No. 2:12-CV-00272-MMD, 2012 WL 3536767, at *5 (D. Nev. Aug. 15, 2012) (granting intervention to Nevada Legislature in constitutional action brought against state officers sued in their official capacity so the Legislature could defend the constitutionality of Nevada laws).

Furthermore, the Supreme Court has recognized that a state legislature is entitled to defend the constitutionality of its legislation in federal court when the state legislature is authorized to do so under state law. See Karcher v. May, 484 U.S. 72, 82 (1987) ("Since the New Jersey Legislature had authority under state law to represent the State's interests in both the District Court and the Court of Appeals, we need not vacate the judgments below for lack of a proper defendant-appellant.").[2]

Under Nevada state law, the Legislature is authorized to appear in any action or proceeding before any federal or state court "[w]hen deemed necessary or advisable to protect the official interests of the Legislature in [the] action or proceeding." NRS 218F.720(1). This includes any action or proceeding in federal or state court where a party:

> (a) Alleges that the Legislature, by its actions or failure to act, has violated the Constitution, treaties or laws of the United States or the Constitution or laws of this State; or
> (b) Challenges, contests or raises as an issue, either in law or in equity, in whole or in part, or facially or as applied, the meaning, intent, purpose, scope, applicability, validity,

[2] See also Ariz. State Legislature v. Ariz. Indep. Redistricting Comm'n, 135 S.Ct. 2652, 2664 (2015) (holding that the Arizona Legislature had Article III standing as "an institutional plaintiff asserting an institutional injury").

> enforceability or constitutionality of any law, resolution, initiative, referendum or other legislative or constitutional measure, including, without limitation, on grounds that it is ambiguous, unclear, uncertain, imprecise, indefinite or vague, is preempted by federal law or is otherwise inapplicable, invalid, unenforceable or unconstitutional[.]

NRS 218F.720(2). Therefore, based on the authority granted by NRS 218F.720, the Legislature is authorized by state law to intervene in this case and defend the constitutionality of the challenged provisions. See People's Legislature v. Miller, No. 2:12-CV-00272-MMD, 2012 WL 3536767, at *5 (D. Nev. Aug. 15, 2012) (noting that "NRS § 218F.720 therefore grants the Legislature an unconditional right to intervene.").

II. Overview of the challenged provisions of SB 539.

The challenged provisions establish a reporting system that requires certain manufacturers of diabetes drugs to provide the Nevada Department of Health and Human Services (NDHHS) with certain information relating to those drugs, including certain information relating to the prices and costs of those drugs. SB 539, 2017 Nev. Stat., ch. 592, §§ 3.6, 3.8, 4, 4.3, 6, 7, 8 & 9, at 4297-4307. The challenged provisions also require NDHHS to make certain information relating to those drugs publicly available, including on the Internet website maintained by NDHHS. Id. § 6, at 4301-02.

The challenged provisions generally become effective on October 1, 2017. Id. § 28, at 4310. However, S.B. 539 contains a transitory section that adjusts the reporting deadlines for the first reporting period, so the affected manufacturers do not have to file their first reports until July 1, 2018. Id. § 26.9, at 4309-10. Under the transitory section, by November 1, 2017, NDHHS must place on its website certain lists identifying drugs that are essential for treating diabetes. Id. Based on those lists, by July 1, 2018, the manufacturers whose drugs appear on the lists must submit to NDHHS their first reports that are required by the challenged provisions. Id. Finally, based on the information submitted by the manufacturers, NDHHS, by September 1, 2018, must compile its first report analyzing the manufacturers'' information regarding diabetes drugs as required by the challenged provisions. Id.

III. Overview of Plaintiffs' constitutional claims.

In their facial attack, Plaintiffs raise several complex constitutional claims. First, Plaintiffs claim that the challenged provisions are facially invalid because they are preempted by federal law under the Supremacy Clause. (ECF No. 27 at 10-17.) Plaintiffs allege that the challenged provisions are preempted under the doctrine of conflict preemption because the provisions conflict with federal patent laws and federal trade-secret laws by standing as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in enacting those federal laws. Id.

Plaintiffs also claim that the challenged provisions are facially invalid because they violate the Takings Clause. (ECF No. 27 at 17-19.) Plaintiffs allege that the challenged provisions constitute an unconstitutional taking of private property for public use because the provisions require manufacturers of the diabetes drugs to disclose trade secrets to the public which has the effect of destroying their private property interests in their intellectual property. Id.

Finally, Plaintiffs claim that the challenged provisions are facially invalid because they violate the dormant Commerce Clause. (ECF No. 27 at 19-22.) Plaintiffs allege that the challenged provisions impose unreasonable burdens on interstate commerce which are excessive in relation to the potential local benefits that the provisions may have on public health, safety and welfare. Id.

IV. The Legislature qualifies for intervention of right and permissive intervention.

FRCP 24 provides for intervention of right and permissive intervention. Sw. Ctr. for Biological Diversity v. Berg, 268 F.3d 810, 817 (9th Cir. 2001). The Legislature qualifies for intervention of right under FRCP 24(a)(2) and permissive intervention under FRCP 24(b)(1)(B) and FRCP 24(b)(2)(A).

A. Intervention of right under FRCP 24(a)(2).

Upon timely motion, the Court must permit a movant to intervene who "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." FRCP 24(a)(2). When evaluating motions to intervene of right, the Court "construe[s] Rule 24 liberally in favor of potential intervenors, focusing on practical considerations rather than technical distinctions." PEST Comm. v. Miller, 648 F.Supp.2d 1202, 1211 (D. Nev. 2009).

To qualify for intervention of right, the movant bears the burden of showing that four requirements are met: (1) the movant's motion to intervene must be timely; (2) the movant must have a significantly protectable interest relating to the property or transaction that is the subject of the action; (3) the movant must be situated such that the disposition of the action may impair or impede the movant's ability to protect that interest; and (4) the movant's interest must not be adequately represented by existing parties. Id. (citing Arakaki v. Cayetano, 324 F.3d 1078, 1083 (9th Cir. 2003)). In this case, the Legislature meets each of the four requirements.

1. The Legislature's motion to intervene is timely.

Timeliness is the threshold requirement for any motion to intervene under FRCP 24. PEST Comm., 648 F.Supp.2d at 1211, 1214 (applying timeliness requirement to intervention of right and permissive intervention). In determining whether a motion to intervene is timely, the Court considers three factors: (1) the stage of the proceedings when the motion is filed; (2) any prejudice to the rights of existing parties from intervention at that stage; and (3) the length and reason for any delay in seeking intervention. PEST Comm., 648 F.Supp.2d at 1211-12.

This case is in its earliest stages, and the Legislature did not delay in seeking intervention. Plaintiffs filed their complaint on September 1, 2017 (ECF No. 1), and they served the summons and complaint on the Nevada Attorney General's office on September 13, 2017 (ECF Nos. 29 & 30). Also on September 13, 2017, Plaintiffs filed and served their motion for preliminary injunction (ECF No. 27). The Legislature filed its motion to intervene on September 26, 2017, less than one month after Plaintiffs commenced this case and less than two weeks after they served the summons and complaint and their

motion for preliminary injunction on the Nevada Attorney General's office.

Because the Legislature acted with appropriate haste and diligence to intervene during the earliest stages of this case, the Legislature's intervention will not delay the proceedings, complicate the management of the case or cause any prejudice to existing parties. Therefore, the Legislature's motion to intervene is timely. See PEST Comm., 648 F.Supp.2d at 1212 (finding motion to intervene timely when it was filed two months after defendant filed answer to amended complaint); EEOC v. Taylor Elec. Co., 155 F.R.D. 180, 182 (N.D. Ill. 1994) (finding motion to intervene timely when it was filed four months after plaintiff commenced action).

2. The Legislature has significantly protectable interests in the subject matter of this action which will be impaired if Plaintiffs succeed on their claims.

For purposes of intervention of right, the movant must have a significantly protectable interest in the subject matter of the action and must be situated such that the disposition of the action may impair or impede the movant's ability to protect that interest. PEST Comm., 648 F.Supp.2d at 1211-12. The movant satisfies these requirements if: (1) the movant asserts an interest that is protected under federal or state law; and (2) there is a relationship between the movant's protected interest and plaintiffs' claims such that the movant will suffer a practical impairment of its interest if plaintiffs succeed on their claims. Id. at 1212. When plaintiffs seek declaratory relief that statutes are unconstitutional, the movant is entitled to intervene to defend the validity of the statutes if the movant's protected interest would be impaired, as a practical matter, by a declaration that the statutes are unconstitutional. Cal. ex rel. Lockyer v. United States, 450 F.3d 436, 441-45 (9th Cir. 2006).

In the context of defending the validity of state statutes, federal courts have recognized that a state legislature may have an independent "legal interest in defending the constitutionality of [its] laws" that is separate and distinct from the interests of state officials who are charged with administering those laws. Ne. Ohio Coal. for Homeless v. Blackwell, 467 F.3d 999, 1007 (6th Cir. 2006). For example, in a

case challenging the constitutionality of Ohio's election laws where Ohio's Secretary of State was named as the defendant, the Sixth Circuit allowed the State of Ohio and its General Assembly to intervene in the case because "the Secretary's primary interest is in ensuring the smooth administration of the election, while the State and General Assembly have an independent interest in defending the validity of Ohio laws and ensuring that those laws are enforced." Id. at 1008.

Under Nevada law, the Legislature has an independent legal right to defend the constitutionality of its laws under NRS 218F.720, which provides that the Legislature may elect to intervene in any action or proceeding when a party alleges that the Legislature has violated the Federal or State Constitution. To intervene, the Legislature must file "a motion or request to intervene in the form required by the rules, laws or regulations applicable to the action or proceeding." NRS 218F.720(2). If the Legislature files such a motion or request to intervene:

> the Legislature has an *unconditional right and standing to intervene* in the action or proceeding and to present its arguments, claims, objections or defenses, in law or fact, whether or not the Legislature's interests are adequately represented by existing parties and whether or not the State or any agency, officer or employee of the State is an existing party.

NRS 218F.720(3) (emphasis added).

Because NRS 218F.720 is a state statute, it cannot grant the Legislature an unconditional right to intervene in federal court. FRCP 24(a)(1). However, it does establish that the Legislature has an independent legal interest in defending the constitutionality of its laws that is separate and distinct from the interests of state officials who are charged with administering those laws. Indeed, the Supreme Court has recognized that a state legislature is a "proper defendant-appellant" to defend the constitutionality of legislation in federal court when state law gives the legislature a right to intervene in the litigation. Karcher v. May, 484 U.S. 72, 82 (1987) ("Since the New Jersey Legislature had authority under state law to represent the State's interests in both the District Court and the Court of Appeals, we need not vacate the judgments below for lack of a proper defendant-appellant."). Thus, because Nevada

law gives the Legislature a right to intervene in this litigation, the Legislature is a proper defendant to defend the constitutionality of SB 539 in federal court. People's Legislature v. Miller, No. 2:12-CV-00272-MMD, 2012 WL 3536767, at *5 (D. Nev. Aug. 15, 2012) (granting intervention to Nevada Legislature in constitutional action brought against state officers sued in their official capacity so the Legislature could defend the constitutionality of Nevada laws).

Furthermore, it is clear that the Legislature's interests will be impaired if Plaintiffs succeed on their claims. Plaintiffs are challenging the validity of legislation enacted by the Legislature in the exercise of its historic police powers to regulate for the benefit of public health, safety and welfare, which are areas that have been "traditionally occupied by the States." Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977); Hillsborough Cnty. v. Automated Med. Labs., 471 U.S. 707, 715-16 (1985) (recognizing the States' historic police powers to regulate "matters related to health and safety"). As a consequence, this case strikes at the heart of the Legislature's sovereign powers under our federal system of shared government, and this case will have significant impacts on the historic and traditional balance of powers between the Federal Government and the State Legislature to regulate for the benefit of public health, safety and welfare.

Because the Legislature has a right to defend its sovereign powers to regulate for the benefit of public health, safety and welfare of the people of Nevada, the Legislature has a substantial interest in the subject matter of this action which will be impaired if the Legislature is not permitted to intervene. Therefore, the Legislature has established that it has significantly protectable interests in the subject matter of this action which will be impaired if Plaintiffs succeed on their claims.

3. The Legislature's interests are not adequately represented by existing parties.

The Legislature must satisfy only a minimal burden to demonstrate that existing parties do not adequately represent its interests, and it need only show that representation by existing parties may be inadequate, not that it will be inadequate. Sw. Ctr. for Biological Diversity, 268 F.3d at 823. Courts

typically consider three factors when determining whether existing parties adequately represent the interests of a proposed intervenor: (1) whether the interests of existing parties are such that they will undoubtedly make all of the proposed intervenor's arguments; (2) whether existing parties are capable and willing to make such arguments; and (3) whether the proposed intervenor would offer any necessary elements to the proceeding that existing parties would neglect. PEST Comm., 648 F.Supp.2d at 1212.

As a general rule, there is a presumption that a state official adequately represents the interests of *private* parties in defending the constitutionality of state statutes because the state official is acting in a representative capacity on behalf of the citizens of the state and because the state official and the private parties share the same ultimate objective, which is to uphold the statutes against constitutional attack. Id. at 1212-13. This presumption, however, does not apply here because the Legislature is a governmental entity—not a private party—and the Legislature has an independent legal interest in defending the constitutionality of SB 539 that is separate and distinct from the interests of the existing Defendants whose primary concerns are necessarily focused on their implementation of the legislation rather than on the facial validity of the legislation under the historic and traditional balance of powers between the Federal Government and the State Legislature to regulate for the benefit of public health, safety and welfare. See Ne. Ohio Coal., 467 F.3d at 1007-08.

For example, in their opposition to Plaintiffs' motion for preliminary injunction, the existing Defendants make arguments that are focused primarily on their implementation of the challenged provisions rather than on the Legislature's sovereign powers to enact the challenged provisions as facially constitutional laws intended to regulate for the benefit of public health, safety and welfare of the people of Nevada. In particular, the existing Defendants primarily argue that preliminary injunctive relief is inappropriate at this early stage of the litigation because Plaintiffs' claims are not yet ripe given that NDHHS has not completed the necessary steps to implement the challenged provisions—including adopting necessary administrative rules and regulations—and therefore it has not applied the challenged

provisions to any particular manufacturers in any way that threatens imminent and irreparable harm. (ECF No. 37 at 2-8.) In the absence of such implementation, the existing Defendants ask the Court to defer ruling on the preliminary injunction with regard to most of the challenged provisions until NDHHS "has had opportunity to adopt regulations." Id. at 8.

Although the Legislature does not disagree with the arguments made by the existing Defendants, the Legislature must be given the opportunity to defend its sovereign powers by making arguments that focus primarily on the facial validity of the challenged provisions as a proper exercise of the Legislature's historic and traditional police powers to regulate for the benefit of public health, safety and welfare. Therefore, because the Legislature's interests are not adequately represented by the arguments made by the existing Defendants, the Legislature is entitled to intervention of right under FRCP 24(a)(2). See Ne. Ohio Coal., 467 F.3d at 1007-08.

B. Permissive intervention under FRCP 24(b)(1)(B) and FRCP 24(b)(2)(A).

The Court has the discretion under FRCP 24(b)(1)(B) to permit intervention by a movant who submits a timely motion and who "has a claim or defense that shares with the main action a common question of law or fact." Freedom from Religion Found. v. Geithner, 644 F.3d 836, 843-44 (9th Cir. 2011). In exercising its discretion, the Court should consider whether intervention will unduly delay or prejudice the original parties, whether the movant's interests are adequately represented by existing parties, and whether judicial economy favors intervention. PEST Comm., 648 F.Supp.2d at 1214.

The Court also has the discretion under FRCP 24(b)(2)(A) to permit intervention by a governmental agency when plaintiffs' claims are based on a law administered by that agency. See People's Legislature v. Miller, No. 2:12-CV-00272-MMD, 2012 WL 3536767, at *5 (D. Nev. Aug. 15, 2012) (granting intervention to Nevada Legislature in constitutional action brought against state officers sued in their official capacity so the Legislature could defend the constitutionality of Nevada laws). Permissive intervention ordinarily should be granted to a governmental agency where the legal issues in

the case may have a substantial impact on "the maintenance of its statutory authority and the performance of its public duties." SEC v. U.S. Realty & Impr. Co., 310 U.S. 434, 460 (1940). Thus, where the governmental agency's interest in the case "is a public one" and it intends to raise claims or defenses concerning questions of law involved in the main action, permissive intervention should be granted, especially when the agency's intervention "might be helpful in [a] difficult and delicate area." United States v. Local 638, Enter. Ass'n of Pipefitters, 347 F.Supp.164, 166 (S.D.N.Y. 1972) (quoting SEC v. U.S. Realty & Impr. Co., 310 U.S. 434, 460 (1940)).

In this case, considerations of equity, judicial economy and fairness militate in favor of the Court granting permissive intervention to the Legislature. As discussed previously, the Legislature's interests are not adequately represented by the arguments made by the existing Defendants because those arguments are focused primarily on their implementation of the challenged provisions rather than on the Legislature's sovereign powers to enact the challenged provisions as facially constitutional laws intended to regulate for the benefit of public health, safety and welfare of the people of Nevada. By permitting the Legislature to intervene, the Court would be facilitating a more comprehensive and thorough presentation of the controlling law and a better understanding of the issues, and the Court would be ensuring that the views of the Legislature are fairly and adequately represented and are not prejudiced by this case.

In addition, because this case is in its earliest stages, intervention will not unduly delay the proceedings or prejudice the rights of existing parties. Therefore, even assuming the Legislature does not qualify for intervention as of right under FRCP 24(a)(2), the Court should exercise its discretion and allow the Legislature to intervene under the standards for permissive intervention set forth in FRCP 24(b)(1)(B) and FRCP 24(b)(2)(A). See People's Legislature v. Miller, No. 2:12-CV-00272-MMD, 2012 WL 3536767, at *5 (D. Nev. Aug. 15, 2012) (granting intervention to Nevada Legislature in constitutional action brought against state officers sued in their official capacity so the Legislature

could defend the constitutionality of Nevada laws).

CONCLUSION

Based upon the foregoing, the Legislature respectfully asks the Court to grant the Legislature's motion to intervene as a defendant to defend the constitutionality of SB 539.

DATED: This **26th** day of September, 2017.

Respectfully submitted,

BRENDA J. ERDOES
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ADDENDUM

NRS 218F.720 Authority to provide legal representation in actions and proceedings; exemption from fees, costs and expenses; standards and procedures for exercising unconditional right and standing to intervene; payment of costs and expenses of representation.

1. When deemed necessary or advisable to protect the official interests of the Legislature in any action or proceeding, the Legislative Commission, or the Chair of the Legislative Commission in cases where action is required before a meeting of the Legislative Commission is scheduled to be held, may direct the Legislative Counsel and the Legal Division to appear in, commence, prosecute, defend or intervene in any action or proceeding before any court, agency or officer of the United States, this State or any other jurisdiction, or any political subdivision thereof. In any such action or proceeding, the Legislature may not be assessed or held liable for:

(a) Any filing or other court or agency fees; or

(b) The attorney's fees or any other fees, costs or expenses of any other parties.

2. If a party to any action or proceeding before any court, agency or officer:

(a) Alleges that the Legislature, by its actions or failure to act, has violated the Constitution, treaties or laws of the United States or the Constitution or laws of this State; or

(b) Challenges, contests or raises as an issue, either in law or in equity, in whole or in part, or facially or as applied, the meaning, intent, purpose, scope, applicability, validity, enforceability or constitutionality of any law, resolution, initiative, referendum or other legislative or constitutional measure, including, without limitation, on grounds that it is ambiguous, unclear, uncertain, imprecise, indefinite or vague, is preempted by federal law or is otherwise inapplicable, invalid, unenforceable or unconstitutional,

➥ the Legislature may elect to intervene in the action or proceeding by filing a motion or request to intervene in the form required by the rules, laws or regulations applicable to the action or proceeding. The motion or request to intervene must be accompanied by an appropriate pleading, brief or dispositive motion setting forth the Legislature's arguments, claims, objections or defenses, in law or fact, or by a motion or request to file such a pleading, brief or dispositive motion at a later time.

3. Notwithstanding any other law to the contrary, upon the filing of a motion or request to intervene pursuant to subsection 2, the Legislature has an unconditional right and standing to intervene in the action or proceeding and to present its arguments, claims, objections or defenses, in law or fact, whether or not the Legislature's interests are adequately represented by existing parties and whether or not the State or any agency, officer or employee of the State is an existing party. If the Legislature intervenes in the action or proceeding, the Legislature has all the rights of a party.

4. The provisions of this section do not make the Legislature a necessary or indispensable party to any action or proceeding unless the Legislature intervenes in the action or proceeding, and no party to any action or proceeding may name the Legislature as a party or move to join the Legislature as a party based on the provisions of this section.

5. The Legislative Commission may authorize payment of the expenses and costs incurred pursuant to this section from the Legislative Fund.

6. As used in this section:

(a) "Action or proceeding" means any action, suit, matter, cause, hearing, appeal or proceeding.

(b) "Agency" means any agency, office, department, division, bureau, unit, board, commission, authority, institution, committee, subcommittee or other similar body or entity,

including, without limitation, any body or entity created by an interstate, cooperative, joint or interlocal agreement or compact.

(c) "Legislature" means:

(1) The Legislature or either House; or

(2) Any current or former agency, member, officer or employee of the Legislature, the Legislative Counsel Bureau or the Legislative Department.

(Added to NRS by 1965, 1461; A 1971, 1546; 1995, 1108; 1999, 2203; 2007, 3305; 2009, 1565; 2011, 3244)—(Substituted in revision for NRS 218.697)

CERTIFICATE OF SERVICE

I hereby certify that I am an employee of the Nevada Legislative Counsel Bureau, Legal Division, and that on the **26th** day of September, 2017, pursuant to FRCP 5(b) and Local Rule Part IC, I filed and served a true and correct copy of Nevada Legislature's Motion to Intervene as Defendant to Defend Constitutionality of Senate Bill No. 539 (2017), by using the Court's CM/ECF system. I further certify that service will be accomplished electronically by the CM/ECF system directed to the following:

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INDEX OF EXHIBITS TO NEVADA LEGISLATURE'S MOTION TO INTERVENE

Exhibit No.	Description of Exhibits
1	Nevada Legislature's Proposed Answer to Plaintiffs' Complaint for Declaratory and Injunctive Relief.

Nevada Legislature's Motion to Intervene

Exhibit 1—Nevada Legislature's Proposed Answer to Plaintiffs' Complaint for Declaratory and Injunctive Relief

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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; and BIOTECHNOLOGY INNOVATION ORGANIZATION, 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** **NEVADA LEGISLATURE'S PROPOSED ANSWER TO PLAINTIFFS' COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

PROPOSED ANSWER

Proposed Intervenor-Defendant Nevada Legislature (Legislature), by and through its counsel the Legal Division of the Legislative Counsel Bureau (LCB), hereby submits this proposed answer to Plaintiffs' complaint for declaratory and injunctive relief that was filed on September 1, 2017 (ECF No. 1). The Legislature's proposed answer is being submitted in conjunction with the Legislature's motion to intervene under FRCP 24(c), which requires a motion to intervene to be "accompanied by a pleading that sets out the claim or defense for which intervention is sought." The Legislature proposes to answer Plaintiffs' complaint for declaratory and injunctive relief as follows:

GENERAL DENIAL OF ALL THE ALLEGATIONS

In their complaint for declaratory and injunctive relief, Plaintiffs allege constitutional claims against the validity of several provisions of Senate Bill No. 539 (hereafter the "challenged provisions"). SB 539, 2017 Nev. Stat., ch. 592, §§ 3.6, 3.8, 4, 4.3, 6, 7, 8 & 9, at 4297-4307. Plaintiffs allege the challenged provisions are unconstitutional under the Supremacy Clause of the Federal Constitution, the Takings Clause of the Federal Constitution and the dormant Commerce Clause of the Federal Constitution. The Legislature, by a general denial in good faith, denies all the allegations of Plaintiffs' complaint for declaratory and injunctive relief—including the jurisdictional grounds—because the challenged provisions are constitutional and do not violate the Supremacy Clause of the Federal Constitution, the Takings Clause of the Federal Constitution or the dormant Commerce Clause of the Federal Constitution. FRCP 8(b)(3) ("A party that intends in good faith to deny all the allegations of a pleading—including the jurisdictional grounds—may do so by a general denial.").

AFFIRMATIVE DEFENSES

1. The Legislature pleads as an affirmative defense that the complaint fails to state a claim upon which relief can be granted.

2. The Legislature pleads as an affirmative defense that Plaintiffs have failed to join all necessary parties who are needed for a just adjudication.

3. The Legislature pleads as affirmative defenses that Plaintiffs lack capacity to sue and standing; that Plaintiffs' claims do not present a justiciable case or controversy; that Plaintiffs' claims are not ripe for adjudication; and that the Court lacks jurisdiction of the subject matter.

4. The Legislature pleads as an affirmative defense that Plaintiffs' claims are barred by the doctrine of immunity, including, without limitation, sovereign immunity, official immunity, absolute immunity and qualified immunity.

5. The Legislature pleads as an affirmative defense that, pursuant to NRS 218F.720, the Legislature may not be assessed or held liable for any filing or other court fees or the attorney's fees or other fees, costs or expenses of any other parties.

6. The Legislature reserves its right to plead, raise or assert any additional affirmative defenses which are not presently known to the Legislature, following its reasonable inquiry under the circumstances, but which may become known to the Legislature as a result of discovery, further pleadings, or the acquisition of information from any other source during the course of this litigation.

PRAYER FOR RELIEF

The Legislature prays for the following relief:

1. That the Court enter judgment in favor of the Legislature and all other Defendants and against Plaintiffs on all claims and prayers for relief directly or indirectly pled in the complaint;

2. That the Court enter judgment in favor of the Legislature and all other Defendants and against Plaintiffs for costs and attorney's fees as determined by law; and

3. That the Court grant such other relief in favor of the Legislature and all other Defendants and against Plaintiffs as the Court may deem just and proper.

DATED: This **26th** day of September, 2017.

Respectfully submitted,

BRENDA J. ERDOES
Legislative Counsel

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TAB 3

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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

NEVADA LEGISLATURE'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Hearing Date: October 17, 2017

OPPOSITION

Proposed Intervenor-Defendant Nevada Legislature (Legislature), by and through its counsel the Legal Division of the Legislative Counsel Bureau (LCB), hereby files its opposition to Plaintiffs' motion for preliminary injunction (ECF No. 27) which seeks to enjoin implementation of specific provisions of Senate Bill No. 539 (hereafter the "challenged provisions"). SB 539, 2017 Nev. Stat., ch. 592, §§ 3.6, 3.8, 4, 4.3, 6, 7, 8 & 9, at 4297-4307. The Legislature's opposition is being filed in conjunction with its motion to intervene as a defendant to defend the constitutionality of SB 539 (ECF No. 39), which the Legislature filed on September 26, 2017.[1]

The Legislature respectfully asks the Court to deny the motion for preliminary injunction because Plaintiffs: (1) are not likely to succeed on the merits of their facial claims that the challenged provisions are preempted and unconstitutional under all circumstances; (2) are not likely to suffer substantial and immediate irreparable harm from the challenged provisions before their full implementation and application by the state; and (3) are not entitled to preliminary injunctive relief enjoining the challenged provisions before their full implementation and application by the state.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

Because Plaintiffs have directed their constitutional claims only at the challenged provisions and not at SB 539 in its entirety, the constitutional review in this case is limited to the challenged provisions, and the Court should ensure that the remaining provisions of SB 539 are not affected by this case. See Dalton v. Little Rock Family Planning Servs., 516 U.S. 474, 476 (1996) (explaining that federal court's

[1] On Sept. 29, 2017, Plaintiffs filed a response stating they did not oppose the motion to intervene (ECF No. 41). However, if the Legislature has not been granted intervenor status when the Court considers the motion for preliminary injunction, the Legislature asks the Court to treat its opposition as an amicus brief. See PEST Comm. v. Miller, 648 F.Supp.2d 1202, 1214 (D. Nev. 2009) (treating responsive documents filed by proposed intervenor-defendants "as the equivalent of an amicus brief").

constitutional review should not extend "further than necessary to dispose of the case before it.").

In reviewing Plaintiffs' constitutional claims, the Court should be guided by several fundamental principles of constitutional review. First, because "[s]tate statutes, like federal ones, are entitled to the presumption of constitutionality until their invalidity is judicially declared," Davies Warehouse Co. v. Bowles, 321 U.S. 144, 153 (1944), the Court must "start therefore with a presumption that the state statute is valid and ask whether [Plaintiffs have] shouldered the burden of overcoming that presumption." Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 661-62 (2003) (plurality op.) (citation omitted). Second, because Plaintiffs are attacking the validity of the provisions before they have been implemented and applied by the state, their constitutional claims can be based only on the facial validity of the challenged provisions and cannot be based on the potential effects or consequences of those provisions as applied to any particular manufacturer. See Wash. State Grange v. Wash. State Republican Party, 552 U.S. 442, 449-50 (2008) (explaining that state statutes can be challenged only on facial grounds when the state has had no opportunity to implement and apply those statutes). As a result, "[i]n determining whether a law is facially invalid, [the Court] must be careful not to go beyond the statute's facial requirements and speculate about 'hypothetical' or 'imaginary' cases." Id. Moreover, a facial challenge is the most difficult constitutional challenge to mount successfully because Plaintiffs must establish that there are no circumstances under which the challenged provisions can operate constitutionally. Id. at 449-51.

The first step in reviewing Plaintiffs' facial claims is to interpret the challenged provisions under Nevada's rules of statutory interpretation to determine their plain meaning and intent. In applying those rules, the Court must "construe the [provisions] narrowly and resolve any ambiguities in favor of the interpretation that most clearly supports constitutionality." S.D. Myers, Inc. v. City of San Francisco, 253 F.3d 461, 468 (9th Cir. 2001). Plaintiffs' facial claims are all based on their overly broad interpretation that the challenged provisions require manufacturers to disclose trade secrets. However,

the plain language and legislative history of the challenged provisions—along with reason and public policy—amply demonstrate that the provisions are much narrower in scope and do not require manufacturers to disclose trade secrets. Because this reasonable and plausible interpretation of the challenged provisions alleviates any constitutional doubts regarding the validity of the provisions, the Court must adopt this interpretation because "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." Hooper v. California, 155 U.S. 648, 657 (1895). Consequently, Plaintiffs are not likely to succeed on the merits of their facial claims.

Furthermore, because facial challenges require unconstitutionality *under all circumstances*, Plaintiffs are not likely to succeed on the merits of their facial claims because there are circumstances under which the challenged provisions can operate constitutionally. Plaintiffs also have not established that the challenged provisions conflict with any congressional purposes and objectives of the federal patent laws or federal trade-secret laws, and they have not established that the challenged provisions interfere with existing property rights to such a degree that the interference amounts to a regulatory taking in violation of the Takings Clause. Finally, Plaintiffs have not established that the challenged provisions impose unreasonable burdens on interstate commerce which are excessive in relation to the potential local benefits in violation of the Commerce Clause. Therefore, Plaintiffs' motion for preliminary injunction should be denied.

II. Overview of the challenged provisions of SB 539.

The challenged provisions establish a reporting system that requires certain manufacturers of diabetes drugs to provide the Nevada Department of Health and Human Services (NDHHS) with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs. SB 539, 2017 Nev. Stat., ch. 592, §§ 3.6, 3.8, 4, 4.3, 6, 7, 8 & 9, at 4297-4307. In particular, manufacturers with diabetes drugs on the essential-drugs list must provide NDHHS with a report containing business information relating to: (1) the costs of producing and selling the drugs; (2) the

profits earned from the drugs; (3) the costs of certain patient assistance programs, coupons or rebates associated with the drugs; (4) the history of increases in wholesale acquisition costs of the drugs; and (5) any other data that NDHHS prescribes by regulation to analyze the costs of the drugs, trends in those costs and rebates available for the drugs. Id. § 3.8, at 4297-98. Additionally, if diabetes drugs on the essential-drugs list have been subject to certain increases in their wholesale acquisition cost, manufacturers must provide NDHHS with a report describing the reasons for the increase, including: (1) each factor that has contributed to the increase; (2) the percentage of the total increase that is attributable to each factor; (3) an explanation of the role of each factor in the increase; and (4) any other information that NDHHS prescribes by regulation. Id. § 4, at 4298. The challenged provisions generally become effective on October 1, 2017. Id. § 28, at 4310. However, SB 539 contains a transitory section that adjusts the reporting deadlines for the first reporting period, so the affected manufacturers do not have to file their first reports until July 1, 2018. Id. § 26.9, at 4309-10.

III. Based on the plain language and legislative history of the challenged provisions—along with reason and public policy—the challenged provisions do not require manufacturers to disclose trade secrets.

The first step in reviewing Plaintiffs' facial claims is to interpret the challenged provisions because "it is impossible to determine whether a statute reaches too far without first knowing what the statute covers." United States v. Williams, 553 U.S. 285, 293 (2008). In interpreting the challenged provisions, the Court "looks to Nevada rules of statutory construction to determine the meaning of a Nevada statute." 7912 Limbwood Ct. Trust v. Wells Fargo Bank, 979 F.Supp.2d 1142, 1147 (D. Nev. 2013).

Plaintiffs' facial claims are all based on their incorrect statutory interpretation that "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." (ECF No. 27 at 10.) However, as properly interpreted under Nevada's rules of statutory interpretation, the challenged provisions do not require manufacturers to disclose trade

secrets. Therefore, Plaintiffs are not likely to succeed on the merits of their facial claims.

Under Nevada's rules of statutory interpretation, courts will usually give a statute "its plain meaning, unless doing so violates the spirit of the act or produces absurd or unreasonable results." L.V. Police Prot. Ass'n v. Dist. Ct., 130 P.3d 182, 191 (Nev. 2006) (internal quotations and footnotes omitted). Thus, in most cases "[w]hen the Legislature's intent is clear from the plain language, [courts] will give effect to such intention and construe the statute's language to effectuate rather than nullify its manifest purpose." We the People Nev. v. Miller, 192 P.3d 1166, 1170-71 (Nev. 2008). By contrast, when "the statute's apparent plain meaning results in a meaning that runs counter to the 'spirit' of the statute, [courts] may look outside the statute's language." MGM Mirage v. Nev. Ins. Guar. Ass'n, 209 P.3d 766, 769-70 (Nev. 2009). Under such circumstances, courts "adhere to the rule of statutory construction that the intent of a statute will prevail over the literal sense of its words." Id. (quoting Universal Elec v. State Labor Comm'r, 847 P.2d 1372, 1374 (Nev. 1993)).

Additionally, when the statute is ambiguous or otherwise does not speak to the issue in question, courts will "look to reason and public policy to determine what the Legislature intended." PEBP v. L.V. Metro. Police Dep't, 179 P.3d 542, 548 (Nev. 2008). In making this inquiry, courts will examine "the statute's historical background and spirit" and the circumstances which prompted the Legislature to enact the statute. Id. Courts will also consider the practical effects and consequences of each possible interpretation and will strive to avoid interpretations which lead to unreasonable or absurd results. Nev. Tax Comm'n v. Bernhard, 683 P.2d 21, 23 (Nev. 1984). The goal of this inquiry is to adopt an interpretation that best captures the Legislature's objective in enacting the statute without violating the statute's underlying spirit or purpose. Nev. Mining Ass'n v. Erdoes, 26 P.3d 753, 757 (Nev. 2001).

Finally, when one possible interpretation of the statute would raise serious constitutional problems, courts will generally reject that interpretation if it is fairly possible to construe the statute in an alternative manner that avoids the constitutional problems. Sheriff v. Wu, 708 P.2d 305, 306 (Nev.

1985). This rule is paramount to all other rules of statutory interpretation because the duty of courts to save the statute from an unconstitutional interpretation is derived from the separation of powers which—out of respect for a coequal branch of government whose legislative members also take an oath to uphold the Constitution—requires courts to presume the Legislature "legislates in the light of constitutional limitations." Rust v. Sullivan, 500 U.S. 173, 191 (1991). Therefore, based on the separation of powers, courts must adopt any reasonable interpretation which will save the statute from unconstitutionality. Id. at 190; Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Const. Trades Council, 485 U.S. 568, 574-75 (1988); Illinois v. Krull, 480 U.S. 340, 351 (1987).

Plaintiffs' facial claims are all based on the flawed premise that the only way manufacturers will be able to comply with the challenged provisions is to disclose "confidential, competitively sensitive, proprietary information regarding the production, cost, pricing, marketing, and advertising of their patented diabetes medicines." (ECF No. 27 at 10.) Although, on its face, the plain language of the challenged provisions clearly requires manufacturers to provide NDHHS with certain business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs, there is nothing in the plain language that requires manufacturers to satisfy their disclosure requirements by providing "confidential, competitively sensitive, proprietary information" that constitutes a *trade secret*. See SB 539, 2017 Nev. Stat., ch. 592, §§ 3.8-4, at 4297-98. Therefore, based on the plain language of the challenged provisions, manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a *trade secret*. See Littlejohn v. Bic Corp., 851 F.2d 673, 685 (3d Cir. 1988) (explaining that "non-trade secret but confidential business information is not entitled to the same level of protection from disclosure as trade secret information."); Hammock v. Hoffmann-LaRoche, Inc., 662 A.2d 546, 560 (N.J. 1995) ("Confidential information and proprietary information are not entitled to the same level of protection from disclosure as trade secret information."); ICG

Commc'ns v. Allegiance Telecom, 211 F.R.D. 610, 614 (N.D. Cal. 2002) ("Other confidential business information is generally afforded even less protection than trade secrets.").

Courts have recognized that "[t]he traditional form of confidential commercial information that militates against disclosure is the existence of trade secrets where disclosure would create a sufficient threat of irreparable harm." Mine Safety Appliances v. N. River Ins., 73 F.Supp.3d 544, 560 (W.D. Pa. 2014). However, confidential business information that does not rise to the level of a trade secret is not entitled to the same level of protection from disclosure as a trade secret. Id. As a result, the mere fact that a business has deemed its business information to be confidential does not mean that the confidential business information is entitled to protection as a trade secret. Id. Rather, to be entitled to trade-secret protection, the confidential business information must meet the legal standards for trade secrets "under the substantive law." Id.

Nevada, like most other states, has adopted the Uniform Trade Secrets Act (UTSA) to protect information that constitutes a trade secret. NRS 600A.010 et seq. Under the UTSA, "[w]hether information is a trade secret generally is a question of fact." Finkel v. Cashman Prof'l, 270 P.3d 1259, 1264 (Nev. 2012). Because the determination of trade-secret status is generally a question of fact, no specific category of information—such as pricing information—receives trade-secret protection automatically as a matter of law. IKON Office Solutions v. Am. Office Prods., 178 F.Supp.2d 1154, 1169-70 (D. Or. 2001) ("Although pricing information and marketing strategy can be a trade secret, IKON has not directed the court's attention to any materials of this nature that truly warrant protection as a trade secret, as opposed to general business knowledge."), *aff'd*, 61 F.App'x 378 (9th Cir. 2003). As a result, not all business information regarding the production, cost, pricing, marketing and advertising of goods or services constitutes a trade secret. Frantz v. Johnson, 999 P.2d 351, 359 (Nev. 2000) ("We emphasize that not every customer and pricing list will be protected as a trade secret."); Cambridge Filter Corp. v. Int'l Filter Co., 548 F.Supp. 1301, 1306 (D. Nev. 1982) ("[A]n efficient

method of computing costs or pricing is not a trade secret unless it utilizes improved or secret factors."); Camp Creek Hospitality Inns v. Sheraton Franchise Corp., 139 F.3d 1396, 1411 n.25 (11th Cir. 1998) ("We are cognizant of the fact that not all confidential information rises to the level of a trade secret.").[2]

For example, in a case interpreting the UTSA, the Nevada Supreme Court held that pricing information submitted by a hospital to NDHHS under state law, which included the hospital's "listing of discounts given to various preferred provider organizations," did not constitute a trade secret. Neal v. Griepentrog, 837 P.2d 432, 435 (Nev. 1992). In another case, although a drug manufacturer's cost of producing a drug was found to be a trade secret under the facts, the federal district court concluded that a competitor did not misappropriate the trade secret because the competitor's knowledge of the "production cost would be useless as a practical matter without sufficient detail to enable [the competitor] to know what costs were included or excluded from the figure." Microbix Biosystems v. Biowhittaker, Inc., 172 F.Supp.2d 665, 679 (D. Md. 2000).

Therefore, because not all business information regarding the production, cost, pricing, marketing and advertising of goods or services constitutes trade-secret information, the plain language of the challenged provisions does not, on its face, require manufacturers to disclose trade secrets. Furthermore, to the extent that manufacturers believe they cannot satisfy their disclosure requirements without revealing trade-secret information, manufacturers may enter into confidentiality agreements with NDHHS to provide the trade-secret information confidentially to the agency without losing its protected trade-secret status. See SB 539, 2017 Nev. Stat., ch. 592, § 7, at 4302-03 (authorizing NDHHS to adopt

[2] See also W. Med. Consultants v. Johnson, 80 F.3d 1331, 1337 (9th Cir. 1996) (marketing plans and specialized customer information were not trade secrets under facts); Progressive Prod. v. Swartz, 258 P.3d 969, 978 (Kan. 2011) (pricing information was not trade secret under facts where "[p]rices were available to customers."); Optic Graphics v. Agee, 591 A.2d 578, 585-87 (Md. Ct. App. 1991) (pricing information and marketing strategy were not trade secrets under facts); CDC Restoration & Const. v. Tradesmen Contractors, 274 P.3d 317, 324 (Utah Ct. App. 2012); (pricing information was not trade secret under facts).

regulations prescribing the "form and manner" in which manufacturers are to provide the necessary information to NDHHS); NRS 600A.070(5) (recognizing that trade secrets may be protected by "[a]llowing the owner of the trade secret to obtain a signed agreement of confidentiality from any party who obtains knowledge of the trade secret.").

It is well settled that the UTSA "does not purport to limit or override an express contractual arrangement governing the confidential exchange of proprietary information." Nilssen v. Motorola, Inc., 963 F.Supp. 664, 680 (N.D. Ill. 1997). Therefore, "because a confidentiality agreement is a valid contract enforceable according to its terms . . . a contract that defines the degree of confidentiality among the parties also serves to establish—and to define—the duty of confidentiality" among the parties under the UTSA. Id.; Roton Barrier, Inc. v. Stanley Works, 79 F.3d 1112, 1118 (Fed. Cir. 1996) ("As a result of the Confidentiality Agreement, any trade secrets were acquired by Stanley under circumstances giving rise to a duty to maintain its secrecy or limit its use as set forth in [the UTSA].").

It also is well settled that the UTSA allows the owner of a trade secret to disclose it to "a limited number of outsiders for a particular purpose" without losing its protected trade-secret status. A.H. Emery Co. v. Marcan Prods., 389 F.2d 11, 16 (2d Cir. 1968); Centrifugal Acquisition Corp. v. Moon, 849 F.Supp.2d 814, 834 (E.D. Wis. 2012). When such a limited disclosure is made, it "imposes a duty of confidentiality on the part of the person to whom the disclosure is made." Rockwell Graphic Sys. v. DEV Indus., 925 F.2d 174, 177 (7th Cir. 1991); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 475 (1974) (explaining that the "necessary element of secrecy is not lost, however, if the holder of the trade secret reveals the trade secret to another in confidence, and under an implied obligation not to use or disclose it." (internal quotations omitted)).

There is nothing in the plain language of the challenged provisions that precludes manufacturers from entering into confidentiality agreements with NDHHS to protect trade-secret information provided in their reports. If manufacturers make such disclosures to NDHHS under confidentiality agreements

for the limited purpose of complying with the challenged provisions, the trade-secret information would not lose its protected trade-secret status, and NDHHS would have a duty of confidentiality to protect the trade-secret information from public disclosure. Consequently, the plain language of the challenged provisions does not, on its face, require manufacturers to disclose trade secrets in a manner that destroys their protected trade-secret status.

Finally, although the challenged provisions amend the definition of "trade secret" in the UTSA, the Legislature's intent was not to strip trade-secret protection from legitimate trade-secret information that manufacturers properly protect from disclosure by either: (1) ensuring that the trade-secret information is not revealed in their reports to NDHHS; or (2) providing the trade-secret information in their reports to NDHHS under the terms of a confidentiality agreement. The Legislature's intent was to ensure that if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure, the manufacturers cannot later claim that the information still retains its protected trade-secret status, especially since some of the information may be posted on the Internet if the manufacturers have not undertaken the proper means to protect the trade-secret information from disclosure.

The Legislature amended the definition of "trade secret" in the UTSA to exclude "any information that a manufacturer is required to report" under the challenged provisions but only "to the extent that such information is *required* to be disclosed by those sections." SB 539, 2017 Nev. Stat., ch. 592, § 9, at 4307 (emphasis added). As discussed already, the challenged provisions do not *require* manufacturers to disclose trade secrets. Therefore, the amended definition of "trade secret" does not disturb the existing protection afforded to trade-secret information under the UTSA if manufacturers have undertaken the proper means to protect the trade-secret information from disclosure.

However, if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure, that information

would lose its protected trade-secret status because of the manufacturers' own failure to undertake reasonable efforts to protect its secrecy. NRS 600A.030(5)(b); Motor City Bagels v. Am. Bagel Co., 50 F.Supp.2d 460, 480 (D. Md. 1999) ("[T]he plaintiffs' failure to exact agreements from potential investors to maintain the secrecy of the business plan is inconsistent with recognition of the document as a trade secret under the MUTSA."). Under such circumstances, the amended definition of "trade secret" ensures that those manufacturers—which have disclosed the trade-secret information in their reports without protecting its secrecy—cannot later claim that the information still retains its protected trade-secret status and thereby invoke the remedies of the UTSA, such as the procedures for removing trade secrets posted on the Internet. NRS 600A.055.

Therefore, contrary to Plaintiffs' contentions, there is nothing in the plain language of the challenged provisions that "strips trade-secret protection and *mandates* public disclosure of confidential information, eradicating trade-secret protection in other states," or that "burdens interstate commerce by eviscerating commercial rights other states grant, stripping a broad compass of trade-secret protection for *all* manufacturers of essential diabetes drugs." (ECF No. 27 at 27, 30.) The plain language of the challenged provisions is much narrower in scope because it removes trade-secret protection only if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure. Consequently, there is nothing in the plain language of the challenged provisions that *requires* manufacturers to disclose trade secrets.

Moreover, even assuming there is any doubt regarding the meaning of the challenged provisions, that doubt must be resolved by adopting an interpretation that best captures the Legislature's objective in enacting the legislation. Based on the legislative history of the challenged provisions, the Legislature's objective was to draw a reasonable balance between obtaining more information for policymaking while also protecting some proprietary information from disclosure. As explained in legislative hearings, the Legislature wanted to provide policymakers and consumers with more information about the factors

contributing to the cost of diabetes drugs, so they are better informed when developing policies regarding public health, safety and welfare.[3] Hearing SB 539 Sen. Comm. Health & Human Servs., 79th Leg., at 3-5 (Nev. May 26, 2017) (Leg. Ex 1). For example, when testifying on similar legislation in SB 265, Senator Cancela stated:

> I sincerely believe increased transparency leads to decreased costs. When consumers have more information, they are able to make better decisions. We, as policymakers, can enact laws based on where we identify problems in the system if we have the data. I am confident, while this may not have a direct provision to return money to the consumer, it will provide us with the tools to make decisions about drug costs.

Hearing SB 265 Sen. Comm. Health & Human Servs., 79th Leg., at 5 (Nev. May 3, 2017) (Leg. Ex. 2). Similarly, Senator Hammond stated "[o]nce we shine a light on this subject, we should be able to identify the difficulties." Id. at 6.

However, in seeking more information, the Legislature also recognized that some proprietary information would need to protected from disclosure. For example, Senator Hammond stated:

> 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 . . . the PBMs [pharmacy benefit managers] do not want to share all their numbers. Would it hurt to disclose some of the numbers for the rebates, and would it . . . 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.

Hearing SB 539 Sen. Comm. Health & Human Servs., 79th Leg., at 25-26 (Nev. May 26, 2017) (Leg. Ex. 1) (emphasis added).

Thus, in resolving any doubt regarding the meaning of the challenged provisions, those provisions must be interpreted to carry out the Legislature's objective which was to require manufacturers to

[3] Under Fed. R. Evid. 201, the Legislature requests the Court to take judicial notice of the legislative hearings because they are public records. See United States v. Camp, 723 F.2d 741, 744 n.** (9th Cir. 1984); Zephyr v. Saxon Mortgage Servs., 873 F.Supp.2d 1223, 1226 (E.D. Cal. 2012).

provide NDHHS with as much business information as possible about the factors contributing to the cost of diabetes drugs while also protecting some proprietary information from disclosure. Because not all business information regarding the production, cost, pricing, marketing and advertising of diabetes drugs is proprietary information that constitutes a trade secret, the challenged provisions must be interpreted to require manufacturers to provide NDHHS with all information that does not constitute a trade secret. However, in order to protect proprietary information that constitutes a trade secret, the challenged provisions must not be interpreted to require manufacturers to disclose trade secrets. Not only does this interpretation best capture the Legislature's objective in enacting the challenged provisions, but it also is consistent with reason and public policy and avoids unreasonable or absurd results.

Trade-secret law has been part of our nation's public policy for nearly 150 years. Kewanee Oil, 416 U.S. at 493 n.23 (noting that "trade secret law was imported into this country from England by means of the landmark case of Peabody v. Norfolk, 98 Mass. 452 (1868)."). The purpose of trade-secret law is to carefully balance the public's interest in protecting the secrecy of business information to encourage invention and innovation and discourage unfair competition and unethical business practices against the public's interest in the disclosure of business information to foster knowledge, understanding, learning and advancement. Kewanee Oil, 416 U.S. at 480-93. In striking that balance, "not every commercial secret qualifies as a trade secret." Enter. Leasing Co. v. Ehmke, 3 P.3d 1064, 1070 (Ariz. Ct. App. 1999). Thus, as a matter of public policy, trade-secret law has been the historical yardstick for determining which type of confidential business information is protected from disclosure as a trade secret and which type of confidential business information is not so protected.

Given this long-standing historical pedigree, it would be unreasonable and absurd to interpret the challenged provisions as unraveling the careful balance struck by trade-secret law over the last century and a half, especially since there is nothing in the plain language or legislative history of the challenged provisions to indicate that the Legislature intended to unwind those 150 years of trade-secret law.

Therefore, based on reason and public policy, the challenged provisions must be interpreted to require manufacturers to provide NDHHS with all information that does not constitute a trade secret. However, in order to protect proprietary information that constitutes a trade secret, the challenged provisions must not be interpreted to require manufacturers to disclose trade secrets.

Lastly, even assuming there is any remaining doubt regarding the meaning of the challenged provisions, the Court must "construe the [provisions] narrowly and resolve any ambiguities in favor of the interpretation that most clearly supports constitutionality." S.D. Myers, 253 F.3d at 468. The Supreme Court has the explained the purpose of this paramount rule of construction as follows:

> [O]ne of the canon's chief justifications is that it allows courts to *avoid* the decision of constitutional questions. It is a tool for choosing between competing plausible interpretations of a statutory text, resting on the reasonable presumption that [the Legislature] did not intend the alternative which raises serious constitutional doubts.

Clark v. Martinez, 543 U.S. 371, 381 (2005).

Plaintiffs' facial claims are all based on their overly broad interpretation that the challenged provisions require manufacturers to disclose trade secrets. However, the plain language and legislative history of the challenged provisions—along with reason and public policy—amply demonstrate that the provisions are much narrower in scope and do not require manufacturers to disclose trade secrets. Because this reasonable and plausible interpretation of the challenged provisions alleviates any constitutional doubts regarding the validity of the provisions, the Court must adopt this interpretation because "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." Hooper v. California, 155 U.S. 648, 657 (1895). Consequently, as discussed next, Plaintiffs are not likely to succeed on the merits of their facial claims.[4]

[4] If the Court disagrees with this reasonable and plausible interpretation of the challenged provisions, the Court must certify the state-law question of statutory interpretation to the Nevada Supreme Court under NRAP 5. Arizonans for Official English v. Arizona, 520 U.S. 43, 77-80 (1997) (explaining that

continued on next page . . .

IV. Plaintiffs are not likely to succeed on the merits of their facial claims that the challenged provisions are preempted by federal patent laws and federal trade-secret laws under all circumstances.

Plaintiffs contend that the challenged provisions are preempted under the doctrine of conflict preemption because the provisions conflict with federal patent laws and federal trade-secret laws by standing as an obstacle to the accomplishment and execution of the purposes and objectives of Congress in enacting those laws. (ECF No. 27 at 20-26.) Conflict preemption may occur when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hillsborough Cnty. v. Automated Med. Labs., 471 U.S. 707, 713 (1985); Arizona v. United States, 567 U.S. 387, 399-400 (2012). Under that standard, "[w]hat is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000).

In most cases, there is a general presumption against federal preemption when "the field which Congress is said to have pre-empted has been traditionally occupied by the States." United States v. Locke, 529 U.S. 89, 108 (2000) (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)); Hillman v. Maretta, 133 S.Ct. 1943, 1950 (2013). Such traditional areas of state regulation include public health, safety and welfare matters. Hillsborough Cnty., 471 U.S. at 715-16. However, in some cases, the general presumption against federal preemption "is not triggered when the State regulates in an area where there has been a history of significant federal presence." Locke, 529 U.S. at 108; Chamber of Commerce v. Whiting, 563 U.S. 582, 604-05 (2011). One such area with a history of significant federal presence is patent law. Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 146-57 (1989). By contrast,

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federal courts must certify state-law questions of statutory interpretation when "the statute is susceptible of . . . an interpretation [that] would avoid or substantially modify the federal constitutional challenge to the statute."). Federal courts may certify such questions *sua sponte*, even if no party requests certification or all parties object to certification. Parents Cmty. Schs. v. Seattle Sch. Dist., 294 F.3d 1085, 1086 (9th Cir. 2002).

trade-secret law is a traditional area of state regulation where there has not been a history of significant federal presence similar to patent law. Kewanee Oil, 416 U.S. at 479-93.

In order for conflict preemption to apply, there must be a real and actual conflict between the federal and state law because "[t]he existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982). Furthermore, claims of conflict preemption usually cannot be resolved on a facial challenge because conflict preemption "requires [the Court] to consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written." Rath Packing, 430 U.S. at 526. Finally, if the Court finds conflict preemption, the Court may enjoin only those applications of the state law that actually conflict with the federal law, and the Court must avoid a "blanket invalidation" that precludes valid applications of the state law. Dalton, 516 U.S. at 476-78.

Plaintiffs contend that the challenged provisions conflict with the exclusive patent rights given to manufacturers of patented diabetes drugs by federal patent laws, although Plaintiffs fail to cite or quote any specific statutory language from those laws to support their contention. (ECF No. 27 at 20-23.) The Supreme Court has stated that "[t]he grant of a patent is the grant of a statutory monopoly." Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 229 (1964). Plaintiffs argue that by giving the patent owner a statutory monopoly, the purpose and objective of Congress was to create "an incentive for innovation. The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace." King Instr. Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995). Thus, Plaintiffs argue that during the period of exclusivity, the patent owner may "charge prices of its choosing, including supracompetitive prices." King Drug Co. v. Smithkline Beecham Corp., 791 F.3d 388, 401 (3d Cir. 2015).

Plaintiffs claim that the challenged provisions conflict with the federally authorized period of

exclusivity because they "punish" manufacturers of patented diabetes drugs that experience increases in their wholesale acquisition cost as follows:

> The punishment is compelled disclosure of additional confidential pricing information and loss of trade-secret protection for that information. 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.

(ECF No. 27 at 22) (citation omitted).

As a preliminary matter, the challenged provisions apply to any diabetes drugs designated by NDHHS as essential diabetes drugs, whether or not those drugs are patented. Thus, there clearly are circumstances where the challenged provisions do not implicate federal patent laws and can operate validly without any alleged conflict under the preemption doctrine. Because those circumstances exist, the provisions cannot be declared facially unconstitutional. Wash. State Grange, 552 U.S. at 449.

Further, there is nothing in the challenged provisions that punishes manufacturers of patented diabetes drugs or restrains them from exercising their right under federal patent laws to set prices. The provisions do not place any caps or limits on the prices that may be charged for patented diabetes drugs, and the provisions do not require manufacturers to disclose trade secrets. As properly interpreted under Nevada's rules of statutory interpretation, the provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a trade secret. Plaintiffs have not pointed to any specific statutory language from the federal patent laws or any congressional purpose or objective underpinning those laws that would prohibit Nevada from requiring manufacturers of patented diabetes drugs to disclose business information that does not constitute a trade secret in order to provide its policymakers and consumers with more information about the factors contributing to the cost of diabetes

drugs, so they are better informed when developing policies regarding public health, safety and welfare.

Finally, Plaintiffs' reliance on Biotech. Indus. Org. (BIO) v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007), is wholly misplaced. In that case, the Federal Circuit held that federal patent laws preempted a D.C. law that placed *actual* price limitations on patented drugs because the law operated as an *actual* price control by expressly prohibiting manufacturers from charging excessive prices for their patented drugs and by imposing *actual* penalties for violations, including injunctions, fines, and damages. Id. at 1374. Because the challenged provisions do not operate as an *actual* price control and do not impose any *actual* penalties on manufacturers for exercising their right under federal patent laws to set prices, the decision in BIO has no application to this case. Therefore, because Plaintiffs have not established that the challenged provisions conflict with congressional purposes and objectives of the federal patent laws, Plaintiffs are not likely to succeed on the merits of their facial claims.

Plaintiffs also contend that the challenged provisions conflict with congressional purposes and objectives of the Defend Trade Secrets Act (DTSA), 18 U.S.C. §§ 1836 et seq., which Congress enacted in 2016 to create a federal private right of action for misappropriation of trade secrets. (ECF No. 27 at 24-26.) Plaintiffs argue that "SB 539 guts the trade-secret protection afforded by the federal government and every state for confidential information associated with essential diabetes drugs. This mass nullification frustrates Congress's goal in the DTSA to enhance trade-secret protections." Id. at 26.

As a preliminary matter, when Congress enacted the DTSA, it included an express anti-preemption clause which provides: "Nothing in the amendments made by this section shall be construed to . . . preempt any other provision of law." DTSA § 2(f), Pub. L. No. 114-153, 130 Stat. 376 (2016). Therefore, by including this anti-preemption clause in the federal legislation, Congress clearly expressed its intent that the DTSA should not be construed to preempt state laws. See CSX Transp. v. Easterwood, 507 U.S. 658, 664 (1993) (explaining that when Congress includes express preemption clauses in federal law, the plain language of the clauses "contains the best evidence of Congress' pre-emptive intent.");

Locke, 529 U.S. at 104-07 (interpreting anti-preemption clauses).

Further, the challenged provisions do not "gut" trade-secret protection because the provisions do not require manufacturers to disclose trade secrets. As properly interpreted under Nevada's rules of statutory interpretation, the provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a trade secret. Additionally, as already discussed, it would be unreasonable and absurd to interpret the challenged provisions as unraveling the careful balance struck by trade-secret law over the last century and a half, especially since there is nothing in the plain language or legislative history of the provisions to indicate that the Legislature intended to unwind 150 years of trade-secret law. Therefore, because Plaintiffs have not established that the challenged provisions conflict with congressional purposes and objectives of the federal trade-secret laws, Plaintiffs are not likely to succeed on the merits of their facial claims.

V. Plaintiffs are not likely to succeed on the merits of their facial claims that the challenged provisions violate the Takings Clause under all circumstances.

Plaintiffs contend that the challenged provisions constitute an unconstitutional taking of private property for public use because "SB 539 extinguishes pharmaceutical manufacturers' property interest in the confidentiality of their trade secrets and thus works a categorical taking." (ECF No. 27 at 27.) A categorical taking may occur when a state law denies all economically beneficial or productive use of *tangible* property. Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1015 (1992). Because trade secrets constitute *intangible* property, courts generally do not analyze alleged takings of trade secrets under the standards for categorical takings. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1005-14 (1984); Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 306-08 (1st Cir. 2005); Philip Morris, Inc. v. Reilly, 312 F.3d

24, 33-35 (1st Cir. 2002). Instead, courts generally analyze alleged takings of trade secrets under the standards for regulatory takings. Id.

Under those standards, it is possible for a statute to interfere with existing property rights to such a degree that the interference will be recognized as a regulatory taking. Connolly v. Pension Benefit Guar. Corp., 475 U.S. 211, 224 (1986). To determine whether a statute causes a regulatory taking, courts apply a balancing test that considers three factors: (1) the purpose of the statute and the nature of the governmental action; (2) the economic impact of the statute; and (3) the extent to which the statute interferes with reasonable investment-backed expectations. Penn Cent. Transp. Co. v. New York City, 438 U.S. 104, 124 (1978). The purpose of the statute and the nature of the governmental action are critical factors in determining whether a regulatory taking has occurred. When the statute serves legitimate and important public interests and the nature of the governmental action substantially advances those interests, a regulatory taking is less likely to be found. See Keystone Bituminous Coal Ass'n v. DeBenedictis, 480 U.S. 470, 485-93 (1987). Further, it is well established that "mere diminution in the value of property, however serious, is insufficient to demonstrate a taking." Concrete Pipe & Prods. v. Constr. Laborers Pension Trust, 508 U.S. 602, 645 (1993). A regulatory taking will occur only if the statute "goes too far." Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922).

Plaintiffs argue that SB 539 "strips trade-secret protection and *mandates* public disclosure of confidential information, eradicating trade-secret protection in other states." (ECF No. 27 at 27.) However, the challenged provisions do not strip trade-secret protection and mandate public disclosure because the provisions do not require manufacturers to disclose trade secrets. As properly interpreted under Nevada's rules of statutory interpretation, the provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business

information to NDHHS but which do not reveal information that constitutes a trade secret. Because the challenged provisions do not require manufacturers to disclose trade secrets, there is no protected property interest subject to the Takings Clause. Rowe, 429 F.3d at 308 ("Given that there are no trade secrets involved with these client contracts, there is no 'property' subject to the Takings Clause.").

Further, Nevada has legitimate and important public interests in requiring manufacturers to disclose business information that is not a trade secret in order to provide policymakers and consumers with more information about the factors contributing to the cost of diabetes drugs, so they are better informed when developing policies regarding public health, safety and welfare. Because this business information is not a trade secret, the economic impact of the challenged provisions is minimal, and the provisions do not interfere with reasonable investment-backed expectations. Because Plaintiffs have not established that the challenged provisions interfere with existing property rights to such a degree that the interference amounts to a regulatory taking, Plaintiffs are not likely to succeed on the merits of their facial claims that the challenged provisions violate the Takings Clause under all circumstances.

VI. Plaintiffs are not likely to succeed on the merits of their facial claims that the challenged provisions violate the dormant Commerce Clause under all circumstances.

Plaintiffs contend that the challenged provisions impose unreasonable burdens on interstate commerce which are excessive in relation to the potential local benefits. (ECF No. 27 at 27-31.) If the practical effects of a state law directly control commerce occurring wholly outside the state's borders, the state law may impose unreasonable burdens on interstate commerce. Healy v. Beer Inst., 491 U.S. 324, 336 (1989); Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 580-84 (1986). A state law also may impose unreasonable burdens on interstate commerce if the practical effects of the state law impose burdens that are clearly excessive in relation to the potential local benefits. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

Plaintiffs argue that the challenged provisions have an extraterritorial reach because "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." (ECF No. 27 at 29.) However, the challenged provisions do not establish a price cap because the provisions do not impose any *actual* price controls and do not impose any *actual* penalties on manufacturers for exercising their right to set whatever prices they choose. Nevada's provisions do not control the prices charged by manufacturers in Nevada or any other state. Manufacturers may set those prices as they choose, regardless of whether they disclose the necessary business information to NDHHS. Nevada's provisions simply require that if manufacturers elect to conduct business in Nevada, they must disclose the necessary business information to NDHHS. Thus, SB 539 does not have an extraterritorial reach because it "does not require out-of-state commerce to be conducted according to in-state terms. It requires only that in-state commerce be conducted according to in-state terms." Rowe, 429 F.3d at 312.

Plaintiffs also argue that "SB 539 burdens interstate commerce by eviscerating commercial rights other states grant, stripping a broad compass of trade-secret protection for *all* manufacturers of essential diabetes drugs." (ECF No. 27 at 30.) However, the challenged provisions do not strip trade-secret protection from *any* manufacturers because the provisions do not require manufacturers to disclose trade secrets. As properly interpreted under Nevada's rules of statutory interpretation, the provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a trade secret. Because Plaintiffs have not established that the challenged provisions impose unreasonable burdens on interstate commerce which are excessive in relation to the potential local benefits, Plaintiffs are not likely to succeed on the merits of their facial claims that the challenged provisions violate the dormant Commerce Clause under all circumstances.

VII. Plaintiffs cannot meet their heavy burden to prove that they are entitled to preliminary injunctive relief enjoining the challenged provisions before their full implementation and application by the state.

A preliminary injunction is an "extraordinary and drastic remedy" that is "never awarded as of right." Munaf v. Geren, 553 U.S. 674, 689-90 (2008). Because a preliminary injunction is such an extraordinary and drastic remedy, federal courts may grant a preliminary injunction to enjoin newly-enacted laws only if absolutely necessary to preserve the status quo pending further judicial review. See Winter v. Nat. Res. Def. Council, 555 U.S. 7, 20-24 (2008); Int'l Franchise Ass'n v. City of Seattle, 97 F.Supp.3d 1256, 1285-86 (W.D. Wash. 2015) (denying preliminary injunction to enjoin newly-enacted city ordinance), *aff'd*, 803 F.3d 389 (9th Cir. 2015), *cert. denied*, 136 S.Ct. 1838 (2016).

Because our democratic society is structured on the rule of law, it favors prompt implementation of new laws enacted by our elected representatives. Int'l Franchise Ass'n, 97 F.Supp.3d at 1285-86 ("The public has an interest in ensuring that laws passed by its legislative body are implemented."). Consequently, Plaintiffs must meet a heavy burden to prove that they are entitled to preliminary injunctive relief because "the need to show 'substantial and immediate irreparable injury' is especially strong when plaintiffs seek to enjoin the activity of a state or local government." Int'l Franchise Ass'n, 97 F.Supp.3d at 1285 (quoting Hodgers-Durgin v. de la Vina, 199 F.3d 1037, 1042 (9th Cir. 1999)). As stated by the Ninth Circuit, "[t]he Supreme Court has repeatedly cautioned that, absent a threat of immediate and irreparable harm, the federal courts should not enjoin a state to conduct its business in a particular way." Hodgers-Durgin, 199 F.3d at 1042.

Therefore, to meet their heavy burden, Plaintiffs may not rely on a minimal showing of a mere possibility of irreparable harm because "[i]ssuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Winter, 555 U.S. at 22. As a result, unless Plaintiffs can make a clear showing that they face substantial and

immediate irreparable harm from the challenged provisions, preliminary injunctive relief must be denied because "a preliminary injunction will not be issued simply to prevent the possibility of some remote future injury." Winter, 555 U.S. at 22.

Finally, in weighing the public interests at stake, the public has a substantial interest in ensuring that newly-enacted laws are promptly implemented without interruption or delay. Int'l Franchise Ass'n, 97 F.Supp.3d at 1285-86. When prompt implementation of newly-enacted laws is enjoined by a preliminary injunction, the injunction actually disturbs the status quo because in our democratic society which is structured on the rule of law, the status quo is that laws should be implemented not enjoined. Id. ("[C]ontrary to plaintiffs' contentions, granting injunctive relief would not maintain the status quo. Here, the status quo is the Ordinance, which the citizens of Seattle expect to go into effect."). Therefore, Plaintiffs must meet a heavy burden to prove that they are entitled to preliminary injunctive relief enjoining the challenged provisions before their full implementation and application by the state.

Plaintiffs cannot meet their heavy burden. Because the affected manufacturers do not have to file their first reports until July 1, 2018, Plaintiffs are not likely to suffer substantial and immediate irreparable harm from the challenged provisions before their implementation by the state. Further, the public interest would be best served by allowing NDHHS to adopt the necessary regulations to implement the newly-enacted laws. Under such circumstances, Plaintiffs have not made a clear showing that they are entitled to preliminary injunctive relief.

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CONCLUSION

Based upon the foregoing, the Legislature respectfully asks the Court to deny Plaintiffs' motion for preliminary injunction (ECF No. 27).

DATED: This **1st** day of October, 2017.

Respectfully submitted,

BRENDA J. ERDOES
Legislative Counsel

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CERTIFICATE OF SERVICE

I hereby certify that I am an employee of the Nevada Legislative Counsel Bureau, Legal Division, and that on the **1st** day of October, 2017, pursuant to FRCP 5(b) and Local Rule Part IC, I filed and served a true and correct copy of Nevada Legislature's Opposition to Plaintiffs' Motion for Preliminary Injunction, by using the Court's CM/ECF system. I further certify that service will be accomplished electronically by the CM/ECF system directed to the following:

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INDEX OF EXHIBITS TO NEVADA LEGISLATURE'S OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Exhibit No.	Description of Exhibits
1	Hearing SB 539 Sen. Comm. Health & Human Servs., 79th Leg., (Nev. May 26, 2017).
2	Hearing SB 265 Sen. Comm. Health & Human Servs., 79th Leg., (Nev. May 3, 2017).

Nevada Legislature's Opposition to Plaintiffs' Motion For Preliminary Injunction

Legislature Exhibit 1—

Hearing SB 539 Sen. Comm. Health & Human Servs., 79th Leg., (Nev. May 26, 2017)

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

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 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

Nevada Legislature's Opposition to Plaintiffs' Motion For Preliminary Injunction

Legislature Exhibit 2—

Hearing SB 265 Sen. Comm. Health & Human Servs., 79th Leg. (Nev. May 3, 2017)

MINUTES OF THE
SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES

Seventy-ninth Session
May 3, 2017

The Senate Committee on Health and Human Services was called to order by Chair Pat Spearman at 3:37 p.m. on Wednesday, May 3, 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 Yvanna D. Cancela, Senatorial District No. 10
Assemblywoman Amber Joiner, Assembly District No. 24
Assemblyman James Oscarson, Assembly District No. 36
Assemblywoman Melissa Woodbury, Assembly District No. 23

STAFF MEMBERS PRESENT:

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

OTHERS PRESENT:

Steven L. Phillips, M.D., Treasurer, Nevada Physician Order for Life-Sustaining Treatment; President, Geriatric Specialty Care
Catherine O'Mara, Nevada State Medical Association
Barry Gold, AARP Nevada

Michael Hackett, Nevada Academy of Physician Assistants; Nevada Public Health Association; Nevada Primary Care Association
Chelsea Capurro, Nevada Advance Practice Nurses Association; Health Services Coalition
Brooke Maylath, President, Transgender Allies Group
Jared Busker, Children's Advocacy Alliance
Jon Sasser, Legal Aid Center of Southern Nevada
Shannon Sprout, Deputy Administrator, Division of Health Care Financing and Policy, Department of Health and Human Services
Ryan Beaman, Clark County Firefighters Local 1908
Regan Comis, Nevada Association of Health Plans
Jan Crandy
Brian Patchett, CEO, Easter Seals Nevada
Stephanie Hill
Edward Ableser, Administrator, Aging and Disability Services Division, Department of Health and Human Services
George Ross, Hospital Corporation of America, Inc.; Touro University; Las Vegas HEALS
Bill Welch, Nevada Hospital Association
Paul Moradkhan, Las Vegas Metro Chamber of Commerce
Kelly Crompton, City of Las Vegas
Lisa Foster, State of Nevada Association of Providers
Mary Liveratti
Katherine Ryder, Director, A Team NV, Advocacy, Awareness, Advisement
Barbara Paulson, Nevadans for the Common Good
Jeffrey Klein, Chair, Legislative Subcommittee, Nevada Commission on Aging; President, Nevada Senior Services
Sam Lieberman, Easter Seals Nevada
Nancy Brune, Executive Director, Guinn Center for Policy Priorities
Ed Guthrie, Opportunity Village
Marta Jensen, Acting Administrator, Division of Health Care Financing and Policy, Department of Health and Human Services
John Yacenda, President, Nevada Silver Haired Legislative Forum

CHAIR SPEARMAN:
I will open the work session on Senate Bill (S.B.) 265.

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

MEGAN COMLOSSY (Policy Analyst):
Senate Bill 265 was heard in Committee on March 29, as noted in the work session document (Exhibit C). The bill makes various changes related to prescription drugs. It requires the Department of Health and Human Services (DHHS) to identify essential prescription drugs for the treatment of diabetes; requires manufacturers of these drugs to submit information related to costs and to reimburse purchasers of those drugs if costs increase more than a certain amount each year; and requires that insurers are notified of imminent cost increases, among other things. The bill also requires pharmaceutical sales representatives to be licensed and report certain information annually. It authorizes students who attend private school, as well as certain employees, to self-administer medication for certain conditions, including diabetes.

Proposed Amendment 3888 to S.B. 265 is attached to the work session document and was proposed following the bill hearing.

SENATOR YVANNA D. CANCELA (Senatorial District No. 10):
The amendment clarifies language to ensure the changes can be properly enacted. The bulk of section 6 has been deleted, namely the language requiring a refund to be processed and returned to the consumer. Some language was challenged. Based on a recommendation from the Legislative Counsel Bureau, the language causing concern has been removed because there may be a conflict with the federal Commerce Clause. I kept the language allowing the Department of Health and Human Services to determine the total cost and development of essential diabetes drugs because it is the core of the bill.

Section 7 copies the transparency language from Assembly Bill (A.B.) 215.

ASSEMBLY BILL 215: Requires the reporting of certain information relating to prescription drugs. (BDR 57-284)

This language in S.B. 265 has broadened. Section 7, subsection 1, paragraph (a) addresses research and development language; paragraph (b) addresses the cost of producing the drug; paragraph (c) is the administrative cost and marketing; paragraph (d) is profit from the drug plus the overall profit from the drug to the manufacturer; paragraph (e) addresses the financial assistance provided by the manufacturer; paragraph (f) addresses the cost of coupons provided directly to consumers and the cost attributable to the redemption of those coupons to the manufacturer; paragraph (g) addresses the

wholesale acquisition of the drug; paragraph (h) addresses the history of increases in cost of the drug; paragraph (k) gives the DHHS discretion to require any additional information in order to create a proper report on drug pricing.

Section 7, subsection 2, indicates the report will go online on or before June 1 of each year.

Section 8 deals with the 90-day notification for price increases. This notification will now be given to the Department of Health and Human Services.

Section 9 addresses the nonprofit disclosure. This language has been significantly cleaned up to ensure we are capturing the correct information. Originally, we addressed only manufacturers and now it also includes contributions from trade groups, payments and donations. The section also addresses how the information should be posted on the nonprofit's Website.

Section 12 indicates all of the transparency language as well as the nonprofit disclosure which will be posted online on the DHHS Website.

Section 13 ensures the DHHS is not liable for inaccurate information.

Section 14 addresses the appropriate language for the DHHS to enact regulations to implement these provisions.

Sections 18 through 24 deal with the licensing of a pharmaceutical sales representative to be clear regarding what the pharmaceutical representative will be licensed for and what the licensing process will entail. It also allows for the DHHS to create such regulations. The deleted language references penalties and the disciplinary actions in the original bill.

Section 23 outlines what will be included in the annual report provided by the pharmaceutical representatives; specifically, a list of providers of health care whom the pharmaceutical representatives contacted. The application requests the name and manufacturer of each drug and each provider of health care to whom the pharmaceutical representative provided compensation, including gifts, food or free supplies and the values of such compensation.

Section 24 references business registration and whether or not the pharmaceutical representatives have a current registration.

Section 25 has been deleted.

Section 27 previously identified employers and schools regarding the self-administration of insulin. This section is now limited to schools to ensure we cover public, private and charter schools.

Section 30 leaves in language to ensure individuals are given notice as to whether or not the drugs that are on the list compiled by the DHHS will be removed from the formulary. The intent of the language is for those individuals shopping for individual policies to be made aware of the drugs that will or will not be on the formulary.

Section 44.5 outlines the dates for each provision of the bill to be enacted. Specifically, on November 1, the first list of drugs compiled by the Department of Health and Human Services will be complete and posted on the Website. On July 1, 2018 the Department will work with the manufacturers to ensure reports are submitted for any drug on the formulary. The first analysis from the Department will be provided on or before September 1, 2018. Section 45 clarifies that the act becomes effective on passage and approval of S.B. 265 and when the regulations need to be enacted.

While the rewrite in section 6 is in regard to the refund portion of the bill, there were some issues. I am still hopeful there is a process by which a refund can be created. I am looking at different options, but I am not prepared to present any to the Committee today.

SENATOR HARDY:
How is this bill going to decrease the cost to the consumer?

SENATOR CANCELA:
I sincerely believe increased transparency leads to decreased costs. When consumers have more information, they are able to make better decisions. We, as policymakers, can enact laws based on where we identify problems in the system if we have the data. I am confident, while this may not have a direct provision to return money to the consumer, it will provide us with the tools to make decisions about drug costs.

SENATOR HARDY:
If I were a manufacturer, I would ask the language to be broadened to include pharmacy benefit managers, retailers and wholesalers so there is more transparency. As the discount gets shared, it gets bigger and bigger. The bigger the start, the more percentage there is in dollars. I would like to see even more transparency than what is already written into the bill. I will be voting no today with a firm resolve to vote for the bill on the Senate Floor because I think it will be a good bill.

SENATOR HAMMOND:
When I first read the bill and heard testimony, I was sure there would not be enough time to process it during this Session. This is a huge issue that I felt warranted more time. There are numerous stakeholders and many moving parts. I found out there were provisions needing to be deleted and some provisions that could not be accomplished. When people came to talk to me about the bill, I said it might be something to look at again during the Interim. When people talked to me about the bill, it was in regard to the price caps. I did not want Nevada to be the state that put caps on pricing. It was not necessarily about the price caps but about all of us who are consumers who must understand the process. In the end, we want the price savings to be passed along to the consumer. We need to shine light on the entire process so the consumer is the winner but go a little bit further. Is that what you are still working toward?

SENATOR CANCELA:
When I first started working on this bill I asked for input from the stakeholders. Unfortunately, I received very little feedback, and the discussions are just now beginning. The problem begins at the top with the manufacturer. Every other cog in the system reacts to the price-setting behavior of the manufacturer. We only have 33 days left in the Session, and I want to make sure the bill will move as it has the potential to help so many people.

SENATOR HAMMOND:
Once we shine a light on this subject, we should be able to identify the difficulties. I want to vote yes today with a firm resolve to vote yes on the Senate Floor. I want us to make sure we have transparency on every level of the chain from the manufacturer down, so the consumer wins. The consumer needs to be getting the savings, rebates and refunds.

SENATOR CANCELA:
I am still open to having these conversations, but I am also aware of the politicking taking place around the Country on this issue which ends up with finger-pointing and inaction. I am not interested in ending this the same way. I want to make sure we do everything possible to vote out a good bill. I know the starting point is with the manufacturers, and that is my direction for the bill.

SENATOR HAMMOND:
We are on the same page. With the data being made available on the Internet, it will allow the consumer to make his or her own decision.

CHAIR SPEARMAN:
We are trying to get this language right for the consumers so someone who needs lifesaving drugs can afford those drugs, can afford to eat, can afford to pay their rent or mortgage and can afford to buy things for their children.

SENATOR RATTI:
I was a yes at the end of the hearing. I am a yes today. I am pretty sure I will be a yes when this bill comes to the Senate Floor for a vote. There is really good policy in this bill. I think if the bill passes in its current form, we would be making a huge difference with the families who are drowning by an escalation of drugs costs. It is not about blame or pointing fingers, it is about concrete things we can do to address a piece of this problem. I would not hold up the bill to make sure we address other pieces; I would be pushing this bill forward to ensure we are addressing the issues with good policy. I hope when we get to the Senate Floor vote, there is a way to get price management back into the bill without violating the Commerce Clause. Families with diabetes can no longer wait for the perfect solution. We need to provide a solution for these families, and we need it soon. I look forward to supporting the bill when it comes to the Senate Floor for a vote.

SENATOR WOODHOUSE:
You have made some great strides with the subject matter in this bill. Whether we can make anything further happen this Session, we will see; if not, we will continue to move forward. I was a yes after the hearing, I am a yes today, and I will be a yes on the Senate Floor.

CHAIR SPEARMAN:
I want to go back to something you said about the Commerce Clause and the refund. I was troubled about something I heard in the Senate Commerce, Labor and Energy Committee this morning when someone was testifying about changing formularies and costs in the middle of a plan. The numbers the person provided was one drug with a cost of $700. By looking for something else that was comparable, they found a new cost of $1. Another drug was $84,000 a year or something like $2,000 a pill. I am hoping that everyone who has a stake in this bill will at least come and talk to you as the sponsor.

I have heard pharmaceutical companies provide coupons with many of them being available online. I have also heard not everyone has a computer or the availability to access one. Of the people who need this help, most are senior citizens. If these people do not have a computer, they do not have access to the information proposed to be online. Even people who have a computer may not know to go online to look for coupons or discounts for their drugs.

I support the bill but wondered if you would be amenable to discussing a price reduction, for a period of time, to equal the amount being offered in coupons. There is usually some sort of actuarial formula to allow the printing of $50 million worth of coupons and expect about half of them to be redeemed. Is there a way to reduce the cost of the drug to the equivalent of the discount in regard to the coupons? I do not even know if this could happen, but if a coupon reduces the cost of a drug, that tells me in the business process and marketing there is a formula to deduct a certain amount from the cost of the drug.

SENATOR CANCELA:
I would be open to looking into that option as a possibility with the help of the Legislative Counsel Bureau.

SENATOR HAMMOND:
From your questions it sounds like you are asking about the pharmacy benefit managers. That was the testimony I heard from listening to the Committee hearing this morning.

CHAIR SPEARMAN:
I am talking about the manufacturers which Senator Cancela said were the catalysts, and everything else is responding to the catalyst. With that being the case, the catalyst indicated they had coupons available. Instead of expecting

someone to go online because the business process includes the deduction if everyone cashes in, then why not provide the same reduction as the coupons?

SENATOR HAMMOND:
When I was listening this morning, those people who were against the bill were the pharmacy benefit managers who receive some of those rebates also. It is important to review the whole supply chain.

CHAIR SPEARMAN:
Everyone is responding to the catalyst, and that is what I want to address.

SENATOR RATTI MOVED TO AMEND AND DO PASS AS AMENDED S.B. 265.

SENATOR WOODHOUSE SECONDED THE MOTION.

THE MOTION PASSED. (SENATOR HARDY VOTED NO.)

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I will open the hearing on Assembly Bill 199.

ASSEMBLY BILL 199 (1st Reprint): Revises provisions relating to end-of-life care. (BDR 40-813)

ASSEMBLYWOMAN MELISSA WOODBURY (Assembly District No. 23):
I was happy to work on the language for this bill with Sally Hardwick, Chair, Nevada Physician Order for Life-Sustaining Treatment, but she could not be here to testify today.

Assembly Bill 199 makes various changes to the Physician Order for Life-Sustaining Treatment or POLST as a result of issues raised through the Interim Legislative Committee on Health Care. The POLST was first established in *Nevada Revised Statutes* (NRS) in 2013 when the Legislature unanimously passed A.B. No. 344 of the 77th Session. The bill before you aims to update the POLST process to conform with national practices. The POLST is a medical order that indicates the types of medical treatment a patient wishes to receive toward the end of life, giving terminally ill patients more control over their end-of-life care.

TAB 4

TAB 4

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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

DEFENDANT NEVADA LEGISLATURE'S MOTION FOR SUMMARY JUDGMENT

ORAL ARGUMENT REQUESTED

MOTION

Defendant Nevada Legislature (Legislature), by and through its counsel the Legal Division of the Legislative Counsel Bureau (LCB), hereby files its motion for summary judgment on all of Plaintiffs' constitutional claims challenging the facial validity of specific provisions of Senate Bill No. 539 (hereafter the "challenged provisions"). SB 539, 2017 Nev. Stat., ch. 592, §§ 3.6, 3.8, 4, 4.3, 6, 7, 8 & 9, at 4297-4307. The Legislature's motion for summary judgment is made under FRCP 56 and is based upon the following Memorandum of Points and Authorities, all pleadings, documents and exhibits on file in this case and any oral arguments the Court may allow. The Legislature's motion for summary judgment is being filed in conjunction with the Legislature's motion to consolidate the hearing on the summary-judgment motion with the hearing on Plaintiffs' motion for preliminary injunction (ECF No. 27), which is scheduled for October 17, 2017.[1]

The Legislature respectfully asks the Court to grant the Legislature's motion for summary judgment and enter final judgment in favor of Defendants on all causes of action and claims for relief alleged in Plaintiffs' complaint because: (1) Plaintiffs' facial claims present only pure issues of law that require no factual development, so there are no genuine issues or disputes as to any material fact; and (2) the challenged provisions are constitutional on their face, so Defendants are entitled to summary judgment on the facial claims as a matter of law.[2]

As properly interpreted under Nevada's rules of statutory interpretation, the challenged provisions do not require manufacturers to disclose trade secrets. Consequently, because Plaintiffs' facial claims

[1] Before filing its motion to consolidate, the Legislature will confer with the other parties to determine whether they are willing to stipulate to consolidate the hearings.

[2] It is well settled that if a plaintiff's claims fail as a matter of law on a motion for summary judgment, all defendants are entitled to a final judgment in their favor on those claims, regardless of whether they joined in the motion. See Lewis v. Lynn, 236 F.3d 766, 768 (5th Cir. 2001); True the Vote v. Hosemann, 43 F.Supp.3d 693, 708 n.59 (S.D. Miss. 2014).

are all based on their incorrect statutory interpretation that the challenged provisions require manufacturers to disclose trade secrets, Plaintiffs cannot prove the merits of their facial claims as a matter of law. Therefore, the challenged provisions are constitutional on their face, and Defendants are entitled to summary judgment as a matter of law.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

Because Plaintiffs have directed their constitutional claims only at the challenged provisions and not at SB 539 in its entirety, the constitutional review in this case is limited to the challenged provisions, and the Court should ensure that the remaining provisions of SB 539 are not affected by this case. See Dalton v. Little Rock Family Planning Servs., 516 U.S. 474, 476 (1996) (explaining that federal court's constitutional review should not extend "further than necessary to dispose of the case before it.").

In reviewing Plaintiffs' constitutional claims, the Court should be guided by several fundamental principles of constitutional review. First, because "[s]tate statutes, like federal ones, are entitled to the presumption of constitutionality until their invalidity is judicially declared," Davies Warehouse Co. v. Bowles, 321 U.S. 144, 153 (1944), the Court must "start therefore with a presumption that the state statute is valid and ask whether [Plaintiffs have] shouldered the burden of overcoming that presumption." Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 661-62 (2003) (plurality op.) (citation omitted). Second, because Plaintiffs are attacking the validity of the provisions before they have been implemented and applied by the state, their constitutional claims can be based only on the facial validity of the challenged provisions and cannot be based on the potential effects or consequences of those provisions as applied to any particular manufacturer. See Wash. State Grange v. Wash. State Republican Party, 552 U.S. 442, 449-50 (2008) (explaining that state statutes can be challenged only on facial grounds when the state has had no opportunity to implement and apply those statutes). As a result, "[i]n determining whether a law is facially invalid, [the Court] must be careful not to go beyond

the statute's facial requirements and speculate about 'hypothetical' or 'imaginary' cases." Id. Moreover, a facial challenge is the most difficult constitutional challenge to mount successfully because Plaintiffs must establish that there are no circumstances under which the challenged provisions can operate constitutionally. Id. at 449-51.

On a motion for summary judgment, Defendants are entitled to summary judgment on Plaintiffs' facial claims if Defendants show that there are no genuine issues or disputes as to any material fact and they are entitled to judgment as a matter of law. FRCP 56; Village of Schaumburg v. Citizens for Better Env't, 444 U.S. 620, 634-35 (1980) (affirming summary judgment on facial challenge and noting that such a challenge was "a question of law" that involved no factual disputes). Thus, Plaintiffs' facial claims may be resolved on summary judgment because the facial claims present only pure issues of law that require no factual development. Id.; Freedom to Travel Campaign v. Newcomb, 82 F.3d 1431, 1435 (9th Cir. 1996) (explaining that facial claims may be resolved on summary judgment because they "are pure questions of law that require no factual development.").[3] As a result, because there are no factual issues to be decided by the Court, Plaintiffs' facial claims do not present any genuine issues or disputes as to any material fact, and the Court must resolve Plaintiffs' facial claims as a matter of law.

The first step in reviewing Plaintiffs' facial claims is to interpret the challenged provisions under Nevada's rules of statutory interpretation to determine their plain meaning and intent. Under Nevada's rules, the interpretation of the challenged provisions is a pure issue of law. MGM Mirage v. Nev. Ins. Guar. Ass'n, 209 P.3d 766, 768 (Nev. 2009). In applying Nevada's rules, the Court must "construe the

[3] See also United Youth Careers v. City of Ames, 412 F.Supp.2d 994, 1000 (S.D. Iowa 2006) ("[T]he only question to be determined at this juncture is whether Defendant's ordinance is facially unconstitutional, as alleged by the Plaintiffs. As this question is a purely legal one, summary judgment review is particularly appropriate."); Gospel Missions of Am. v. Bennett, 951 F.Supp. 1429, 1439 (C.D. Cal. 1997) ("The facial invalidity of the City and County ordinances is a question of law properly determined by the Court. Accordingly, the Court may rule on the merits of Plaintiffs' facial challenge to the constitutionality of the City and County ordinances pursuant to FRCP 56.").

[provisions] narrowly and resolve any ambiguities in favor of the interpretation that most clearly supports constitutionality." S.D. Myers, Inc. v. City of San Francisco, 253 F.3d 461, 468 (9th Cir. 2001). Plaintiffs' facial claims are all based on their overly broad interpretation that the challenged provisions require manufacturers to disclose trade secrets. However, the plain language and legislative history of the challenged provisions—along with reason and public policy—amply demonstrate that the provisions are much narrower in scope and do not require manufacturers to disclose trade secrets. Because this reasonable and plausible interpretation of the challenged provisions alleviates any constitutional doubts regarding the validity of the provisions, the Court must adopt this interpretation because "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." Hooper v. California, 155 U.S. 648, 657 (1895). Consequently, because Plaintiffs' facial claims are all based on their incorrect statutory interpretation that the challenged provisions require manufacturers to disclose trade secrets, Plaintiffs cannot prove the merits of their facial claims as a matter of law.

Furthermore, because facial challenges require unconstitutionality *under all circumstances*, Plaintiffs cannot prove the merits of their facial claims as a matter of law because there are circumstances under which the challenged provisions can operate constitutionally. Plaintiffs also cannot prove the merits of their facial claims as a matter of law because: (1) the challenged provisions do not conflict with any congressional purposes and objectives of the federal patent laws or federal trade-secret laws in violation of the Supremacy Clause; (2) the challenged provisions do not interfere with existing property rights to such a degree that the interference amounts to a regulatory taking in violation of the Takings Clause; and (3) the challenged provisions do not impose unreasonable burdens on interstate commerce which are excessive in relation to the potential local benefits in violation of the Commerce Clause. Therefore, because the challenged provisions are constitutional on their face, Defendants are entitled to summary judgment as a matter of law.

II. Statement that there are no genuine issues or disputes as to any material fact.

Under Local Rule 56-1, motions for summary judgment must include a concise statement setting forth each fact material to the disposition of the motion that the party claims is or is not genuinely in issue or dispute. However, as discussed already, Plaintiffs' facial claims present only pure issues of law that require no factual development. Consequently, because there are no factual issues to be decided by the Court, Plaintiffs' facial claims do not present any genuine issues or disputes as to any material fact, and the Court must resolve Plaintiffs' facial claims as a matter of law. Citizens for Better Env't, 444 U.S. at 634-35; Freedom to Travel Campaign, 82 F.3d at 1435.

III. Overview of the challenged provisions of SB 539.

The challenged provisions establish a reporting system that requires certain manufacturers of diabetes drugs to provide the Nevada Department of Health and Human Services (NDHHS) with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs. SB 539, 2017 Nev. Stat., ch. 592, §§ 3.6, 3.8, 4, 4.3, 6, 7, 8 & 9, at 4297-4307. In particular, manufacturers with diabetes drugs on the essential-drugs list must provide NDHHS with a report containing business information relating to: (1) the costs of producing and selling the drugs; (2) the profits earned from the drugs; (3) the costs of certain patient assistance programs, coupons or rebates associated with the drugs; (4) the history of increases in wholesale acquisition costs of the drugs; and (5) any other data that NDHHS prescribes by regulation to analyze the costs of the drugs, trends in those costs and rebates available for the drugs. Id. § 3.8, at 4297-98. Additionally, if diabetes drugs on the essential-drugs list have been subject to certain increases in their wholesale acquisition cost, manufacturers must provide NDHHS with a report describing the reasons for the increase, including: (1) each factor that has contributed to the increase; (2) the percentage of the total increase that is attributable to each factor; (3) an explanation of the role of each factor in the increase; and (4) any other information that NDHHS prescribes by regulation. Id. § 4, at 4298. The challenged provisions

generally become effective on October 1, 2017. Id. § 28, at 4310. However, SB 539 contains a transitory section that adjusts the reporting deadlines for the first reporting period, so the affected manufacturers do not have to file their first reports until July 1, 2018. Id. § 26.9, at 4309-10.

IV. Based on the plain language and legislative history of the challenged provisions—along with reason and public policy—the challenged provisions do not require manufacturers to disclose trade secrets.

The first step in reviewing Plaintiffs' facial claims is to interpret the challenged provisions because "it is impossible to determine whether a statute reaches too far without first knowing what the statute covers." United States v. Williams, 553 U.S. 285, 293 (2008). In interpreting the challenged provisions, the Court "looks to Nevada rules of statutory construction to determine the meaning of a Nevada statute." 7912 Limbwood Ct. Trust v. Wells Fargo Bank, 979 F.Supp.2d 1142, 1147 (D. Nev. 2013). Under those rules, the interpretation of the challenged provisions is a pure question of law because the meaning of the provisions is not dependent upon and must be resolved without reference to any particular facts or circumstances. MGM Mirage, 209 P.3d at 768; Sheriff v. Encoe, 885 P.2d 596, 598 (Nev. 1994) ("The proper construction of a statute is a legal question rather than a factual question."); Beavers v. State Dep't Mtr. Vehs., 851 P.2d 432, 434 n.1 (Nev 1993) ("A 'pure legal question' is a question that is not dependent upon, and must necessarily be resolved without reference to any fact in the case before the court. An example of a pure legal question might be a challenge to the facial validity of a statute.").

Plaintiffs' facial claims are all based on their incorrect statutory interpretation that "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." (ECF No. 1 at 2; ECF No. 27 at 10.) However, as properly interpreted under Nevada's rules of statutory interpretation, the challenged provisions do not require manufacturers to disclose trade secrets. Consequently, because Plaintiffs' facial claims are all based on their incorrect

statutory interpretation that the challenged provisions require manufacturers to disclose trade secrets, Plaintiffs cannot prove the merits of their facial claims as a matter of law, and Defendants are entitled to summary judgment as a matter of law.

Under Nevada's rules of statutory interpretation, courts will usually give a statute "its plain meaning, unless doing so violates the spirit of the act or produces absurd or unreasonable results." L.V. Police Prot. Ass'n v. Dist. Ct., 130 P.3d 182, 191 (Nev. 2006) (internal quotations and footnotes omitted). Thus, in most cases "[w]hen the Legislature's intent is clear from the plain language, [courts] will give effect to such intention and construe the statute's language to effectuate rather than nullify its manifest purpose." We the People Nev. v. Miller, 192 P.3d 1166, 1170-71 (Nev. 2008). By contrast, when "the statute's apparent plain meaning results in a meaning that runs counter to the 'spirit' of the statute, [courts] may look outside the statute's language." MGM Mirage, 209 P.3d at 769-70. Under such circumstances, courts "adhere to the rule of statutory construction that the intent of a statute will prevail over the literal sense of its words." Id. (quoting Universal Elec. v. State Labor Comm'r, 847 P.2d 1372, 1374 (Nev. 1993)).

Additionally, when the statute is ambiguous or otherwise does not speak to the issue in question, courts will "look to reason and public policy to determine what the Legislature intended." PEBP v. L.V. Metro. Police Dep't, 179 P.3d 542, 548 (Nev. 2008). In making this inquiry, courts will examine "the statute's historical background and spirit" and the circumstances which prompted the Legislature to enact the statute. Id. Courts will also consider the practical effects and consequences of each possible interpretation and will strive to avoid interpretations which lead to unreasonable or absurd results. Nev. Tax Comm'n v. Bernhard, 683 P.2d 21, 23 (Nev. 1984). The goal of this inquiry is to adopt an interpretation that best captures the Legislature's objective in enacting the statute without violating the statute's underlying spirit or purpose. Nev. Mining Ass'n v. Erdoes, 26 P.3d 753, 757 (Nev. 2001).

Finally, when one possible interpretation of the statute would raise serious constitutional problems, courts will generally reject that interpretation if it is fairly possible to construe the statute in an alternative manner that avoids the constitutional problems. Sheriff v. Wu, 708 P.2d 305, 306 (Nev. 1985). This rule is paramount to all other rules of statutory interpretation because the duty of courts to save the statute from an unconstitutional interpretation is derived from the separation of powers which—out of respect for a coequal branch of government whose legislative members also take an oath to uphold the Constitution—requires courts to presume the Legislature "legislates in the light of constitutional limitations." Rust v. Sullivan, 500 U.S. 173, 191 (1991). Therefore, based on the separation of powers, courts must adopt any reasonable interpretation which will save the statute from unconstitutionality. Id. at 190; Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Const. Trades Council, 485 U.S. 568, 574-75 (1988); Illinois v. Krull, 480 U.S. 340, 351 (1987).

Plaintiffs' facial claims are all based on the flawed premise that the only way manufacturers will be able to comply with the challenged provisions is to disclose "confidential, competitively sensitive, proprietary information regarding the production, cost, pricing, marketing, and advertising of their patented diabetes medicines." (ECF No. 1 at 2; ECF No. 27 at 10.) Although, on its face, the plain language of the challenged provisions clearly requires manufacturers to provide NDHHS with certain business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs, there is nothing in the plain language that requires manufacturers to satisfy their disclosure requirements by providing "confidential, competitively sensitive, proprietary information" that constitutes a *trade secret*. See SB 539, 2017 Nev. Stat., ch. 592, §§ 3.8-4, at 4297-98. Therefore, based on the plain language of the challenged provisions, manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a *trade secret*. See Littlejohn v. Bic Corp., 851 F.2d 673, 685 (3d Cir. 1988) (explaining that "non-trade secret but confidential business

information is not entitled to the same level of protection from disclosure as trade secret information."); Hammock v. Hoffmann-LaRoche, Inc., 662 A.2d 546, 560 (N.J. 1995) ("Confidential information and proprietary information are not entitled to the same level of protection from disclosure as trade secret information."); ICG Commc'ns v. Allegiance Telecom, 211 F.R.D. 610, 614 (N.D. Cal. 2002) ("Other confidential business information is generally afforded even less protection than trade secrets.").

Courts have recognized that "[t]he traditional form of confidential commercial information that militates against disclosure is the existence of trade secrets where disclosure would create a sufficient threat of irreparable harm." Mine Safety Appliances v. N. River Ins., 73 F.Supp.3d 544, 560 (W.D. Pa. 2014). However, confidential business information that does not rise to the level of a trade secret is not entitled to the same level of protection from disclosure as a trade secret. Id. As a result, the mere fact that a business has deemed its business information to be confidential does not mean that the confidential business information is entitled to protection as a trade secret. Id. Rather, to be entitled to trade-secret protection, the confidential business information must meet the legal standards for trade secrets "under the substantive law." Id.

Nevada, like most other states, has adopted the Uniform Trade Secrets Act (UTSA) to protect information that constitutes a trade secret. NRS 600A.010 et seq. Under the UTSA, "[w]hether information is a trade secret generally is a question of fact." Finkel v. Cashman Prof'l, 270 P.3d 1259, 1264 (Nev. 2012). Because the determination of trade-secret status is generally a question of fact, no specific category of information—such as pricing information—receives trade-secret protection automatically as a matter of law. IKON Office Solutions v. Am. Office Prods., 178 F.Supp.2d 1154, 1169-70 (D. Or. 2001) ("Although pricing information and marketing strategy can be a trade secret, IKON has not directed the court's attention to any materials of this nature that truly warrant protection as a trade secret, as opposed to general business knowledge."), *aff'd*, 61 F.App'x 378 (9th Cir. 2003). As a result, not all business information regarding the production, cost, pricing, marketing and

advertising of goods or services constitutes a trade secret. Frantz v. Johnson, 999 P.2d 351, 359 (Nev. 2000) ("We emphasize that not every customer and pricing list will be protected as a trade secret."); Cambridge Filter Corp. v. Int'l Filter Co., 548 F.Supp. 1301, 1306 (D. Nev. 1982) ("[A]n efficient method of computing costs or pricing is not a trade secret unless it utilizes improved or secret factors."); Camp Creek Hospitality Inns v. Sheraton Franchise Corp., 139 F.3d 1396, 1411 n.25 (11th Cir. 1998) ("We are cognizant of the fact that not all confidential information rises to the level of a trade secret.").[4]

For example, in a case interpreting the UTSA, the Nevada Supreme Court held that pricing information submitted by a hospital to NDHHS under state law, which included the hospital's "listing of discounts given to various preferred provider organizations," did not constitute a trade secret. Neal v. Griepentrog, 837 P.2d 432, 435 (Nev. 1992). In another case, although a drug manufacturer's cost of producing a drug was found to be a trade secret under the facts, the federal district court concluded that a competitor did not misappropriate the trade secret because the competitor's knowledge of the "production cost would be useless as a practical matter without sufficient detail to enable [the competitor] to know what costs were included or excluded from the figure." Microbix Biosystems v. Biowhittaker, Inc., 172 F.Supp.2d 665, 679 (D. Md. 2000).

Therefore, because not all business information regarding the production, cost, pricing, marketing and advertising of goods or services constitutes trade-secret information, the plain language of the challenged provisions does not, on its face, require manufacturers to disclose trade secrets. Furthermore, to the extent that manufacturers believe they cannot satisfy their disclosure requirements without

[4] See also W. Med. Consultants v. Johnson, 80 F.3d 1331, 1337 (9th Cir. 1996) (marketing plans and specialized customer information were not trade secrets under facts); Progressive Prod. v. Swartz, 258 P.3d 969, 978 (Kan. 2011) (pricing information was not trade secret under facts where "[p]rices were available to customers."); Optic Graphics v. Agee, 591 A.2d 578, 585-87 (Md. Ct. App. 1991) (pricing information and marketing strategy were not trade secrets under facts); CDC Restoration & Const. v. Tradesmen Contractors, 274 P.3d 317, 324 (Utah Ct. App. 2012); (pricing information was not trade secret under facts).

revealing trade-secret information, manufacturers may enter into confidentiality agreements with NDHHS to provide the trade-secret information confidentially to the agency without losing its protected trade-secret status. See SB 539, 2017 Nev. Stat., ch. 592, § 7, at 4302-03 (authorizing NDHHS to adopt regulations prescribing the "form and manner" in which manufacturers are to provide the necessary information to NDHHS); NRS 600A.070(5) (recognizing that trade secrets may be protected by "[a]llowing the owner of the trade secret to obtain a signed agreement of confidentiality from any party who obtains knowledge of the trade secret.").

It is well settled that the UTSA "does not purport to limit or override an express contractual arrangement governing the confidential exchange of proprietary information." Nilssen v. Motorola, Inc., 963 F.Supp. 664, 680 (N.D. Ill. 1997). Therefore, "because a confidentiality agreement is a valid contract enforceable according to its terms . . . a contract that defines the degree of confidentiality among the parties also serves to establish—and to define—the duty of confidentiality" among the parties under the UTSA. Id.; Roton Barrier, Inc. v. Stanley Works, 79 F.3d 1112, 1118 (Fed. Cir. 1996) ("As a result of the Confidentiality Agreement, any trade secrets were acquired by Stanley under circumstances giving rise to a duty to maintain its secrecy or limit its use as set forth in [the UTSA].").

It also is well settled that the UTSA allows the owner of a trade secret to disclose it to "a limited number of outsiders for a particular purpose" without losing its protected trade-secret status. A.H. Emery Co. v. Marcan Prods., 389 F.2d 11, 16 (2d Cir. 1968); Centrifugal Acquisition Corp. v. Moon, 849 F.Supp.2d 814, 834 (E.D. Wis. 2012). When such a limited disclosure is made, it "imposes a duty of confidentiality on the part of the person to whom the disclosure is made." Rockwell Graphic Sys. v. DEV Indus., 925 F.2d 174, 177 (7th Cir. 1991); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 475 (1974) (explaining that the "necessary element of secrecy is not lost, however, if the holder of the trade secret reveals the trade secret to another in confidence, and under an implied obligation not to use or disclose it." (internal quotations omitted)).

There is nothing in the plain language of the challenged provisions that precludes manufacturers from entering into confidentiality agreements with NDHHS to protect trade-secret information provided in their reports. If manufacturers make such disclosures to NDHHS under confidentiality agreements for the limited purpose of complying with the challenged provisions, the trade-secret information would not lose its protected trade-secret status, and NDHHS would have a duty of confidentiality to protect the trade-secret information from public disclosure. Consequently, the plain language of the challenged provisions does not, on its face, require manufacturers to disclose trade secrets in a manner that destroys their protected trade-secret status.

Finally, although the challenged provisions amend the definition of "trade secret" in the UTSA, the Legislature's intent was not to strip trade-secret protection from legitimate trade-secret information that manufacturers properly protect from disclosure by either: (1) ensuring that the trade-secret information is not revealed in their reports to NDHHS; or (2) providing the trade-secret information in their reports to NDHHS under the terms of a confidentiality agreement. The Legislature's intent was to ensure that if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure, the manufacturers cannot later claim that the information still retains its protected trade-secret status, especially since some of the information may be posted on the Internet if the manufacturers have not undertaken the proper means to protect the trade-secret information from disclosure.

The Legislature amended the definition of "trade secret" in the UTSA to exclude "any information that a manufacturer is required to report" under the challenged provisions but only "to the extent that such information is *required* to be disclosed by those sections." SB 539, 2017 Nev. Stat., ch. 592, § 9, at 4307 (emphasis added). As discussed already, the challenged provisions do not *require* manufacturers to disclose trade secrets. Therefore, the amended definition of "trade secret" does not disturb the existing protection afforded to trade-secret information under the UTSA if manufacturers have

undertaken the proper means to protect the trade-secret information from disclosure.

However, if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure, that information would lose its protected trade-secret status because of the manufacturers' own failure to undertake reasonable efforts to protect its secrecy. NRS 600A.030(5)(b); Motor City Bagels v. Am. Bagel Co., 50 F.Supp.2d 460, 480 (D. Md. 1999) ("[T]he plaintiffs' failure to exact agreements from potential investors to maintain the secrecy of the business plan is inconsistent with recognition of the document as a trade secret under the MUTSA."). Under such circumstances, the amended definition of "trade secret" ensures that those manufacturers—which have disclosed the trade-secret information in their reports without protecting its secrecy—cannot later claim that the information still retains its protected trade-secret status and thereby invoke the remedies of the UTSA, such as the procedures for removing trade secrets posted on the Internet. NRS 600A.055.

Therefore, contrary to Plaintiffs' contentions, there is nothing in the plain language of the challenged provisions that "strips trade-secret protection and *mandates* public disclosure of confidential information, eradicating trade-secret protection in other states," or that "burdens interstate commerce by eviscerating commercial rights other states grant, stripping a broad compass of trade-secret protection for *all* manufacturers of essential diabetes drugs." (ECF No. 1 at 35, ECF No. 27 at 27, 30.) The plain language of the challenged provisions is much narrower in scope because it removes trade-secret protection only if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure. Consequently, there is nothing in the plain language of the challenged provisions that *requires* manufacturers to disclose trade secrets.

Moreover, even assuming there is any doubt regarding the meaning of the challenged provisions, that doubt must be resolved by adopting an interpretation that best captures the Legislature's objective in

enacting the legislation. Based on the legislative history of the challenged provisions, the Legislature's objective was to draw a reasonable balance between obtaining more information for policymaking while also protecting some proprietary information from disclosure. As explained in legislative hearings, the Legislature wanted to provide policymakers and consumers with more information about the factors contributing to the cost of diabetes drugs, so they are better informed when developing policies regarding public health, safety and welfare.[5] Hearing SB 539 Sen. Comm. Health & Human Servs., 79th Leg., at 3-5 (Nev. May 26, 2017) (Leg. Ex. 1 to Opp'n to Mot. for Prelim. Inj. (ECF No. 42-1)). For example, when testifying on similar legislation in SB 265, Senator Cancela stated:

> I sincerely believe increased transparency leads to decreased costs. When consumers have more information, they are able to make better decisions. We, as policymakers, can enact laws based on where we identify problems in the system if we have the data. I am confident, while this may not have a direct provision to return money to the consumer, it will provide us with the tools to make decisions about drug costs.

Hearing SB 265 Sen. Comm. Health & Human Servs., 79th Leg., at 5 (Nev. May 3, 2017) (Leg. Ex. 2 to Opp'n to Mot. for Prelim. Inj. (ECF No. 42-1)). Similarly, Senator Hammond stated "[o]nce we shine a light on this subject, we should be able to identify the difficulties." Id. at 6.

However, in seeking more information, the Legislature also recognized that some proprietary information would need to protected from disclosure. For example, Senator Hammond stated:

> 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 . . . the PBMs [pharmacy benefit managers] do not want to share all their numbers. Would it hurt to disclose some of the numbers for the rebates, and would it . . . 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.

[5] Under Fed. R. Evid. 201, the Legislature requests the Court to take judicial notice of the legislative hearings because they are public records. See United States v. Camp, 723 F.2d 741, 744 n.** (9th Cir. 1984); Zephyr v. Saxon Mortgage Servs., 873 F.Supp.2d 1223, 1226 (E.D. Cal. 2012).

Hearing SB 539 Sen. Comm. Health & Human Servs., 79th Leg., at 25-26 (Nev. May 26, 2017) (Leg. Ex. 1 to Opp'n to Mot. for Prelim. Inj. (ECF No. 42-1)) (emphasis added).

Thus, in resolving any doubt regarding the meaning of the challenged provisions, those provisions must be interpreted to carry out the Legislature's objective which was to require manufacturers to provide NDHHS with as much business information as possible about the factors contributing to the cost of diabetes drugs while also protecting some proprietary information from disclosure. Because not all business information regarding the production, cost, pricing, marketing and advertising of diabetes drugs is proprietary information that constitutes a trade secret, the challenged provisions must be interpreted to require manufacturers to provide NDHHS with all information that does not constitute a trade secret. However, in order to protect proprietary information that constitutes a trade secret, the challenged provisions must not be interpreted to require manufacturers to disclose trade secrets. Not only does this interpretation best capture the Legislature's objective in enacting the challenged provisions, but it also is consistent with reason and public policy and avoids unreasonable or absurd results.

Trade-secret law has been part of our nation's public policy for nearly 150 years. Kewanee Oil, 416 U.S. at 493 n.23 (noting that "trade secret law was imported into this country from England by means of the landmark case of Peabody v. Norfolk, 98 Mass. 452 (1868)."). The purpose of trade-secret law is to carefully balance the public's interest in protecting the secrecy of business information to encourage invention and innovation and discourage unfair competition and unethical business practices against the public's interest in the disclosure of business information to foster knowledge, understanding, learning and advancement. Kewanee Oil, 416 U.S. at 480-93. In striking that balance, "not every commercial secret qualifies as a trade secret." Enter. Leasing Co. v. Ehmke, 3 P.3d 1064, 1070 (Ariz. Ct. App. 1999). Thus, as a matter of public policy, trade-secret law has been the historical yardstick for determining which type of confidential business information is protected from disclosure as a trade secret and which type of confidential business information is not so protected.

Given this long-standing historical pedigree, it would be unreasonable and absurd to interpret the challenged provisions as unraveling the careful balance struck by trade-secret law over the last century and a half, especially since there is nothing in the plain language or legislative history of the challenged provisions to indicate that the Legislature intended to unwind those 150 years of trade-secret law. Therefore, based on reason and public policy, the challenged provisions must be interpreted to require manufacturers to provide NDHHS with all information that does not constitute a trade secret. However, in order to protect proprietary information that constitutes a trade secret, the challenged provisions must not be interpreted to require manufacturers to disclose trade secrets.

Lastly, even assuming there is any remaining doubt regarding the meaning of the challenged provisions, the Court must "construe the [provisions] narrowly and resolve any ambiguities in favor of the interpretation that most clearly supports constitutionality." S.D. Myers, 253 F.3d at 468. The Supreme Court has the explained the purpose of this paramount rule of construction as follows:

> [O]ne of the canon's chief justifications is that it allows courts to *avoid* the decision of constitutional questions. It is a tool for choosing between competing plausible interpretations of a statutory text, resting on the reasonable presumption that [the Legislature] did not intend the alternative which raises serious constitutional doubts.

Clark v. Martinez, 543 U.S. 371, 381 (2005).

Plaintiffs' facial claims are all based on their overly broad interpretation that the challenged provisions require manufacturers to disclose trade secrets. However, the plain language and legislative history of the challenged provisions—along with reason and public policy—amply demonstrate that the provisions are much narrower in scope and do not require manufacturers to disclose trade secrets. Because this reasonable and plausible interpretation of the challenged provisions alleviates any constitutional doubts regarding the validity of the provisions, the Court must adopt this interpretation because "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." Hooper v. California, 155 U.S. 648, 657 (1895). Consequently, as discussed next,

Plaintiffs cannot prove the merits of their facial claims as a matter of law.[6]

V. Plaintiffs cannot prove the merits of their facial claims that the challenged provisions are preempted by federal patent laws and federal trade-secret laws under all circumstances.

Plaintiffs contend that the challenged provisions are preempted under the doctrine of conflict preemption because the provisions conflict with federal patent laws and federal trade-secret laws by standing as an obstacle to the accomplishment and execution of the purposes and objectives of Congress in enacting those laws. (ECF No. 1 at 25-29; ECF No. 27 at 20-26.) Conflict preemption may occur when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hillsborough Cnty. v. Automated Med. Labs., 471 U.S. 707, 713 (1985); Arizona v. United States, 567 U.S. 387, 399-400 (2012). Under that standard, "[w]hat is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000).

In most cases, there is a general presumption against federal preemption when "the field which Congress is said to have pre-empted has been traditionally occupied by the States." United States v. Locke, 529 U.S. 89, 108 (2000) (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)); Hillman v. Maretta, 133 S.Ct. 1943, 1950 (2013). Such traditional areas of state regulation include public health, safety and welfare matters. Hillsborough Cnty., 471 U.S. at 715-16. However, in some cases, the general presumption against federal preemption "is not triggered when the State regulates in an area

[6] If the Court disagrees with this reasonable and plausible interpretation of the challenged provisions, the Court must certify the state-law question of statutory interpretation to the Nevada Supreme Court under NRAP 5. Arizonans for Official English v. Arizona, 520 U.S. 43, 77-80 (1997) (explaining that federal courts must certify state-law questions of statutory interpretation when "the statute is susceptible of . . . an interpretation [that] would avoid or substantially modify the federal constitutional challenge to the statute."). Federal courts may certify such questions *sua sponte*, even if no party requests certification or all parties object to certification. Parents Cmty. Schs. v. Seattle Sch. Dist., 294 F.3d 1085, 1086 (9th Cir. 2002).

where there has been a history of significant federal presence." Locke, 529 U.S. at 108; Chamber of Commerce v. Whiting, 563 U.S. 582, 604-05 (2011). One such area with a history of significant federal presence is patent law. Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 146-57 (1989). By contrast, trade-secret law is a traditional area of state regulation where there has not been a history of significant federal presence similar to patent law. Kewanee Oil, 416 U.S. at 479-93.

In order for conflict preemption to apply, there must be a real and actual conflict between the federal and state law because "[t]he existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982). Furthermore, claims of conflict preemption usually cannot be resolved on a facial challenge because conflict preemption "requires [the Court] to consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written." Rath Packing, 430 U.S. at 526. Finally, if the Court finds conflict preemption, the Court may enjoin only those applications of the state law that actually conflict with the federal law, and the Court must avoid a "blanket invalidation" that precludes valid applications of the state law. Dalton, 516 U.S. at 476-78.

Plaintiffs contend that the challenged provisions conflict with the exclusive patent rights given to manufacturers of patented diabetes drugs by federal patent laws, although Plaintiffs fail to cite or quote any specific statutory language from those laws to support their contention. (ECF No. 1 at 25-29; ECF No. 27 at 20-23.) The Supreme Court has stated that "[t]he grant of a patent is the grant of a statutory monopoly." Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 229 (1964). Plaintiffs argue that by giving the patent owner a statutory monopoly, the purpose and objective of Congress was to create "an incentive for innovation. The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace." King Instr. Corp. v. Perego, 65 F.3d 941, 950 (Fed. Cir. 1995). Thus, Plaintiffs argue that during the period of exclusivity,

the patent owner may "charge prices of its choosing, including supracompetitive prices." King Drug Co. v. Smithkline Beecham Corp., 791 F.3d 388, 401 (3d Cir. 2015).

Plaintiffs claim that the challenged provisions conflict with the federally authorized period of exclusivity because they "punish" manufacturers of patented diabetes drugs that experience increases in their wholesale acquisition cost as follows:

> The punishment is compelled disclosure of additional confidential pricing information and loss of trade-secret protection for that information. 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.

(ECF No. 27 at 22) (citation omitted).

As a preliminary matter, the challenged provisions apply to any diabetes drugs designated by NDHHS as essential diabetes drugs, whether or not those drugs are patented. Thus, there clearly are circumstances where the challenged provisions do not implicate federal patent laws and can operate validly without any alleged conflict under the preemption doctrine. Because those circumstances exist, the provisions cannot be declared facially unconstitutional. Wash. State Grange, 552 U.S. at 449.

Further, there is nothing in the challenged provisions that punishes manufacturers of patented diabetes drugs or restrains them from exercising their right under federal patent laws to set prices. The provisions do not place any caps or limits on the prices that may be charged for patented diabetes drugs, and the provisions do not require manufacturers to disclose trade secrets. As properly interpreted under Nevada's rules of statutory interpretation, the provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a trade secret. Plaintiffs have not pointed to any specific statutory language from the federal patent laws or any congressional purpose or objective

underpinning those laws that would prohibit Nevada from requiring manufacturers of patented diabetes drugs to disclose business information that does not constitute a trade secret in order to provide its policymakers and consumers with more information about the factors contributing to the cost of diabetes drugs, so they are better informed when developing policies regarding public health, safety and welfare.

Finally, Plaintiffs' reliance on Biotech. Indus. Org. (BIO) v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007), is wholly misplaced. In that case, the Federal Circuit held that federal patent laws preempted a D.C. law that placed *actual* price limitations on patented drugs because the law operated as an *actual* price control by expressly prohibiting manufacturers from charging excessive prices for their patented drugs and by imposing *actual* penalties for violations, including injunctions, fines, and damages. Id. at 1374. Because the challenged provisions do not operate as an *actual* price control and do not impose any *actual* penalties on manufacturers for exercising their right under federal patent laws to set prices, the decision in BIO has no application to this case. Therefore, because Plaintiffs have not established that the challenged provisions conflict with congressional purposes and objectives of the federal patent laws, Plaintiffs cannot prove the merits of their facial claims.

Plaintiffs also contend that the challenged provisions conflict with congressional purposes and objectives of the Defend Trade Secrets Act (DTSA), 18 U.S.C. §§ 1836 et seq., which Congress enacted in 2016 to create a federal private right of action for misappropriation of trade secrets. (ECF No. 1 at 29-33; ECF No. 27 at 24-26.) Plaintiffs argue that "SB 539 guts the trade-secret protection afforded by the federal government and every state for confidential information associated with essential diabetes drugs. This mass nullification frustrates Congress's goal in the DTSA to enhance trade-secret protections." (ECF No. 27 at 26.)

As a preliminary matter, when Congress enacted the DTSA, it included an express anti-preemption clause which provides: "Nothing in the amendments made by this section shall be construed to . . . preempt any other provision of law." DTSA § 2(f), Pub. L. No. 114-153, 130 Stat. 376 (2016).

Therefore, by including this anti-preemption clause in the federal legislation, Congress clearly expressed its intent that the DTSA should not be construed to preempt state laws. See CSX Transp. v. Easterwood, 507 U.S. 658, 664 (1993) (explaining that when Congress includes express preemption clauses in federal law, the plain language of the clauses "contains the best evidence of Congress' pre-emptive intent."); Locke, 529 U.S. at 104-07 (interpreting anti-preemption clauses).

Further, the challenged provisions do not "gut" trade-secret protection because the provisions do not require manufacturers to disclose trade secrets. As properly interpreted under Nevada's rules of statutory interpretation, the provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a trade secret. Additionally, as already discussed, it would be unreasonable and absurd to interpret the challenged provisions as unraveling the careful balance struck by trade-secret law over the last century and a half, especially since there is nothing in the plain language or legislative history of the provisions to indicate that the Legislature intended to unwind 150 years of trade-secret law. Therefore, because Plaintiffs have not established that the challenged provisions conflict with congressional purposes and objectives of the federal trade-secret laws, Plaintiffs cannot prove the merits of their facial claims.

VI. Plaintiffs cannot prove the merits of their facial claims that the challenged provisions violate the Takings Clause under all circumstances.

Plaintiffs contend that the challenged provisions constitute an unconstitutional taking of private property for public use because "SB 539 extinguishes pharmaceutical manufacturers' property interest in the confidentiality of their trade secrets and thus works a categorical taking." (ECF No. 1 at 34-36; ECF No. 27 at 27.) A categorical taking may occur when a state law denies all economically beneficial or

productive use of *tangible* property. Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1015 (1992). Because trade secrets constitute *intangible* property, courts generally do not analyze alleged takings of trade secrets under the standards for categorical takings. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1005-14 (1984); Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 306-08 (1st Cir. 2005); Philip Morris, Inc. v. Reilly, 312 F.3d 24, 33-35 (1st Cir. 2002). Instead, courts generally analyze alleged takings of trade secrets under the standards for regulatory takings. Id.

Under those standards, it is possible for a statute to interfere with existing property rights to such a degree that the interference will be recognized as a regulatory taking. Connolly v. Pension Benefit Guar. Corp., 475 U.S. 211, 224 (1986). To determine whether a statute causes a regulatory taking, courts apply a balancing test that considers three factors: (1) the purpose of the statute and the nature of the governmental action; (2) the economic impact of the statute; and (3) the extent to which the statute interferes with reasonable investment-backed expectations. Penn Cent. Transp. Co. v. New York City, 438 U.S. 104, 124 (1978). The purpose of the statute and the nature of the governmental action are critical factors in determining whether a regulatory taking has occurred. When the statute serves legitimate and important public interests and the nature of the governmental action substantially advances those interests, a regulatory taking is less likely to be found. See Keystone Bituminous Coal Ass'n v. DeBenedictis, 480 U.S. 470, 485-93 (1987). Further, it is well established that "mere diminution in the value of property, however serious, is insufficient to demonstrate a taking." Concrete Pipe & Prods. v. Constr. Laborers Pension Trust, 508 U.S. 602, 645 (1993). A regulatory taking will occur only if the statute "goes too far." Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922).

Plaintiffs argue that SB 539 "strips trade-secret protection and *mandates* public disclosure of confidential information, eradicating trade-secret protection in other states." (ECF No. 1 at 34-36; ECF No. 27 at 27.) However, the challenged provisions do not strip trade-secret protection and mandate public disclosure because the provisions do not require manufacturers to disclose trade secrets. As

properly interpreted under Nevada's rules of statutory interpretation, the provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a trade secret. Because the challenged provisions do not require manufacturers to disclose trade secrets, there is no protected property interest subject to the Takings Clause. Rowe, 429 F.3d at 308 ("Given that there are no trade secrets involved with these client contracts, there is no 'property' subject to the Takings Clause.").

Further, Nevada has legitimate and important public interests in requiring manufacturers to disclose business information that is not a trade secret in order to provide policymakers and consumers with more information about the factors contributing to the cost of diabetes drugs, so they are better informed when developing policies regarding public health, safety and welfare. Because this business information is not a trade secret, the economic impact of the challenged provisions is minimal, and the provisions do not interfere with reasonable investment-backed expectations. Because Plaintiffs have not established that the challenged provisions interfere with existing property rights to such a degree that the interference amounts to a regulatory taking, Plaintiffs cannot prove the merits of their facial claims that the challenged provisions violate the Takings Clause under all circumstances.

VII. Plaintiffs cannot prove the merits of their facial claims that the challenged provisions violate the dormant Commerce Clause under all circumstances.

Plaintiffs contend that the challenged provisions impose unreasonable burdens on interstate commerce which are excessive in relation to the potential local benefits. (ECF No. 1 at 37-40; ECF No. 27 at 27-31.) If the practical effects of a state law directly control commerce occurring wholly outside the state's borders, the state law may impose unreasonable burdens on interstate commerce.

Healy v. Beer Inst., 491 U.S. 324, 336 (1989); Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 580-84 (1986). A state law also may impose unreasonable burdens on interstate commerce if the practical effects of the state law impose burdens that are clearly excessive in relation to the potential local benefits. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

Plaintiffs argue that the challenged provisions have an extraterritorial reach because "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." (ECF No. 27 at 29.) However, the challenged provisions do not establish a price cap because the provisions do not impose any *actual* price controls and do not impose any *actual* penalties on manufacturers for exercising their right to set whatever prices they choose. Nevada's provisions do not control the prices charged by manufacturers in Nevada or any other state. Manufacturers may set those prices as they choose, regardless of whether they disclose the necessary business information to NDHHS. Nevada's provisions simply require that if manufacturers elect to conduct business in Nevada, they must disclose the necessary business information to NDHHS. Thus, SB 539 does not have an extraterritorial reach because it "does not require out-of-state commerce to be conducted according to in-state terms. It requires only that in-state commerce be conducted according to in-state terms." Rowe, 429 F.3d at 312.

Plaintiffs also argue that "SB 539 burdens interstate commerce by eviscerating commercial rights other states grant, stripping a broad compass of trade-secret protection for *all* manufacturers of essential diabetes drugs." (ECF No. 27 at 30.) However, the challenged provisions do not strip trade-secret protection from *any* manufacturers because the provisions do not require manufacturers to disclose trade secrets. As properly interpreted under Nevada's rules of statutory interpretation, the provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the

necessary business information to NDHHS but which do not reveal information that constitutes a trade secret. Because Plaintiffs have not established that the challenged provisions impose unreasonable burdens on interstate commerce which are excessive in relation to the potential local benefits, Plaintiffs cannot prove the merits of their facial claims that the challenged provisions violate the dormant Commerce Clause under all circumstances.

CONCLUSION

Based upon the foregoing, the Legislature respectfully asks the Court to grant the Legislature's motion for summary judgment and enter final judgment in favor of Defendants on all causes of action and claims for relief alleged in Plaintiffs' complaint for declaratory and injunctive relief that was filed on September 1, 2017 (ECF No. 1).

DATED: This **5th** day of October, 2017.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I am an employee of the Nevada Legislative Counsel Bureau, Legal Division, and that on the **5th** day of October, 2017, pursuant to FRCP 5(b) and Local Rule Part IC, I filed and served a true and correct copy of Nevada Legislature's Motion for Summary Judgment, by using the Court's CM/ECF system. I further certify that service will be accomplished electronically by the CM/ECF system directed to the following:

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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

DEFENDANT NEVADA LEGISLATURE'S CONSOLIDATED REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT

ORAL ARGUMENT REQUESTED

Defendant Nevada Legislature (Legislature), by and through its counsel the Legal Division of the Legislative Counsel Bureau (LCB), hereby files its consolidated reply in support of its motion for summary judgment (ECF No. 46) and opposition to Plaintiffs' cross-motion for summary judgment (ECF No. 66).[1] The Legislature respectfully asks the Court to grant its motion for summary judgment on all of Plaintiffs' facial claims challenging the validity of specific provisions of SB 539 (hereafter the

[1] On Nov. 7, 2017, the Court approved a stipulation and order (ECF No. 71) allowing the Legislature to file a consolidated reply and opposition not exceeding 30 pages, excluding exhibits, under LR 7-3(a).

"challenged provisions"),[2] deny Plaintiffs' cross-motion for summary judgment, and enter final judgment in favor of Defendants on all of Plaintiffs' facial claims because: (1) Plaintiffs' facial claims present only pure issues of law that require no factual development, so there are no genuine issues or disputes as to any material fact; and (2) the challenged provisions are constitutional on their face, so Defendants are entitled to summary judgment on the facial claims as a matter of law.[3]

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

As thoroughly discussed in the Legislature's motion for summary judgment (ECF No. 46 at 7-18), Plaintiffs' facial claims are all based on their overly broad interpretation that the challenged provisions require manufacturers to disclose trade secrets. However, the plain language and legislative history of the challenged provisions—along with reason and public policy—amply demonstrate that the provisions are much narrower in scope and do not require manufacturers to disclose trade secrets. Because this reasonable and plausible interpretation of the challenged provisions alleviates any constitutional doubts regarding the validity of the provisions, the Court must adopt this interpretation because "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." Hooper v. California, 155 U.S. 648, 657 (1895).

Thus, as properly interpreted under Nevada's rules of statutory interpretation, the challenged provisions do not require manufacturers to disclose trade secrets. Consequently, because Plaintiffs'

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[2] SB 539, 2017 Nev. Stat., ch. 592, §§ 3.6, 3.8, 4, 4.3, 6, 7, 8 & 9, at 4297-4307.

[3] The other Defendants, Governor Brian Sandoval and Director Richard Whitley, have not filed a motion for summary judgment or joined in the Legislature's motion for summary judgment, but they have filed an opposition (ECF No. 74) to Plaintiffs' cross-motion for summary judgment. Even though the other Defendants have not requested summary judgment in their favor, it is well settled that if a plaintiff's claims fail as a matter of law on a motion for summary judgment filed by any defendant, then all defendants are entitled to a final judgment in their favor on those claims, regardless of whether they joined in the motion. See Lewis v. Lynn, 236 F.3d 766, 768 (5th Cir. 2001); True the Vote v. Hosemann, 43 F.Supp.3d 693, 708 n.59 (S.D. Miss. 2014).

facial claims are all based on their incorrect statutory interpretation that the challenged provisions require manufacturers to disclose trade secrets, Plaintiffs cannot prove the merits of their facial claims as a matter of law. Therefore, the challenged provisions are constitutional on their face, and Defendants are entitled to summary judgment on the facial claims as a matter of law.

However, if this Court disagrees with the Legislature's reasonable and plausible interpretation of the challenged provisions which alleviates any constitutional doubts regarding the validity of the provisions, this Court is required by well-established principles of federalism to certify the state-law question of statutory interpretation to the Nevada Supreme Court under NRAP 5. It is well established that in federal constitutional challenges to the validity of state statutes, federal courts generally have a duty to certify state-law questions of statutory interpretation to the state's highest court when the statutes are susceptible to state-law interpretations that would avoid or substantially modify the federal constitutional challenges. Arizonans for Official English v. Arizona, 520 U.S. 43, 77-80 (1997).

Finally, even assuming the challenged provisions could be interpreted to require manufacturers to disclose business information that constitutes a trade secret—and even assuming such a requirement would be invalid as applied to certain manufacturers—the challenged provisions cannot be declared facially unconstitutional *under all circumstances* and cannot be enjoined in all of their applications because it is undisputedly constitutional for the challenged provisions to require manufacturers to disclose business information that does not constitute a trade secret. Therefore, because the challenged provisions cannot be declared facially unconstitutional *under all circumstances*, Plaintiffs' facial claims fail as a matter of law, and Defendants are entitled to summary judgment on the facial claims as a matter of law. As a result, the Legislature respectfully asks the Court to grant the Legislature's motion for summary judgment on all of Plaintiffs' facial claims, deny Plaintiffs' cross-motion for summary judgment, and enter final judgment in favor of Defendants on all causes of action and claims for relief alleged in Plaintiffs' complaint.

II. Because Plaintiffs' facial claims present only pure issues of law that require no factual development, the statements made by particular manufacturers in their declarations speculating on how the challenged provisions may be applied to those manufacturers are irrelevant and inadmissible in evidence and cannot be considered on summary judgment to determine whether the challenged provisions are facially constitutional.

On a motion for summary judgment, the materials submitted by a party in support of or in opposition to summary judgment must be "admissible in evidence." FRCP 56(c)(2); Hollingsworth Solderless Terminal Co. v. Turley, 622 F.2d 1324, 1335 n.9 (9th Cir. 1980) ("In general, only admissible evidence may properly be considered by a trial court in granting summary judgment."); Allen v. Trounday, 657 F.Supp. 780, 784 (D. Nev. 1987) ("Generally, only admissible evidence may properly be considered by a trial court in granting summary judgment."). Therefore, to be admissible in evidence on summary judgment, the materials submitted by a party must be "relevant to disputed factual issues that are truly material to the litigation." Gen. Bus. Sys. v. N. Am. Philips Corp., 699 F.2d 965, 971 (9th Cir. 1983). As a result, "statements in declarations based on speculation or improper legal conclusions, or argumentative statements, are not facts and likewise will not be considered on a motion for summary judgment." Burch v. Regents of Univ. of Cal., 433 F.Supp.2d 1110, 1119 (E.D. Cal. 2006); EEOC v. Swissport Fueling, 916 F.Supp.2d 1005, 1016 (D. Ariz. 2013) (stating that "a district court may not rely on irrelevant facts, legal conclusions, or speculations on a motion for summary judgment.").

As a general rule, because constitutional claims challenging the facial validity of statutes present only pure issues of law that require no factual development, statements made in affidavits or declarations regarding potential application of the challenged statutes are not admissible in evidence on summary judgment because the statements are not relevant to the facial validity of the statutes and "are not admissible to contradict the clear statutory provisions." Mapco Inc. v. Carter, 573 F.2d 1268, 1282 (Temp. Emer. Ct. App. 1978), *cert. denied*, 437 U.S. 904 (1978). Consequently, such statements cannot be considered on summary judgment because they constitute "conclusionary, speculative, inadmissible evidence, which is also irrelevant." Id. at 1283.

In this case, because Plaintiffs are attacking the validity of the challenged provisions before they have been implemented and applied by the state, their constitutional claims can be based only on the facial validity of the challenged provisions and cannot be based on the potential effects or consequences of those provisions as applied to any particular manufacturer. See Wash. State Grange v. Wash. State Republican Party, 552 U.S. 442, 449-50 (2008) (explaining that state statutes can be challenged only on facial grounds when the state has had no opportunity to implement and apply those statutes). Consequently, "[i]n determining whether a law is facially invalid, [the Court] must be careful not to go beyond the statute's facial requirements and speculate about 'hypothetical' or 'imaginary' cases." Id.

For example, in John Doe No. 1 v. Reed, 561 U.S. 186, 190-93 (2010), the sponsor and certain signers of a controversial referendum petition raised a facial claim against Washington's public records statute contending that the First Amendment prevented the public records statute from being used under all circumstances to obtain the names and addresses of persons who signed referendum petitions because such disclosure had the potential to subject some signers to threats, harassment, and reprisals. The same plaintiffs also raised an as-applied claim contending that such disclosure under the public records statute also violated their First Amendment rights as applied to the controversial referendum petition because "there is a reasonable probability that the signatories of the Referendum 71 [R-71] petition will be subjected to threats, harassment, and reprisals." Id. at 193.

In support of their claims, the plaintiffs submitted evidence and argument that "rests almost entirely on the specific harm they say would attend disclosure of the information on the R–71 petition, or on similarly controversial ones," and they provided "scant evidence or argument beyond the burdens they assert disclosure would impose on R–71 petition signers or the signers of other similarly controversial petitions." Id. at 200-01. The Supreme Court found that the evidence and argument submitted by the plaintiffs could be used to support their as-applied claim that their First Amendment rights would be violated by application of the public records statute to disclose the names and addresses

of the signers of the controversial R-71 referendum petition. Id. However, the Supreme Court rejected the plaintiffs' broad-based facial challenge because their evidence and argument regarding application of the public records statute to the controversial R-71 referendum petition could not be used to establish that the First Amendment prevented the statute from being used under all circumstances to obtain the names and addresses of persons who signed referendum petitions, regardless of whether the referendum was controversial. Id. In reaching its decision, the Supreme Court explained that the plaintiffs had failed to meet the stringent standards to succeed on a facial challenge, but the Court also noted that "upholding the law against a broad-based challenge does not foreclose a litigant's success in a narrower one." Id. at 201.

In this case, Plaintiffs have submitted evidence and argument that is based on the statements made by particular manufacturers in their declarations speculating on how the challenged provisions may be applied to those manufacturers. (ECF Nos. 66-5, 66-6, 66-7, 66-8, 66-9 & 66-10.) For example, Plaintiffs contend the statements in the declarations show that "SB 539 would require them to disclose trade secrets, that these disclosures would cause significant competitive harm, and that SB 539's linkage of disclosures to price increases would impede the companies' ability to set prices that realize the value of their patents." (ECF No. 66 at 11.) It is possible that the statements made by these particular manufacturers in their declarations could be relevant if those manufacturers elect in the future to bring their own cases and pursue as-applied claims against application of the challenged provisions to their particular circumstances. However, in this case, Plaintiffs have pursued only broad-based facial claims which present only pure issues of law that require no factual development. As a result, the statements made by these particular manufacturers in their declarations speculating on how the challenged provisions may be applied to them are irrelevant and inadmissible in evidence and cannot be considered on summary judgment to determine whether the challenged provisions are facially constitutional. Therefore, the Legislature objects to the declarations under FRCP 56(c)(2) because they are irrelevant

and inadmissible in evidence and cannot be considered on summary judgment to determine whether the challenged provisions are facially constitutional.

III. Based on the plain language and legislative history of the challenged provisions—along with reason and public policy—the challenged provisions do not require manufacturers to disclose trade secrets.

As thoroughly discussed in the Legislature's motion for summary judgment (ECF No. 46 at 7-18), Plaintiffs' facial claims are all based on their overly broad interpretation that the challenged provisions require manufacturers to disclose trade secrets. However, the plain language and legislative history of the challenged provisions—along with reason and public policy—amply demonstrate that the provisions are much narrower in scope and do not require manufacturers to disclose trade secrets. Because this reasonable and plausible interpretation of the challenged provisions alleviates any constitutional doubts regarding the validity of the provisions, the Court must adopt this interpretation because "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." Hooper v. California, 155 U.S. 648, 657 (1895). Consequently, Plaintiffs cannot prove the merits of their facial claims as a matter of law.

Plaintiffs contend that the Legislature's reasonable and plausible interpretation of the challenged provisions "ignores or misreads the text of SB 539," and they argue that the challenged provisions must be interpreted as requiring manufacturers to disclose trade secrets. (ECF No. 66 at 18-22.) However, Plaintiffs' interpretation must be rejected because it conflicts with Nevada's rules of statutory interpretation, including Nevada's paramount rule of statutory interpretation that when one possible interpretation of the statute would raise serious constitutional problems, courts must reject that interpretation if it is fairly possible to construe the statute in an alternative manner that avoids the constitutional problems. Bell v. Anderson, 109 Nev. 363, 366 (1993) ("Where a statute is susceptible to more than one interpretation, this court will interpret the statute so that it complies with constitutional standards."); Sheriff v. Wu, 708 P.2d 305, 306 (Nev. 1985); Standard Oil Co. of Cal. v. Pastorino, 94

Nev. 291, 293 (1978).

As a preliminary matter, Plaintiffs contend that "[d]eclarations from six manufacturers each establish that SB 539 requires disclosure of 'trade secrets' under the preexisting definition in Nevada law." (ECF No. 66 at 18.) However, as discussed previously, because the declarations from these manufacturers are irrelevant and inadmissible in evidence for a facial challenge, the declarations cannot be considered on summary judgment to determine whether the challenged provisions are facially constitutional.

Furthermore, it is well established in Nevada law that witnesses cannot provide testimony "on the meaning of a statute," regardless of whether the testimony is provided by affidavit or declaration or at trial. Blackburn v. State, 294 P.3d 422, 425 n.1 (Nev. 2013); A-NLV Cab Co. v. State Taxicab Auth., 825 P.2d 585, 587 (Nev. 1992); United Fire Ins. v. McClelland, 780 P.2d 193, 196 (Nev. 1989). Thus, in resolving questions of statutory interpretation, courts must "rely on the statutes' text and conventional principles of statutory interpretation, not the opinions of [witnesses]." Blackburn, 294 P.3d at 425 n.1. The reason for this rule is that the interpretation of a statute is a pure question of law that is not dependent upon and must be resolved without reference to any particular facts or circumstances. MGM Mirage v. Nev. Ins. Guar. Ass'n, 209 P.3d 766, 768 (Nev. 2009) ("The construction of a statute is a question of law."); Sheriff v. Encoe, 885 P.2d 596, 598 (Nev. 1994) ("The proper construction of a statute is a legal question rather than a factual question."); Beavers v. State Dep't Mtr. Vehs., 851 P.2d 432, 434 n.1 (Nev. 1993) ("A 'pure legal question' is a question that is not dependent upon, and must necessarily be resolved without reference to any fact in the case before the court. An example of a pure legal question might be a challenge to the facial validity of a statute."). Therefore, because Plaintiffs' witnesses cannot provide testimony on the meaning of the challenged provisions, the statements made by the manufacturers in their declarations cannot be considered on summary judgment to determine the proper statutory interpretation of the challenged provisions, including whether the challenged provisions

require manufacturers to disclose trade secrets.

Plaintiffs contend that the Legislature's reasonable and plausible interpretation of the challenged provisions "would render Section 9 superfluous, contrary to basic canons of statutory construction." (ECF No. 66 at 20.) In Section 9, the Legislature amended the definition of "trade secret" in the Uniform Trade Secrets Act (UTSA) to exclude "any information that a manufacturer is required to report" under the challenged provisions but only "to the extent that such information is *required* to be disclosed by those sections." SB 539, 2017 Nev. Stat., ch. 592, § 9, at 4307 (emphasis added). However, as thoroughly discussed in the Legislature's motion for summary judgment (ECF No. 46 at 13-14), the Legislature's reasonable and plausible interpretation of the challenged provisions would not render the amendment in Section 9 superfluous because the Legislature intended the amendment to serve a specific purpose.

By amending the definition of "trade secret" in the UTSA, the Legislature's intent was not to strip trade-secret protection from legitimate trade-secret information that manufacturers properly protect from disclosure by either: (1) ensuring that the trade-secret information is not revealed in their reports to the Nevada Department of Health and Human Services (NDHHS); or (2) providing the trade-secret information in their reports to NDHHS under the terms of a confidentiality agreement. The Legislature's intent was to ensure that if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure, the manufacturers cannot later claim that the information still retains its protected trade-secret status, especially since some of the information may be posted on the Internet if the manufacturers have not undertaken the proper means to protect the trade-secret information from disclosure. Therefore, the amended definition of "trade secret" ensures that those manufacturers—which have disclosed the trade-secret information in their reports without protecting its secrecy—cannot later claim that the information still retains its protected trade-secret status and thereby invoke the remedies of the

UTSA, such as the procedures for removing trade secrets posted on the Internet. NRS 600A.055.

Plaintiffs also contend that "there was no need for the Legislature to put such a requirement in Section 9. It was already in the definition of trade secret that Section 9 amended. To qualify for trade-secret protection under preexisting Nevada law, manufacturers must undertake 'reasonable' steps to preserve the information's confidentiality." (ECF No. 66 at 20-21.) However, even assuming the UTSA already had preexisting provisions regarding when trade-secret protection is lost, under Nevada's rules of statutory interpretation, statutory amendments can be legislative pronouncements of already existing law which remove any doubt regarding interpretation of that law. Welfare Div. v. Maynard, 445 P.2d 153, 155 (Nev. 1968) ("A statutory enactment can be simply a legislative pronouncement of already existing law."); Sheriff v. Smith, 542 P.2d 440, 443 (Nev. 1975); PEBP v. LVMPD, 179 P.3d 542, 554-55 (Nev. 2008). As explained by Justice Scalia:

> But laws often make explicit what might already have been implicit, "for greater caution" and in order "to leave nothing to construction." The Federalist No. 33, pp. 205-206 (J. Cooke ed. 1961) (A. Hamilton). That is why we have long acknowledged that a "sufficient" explanation for the inclusion of a clause can be "found in the desire to remove all doubts" about the meaning of the rest of the text. McCulloch v. Maryland, 4 Wheat. 316, 420, 4 L.Ed. 579 (1819).

Young v. United Parcel Serv., 135 S.Ct. 1338, 1363-64 (2015) (Scalia, J., dissenting).

Therefore, by amending the definition of "trade secret" in the UTSA, the Legislature intended to remove all doubts about the meaning of the UTSA's statutory text and make explicit that if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure, the manufacturers cannot later claim that the information still retains its protected trade-secret status under the UTSA. Accordingly, under the Legislature's reasonable and plausible interpretation of the challenged provisions, the amendment in Section 9 serves a specific purpose and is not superfluous.

Moreover, it is well established that "[t]he canon against surplusage is not an absolute rule." Marx

v. Gen. Revenue Corp., 568 U.S. 371, 385 (2013). Thus, "[w]hile it is generally presumed that statutes do not contain surplusage, instances of surplusage are not unknown." Arlington Cent. Sch. Dist. v. Murphy, 548 U.S. 291, 299 n.1 (2006). Thus, because the canon against surplusage is not an absolute rule, courts do not apply the canon when its application would conflict with the purpose or intent of the statutory provisions. See King v. Burwell, 135 S.Ct. 2480, 2492 (2015); Lamie v. U.S. Trustee, 540 U.S. 526, 536 (2004); Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253 (1992).

In this case, based on the legislative history of the challenged provisions, the Legislature's objective was to require manufacturers to provide NDHHS with as much business information as possible about the factors contributing to the cost of diabetes drugs while also protecting some proprietary information from disclosure. Therefore, the Legislature intended for the challenged provisions to be interpreted to require manufacturers to provide NDHHS with all information that does not constitute a trade secret. To carry out that legislative intent, the Court must adopt the Legislature's reasonable and plausible interpretation that the challenged provisions do not require manufacturers to disclose trade secrets, even if that interpretation would render the amendment in Section 9 superfluous.

Finally, Plaintiffs contend that the Legislature's reasonable and plausible interpretation of the challenged provisions "conflicts with the interpretations of the Attorney General and the Culinary Health Fund." (ECF No. 66 at 18 & 20.) However, such a conflict further demonstrates that the Court must apply Nevada's paramount rule of statutory interpretation that "[w]here a statute may be given conflicting interpretations, one rendering it constitutional, and the other unconstitutional, the constitutional interpretation is favored." Wu, 708 P.2d at 306; Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 66 (2012) ("An interpretation that validates outweighs one that invalidates"). Moreover, Nevada's paramount rule of statutory interpretation is derived from well-settled federal precedent: "[A]s between two possible interpretations of a statute, by one of which it would be unconstitutional and by the other valid, our plain duty is to adopt that which will save the

Act." Rust v. Sullivan, 500 U.S. 173, 190 (1991) (quoting Blodgett v. Holden, 275 U.S. 142, 148 (1927) (opinion of Holmes, J.)). The Supreme Court has the explained the purpose of this paramount rule of construction as follows:

> [O]ne of the canon's chief justifications is that it allows courts to *avoid* the decision of constitutional questions. It is a tool for choosing between competing plausible interpretations of a statutory text, resting on the reasonable presumption that [the Legislature] did not intend the alternative which raises serious constitutional doubts.

Clark v. Martinez, 543 U.S. 371, 381 (2005).

In this case, Plaintiffs' facial claims are all based on their overly broad interpretation that the challenged provisions require manufacturers to disclose trade secrets. However, the plain language and legislative history of the challenged provisions—along with reason and public policy—amply demonstrate that the provisions are much narrower in scope and do not require manufacturers to disclose trade secrets. Because this reasonable and plausible interpretation of the challenged provisions alleviates any constitutional doubts regarding the validity of the provisions, the Court must adopt this interpretation because "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." Hooper, 155 U.S. at 657.

Thus, as properly interpreted under Nevada's rules of statutory interpretation, the challenged provisions do not require manufacturers to disclose trade secrets. Instead, the challenged provisions require manufacturers to provide NDHHS only with business information regarding the production, cost, pricing, marketing and advertising of their diabetes drugs which does not constitute a trade secret. Manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a trade secret. Consequently, because Plaintiffs' facial claims are all based on their incorrect statutory interpretation that the challenged provisions require manufacturers to disclose trade secrets, Plaintiffs cannot prove the merits of their facial claims as a matter of law. Therefore, the challenged provisions

are constitutional on their face, and Defendants are entitled to summary judgment on the facial claims as a matter of law.

IV. If this Court disagrees with the Legislature's reasonable and plausible interpretation of the challenged provisions which alleviates any constitutional doubts regarding the validity of the provisions, this Court is required by well-established principles of federalism to certify the state-law question of statutory interpretation to the Nevada Supreme Court under NRAP 5.

In federal constitutional challenges to the validity of state statutes, federal courts generally have a duty to certify state-law questions of statutory interpretation to the state's highest court when the statutes are susceptible to state-law interpretations that would avoid or substantially modify the federal constitutional challenges. Arizonans for Official English v. Arizona, 520 U.S. 43, 77-80 (1997). As discussed previously, the Legislature's reasonable and plausible interpretation of the challenged provisions alleviates any constitutional doubts regarding the validity of the provisions. Therefore, if this Court disagrees with the Legislature's reasonable and plausible interpretation of the challenged provisions, this Court has a duty under well-established principles of federalism to certify the state-law question of statutory interpretation to the Nevada Supreme Court under NRAP 5.

Under well-established principles of federalism, the general rule is that federal courts should not "consider the [c]onstitutionality of a state statute in the absence of a controlling interpretation of its meaning and effect by the state courts." Arizonans, 520 U.S. at 75 (quoting Poe v. Ullman, 367 U.S. 497, 526 (1961) (Harlan, J., dissenting)); Chaffee v. Roger, 311 F.Supp.2d 962, 970 (D. Nev. 2004) ("We must exercise caution in determining the constitutionality of a state law where the state's highest court has not interpreted its meaning."). This general rule of federal judicial restraint is particularly appropriate in pre-enforcement facial challenges to state statutes because a statutory interpretation by the state courts "might avoid in whole or in part the necessity for federal constitutional adjudication, or at least materially change the nature of the problem." Bellotti v. Baird, 428 U.S. 132, 147 (1976) (quoting Harrison v. NAACP, 360 U.S. 167, 177 (1959)); Beth A. Hardy, Note, Federal Courts—Certification

Before Facial Invalidation: A Return to Federalism, 12 W. New Eng. L. Rev. 217, 240 (1990) ("Certification before facial invalidation will further the principles of federalism which warn against unnecessary interference with state policy and unnecessary adjudication of constitutional questions.").

To effectuate this general rule of federal judicial restraint in the past, federal courts would apply the doctrine of Pullman abstention, which "remitted parties to the state courts for adjudication of the unsettled state-law issues. If settlement of the state-law question did not prove dispositive of the case, the parties could return to the federal court for decision of the federal issues." Arizonans, 520 U.S. at 75-76 (discussing the doctrine of Pullman abstention developed in Railroad Comm'n of Tex. v. Pullman Co., 312 U.S. 496 (1941)). Today, however, the doctrine of Pullman abstention has been mostly supplanted by the state-law certification procedure, which "allows a federal court faced with a novel state-law question to put the question directly to the State's highest court, reducing the delay, cutting the cost, and increasing the assurance of gaining an authoritative response." Arizonans, 520 U.S. at 76.

Under the state-law certification procedure, when a state statute is challenged as facially unconstitutional, federal courts generally must certify state-law questions regarding statutory interpretation to the state's highest court if "the statute is susceptible of . . . an interpretation [that] would avoid or substantially modify the federal constitutional challenge to the statute." Arizonans, 520 U.S. at 77 (quoting Bellotti, 428 U.S. at 148); Chaffee, 311 F.Supp.2d at 970. Thus, like the doctrine of Pullman abstention, state-law certification is "appropriate where an unconstrued state statute is susceptible of a construction by the state judiciary 'which might avoid in whole or in part the necessity for federal constitutional adjudication, or at least materially change the nature of the problem.'" Bellotti, 428 U.S. at 147 (quoting Harrison, 360 U.S. at 177). By utilizing state-law certification, federal courts allow the state's highest court to apply the paramount rule of statutory interpretation that the judiciary must adopt any reasonable interpretation which will save the statute from unconstitutionality. Arizonans, 520 U.S. at 78-79. As stated by the Supreme Court:

> Federal courts, when confronting a challenge to the constitutionality of a federal statute, follow a "cardinal principle": They "will first ascertain whether a construction . . . is fairly possible" that will contain the statute within constitutional bounds. State courts, when interpreting state statutes, are similarly equipped to apply that cardinal principle.

Arizonans, 520 U.S. at 78-79 (quoting Ashwander v. TVA, 297 U.S. 288, 348 (1936) (Brandeis, J., concurring)).

One of the primary purposes of state-law certification is to "avoid federal-court error in deciding state-law questions antecedent to federal constitutional issues." Arizonans, 520 U.S. at 76. In addition, "[t]hrough certification of novel or unsettled questions of state law for authoritative answers by a State's highest court, a federal court may save 'time, energy, and resources and hel[p] build a cooperative judicial federalism.'" Arizonans, 520 U.S. at 77 (quoting Lehman Brothers v. Schein, 416 U.S. 386, 391 (1974)). To achieve these objectives, the Supreme Court has instructed federal courts to utilize state-law certification whenever there is a possibility that certification might obviate the need for adjudication of the federal constitutional challenge because "[t]aking advantage of certification made available by a State may 'greatly simplif[y]' an ultimate adjudication in federal court." Arizonans, 520 U.S. at 79 (quoting Bellotti, 428 U.S. at 151). As further explained by the Supreme Court:

> Warnings against premature adjudication of constitutional questions bear heightened attention when a federal court is asked to invalidate a State's law, for the federal tribunal risks friction-generating error when it endeavors to construe a novel state Act not yet reviewed by the State's highest court. See Rescue Army [v. Mun. Ct. of Los Angeles, 331 U.S. 549, 573-74 (1947)]. "Speculation by a federal court about the meaning of a state statute in the absence of prior state court adjudication is particularly gratuitous when . . . the state courts stand willing to address questions of state law on certification from a federal court." Brockett v. Spokane Arcades, Inc., 472 U.S. 491, 510 (1985) (O'Connor, J., concurring).

Arizonans, 520 U.S. at 79. In line with the Supreme Court, the Ninth Circuit has also directed federal district courts in this circuit to utilize certification, stating that "even when [federal courts] find the plain language of state law dispositive, [they] have an obligation to consider whether novel state-law questions should be certified—and [they] have been admonished in the past for failing to do so."

Parents Cmty. Schs. v. Seattle Sch. Dist., 294 F.3d 1085, 1086 (9th Cir. 2002) (discussing Arizonans).

Under NRAP 5, the Nevada Supreme Court has adopted a "liberal standard" that favors answering state-law questions certified by federal courts because the liberal standard "best serves the purposes of NRAP 5: federalism, comity and judicial efficiency." Volvo Cars of N. Am. v. Ricci, 137 P.3d 1161, 1164 (Nev. 2006). Thus, the Nevada Supreme Court stands willing to answer state-law questions certified by federal courts when: (1) the answer may be determinative of part of the federal case; (2) there exists no clearly controlling Nevada precedent with respect to the questions; and (3) the answer will help settle important issues of law. Hartford Fire Ins. v. Trs. of Const. Indus. Health & Welfare Trust, 208 P.3d 884, 888 (Nev. 2009).

In this case, because all three elements for NRAP 5 certification are met, this Court is presented with a textbook case of a facial challenge where certification of the state-law question of statutory interpretation to the Nevada Supreme Court might obviate the need for adjudication of the federal constitutional challenge. First, because the initial step in reviewing Plaintiffs' facial claims is to interpret the challenged provisions under Nevada's rules of statutory interpretation to determine their plain meaning and intent, the Nevada Supreme Court's answer to the state-law question of statutory interpretation may be determinative of part of the federal case because it "might avoid in whole or in part the necessity for federal constitutional adjudication, or at least materially change the nature of the problem." Bellotti, 428 U.S. at 147 (quoting Harrison, 360 U.S. at 177). Second, because the challenged provisions were recently enacted and have not been implemented and applied by the state, there exists no clearly controlling Nevada precedent with respect to the question of the provisions' proper statutory interpretation. Finally, because the Nevada Supreme Court's answer to the state-law question of statutory interpretation would help resolve a constitutional dispute over important legislation affecting public health, safety and welfare, the Nevada Supreme Court's answer would help settle important issues of law. Under such circumstances, if this Court disagrees with the Legislature's

reasonable and plausible interpretation of the challenged provisions which alleviates any constitutional doubts regarding the validity of the provisions, this Court is required by well-established principles of federalism to certify the state-law question of statutory interpretation to the Nevada Supreme Court under NRAP 5.

V. Even assuming the challenged provisions could be interpreted to require manufacturers to disclose business information that constitutes a trade secret—and even assuming such a requirement would be invalid as applied to certain manufacturers—the challenged provisions cannot be declared facially unconstitutional *under all circumstances* and cannot be enjoined in all of their applications because it is undisputedly constitutional for the challenged provisions to require manufacturers to disclose business information that does not constitute a trade secret.

Plaintiffs contend that the challenged provisions which require manufacturers to disclose business information to NDHHS are "unconstitutional in whole," and they ask for a declaratory judgment that the challenged provisions are facially unconstitutional and a permanent injunction against their implementation or enforcement. (ECF No. 66 at 8.) However, Plaintiffs have not presented any allegations or arguments to support a conclusion that it is unconstitutional for the challenged provisions to require manufacturers to disclose business information that does not constitute a trade secret. Nor could Plaintiffs legitimately present such allegations or arguments because it is well settled that in exercising its traditional police power to regulate for the benefit of public health, safety and welfare, a state may require manufacturers to disclose such business information. Compare Corn Prod. Ref. Co. v. Eddy, 249 U.S. 427, 431-32 (1919), and Nat'l Fertilizer Ass'n v. Bradley, 301 U.S. 178, 179-82 (1937), with Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1005-14 (1984). Because it is undisputedly constitutional for the challenged provisions to require manufacturers to disclose business information that does not constitute a trade secret, the challenged provisions cannot be declared facially unconstitutional or enjoined in all of their applications.

For Plaintiffs' facial challenge to succeed, they must prove that the challenged provisions are unconstitutional under all circumstances:

> A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid. The fact that the [legislative] Act might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid, since we have not recognized an "overbreadth" doctrine outside the limited context of the First Amendment.

United States v. Salerno, 481 U.S. 739, 745 (1987). Because Plaintiffs' facial challenge requires unconstitutionality *under all circumstances*, Plaintiffs' facial challenge must fail given that there are circumstances under which the challenged provisions can operate constitutionally because it is undisputedly constitutional for the challenged provisions to require manufacturers to disclose business information that does not constitute a trade secret.

Furthermore, even assuming the challenged provisions also could be interpreted to require manufacturers to disclose business information that constitutes a trade secret—and even assuming such a requirement would be invalid as applied to certain manufacturers—this Court may enjoin only those applications of the challenged provisions that are invalid, and it must avoid a "blanket invalidation" that precludes valid applications of the challenged provisions. Dalton v. Little Rock Family Planning Servs., 516 U.S. 474, 476-78 (1996). Thus, it is a well-established principle of federal constitutional review that "a federal court should not extend its invalidation of a statute further than necessary to dispose of the case before it," and the "normal rule [is] that partial, rather than facial, invalidation is the required course." Brockett v. Spokane Arcades, 472 U.S. 491, 502-04 (1985). Therefore, before facially invalidating a state statute, a federal court must first determine whether any invalid provisions are severable from valid provisions:

> Generally speaking, when confronting a constitutional flaw in a statute, we try to limit the solution to the problem. We prefer, for example, to enjoin only the unconstitutional applications of a statute while leaving other applications in force, or to sever its problematic portions while leaving the remainder intact.

Ayotte v. Planned Parenthood, 546 U.S. 320, 328-29 (2006) (citations omitted). To determine whether any invalid provisions are severable from valid provisions, a federal court must apply the state's rules of

severability. Ariz. Libertarian Party v. Bayless, 351 F.3d 1277, 1283 (9th Cir. 2003).

In applying Nevada's rules of severability, the Nevada Supreme Court has stated that "[u]nder the severance doctrine, it is 'the obligation of the judiciary to uphold the constitutionality of legislative enactments where it is possible to strike only the unconstitutional portions.'" Flamingo Paradise Gaming v. Chanos, 217 P.3d 546, 555 (Nev. 2009) (quoting Rogers v. Heller, 18 P.3d 1034, 1039 (Nev. 2001)). The Legislature has adopted and statutorily codified Nevada's severance doctrine in the state's severability statute:

> **NRS 0.020 Severability.**
> 1. If any provision of the Nevada Revised Statutes, or the application thereof to any person, thing or circumstance is held invalid, such invalidity shall not affect the provisions or application of NRS which can be given effect without the invalid provision or application, *and to this end the provisions of NRS are declared to be severable*.
> 2. *The inclusion of an express declaration of severability in the enactment of any provision of NRS or the inclusion of any such provision in NRS, does not enhance the severability of the provision so treated or detract from the severability of any other provision of NRS.*

(Emphasis added.)

Under NRS 0.020, there is a legislative presumption in favor of severability that must be applied to every provision of NRS, regardless of whether there is "an express declaration of severability in the enactment of any provision of NRS," and the inclusion of such an express declaration "does not enhance the severability of the provision so treated or detract from the severability of any other provision of NRS." In other words, the presence or absence of a severability clause in enacting legislation does not alter or affect NRS 0.020's legislative presumption in favor of severability, which means that the Legislature has declared its intent that all "provisions of NRS are declared to be severable," regardless of whether there is a severability clause in enacting legislation.

The Nevada Supreme Court has found that the Legislature's "preference in favor of severability is set forth in NRS 0.020(1), which charges courts with preserving statutes to the extent they 'can be given effect without the invalid provision or application.'" Sierra Pac. Power v. State Dep't of Tax'n, 338

P.3d 1244, 1247 (Nev. 2014). However, the Nevada Supreme Court has explained:

> [This] preference is not a mandate, and not all statutory language is severable. Before language can be severed from a statute, a court must first determine whether the remainder of the statute, standing alone, can be given legal effect, and whether preserving the remaining portion of the statute accords with legislative intent.

Id. Thus, NRS 0.020 does not create a conclusive presumption in favor of severability, but creates a rebuttable presumption which places the burden on the party opposing severance to prove under the two-part severability test that the offending provisions or applications cannot be severed and the remaining provisions or applications cannot be saved and given legal effect on their own without the offending provisions or applications. Clark Cnty. v. City of Las Vegas, 550 P.2d 779, 787-88 (Nev. 1976).

In this case, even assuming the challenged provisions could be interpreted to require manufacturers to disclose business information that constitutes a trade secret—and even assuming such a requirement would be invalid as applied to certain manufacturers—the remaining applications of the challenged provisions can be saved and given legal effect on their own without the invalid applications. Moreover, there is nothing in the legislative history to rebut the presumption in favor of severability or to suggest the Legislature intended for the challenged provisions to be rendered unenforceable in their entirety if certain applications are invalidated. To the contrary, based on the legislative history of the challenged provisions, the Legislature's objective was to require manufacturers to provide NDHHS with as much business information as possible about the factors contributing to the cost of diabetes drugs while also protecting some proprietary information from disclosure. Therefore, the Legislature intended for the challenged provisions to be interpreted to require manufacturers to provide NDHHS with all information that does not constitute a trade secret. Under Nevada's severance doctrine, that clear legislative intent must be preserved and given legal effect even if certain applications of the challenged provisions are invalidated.

Consequently, even assuming the challenged provisions could be interpreted to require manufacturers to disclose business information that constitutes a trade secret—and even assuming such a requirement would be invalid as applied to certain manufacturers—the challenged provisions cannot be declared facially unconstitutional *under all circumstances* and cannot be enjoined in all of their applications because it is undisputedly constitutional for the challenged provisions to require manufacturers to disclose business information that does not constitute a trade secret. Therefore, because Plaintiffs' facial claims fail as a matter of law, Defendants are entitled to summary judgment on the facial claims as a matter of law.

CONCLUSION

Based upon the foregoing, the Legislature respectfully asks the Court to grant the Legislature's motion for summary judgment (ECF No. 46) on all of Plaintiffs' facial claims, deny Plaintiffs' cross-motion for summary judgment (ECF No. 66), and enter final judgment in favor of Defendants on all causes of action and claims for relief alleged in Plaintiffs' complaint.

DATED: This **20th** day of November, 2017.

Respectfully submitted,

BRENDA J. ERDOES
Legislative Counsel

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CERTIFICATE OF SERVICE

I hereby certify that I am an employee of the Nevada Legislative Counsel Bureau, Legal Division, and that on the **20th** day of November, 2017, pursuant to FRCP 5(b) and Local Rule Part IC, I filed and served a true and correct copy of Nevada Legislature's Consolidated Reply in Support of Its Motion for Summary Judgment and Opposition to Plaintiffs' Cross-Motion for Summary Judgment, by using the Court's CM/ECF system. I further certify that service will be accomplished electronically by the CM/ECF system directed to the following:

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/s/ Kevin C. Powers
An Employee of the Legislative Counsel Bureau

TAB 6

TAB 6

NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN that the Department of Health and Human Services will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 439.

The workshop will be conducted via videoconference beginning at 9:00 AM on Thursday, February 15, 2018, at the following locations:

Nevada Legislative Counsel Bureau 401 S. Carson St. Room 3137 Carson City, NV 89701	Nevada Legislative Counsel Bureau 555 E. Washington Ave. #5100 Room 4412E Las Vegas, NV 89101
Great Basin College 1500 College Parkway Elko, NV 89801	

These workshops will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

1. Introduction of workshop process
2. Public comment on proposed amendments to Nevada Administrative Code Chapter 439
3. Public Comment

The proposed changes will revise Chapter 439 of the Nevada Administrative Code and are being proposed in accordance with NRS 439.905, NRS 439.915 and Senate Bill 539 of the 2017 Legislative Session.

The proposed regulations provide provisions for the following:

1) Drug transparency reporting.
2) Establishes guidelines for prescription drug manufacturer yearly reporting.
3) Establishes guidelines for pharmacy benefit managers yearly reporting.
4) Establishes guidelines for pharmaceutical sales representative yearly reporting.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Veronica Sheldon, Management Analyst at the following address:

Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@health.nv.gov

Members of the public who require special accommodations or assistance at the workshops are required to notify Veronica Sheldon, Management Analyst, in writing to the Department of Health and Human Services, 4126 Technology Way, Suite 100, Carson City, Nevada, 89706, or by calling (775) 684-4255 at least five (5) working days prior to the date of the public workshop.

You may contact Veronica Sheldon, Management Analyst by calling (775) 684-4255 for further information on the proposed regulations.

A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Department of Health and Human Services
4126 Technology Way
Carson City, NV

Division of Public and Behavioral Health
4220 S. Maryland Parkway, Suite 810, Bldg D
Las Vegas, NV

Nevada State Library and Archives
100 Stewart Street
Carson City, NV

A copy of the regulations and small business impact statement can be found on the Department of Health and Human Services web page:

http://dhhs.nv.gov/HCPWD/Drug_Transparency/

A copy of the public workshop notice can also be found at Nevada Legislature's web page:
https://www.leg.state.nv.us/App/Notice/A/

Copies may be obtained in person, by mail, or by calling the Department of Health and Human Services at (775) 684-4255 in Carson City.

A copy of this notice has been posted at the following locations:

1. Department of Health and Human Services, 4126 Technology Way, First Floor Lobby, Carson City
2. Nevada State Library and Archives, 100 Stewart Street, Carson City
3. Legislative Building, 401 S. Carson Street, Carson City
4. Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas
5. Early Intervention Services, 1020 Ruby Vista Drive, Suite 102, Elko, NV 89801
6. Division of Child and Family Services, 2655 Enterprise Rd, Reno, NV 89512

On the Internet at:
https://notice.nv.gov or http://dhhs.nv.gov/HCPWD/Drug_Transparency/

Copies may also be obtained from any of the public libraries listed below:

Carson City Library
900 North Roop Street
Carson City, NV 89702

Churchill County Library
553 South Main Street
Fallon, NV 89406

Clark County District Library
833 Las Vegas Boulevard North
Las Vegas, NV 89101

Douglas County Library
1625 Library Lane
Minden, NV 89423

Elko County Library
720 Court Street
Elko, NV 89801

Esmeralda County Library
Corner of Crook and 4th Street
Goldfield, NV 89013-0484

Eureka Branch Library
210 South Monroe Street
Eureka, NV 89316-0283

Henderson District Public Library
280 South Water Street
Henderson, NV 89105

Humboldt County Library
85 East 5th Street
Winnemucca, NV 89445-3095

Lander County Library
625 South Broad Street
Battle Mountain, NV 89820-0141

Lincoln County Library
93 Maine Street
Pioche, NV 89043-0330

Lyon County Library
20 Nevin Way
Yerington, NV 89447-2399

Mineral County Library
110 1st Street
Hawthorne, NV 89415-1390

Pahrump Library District
701 East Street
Pahrump, NV 89041-0578

Pershing County Library
1125 Central Avenue
Lovelock, NV 89419-0781

Storey County Library
95 South R Street
Virginia City, NV 89440-0014

Tonopah Public Library
167 Central Street
Tonopah, NV 89049-0449

Washoe County Library
301 South Center Street
Reno, NV 89505-2151

White Pine County Library
950 Campton Street
Ely, NV 89301-1965

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

SMALL BUSINESS IMPACT STATEMENT 2018

PROPOSED AMENDMENTS TO NAC 439

The Nevada Department of Health and Human Services (DHHS) has determined that the proposed amendments should not impose an economic burden upon a small business or have a negative impact on the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes NRS 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement is made pursuant to NRS 233B.0608 (3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608(3), this statement identifies the methods used by the agency in determining the impact of the proposed regulation on a small business in sections 1, 2, 3, and 4 below and provides the reasons for the conclusions of the agency in section 8 below followed by certification by the person responsible for the agency.

Background

Senate Bill 539 was recently passed in June 2017 to compile a list of essential diabetes medications and obtain information related to these medications from drug manufacturers, pharmaceutical benefit managers (PBM), and pharmaceutical sales representatives. DHHS drafted regulations that further detail drug manufacturer, PBM, and pharmaceutical sales representative reporting requirements. The draft regulations also outline the process for drug manufacturers and PBMs to request of DHHS that data elements be declared confidential under the Defend Trade Secrets Act (DTSA). Lastly, the draft regulations define the notification and consent process for confidential data requests received by DHHS.

1) **A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.**

Pursuant to NRS 233B.0608 (2)(a), DHHS has requested input from all known stakeholders.

A Small Business Impact Questionnaire was distributed along with a copy of the proposed regulation changes, using the following organization websites, listservs and social media platforms:

- DHHS Drug Transparency webpage (January 4, 2018)
- Nevada Board of Pharmacy website (January 9, 2018)
- Bureau of Health Care Quality and Compliance Nevada health facilities listserv (January 8, 2018)
- Nevada Medical Association website (January 5, 2018)
- Indian Health Services, Nevada Service Units (January 4, 2018)
- Nevada Department of Health and Human Services Facebook page (January 5, 2018)
- Nevada Division of Public and Behavioral Health Facebook page (January 5, 2018)

- Nevada Primary Care Association newsletter (January 8, 2018)
- Nevada Department of Health and Human Services Twitter page (January 5, 2018)

The questions on the questionnaire were:

1) How many employees are currently employed by your business?
2) Will a specific regulation have an adverse economic effect upon your business?
3) Will the regulation(s) have any beneficial effect upon your business?
4) Do you anticipate any indirect adverse effects upon your business?
5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Comments Received
(11 total responses were received)

Will a specific regulation have an adverse economic effect upon your business?	**Will the regulation (s) have any beneficial effect upon your business?**	**Do you anticipate any indirect adverse effects upon your business?**	**Do you anticipate any indirect beneficial effects upon your business?**
One respondent answered "yes", stating "It will cost an additional $5,000 in staff time to prepare this report. This is only adding to the mountain of paperwork involved in running this business and will not help my business, but only burden it with more redundant paperwork." Five answered "no", and five skipped the question. One respondent stated, "we do advocate for civil rights of individuals with disabilities but we do not do direct services for them nor provide medications nor receive funding from any manufacturer".	Six respondents answered "no" and five skipped the question.	Two respondents answered "yes". One stated "Higher costs of medication for my clients due to additional cost burden of preparing more paperwork for pharmacies and drug manufacturers." The other respondent stated "To subject our employees to having their medications allowed or picked by the State of Nevada will cause undue stress regarding their health care. While we realize the cost of healthcare is considerable, this bill does not allow employers, employees a choice of their own healthcare." Four answered "no", and five skipped the question. One respondent that stated "no" added the condition	Six respondents answered "no" and five skipped the question.

Will a specific regulation have an adverse economic effect upon your business?	Will the regulation (s) have any beneficial effect upon your business?	Do you anticipate any indirect adverse effects upon your business?	Do you anticipate any indirect beneficial effects upon your business?
		"Not unless the cost of the medication goes up for the person taking it."	

2) Describe the manner in which the analysis was conducted.

The Small Business Impact Questionnaire was embedded in an online survey with a link to the proposed amendments to regulation, and distributed to the stakeholders identified above. Responses were reviewed individually and collectively to determine potential impacts of the proposed amendments. Staff have reviewed the regulations to ensure there is not a negative impact on small business.

3) The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation both adverse and beneficial effects and both direct and indirect effects.

Based on a preliminary analysis, DHHS does not anticipate adverse or beneficial direct or indirect economic effects from the proposed regulation on small businesses. Direct or indirect adverse or beneficial economic effects will be better determined by DHHS after the workshop scheduled for February 15, 2018.

4) Provide a description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

DHHS designed the information requests to mirror reports already submitted federally by organizations impacted by the proposed regulation. This will significantly reduce the resources needed to prepare and submit these reports. DHHS will also be holding a workshop on February 15, 2018 allowing for further input by stakeholders regarding the proposed regulations and how they will impact small businesses. These comments will be taken into consideration if any potential negative impact is identified.

5) The estimated cost to the agency for enforcement of the proposed regulation.

No new costs are anticipated for enforcement of the proposed regulation.

6) If the proposed regulation provides a new fee or increases an existing fee, the total annual amount DPBH expects to collect and the manner in which the money will be used.

The proposed regulation does not provide a new fee or increase an existing fee.

7) **An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.**

The proposed regulation does not include duplicative or more stringent provisions than the Nevada Revised Statutes.

8) Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.

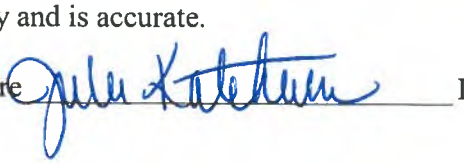
The response rate to the small business impact questionnaire was relatively low, which may be a reflection that stakeholders do not anticipate significant impacts from the proposed regulation. The majority of the respondents indicated no direct or indirect positive or negative impacts from the proposed regulation. Three of the responses reported anticipated negative impacts, with two referencing increased costs due to report preparation. DHHS designed the information requests to mirror reports already submitted federally by organizations impacted by the proposed regulation. This will significantly reduce the resources needed to prepare and submit these reports. The last anticipated negative impact reported by a respondent on the survey stated that the regulation would impose restrictions on the choice of health care and on the choice of available diabetic medications for Nevada residents. The proposed regulation in no way restricts the choice of health care or the choice of available diabetic medications for Nevada residents. Based on DHHS analysis of the proposed regulation and the responses received from the small business impact questionnaire, DHHS has determined that the proposed amendments should not impose an economic burden upon a small business or have a negative impact on the formation, operation or expansion of a small business in Nevada.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Veronica Sheldon at the Nevada Department of Health and Human Services at:

Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City, NV 89701
Veronica Sheldon
Phone: (775) 684-4255
Email: drugtransparency@dhhs.nv.gov

Certification by Person Responsible for the Agency

I, Julie Kotchevar, Deputy Director of the Nevada Department of Health and Human Services certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Signature  Date: 1-29-18

SB539 Drug Transparency Draft Regulations

Definitions:

Defend Trade Secrets Act of 2016 defined as Public Law 114-153.

Department defined as the Department of Health and Human Services.

Manufacturer as defined by NRS 639.009

Pharmacy Benefit Manager means an entity that contracts with or is employed by a third party and manages the pharmacy benefits plan or prescription drug coverage provided by a third party.

Section 1: Drug Transparency Report

The Department will collect detailed information from drug manufacturers and pharmacy benefit managers regarding the costs and rebates related to drugs listed on the List of Essential Diabetes Drugs created and posted on the Department website. The report will include aggregated information and will describe the trends related to drug pricing and how those costs may impact the diabetes disease burden and health system within Nevada.

Section 2: Prescription Drug Manufacturers

1. Drug manufacturers must submit a report in the format listed on the Department website by April 1st for the previous calendar year.
2. If a manufacturer believes that a data element in the report meets the standard of the Defend Trade Secrets Act (DTSA), a request to have the element declared confidential may be submitted.
    a. The request must include a detailed description of why the data element qualifies as a trade secret under the DTSA. This detailed description asserting trade secret protection will be available upon request to the public.
    b. The Department will notify the manufacturer of any request for data elements marked as confidential and will provide the manufacturer a copy of the written request for those records.
    c. The Department will allow the manufacturer thirty days to take legal action under DTSA prior to releasing the information.
    d. The requestor will be notified of the 30-day period and will be provided the detailed description provided by the manufacturer to assert that the data elements qualify as a trade secret under the DTSA.

Section 3: Pharmacy Benefit Managers

1. Pharmacy benefit managers must submit a report in the format listed on the Department website by April 1st for the previous calendar year.
2. If a pharmacy benefit manager believes that a data element in the report meets the standard of the Defend Trade Secrets Act (DTSA) a request to have the element declared confidential may be submitted.

a. The request must include a detailed description of why the data element qualifies as a trade secret under the DTSA. This detailed description asserting trade secret protection will be available upon request to the public.
b. The Department will notify the pharmacy benefit manager of any request for data elements marked as confidential and will provide the manufacturer a copy of the written request for those records.
c. If the pharmacy benefit manager does not consent to the release of the data elements marked confidential to the requestor, the Department will allow the pharmacy benefit manager thirty days to take legal action under DTSA prior to releasing the information.
d. The requestor will be notified of the 30-day period and will be provided the detailed description provided by the pharmacy benefit manager to assert that the data elements qualify as a trade secret under the DTSA.

Section 4: Pharmaceutical Sales Representative

Pharmaceutical sales representatives who are or were registered with the Department during anytime in the previous year must submit a report to the Department by March 1st for the previous calendar year. The report must be submitted in the format listed on the Department website.

Frequently Asked Questions

Pharmaceutical Representatives:

- Reporting for Pharmaceutical Representatives, is it the individual's responsibility or the manufacturer's?
    - Both, please see below for specific requirements.

        - Manufacturers are required to submit a list of names of all pharmaceutical representatives who market prescription drugs in Nevada.

            - Section 4.6(1) of the law states "A **manufacturer** of a prescription drug shall provide to the Department a list of each pharmaceutical sales representative who markets prescription drugs on behalf of the manufacturer to providers of health care licensed, certified or registered in this State, pharmacies or employees thereof, operators or employees of medical facilities or persons licensed or certified under the provisions of title 57 of NRS and update the list at least annually."

        - Each pharmaceutical representative is required to submit a report of all compensation or prescription drug that was provided to a provider of health care licensed, certified or registered in this State, pharmacies and employees thereof, operators and employees of medical facilities and persons licensed or certified under the provisions of title 57 of NRS.

            - Section 4.6(4) of the law states "On or before March 1 of each year, **each person** who was included on a list of pharmaceutical sales representatives submitted pursuant to subsection 1 at any time during the immediately preceding calendar year shall submit to the Department a report, which must include, for the immediately preceding calendar year: (a) A list of providers of health care licensed, certified or registered in this State, pharmacies and employees thereof, operators and employees of medical facilities and persons licensed or certified under the provisions of title 57 of NRS to whom the pharmaceutical sales representative provided: (1) Any type of compensation with a value that exceeds $10; or (2) Total compensation with a value that exceeds $100 in aggregate; and (b) The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of NRS and the name of each such person to whom a free sample was provided."

                - While the law requires the individual to submit the yearly report, manufacturers may submit these yearly reports on behalf of pharmaceutical representatives in their employment.
                - Report formatting and specifics may be found at the end of this document.

- Does this law apply to any/all pharmaceutical representatives and not just those engaging in the sales and marketing of diabetes-related treatments?

    - Yes, this law applies to all pharmaceutical representatives.

- When we provide the list of the company's pharmaceutical sales representatives working in Nevada, is there a format that should be used?

    - An excel file is preferable listing the first name, last name and company that the individual represents. An example is provided below. This information can be e-mailed to drugtransparency@dhhs.nv.gov and should be updated as changes occur within your organization.

Company	Pharmaceutical Representative First Name	Pharmaceutical Representative Last Name

- When are the first reports due?
    - 2017 will be the first reporting period. The reportable period for this first report will be October 1, 2017-December 31, 2017. For all future reporting, the period will be based on the calendar year.

- What format should the reports be in?
    - At this time the Department is not requiring a specific format, however Excel is preferred.
        - The State of Nevada will accept the federal report to fulfill this requirement.

- Are veterinary pharmaceutical representatives required to register in the State of Nevada or provide a yearly report?
    - Only pharmaceutical representatives for human medications are required to register or report under SB 539.

- Are medical device representatives required to register with the State of Nevada and to submit the yearly report?
    - At this time, no medical device representative information is required to be submitted.

Prescriptions Drug Manufacturers:

- Sections 3.8 and 4 of the law require some drug manufacturers to submit certain reports on diabetes drug price increases to DHHS by April 1, 2018. When do you anticipate that DHHS will issue the format and other requirements for these reports?

    - Regulations have been drafted and are available for review on the website http://dhhs.nv.gov/HCPWD/Drug_Transparency/
    - Report formatting and specifics may be found at the end of this document.

Pharmacy Benefit Managers:

- Report formatting and specifics may be found at the end of this document.

Consumers:

- Will this new law limit my access to drugs?
    - Senate Bill 539 does not in any way limit your access to medication. The law is intended to assist DHHS with research and analysis related to increasing costs for various medications required to treat diabetes.

Revised: January 18, 2018

Prescription Drug Manufacturers

Drug manufacturers must submit a report to the Nevada Department of Health and Human Services (DHHS) containing information described in the table below for prescription drugs posted on the DHHS website. Reports must be submitted to drugtransparency@dhhs.nv.gov annually by April 1st for the previous calendar year. DHHS will compile a report, submit and post it in accordance with NRS 439.

Reporting Information	Text or Number
Cost of producing the drug	Number
Total administrative expenditures relating to the drug, including marketing and advertising costs	Number
Profit earned from the drug	Number
Percentage of total profit for the previous calendar year that is attributable to each drug on the list published by the department	Number
Total amount of financial assistance provided through patient prescription assistance programs	Number
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	Number
Wholesale acquisition cost of the drug	Number
History of any increases in the wholesale acquisition cost of the drug over the five 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. • and any explanation for the increase.	Text Number Date Text
Aggregate amount of all rebates provided to pharmacy benefit managers for sales of the drug within Nevada.	Number
Reasons why the wholesale acquisition cost of the drug increased, if it did in the last year. For each drug, list factors contributing to the increase, and: • Percentage of total increase attributable to each factor, and • Explanation of role each factor played in the increase.	Text

Pharmacy Benefit Managers

Pharmacy benefit managers (PBM) must submit a report to the Nevada DHHS containing information described in the table below for prescription drugs posted to the department website. Reports must be submitted to drugtransparency@dhhs.nv.gov annually by April 1st for the previous calendar year. DHHS will compile a report, submit and post it in accordance with NRS 439.

Reporting Information	Text or Number
Total amount of rebates negotiated with manufacturers	Number
Total amount of all rebates described above that were retained by the PBM	Number
Total amount of all rebates negotiated for purchase of such drugs for use by: 1. Recipients of Medicare; 2. Recipients of Medicaid; 3. Persons covered by 3rd parties which are governmental agencies 4. Persons covered by 3rd parties which are NOT governmental agencies; and 5. Plans subject to the Employee Retirement Income Security Act (ERISA) that require compliance with the state reporting requirement.	Numbers and Text

Pharmaceutical Sales Representatives

Pharmaceutical sales representatives on a list submitted to DHHS by drug manufacturers during anytime in the previous calendar year must report to DHHS by March 1st for the previous calendar year, and must include items in the table below. DHHS will compile a report, submit to drugtransparency@dhhs.nv.gov and post it in accordance with NRS 439.

Reporting Information	Text or Number
List of health care providers or facilities to whom: 1. Any type of Compensation with a value that exceeds $10; or 2. Total compensation exceeding $100 in aggregate.	Text
The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a provider of health care licensed, certified or registered in this State, pharmacy or employee thereof, operator or employee of a medical facility or person licensed or certified under the provisions of title 57 of	Text

NRS and the name of each such person to whom a free sample was provided.	

STATE OF NEVADA

Department of Health and Human Services

Nevada Drug Transparency

For questions or to submit reports, you may contact staff by utilizing any of the following methods:

By Mail:
4126 Technology Way, Suite 100
Carson City, NV 89706

By Phone: (775) 684-4255

By E-Mail: drugtransparency@dhhs.nv.gov

TAB 7

TAB 7

SB 539 PUBLIC WORKSHOP

DRAFT MINUTES
February 15, 2018
9:00 a.m.

The Department of Health and Human Services held a public workshop on February 15, 2018, beginning at 9:00 a.m. to consider amendments the Nevada Administrative Code (NAC) Chapter 439.on February 15, 2018, beginning at 9:00 a.m. at the following locations:

Nevada Legislative Counsel Bureau
401 S. Carson St
Room 3137
Carson City, NV 89701

Nevada Legislative Counsel Bureau
555 E. Washington Ave. #5100
Room 4412E
Las Vegas, NV 89101

Great Basin College
1500 College Parkway
Elko, NV 89801

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) STAFF PRESENT:

Carson City Location:
Dr. Julie Kotchevar, Deputy Director DHHS/Interim Administrator DPBH
Rhonda Peña, Administrative Assistant to Deputy Director, Julie Kotchevar

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH (DPBH) STAFF PRESENT:

Elko Location:
Joseph Tucker, Primary Care Office (PCO)
Las Vegas Location:
Scott Jones, Manager, Primary Care Office (PCO)
Carson City Location:
Veronica Sheldon, Primary Care and Health Workforce Development Office
Margot Chappel, Primary Care and Health Workforce Development Manager

Deputy Director of DHHS/Interim Administrator DPBH, Dr. Julie Kotchevar called the SB539 Public Workshop to order at 9:01 a.m. with introductions and process items.

1. **Phone Etiquette**

Dr. Kotchevar asked that people who are calling in to please mute their phone and do not at any time place the call on hold. We will have to disconnect all calls if that happens. This meeting can also be viewed online if you would rather listen in that way.

2. **Process Items**

Dr. Kotchevar stated that the SB 539 Public Workshop is willing to gather information and allow for public comment, but keep in mind that the Bill is actually law, so limit comments specific to the Regulation.

Dr. Kotchevar addressed a typo on the Public Workshop agenda which had the Drug Transparency email address incorrect, should have been drugtransparency@dhhs.nv.gov.

When coming up to make a public comment, please state your name and provide a contact card to Rhonda here in Carson, Joseph in Elko, and Scott in Las Vegas as this will help us have more accurate information on names and organizations. Comments in writing can be left and will be submitted for the record. They can also be emailed and will be part of the public record so there isn't a need for them to be read here. Keep comments brief as we are only allotted 2 hours for use of the room.

Dr. Kotchevar asked Mr. Tucker if there was anyone present in Elko. Mr. Tucker advised that there wasn't anyone currently there.

3. Public Comment

Paul Young with R & R Partners, representing Pharmaceutical Care Management Associates, refers to Section 3; Subsection 2, Subsection B of proposed rule there is a "typo" for lack of a better word, removing "manufacturer" and putting "Policy Benefit Manager" of Section 1. Subsection 2 of our proposal or submittal the Medicare law, it's PCMA's position that the requesting of Medicare Part D information violates federal law. They have read on a couple different cases and statues. That is their (PCMA)'s position that requesting Medicare information be sent to the State is not something that PCMA is able to do at this time, since the same information is already being provided to the Secretary of State and the Feds. PCMA would like to know what the State is requesting regarding the regulation. PCMA is objecting to the proposed law, with regards to transparency and the rebate information.

Dr. Kotchevar asked if there were any other public comments in Las Vegas or Elko. No other comments in Las Vegas or Elko. She opened for any other public comments on anything other than the regulations. None.

4. Adjournment

The meeting adjourned at 9:07AM.

Public comment received for SB 539 Public Workshop

VIA ELECTRONIC DELIVERY

February 15, 2018

Ms. Julie Kotchevar, MA
Deputy Director
Nevada Department of Health and Human Services
Director's Office
4126 Technology Way, Suite 100
Carson City, NV 89706

Re: Draft Regulations to Implement SB 539 Transparency Provisions

Dear Deputy Director Kotchevar:

I am writing to submit comments on behalf of the Biotechnology Innovation Organization (BIO) to highlight our concerns with the draft regulation as posted on the Department's website. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO welcomes the opportunity to comment on the Department's draft regulations to implement transparency provisions of SB 539. BIO continues to believe this legislation is bad for patients and violates trade secret laws.

At the outset, BIO would like to shed some light on the current state of prescription medicines in the United States, because, unfortunately, many popular press accounts focus an overly narrow view on the list prices of a small subset of innovative biopharmaceutical products, rather than focusing on the marketplace as a whole. A brief overview of the *complete* picture of the biopharmaceutical marketplace is helpful in framing the issue. Specifically, according to the trade association representing the generic drug industry in the United States, almost 90% of prescription medicines dispensed in the U.S. are generic.[1] And with FDA's continued movement in approving commercially-available biosimilar medicines, the marketplace for lower-cost biologic products is rapidly expanding. In short, the amazing innovations seen in the biopharmaceutical marketplace over the past several decades are also rapidly matriculating to the lower-cost generic market.

Further, the innovative side of the biopharmaceutical marketplace is strong, but challenges exist. The cost of developing a new drug has increased exponentially since the 1970s. A recent study conducted by the Tufts Center for the Study of Drug Development found that developing a drug that gains market approval can take 10-years or longer, and

[1] Association for Accessible Medicines, *2017 Generic Drug Access & Savings in the U.S. available at:* *http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf*

cost roughly $2.6 billion.[2] There is a high failure rate in biopharmaceuticals research and development (R&D), so investments must take into account the funds spent on products that never make it to market. Furthermore, biopharmaceutical development is increasingly relying on outside private and public market capital as an investment source. Investors, however, have a range of diverse industries to choose from when making capital allocation decisions. Issues like government-imposed price regulations are significant detractions for the investment community when evaluating investment options. Small and emerging companies are responsible for 70% of the global clinical pipeline and 84% of all products in the pipeline are orphan designated programs. Many of these companies work for years, even decades, without products on the market but continue investing millions upon millions in research and development. In fact, 92% of publicly traded biotech companies in the US operate on a negative net income.[3] Reports of overall profit margin are misleading.

The enormous resources required to sustain and drive forward the innovation ecosystem is reflected in the reality that the pharmaceutical industry spends significantly more than almost every other industry on R&D. On average, pharmaceutical companies spend 18.5 percent of revenue on R&D; when looking just at the U.S., one study found that, in 2013, 23.4 percent of domestic sales went to domestic R&D.[4] Complementing this research is data that demonstrates the pharmaceutical industry spent not only the most on domestic R&D annually but also globally, averaging $150 billion globally in 2015. When looking at a company's profit, it should be measured in the return on equity. When looking at all other industries, the biopharmaceutical industry ranks 45th, yet it is time and again ranked first on investment in R&D. The entire budget for the National Institutes of Health (NIH) was $30 billion.[5] The direct and indirect economic impact in the State of Nevada is approximately $2.4 billion.[6] The biopharmaceutical industry alone is currently conducting nearly 650 clinical trials recruiting or in progress within the State of Nevada.[7] In short, while the innovation necessary to drive development of new treatments continues, the process is increasingly more difficult – and more expensive. But hope for patients with previously untreatable diseases continues to rise as evidenced by the vast pipeline emphasizing unmet needs.

Section 1: Drug Transparency does not focus on patients, is not holistic, and does not enhance the innovative healthcare ecosystem

BIO believes firmly that any transparency provisions should focus on what matters most for patients, including lowering out of pocket costs and improving patient access. This transparency law is fundamentally flawed. More focus should be placed in areas that will directly help consumers, including ensuring that they know what their actual cost-sharing obligations are, how plans are using manufacturers' rebates, and what drugs are available on their health plan's formulary. More transparency is needed to understand how health plans and other middlemen are using these rebates and discounts and whether these savings are being passed on to consumers, as that is the kind of information helpful to patients and consumers.

[2] Lamberti M. and Getz, K. Profiles of New Approaches to Improving the Efficiency and Performance of Pharmaceutical Drug Development. Tufts Center for the Study of Drug Development. May 2015.
[3] Factset, BIO Industry Analysis, January 2016
[4] Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA annual membership survey. Washington, DC: PhRMA; 2015, as reported here: http://phrma-docs.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf (last accessed March 10, 2017).
[5] NIH Website and EvaluatePharma Report, 2015.
[6] The Economic Impact of the US Bio-Pharmaceutical Industry: National and State Estimates, May 2016.
[7] www.clinicaltrials.gov Search performed: February 12, 2018.

Moreover, we believe that this law will have a negative impact on small, emerging biotechnology companies. If a small company is developing new innovative drugs for Diabetes that would likely end up on the list or they will already have a drug included on the list of "essential diabetes drugs," it will be overly burdened by the reporting requirements currently included in the law, ultimately impacting patients with unmet needs. Small, emerging companies must use their limited resources as efficiently as possible to continue to supply the therapies patients need and to invest in future innovation. Any reporting requirements that force researchers and scientists to incorporate burdensome accounting measures into their laboratory practices risk diverting the scarce resources of these companies. Patients are ultimately the ones who suffer, since resources would be diverted away from innovative research and drug development.

While BIO appreciates the Department's efforts to maintain the information reported in aggregate, we are concerned that there are not enough confidentiality protections in the law or in the regulations. While certain information may be in aggregate form in the report included on the internet, if a company were to only have one drug on the list of Essential Diabetes Drugs, specific data will be much easier for the public to determine rebate and cost data unless the term "aggregate" included rebate dollars of all companies together rather than simply by company. We believe this is an important distinction; one which should be reflected in regulation.

Section 2. Prescription Drug Manufacturers—Trade Secret Protections are Not Consistent with Federal Law

Section 2 of the draft regulation appears to use the terms "request" and "requester" interchangeably with manufacturers and a possible request from the public for information that should be protected under the federal Defend Trade Secrets Act (DTSA).[8] BIO believes there should be greater clarity in the draft that indicates the difference between a request to keep information confidential under the DTSA by the manufacturer under 2(2)(a), and what appears to be a request for disclosure by the general public in 2(2)(d).

BIO is pleased that the Department seemingly intends to protect trade secret information as provided for under the DTSA. However, we believe the requirements in Section 2, are not consistent with federal requirements. In the DTSA, information is a trade secret if it has commercial value, and the company or person has taken reasonable steps to ensure its security. The DTSA gives the holder of trade secrets, the power to implement strict policies maintaining confidentiality of trade secrets to prevent litigation. However, the DTSA does provide for a remedy in federal courts.

Nevertheless, one major difficulty BIO has with this regulation, is that the state assumes the information is not protected unless the manufacturer requests it remain confidential. The manufacturer would then need to challenge it in the courts, but the information is being disclosed to the state based upon passage of the law, regardless of the steps the manufacturer has taken to keep it confidential. The draft regulation would grant the manufacturer 30 days to challenge the disclosure and take legal action. While each company may be different, because companies maintain that much of this information is confidential trade secrets, then it would stand to assume companies would automatically be in federal court perpetually every year. This is not a positive business environment and could stand to harm innovation and clinical trials in the State of Nevada. Moreover, these requirements would overly burden small biotechnology firms who would not only be

[8] 18 U.S.C. § 1836, et seq.

overwhelmed with reporting requirements, but they would also be forced to spend money on unwarranted litigation under the DTSA every year.

***

Thank you for the opportunity to comment on the draft regulations to implement SB 539. Should you have any questions regarding our comments, please do not hesitate to contact me at 202-962-9200.

Sincerely,

/s/

Jack Geisser
Director, Healthcare Policy, Medicaid, and State Initiatives

Culinary Health Fund

February 15, 2018

Attention: DHHS
drugtransparency@dhhs.nv.gov

Subject: Proposed Regulations regarding SB539

Thank you for the opportunity to participate in the regulation setting process for SB539.

Unite HERE Health, through the Culinary Health Fund, has actively supported this first-in-nation legislation to make more transparent the process of setting and increasing pricing for essential diabetic medications. We are following the implementation of this legislation with great interest and hope that it becomes, as intended, a step forward in understanding prescription pricing and patient impact in Nevada. Through the filings submitted on our behalf concerning PhRMA and BIO's current lawsuit to oppose implementation of this legislation, DHHS is already aware of our concerns regarding these regulations.

Briefly, we support the full implementation of this statute. We find the current lawsuit by PHRMA and BIO to be meritless and a distraction from full implementation. We find it unfortunate that the proposed regulations purport to permit regulated drug manufacturers to withhold information from the public about their pricing decisions based on the federal Defend Trade Secrets Act ("DTSA"). The DTSA does not preempt state trade-secrets laws and, by its terms, does not apply to a state government's "otherwise lawful activity"—including its disclosure of information pursuant to state law. 18 U.S.C. § 1833(a). The DTSA provides no support for adopting regulations that are clearly contrary to SB 539.

If DHHS nonetheless adopts regulations that permit regulated drug manufacturers to mark information as confidential, it should make clear that the regulations are temporary and may be superseded based on the outcome of PhRMA's lawsuit. DHHS should not promise to maintain the confidentiality of reports if a court subsequently determines that PhRMA's challenge to SB 539 is without basis.

Such temporary regulations, should they be adopted, must also be far clearer on the basis on which a regulated manufacturer may claim confidentiality. The proposed regulations state: "If a manufacturer believes that a data element in the report meets the standard of the Defend Trades Secret Act (DTSA), a request to have the element declared confidential may be submitted." It is unclear what the phrase "meets the standard of the Defend Trades Secret Act" means. The DTSA contains a definition of a trade secret, but not all use of a trade secret constitutes "misappropriation" under that statute. *See* 18 U.S.C. § 1839(5). Even under DHHS's misguided interpretation of the DTSA's scope, it is not enough that certain information "qualifies as a trade secret under the DTSA" for DHHS to withhold information from the public. Only if DHHS is affirmatively precluded by federal law from disclosing information that SB 539 commands it to make public may DHHS withhold this information.

Section 2(2) of the proposed regulation should therefore read: "If a manufacturer believes that public disclosure of a data element in the report by DHHS would constitute the misappropriation of a trade secret under the Defend Trade Secrets Act, 18 U.S.C. § 1836 *et seq*. sufficient to confer jurisdiction under 18 U.S.C. § 1836(b), a request to have the element declared confidential may be submitted." Section 2(2)(a) should read: "The request must include a detailed description of why disclosure of the date element by DHHS would constitute the misappropriation of a trade secret under the DTSA." Section 2(2)(d) should read: "The requester will be notified of the 30-day period and will be provided the detailed description provided by the manufacturer to assert that disclosure of the data elements would constitute the misappropriation of a trade secret under the DTSA."

We request that the State return to regulation setting and create new regulations that implement SB 539 as it was adopted and signed by Governor Sandoval at the conclusion of PhRMA's lawsuit. As this letter makes clear, the Culinary Health Fund disagrees with DHHS's interpretation of the law. These comments and the Culinary Health Fund's participation in the adoption of temporary regulations should not be construed to prejudice the Fund's positions in PhRMA's pending lawsuit in any way.

Sincerely,

Bobbette Bond
Policy Director, Unite HERE Health

PhRMA RESEARCH PROGRESS HOPE
950 F STREET, NW, SUITE 300 WASHINGTON, DC 20004 202-835-3400 PhRMA.org

February 14, 2018

BY E-MAIL

Veronica Sheldon
Management Analyst
Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@health.nv.gov

Re: Draft Regulations Implementing Senate Bill 539

Dear Ms. Sheldon:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment regarding the Department of Health and Human Services' ("Department") draft regulations implementing Senate Bill 539 of the 2017 Legislative Session. PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical research and biotechnology companies. PhRMA members are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives, including essential diabetes medicines. Since 2000, PhRMA's member companies have invested more than half a trillion dollars in the search for new treatments and cures, with members investing $65.5 billion in 2016 in the discovery and development of new medicines.

As the Department is aware, PhRMA has filed a lawsuit in federal court challenging the constitutionality of various provisions of SB 539. The Department has drafted the proposed regulations in part to address PhRMA's concern in the litigation that SB 539 impermissibly requires the disclosure of manufacturer trade secrets. While PhRMA commends the Department for recognizing the constitutional problems that would arise if it fails to safeguard trade secrets, we remain concerned that the proposed regulations do not establish a process that adequately ensures the protection required. Below, we outline some of our legal and policy concerns with the regulations.

I. Section 1: Drug Transparency Report and Section 2: Prescription Drug Manufacturers

The draft regulations suffer from several flaws that PhRMA fears will render them unworkable in practice absent significant revisions.

First, the prescribed process for challenging a request for confidential information —a manufacturer-initiated lawsuit under the Defend Trade Secrets Act of 2016 ("DTSA")—will impose significant burdens and costs on all parties. Instead, the Department should model its

regulations on existing procedures under the Freedom of Information Act ("FOIA"), 5 U.S.C. §§ 552, *et seq.*, and the Nevada Public Records Act ("Public Records Act"), Nev. Rev. Sta. 239.010. Those laws allow a party submitting information to request that it be treated confidentially, by marking it with a confidentiality legend. The government agency then must determine in the first instance whether the information requested qualifies as confidential and thus exempt from disclosure. A party who disagrees with the government agency's position can begin legal action. This well-established procedure is less expensive, less burdensome, and more predictable.

Second, the proposed regulations are unclear as to what specific information manufacturers must disclose under §§ 3.8 and 4 of SB 539. The regulations would require manufacturers to disclose "costs," "profits," and "administrative expenditures," without any definition of those terms. Without further guidance, manufacturers could adopt different definitions, resulting in reports that are not helpful to the Department and raising fairness concerns if and when the terms are defined after the fact.

Third, the regulations should affirm that the Department will not post manufacturer-specific information in the "Drug Transparency Report" on the Department's website. The regulation as written appears to contemplate that the Department will not include such information, as it provides that the report will include only "aggregated information." To ensure that the Department does not later adopt a different interpretation and disclose trade secrets in the report, the regulation should make this point crystal clear.

Fourth, the regulations should correct what appears to be a clerical error and track the statutory requirement that manufacturers' initial report pursuant to § 3.8 is due on July 1, 2018, not April 1, 2018. *See* SB 539 § 26.9. The regulations should also confirm that because the Department has not published the list of essential diabetes medicines required by § 3.6(2), no reporting required by § 4 is due until April 1, 2019. *See id.*

We address each of these issues in further detail below.

A. Process Concerns Regarding Protecting Trade Secret Information

The Department has argued in federal court against invalidation of SB 539 because it remained conceivable that the Department could "adopt regulations to address the protection of trade secrets."[1] PhRMA appreciates the Department's acknowledgement that trade secrets must be protected from public disclosure. While the Department's proposed regulations seek to bring SB 539 in line with federal trade secret law, the proposed process falls short and should track other Federal and Nevada state laws more closely. The process discussed below would serve to protect trade secrets while working efficiently for all parties involved.

The proposed regulations attempt to afford trade secret protection by setting forth a process whereby manufacturers can seek to prevent the disclosure of information they deem to be confidential. In doing so, manufacturers must first submit a request to the Department that includes a "detailed description of why the data element qualifies as a trade secret." *See* Draft

[1] *See* Defs.' Opp'n to Pls.' Mot. for Summ. J., *Pharm Research & Mfrs. of Am. v. Sandoval*, No. 17-cv-02315-JCM-CWH (D. Nev. Nov. 17, 2017), ECF No. 74.

Regulations, § 2(a). The regulations propose that the detailed description "will be available upon request to the public." *Id.* If a party then seeks, through a public-records request, any data element noted as confidential, the Department would "notify the manufacturer of [the] request" and "allow the manufacturer thirty days to take legal action under the DTSA prior to releasing the information." *Id.* §§ (b)-(c). The requestor would be notified of the 30-day period and would be given the manufacturers' detailed description explaining why the data qualifies as a trade secret. *Id.* § (d).

The proposed process suffers from a number of flaws. In our view, the Department's final regulations should adopt a process for resolving requests for information that both protects the confidentiality of the materials required to be reported under SB 539 and imposes minimal burden and cost on the parties and the courts. To that end, PhRMA proposes the following revisions to the draft regulations.

1. Requiring Legal Action Under the DTSA

Under the proposed regulations, a manufacturer is required to bring a new lawsuit under the DTSA every time that a private party requests information that the manufacturer deems to be confidential. This process will be incredibly time-consuming and expensive. Trade-secret litigation is especially costly, with one study estimating that the median cost for a trade-secret lawsuit with $1 million to $10 million at risk is $925,000.[2] The median civil litigation in federal court in Nevada takes 42.3 months to go to trial.[3] Nevada's Culinary Health Fund has already vowed to seek the information that manufacturers are required to report under SB 539, ensuring that manufacturers will bear these litigation costs if the proposed regulations are adopted as written. Such an unchecked, repetitive, legal process could have the unnecessary effect of adding to the costs of bringing diabetes medicines to market and thus exacerbate the concern PhRMA has raised in the litigation that SB 539's publication of competitively sensitive price and cost information may lead to unintended effects that prevent drug prices from falling as quickly as they would without the Act. Further, it would impose unnecessary burdens on the courts.

Rather than requiring a manufacturer to initiate a DTSA lawsuit every time a private party requests their confidential information, the Department should model its review process after the Freedom of Information Act or Nevada's own Public Records Act. Under FOIA, it is the government agency—not the courts that decides in the first instance whether the requested information falls within the FOIA exemption for "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). If the agency withholds the requested information on the ground that it qualifies for the exemption, then the requester may file a challenge to that agency determination in federal court. *Id.* § 552(a)(4)(B). Alternatively, if the agency decides that the requested information is not protected and could be made public, the party that originally submitted the information to the agency may itself bring a "reverse FOIA" action in federal court to prevent disclosure. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 285 (1979).

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[2] *See* American Intellectual Property Law Association, 2015 Report of the Economic Survey at I-171.

[3] United States District Courts National Judicial Caseload Profile, http://www.uscourts.gov/sites/default/files/data_tables/fcms_na_distprofile0930.2017.pdf.

Similarly, under the Nevada Public Records Act, a governmental entity must make public records available unless "declared by law to be confidential." Nev. Rev. Stat. § 239.010. The governmental entity decides in the first instance whether the public record is "confidential." *Id.* § 239.0107(d). If the entity concludes that the record is confidential and withholds it on that basis, the requester "may apply to the district court in the county in which the book or record is located for an order" requiring disclosure. *Id.* § 239.011. The governmental entity bears the burden of proving by a preponderance of the evidence that the public record is confidential. *Newspapers, Inc. v. Gibbons*, 266 P.3d 623, 628 (Nev. 2011).

There are several reasons why the government should determine in the first instance whether information is subject to a confidentiality exemption. First, it reduces litigation costs by providing the parties with a neutral evaluation of the confidentiality of the information before the parties decide whether to litigate the issue. A party that would otherwise opt to file suit might be less likely to do so after the agency has determined that the information at issue is or is not confidential. Accordingly, the amount of litigation for all parties, including the Department, may be reduced. Second, it apportions the responsibility for initiating litigation more equitably on the party against whom the agency decides. Third, if the Department were to decide these requests in the first instance, it would likely develop expertise in dealing with these issues, which in turn could lead to decisions that are more timely, consistent, and well-reasoned. Leaving each individual ruling up to the court system could lead to different judges' making different decisions.

Delegating to the Department the responsibility to decide whether to disclose information in the first instance is also particularly appropriate here, where nearly all of the information that SB 539 requires manufacturers to disclose constitutes a trade secret under well-established law from jurisdictions throughout the country.[4] As PhRMA has explained in detail in its briefing in its pending challenge to SB 539, numerous court decisions have held that the advertising, cost, marketing, pricing, and production information that SB 539 requires manufacturers to disclose is a trade secret.[5] It would be improper to require manufacturers to bring legal action to defend these trade secrets in full-blown litigation every time a party submits a public-records request. It would be far less burdensome, consistent with other trade secret regimes, and respectful of the sensitivity of trade secrets for the Department to decide, once, whether it believes that the

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[4] The only exception is the wholesale acquisition cost (WAC) of the drug. *See* SB 539 § 3.8(6).

[5] *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) (holding that "confidential pricing structures and marketing plans" were trade secrets); *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).

information constitutes a trade secret, with an opportunity for the aggrieved party to file a challenge to that determination in court.

2. The "Detailed Description" Requirement

The proposed regulations also depart from standard records-request procedures in requiring manufacturers to support their request for confidentiality with a "detailed description" as to why the information qualifies as a trade secret. Neither FOIA nor the Public Records Act imposes such a requirement.[6] The requirement also appears to serve no purpose under the regulations as drafted, as, under the regulations, the Department plays no role in deciding whether particular information is a trade secret. Thus, it is unclear why the proposed regulations require manufacturers to justify their confidentiality designations to the Department. It is even less clear why this detailed description would be made "available upon request to the public."

Even if the Department were to revise the regulations so that the Department decides in the first instance whether to disclose the requested information, there would still be no reason for a "detailed description" requirement. As noted, the requirement is absent from other transparency laws, including FOIA and the Public Records Act. Instead, under FOIA, for example, companies typically label information as "confidential" if they believe that it satisfies a confidentiality exemption from disclosure. Some companies may also—voluntarily—provide additional explanation to the agency as to why the information qualifies for an exemption to bolster the administrative record. But there is no *requirement* under FOIA or the Public Records Act that companies justify their confidentiality designations when they are submitted.

If the Department retains the "detailed description" requirement, it should, at a minimum, be revised to make clear that the "detailed description" need not include information that is itself a trade secret. Otherwise, the requirement would obviously itself run afoul of the DTSA. Alternatively, the final regulations could provide that the "detailed description" will be available in the first instance only to the Department and would enjoy the same protections from disclosure as the underlying information itself.

3. The 30-Day Notice Period

The proposed regulations provide that, after a party has requested information that a manufacturer has designated confidential, "the Department will allow the manufacturer thirty days to take legal action under the DTSA prior to releasing information." Draft Regulations, § 2(c). As noted above, PhRMA believes that the Department should follow the standard practice and decide in the first instance whether information requested by third parties is exempt from disclosure. However, if the final regulations instead require manufacturers to take legal action without any initial decision by the Department, the regulations should make clear that the Department will not release the requested information until litigation has concluded. In this instance, the release of the information at issue should be stayed until either (i) an appellate court has finally decided the legal challenge and the appellate court's mandate has issued or (ii) a district court has finally decided the challenge and the time for a party to file a notice of appeal has elapsed.

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[6] *See* 5 U.S.C. § 552; Nev. Rev. Stat. § 239.010.

Without this clarity, the regulation could be interpreted to suggest that the Department might still release the information even if a manufacturer has brought legal action under the DTSA. Such an interpretation would force manufacturers to seek a temporary restraining order or preliminary injunction every time they challenge a request for disclosure, which would impose even greater costs on the manufacturers who would have to bring such claims, the Department who would have to defend the claims, and the courts who would have to hear and decide them. Regulations that virtually guarantee such frequent emergency litigation would be unfair, unsound, and unworkable.

If the Department retains the notice period structure, PhRMA requests that the Department consider extending the notice period to 60 days to provide manufacturers with adequate time to evaluate the request, retain counsel, and prepare the relevant legal filings.

4. Other Procedural Safeguards

The final regulations also should ensure that manufacturers have a meaningful opportunity to challenge a request for information through the judicial process. To prove a claim under the DTSA, a moving party must establish that disclosure would constitute (i) "misappropriation" of (ii) a "trade secret." 18 U.S.C. § 1836.

To prove "misappropriation," a manufacturer must show that the Department was planning to disclose the trade secret "without express or implied consent" from the manufacturer and that the Department "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).[7] To ensure that the DTSA provides manufacturers with a meaningful opportunity for judicial review, the Department should revise the proposed regulations to underscore that the Department acquires manufacturers' trade secrets "under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret." *Id.*

To prove that the information is a "trade secret," a manufacturer must show, among other things, that it "has taken reasonable measures to keep such information secret." *Id.* § 1839(3)(A). Again, the final regulations should confirm that, by complying with SB 539's mandatory reporting provisions and requesting that certain information be treated as confidential, manufacturers have "taken reasonable measures to keep such information secret." *Id.*

B. Implementation Concerns

In addition to the legal process concerns identified above, PhRMA is also concerned that the proposed regulations offer no clarity to manufacturers as to what precise information they must disclose. The statute requires manufacturers to disclose information regarding "costs,"

[7] Alternatively, a misappropriation occurs where the trade secret is acquired through "improper means," "accident," or "mistake." *Id.* § 1839(5)(A), (B)(i), (B)(iii). However, none of these would seem applicable in these circumstances.

"profits," and "administrative expenditures," but those terms are reasonably susceptible to multiple interpretations,[8] and the proposed regulations make no attempt to define them.

For example, under the proposed regulations, manufacturers are required to report a "number" that reflects the "cost of producing the drug." The regulations do not define "cost" or explain which costs (*i.e.*, research and development, manufacturing, distributing, etc.) should be included in manufacturers' calculation of the "cost of producing the drug." The regulations do not even specify a relevant time period. Without further guidance, manufacturers inevitably will report different "costs" from other companies, resulting in an apples-to-oranges compilation that will be unhelpful to the Department. The same is true of terms such as "administrative expenditures," "profit," and "financial assistance," all of which are undefined and could reasonably be interpreted differently by manufacturers, the Department, and others.

Regardless of how the Department defines these terms, manufacturers will incur significant costs to comply with these new reporting obligations, as all manufacturers will need to train employees and implement new systems (which for certain manufacturers may lead to significant costs) to compile this information. The Department will likely be asking for information that some manufacturers cannot readily extract from their records as maintained in the ordinary course of business. For some companies, the information will likely reside in different business entities across different levels of the production and distribution system, perhaps different geographic areas. Some companies likely do not analyze and maintain this type of data state-by-state, and the Department may view aggregated data as less informative to Nevada constituents. To minimize the compliance costs in building systems and processes—and to ensure that the Department receives information that is meaningful—it is essential that the Department define, as precisely as possible and as quickly as possible, the information that manufacturers must disclose.

C. Drug Transparency Report

The regulations also provide that the Department will publish a "Drug Transparency Report" on its website, which will include "aggregated information" from manufacturers and "describe the trends related to drug pricing and how those costs may impact the diabetes burden and health system within Nevada." *See Id.* § 1(a). This regulation appears to respond to a concern raised by PhRMA in the federal litigation that § 6 of SB 539 would appear to require the Department to post manufacturer-specific information on its website, which would be preempted by federal law to the extent that the Department disclosed an individual manufacturer's trade secrets.

The Department should clarify that the "Drug Transparency Report" described in § 1 of the proposed regulations will not include information that is manufacturer-specific or that can be reverse-engineered to identify the originating company. The regulations appear to contemplate that the Department will not include such information, as they provide that the report will include

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[8] *See, e.g.*, *Cost*, OXFORD DICTIONARY OF ACCOUNTING (5th ed. 2016) ("There are a number of different ways of defining cost, the major ones being average cost, first-in first-out cost, historical cost, last-in first-out cost, and replacement cost. *See also* FIXED COST; MARGINAL COST; OPPORTUNITY COST.").

"aggregated information." The final regulations should state expressly, however, that the Department will publish only aggregated information.

D. Deadline for Initial Manufacturer Reports

Section 26.9 of SB 539 provides that, in 2018, the reports required under § 3.8 will be due on July 1, 2018. In subsequent years, the report is due on April 1. *See* SB 539 §§ 3.8, 4. The proposed regulations, however, simply state that drug manufacturers must submit the report "by April 1st," without reference to the July 1 deadline for the first manufacturer report in 2018. The final regulations should make clear that, consistent with the statute, manufacturers' initial § 3.8 report is not due until July 1, 2018. The U.S. District Court's decision regarding PhRMA's motion for a preliminary injunction was premised on a July 1, 2018 reporting date. If the Department now adopts an April 1 deadline, PhRMA may need to ask the Court to consider a renewed preliminary injunction motion.

Section 26.9 also provides that "[o]n or before November 1, 2017, the Department . . . shall place on the Internet website maintained by the Department the information prescribed by section 3.6 of this act." Although the Department has published the list of essential diabetes medicines pursuant to § 3.6(1), the Department has *not* yet published the list of essential diabetes medicines pursuant to § 3.6(2), *i.e.*, those medicines whose WAC has increased by more than "[t]he percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year" or "[t]wice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years." Only manufacturers whose drugs appear on the § 3.6(2) list must submit the report contemplated by § 4. Because the Department did not publish the § 3.6(2) list by November 1, 2017 as required (and indeed, still has not published the § 3.6(2) list), the Department should confirm that no § 4 reporting will be due this year on July 1, 2018. The seven-month period that the Legislature required between the initial § 3.6(2) list and the § 4 report is essential to providing manufacturers adequate lead time to prepare their initial § 4 reports. The Department should thus confirm that no § 4 reporting will be due until at the earliest April 1, 2019 (the date on which § 4 reporting is due in 2019 and subsequent years).

II. Section 4: Pharmaceutical Sales Representative

The proposed regulations require registered pharmaceutical sales representatives to submit a report described in section 4.6(4) of SB 539 to the Department on a proposed form by March 1. Section 4.6(4)(a)(1) and (2) describe types of compensation that must be included in the reports, but does not contain a clear definition of "compensation." PhRMA requests that the Department clarify the definition of "compensation" and suggests that the Department consider the definition of "payment or transfer of value" that was adopted in regulations and guidance promulgated and issued pursuant to the federal Physician Payments Sunshine Act.

III. Conclusion

PhRMA appreciates the opportunity to comment on these important regulations. We commend the Department for recognizing that trade secrets must be safeguarded, as failure to do so would raise the serious constitutional problems noted in PhRMA's complaint and litigation

briefs. For the reasons explained above, however, we do not believe that the regulations as currently drafted provide adequate protections for manufacturer trade secrets. In addition, the vagueness of the regulations will multiply the burdens on manufacturers. PhRMA looks forward to working with the Department on these issues at the upcoming workshop and throughout the notice-and-comment process.

Respectfully submitted,

Joanne Chan
Assistant General Counsel
Law

February 13, 2018

Veronica Sheldon, Management Analyst
Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City NV 89706

Via email: drugtransparency@health.nv.gov

Re: Proposed Amendments to the Nevada Administrative Code Chapter 439: Drug Transparency Reporting

Dear Ms. Sheldon:

The Pharmaceutical Care Management Association (PCMA) submits the following comment in response to the Department's proposed rules to implement SB 539 (2017) relating to drug price transparency. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through large and small employers, state governments, health insurance plans, labor unions, Medicaid managed care, Medicare Part D, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide feedback on the proposed rules. First, PCMA appreciates the Department's acknowledgment that certain proprietary price information is protected by the federal Defend Trade Secrets Act and appreciates that the Department has outlined a process to address those protections as the issues arise.

PCMA has two comments on the draft regulation and the PBM data collection form.

1. Section 3(2)(b) of the proposed rule states "The Department will notify the pharmacy benefit manager of any request for data elements marked as confidential and will provide the manufacturer a copy of the written request for those records." We believe that the use of "manufacturer" was inadvertently used in place of "pharmacy benefit manager." PCMA requests that this language be clarified in the following way:

   The Department will notify the pharmacy benefit manager of any request for data elements marked as confidential and will provide the ~~manufacturer~~ pharmacy benefit manager a copy of the written request for those records.

2. The proposed data collection form includes a box to report rebates negotiated for the purchase of drugs for use by recipients of Medicare. However, Medicare is a federal program, and any state law "with respect to" a Part D plan offered by a Part D sponsoring organization is preempted. No requirement for a finding that a state law is *inconsistent* with a Part D standard is needed. All standards established under the Part D program "shall supersede any State law or regulation…with respect to [Part D] plans

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which are offered by [Part D plan sponsors]."[1] Only state laws governing licensure and solvency are saved from preemption.[2] In its final rules implementing the Medicare Advantage and Part D programs, the Centers for Medicare and Medicaid Services (CMS) noted that Congress had clearly enacted broad preemption language in the Medicare Modernization Act (MMA), and that state requirements that derive from case law are also preempted.[3] The courts have also recognized the broad scope of preemption under the MMA, looking at whether there is an established federal standard (i.e., a statute or rule codified in the Code of Federal Regulations), and whether the state statute is a law with respect to that standard (and therefore preempted unless it is a law of general applicability or a minimum plan licensure or solvency).[4]

Under the Medicare Part D (prescription drug program) statute, the Part D plans are required to provide the Centers for Medicare and Medicaid Services with information about prescription drug price concessions and rebates.[5] The terms of SB 539 "relate to" this federal requirement because it requires similar reporting by the same, federally-regulated entities (Part D plans). SB 539 is not a state licensure or solvency standard that is saved from preemption, and its terms are not generally applicable to any type of business in the state—it is the very fact that rebates are negotiated and purchased for Medicare recipients that triggers this provision of the state statute. Thus, federal Medicare law preempts the state law and the proposed data collection form, as they relate to rebates negotiated for the purchase of drugs for used by Medicare recipients. PCMA requests that this data element be stricken from the form.

We appreciate the opportunity to provide comments on this proposed rule and we welcome the opportunity to speak with you about our concerns. Please do not hesitate to contact me at 202-756-5743 if you have any questions.

Sincerely,

April C. Alexander
Assistant Vice President, State Affairs

cc: Margot Chappel, MS, Manager, Primary Care and Health Workforce Development Office, Department of Health and Human Services

[1] Social Security Act § 1856(b)(3), 42 U.S.C. § 1395w-26(b)(3). *See also*, Social Security Act § 1860D-12(g), applying Medicare Advantage preemption standards to Part D.
[2] Id. *See also*, 70 Fed. Reg. 4588, 4663-66 (Jan. 28, 2005). CMS cites, as an example, a state requirement that a plan file Articles of Incorporation with the Secretary of State's office as a permissible state regulation.
[3] 70 Fed. Reg. 4588, 4663-66.
[4] *Pacificare v. Rogers*, 127 Nev. Adv. Rep. 71 (2011); *Uhm v. Humana*, 620 F.3d 1134, 1149, n.20 (9th Cir. 2010)
[5] 42 USC § 1395w-102(d)(2).

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

Pfizer Inc
235 East 42nd Street
New York NY 10017-5755

February 15, 2018

VIA E-MAIL AND FEDERAL EXPRESS

Attn: Veronica Sheldon
Nevada Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City, NV 89706

drugtransparency@dhhs.nv.gov

Re: Comment on SB 539 Drug Transparency Draft Regulations

Dear Ms. Sheldon,

Thank you for providing stakeholders the opportunity to comment on the SB 539 Drug Transparency Draft Regulations (the "Regulations") issued by the Nevada Department of Health and Human Services (the "Department") on January 4, 2018. We understand that the laws implemented by 2017 Nevada Senate Bill 539 ("SB 539") are currently being challenged in litigation. Without waiving any claims or rights and remedies in litigation with respect to SB 539, Pfizer Inc. ("Pfizer") is submitting this letter to the Department to comment on the Regulations.

Pfizer is commenting on both the timing and the contents of the reports manufacturers need to submit under Nev. Rev. Stat. SB 539, §§ 3.8 and 4. Pfizer has several very serious concerns that the Regulations, as currently drafted, would both force the disclosure of Pfizer's trade secrets and strip those trade secrets of legal protection.

I. Confirmation that State Does Not Intend to Implement SB 539 Before July 1, 2018

Section 2 of the Regulations states "Drug manufacturers must submit a report in the format listed on the Department website by April 1st for the previous calendar year."

Although the Regulations reference an April 1 date for manufacturers to report under SB 539, Pfizer notes that the State of Nevada (the "State") has consistently referred to a July 1, 2018 date in the pending litigation with the Pharmaceutical Research and Manufacturers of America' s ("PhRMA") and the Biotechnology Innovation Organization's ("BIO"), *PhRMA v. Sandoval,* 2:17-cv-02315 (D. Nev.). As such, Pfizer believes that the July 1, 2018 date reflects the State's actual position.

In the hearing on PhRMA's motion for a preliminary injunction, to support the State's position that an injunction in October 2017 was not warranted due to a lack of imminent harm to manufacturers, the State's attorneys stated that manufacturers would not have to report under SB 539 until July 1, 2018. *See* Transcript of Proceedings from Motion for Preliminary Judgement at 15, *PhRMA v. Sandoval,* 2:17-cv-02315 (D. Nev.) ("No actual report is going to be filed by a manufacturer before July 1, 2018.").

Further, the Legislature's response to the motion for preliminary injunction stated ". . . SB 539 contains a transitory section that *adjusts the reporting deadlines for the first reporting period,* so the affected manufacturers *do not have to file their first reports until July 1, 2018.*" Nevada Legislature's Opposition to Plaintiffs Motion for Preliminary Injunction at 5, *PhRMA v. Sandoval,* 2:17-cv-02315 (D. Nev.) (emphasis added).

Additionally, the July 1, 2018 reporting date was used in the Attorney General's response to the motion for a preliminary injunction to argue SB 539's reporting provisions did not pose imminent harm to manufacturers. *See* Opposition to Motion for Preliminary Injunction at 5, *PhRMA v. Sandoval,* 2:17-cv-02315 (D. Nev.) ("The Department is unable to place any information, create any reports, or impose any penalties until *after that deadline of July 1, 2018 when manufacturers must report.* Therefore, any harm to trade secret that may be disclosed in these reports *is not imminent.")* (emphasis added).

Lastly, the Court itself stated that manufacturers would not need to begin reporting until July 1, 2018. *See* Transcript of Proceedings from Motion for Preliminary Judgement at 4-5, *PhRMA v. Sandoval,* 2:17-cv-02315 (D. Nev.) (quoting Judge James C. Mahan, "This will all take *effect in July* . . . so it's not like we need a preliminary injunction today to prevent this all from *taking effect next July* ...") (emphasis added).

Pfizer, like many other manufacturers, has relied upon the July 1, 2018 reporting date represented by the State to the Court during the hearing on PhRMA and BIO's motion for a preliminary injunction.

Accordingly, Pfizer requests that the Department clarify the reporting date in the Regulations and align that date with the date represented by the State to the Court. If not, the State should correct its representation made to the Court.

II. Section 2 of the Regulations Forces the Disclosure of Trade Secrets and Strips Them of Trade Secret Protection

The State, in addressing the critical issue of trade secrets by statute, by proposed regulation, and in its court filings, has failed to provide any clear and consistent position on the critical question of trade secret protection of manufacturer information[1]

[1] The Regulations directly contradict the State's own arguments in the pending litigation, as well as Nevada's rules of statutory interpretation. The State asserts in its Motion for Summary Judgement in *PhRMA v. Sandoval* that "as properly interpreted under Nevada's rules of statutory interpretation, the challenged provisions *do not require manufacturers to disclose trade secrets.*" Defendant's Motion for Summary Judgement, *PhRMA v. Sandoval,* 2:17-cv-02315 at 1 (D. Nev.) (emphasis added).

Section 2 of the Regulations currently state "if a manufacturer believes that a data element in the report meets the standards of the Defend Trade Secrets Act (DTSA), a request to have the element declared confidential may be submitted . . . . [T]he request must include a detailed description of why the data element qualifies as a trade secret under the DTSA."

Section 2 of the Regulations indisputably requires manufacturers to disclose trade secrets to comply with Nev. Rev. Stat. SB 539 §§ 3.8 and 4, including, information that relates to costs, profits, pricing, and advertising and marketing strategies associated with a manufacturer's specific drugs.[2] This mandated information derives independent economic value from not being generally known to third-party payers and competitors, and is unquestionably a trade secret under the Defend Trade Secrets Act of 2016 ("DTSA"), as well as Nevada law- unless SB 539 takes effect. *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).

Because Section 2 of the Regulations compels manufacturers to report all information requested by Nev. Rev. Stat. §§ 3.8 and 4, even if that information is a trade secret, the Regulations raise numerous, serious concerns. First, the Regulations do not contain any protections for trade secrets compelled under SB 539. Second, the Regulations would strip reported trade secrets of trade secret protection, nullifying a manufacturer's trade secret protection not just in Nevada, but nationwide. Finally, the Regulations facilitate third party acquisition of manufacturer trade secrets and fail to provide manufacturers with meaningful remedies to protect their trade secrets.

Further, the State asserts in its Response to PhRMA and BIO's motion for summary judgement that ". . . the plain language and the legislative history of the challenged provisions - along with reason and public policy - amply demonstrate that the provisions are much narrower in scope and *do not require manufacturers to disclose trade secrets*." Defendant's Response to Plaintiff's Motion for Summary Judgement, *PhRMA v. Sandoval*, 2:17-cv-02315 at 2 (D. Nev.) (emphasis added).

Pfizer is extremely concerned that the regulatory scheme detailed in Section 2 of the Regulations, by demanding manufacturers disclose trade secrets to comply with SB 539, contradict the State's own arguments in the pending litigation. Further, Pfizer is concerned that the Regulations, as currently drafted, are inconsistent with SB 539's legislative history, public policy, and Nevada's rules of statutory interpretation.

2 *See* Nev. Rev. Stat. SB 539 § 3.8 (requiring manufacturers whose drugs are listed by the Department under Nev. Rev. Stat. SB 539 § 3.6(1) to report to the Department detailed information related to the listed drug' s pricing including, amongst other things, the listed drug's production costs, marketing and advertising costs, profitability, and rebates paid to pharmacy benefit managers); *see also* Nev. Rev. Stat. SB 539 § 4 (requiring manufacturers whose drugs are listed by the Department under Nev. Rev. Stat. SB 539 § 3.6(2) to report to the Department detailed information related to the listed drug' s price increases, including, amongst other things, a list of factors contributing to a price increase and an explanation of the role the factor played in the price increase.).

a. Regulations Do Not Contain Protections for Reported Trade Secrets

First, the Regulations do not contain any protections for trade secrets compelled under SB 539. 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 which the owner of the secret protects his interest from disclosure to others."). Indeed, once a trade secret is public, trade secret protection is gone forever.

Because a trade secret's economic value is dependent on its secrecy, any disclosures involving trade secrets necessitate protections in order to preserve secrecy. For example, in court cases involving trade secrets, trade secret information is only disclosed under a Protective Order and/or is filed under seal. Likewise, trade secret disclosures to third parties, such as a government entity, are and should be accompanied with confidentiality agreements or non-disclosure agreements. Additionally, trade secret disclosures mandated by certain statutes often contain statutory language that indicates the information reported to the government is confidential and not subject to public disclosure. *See* 18 Vt. Stat. Ann. §4635(e) ("Information provided to the Office of the Attorney General ... is exempt from public inspection and copying under the Public Records Act and shall not be released in a manner . . . that is likely to compromise the financial, competitive, or proprietary nature of the information.").

SB 539 and the Regulations offer no protections to ensure a manufacturer's trade secrets will be kept confidential or provide any guarantees against further dissemination once disclosed to the Department. Nothing in SB 539 or the Regulations limit what the Department can do with reported trade secrets. Specifically, while the Regulations require manufacturers to request information be deemed confidential, the Regulations do not indicate (1) if the Department will decide if the manufacturer' s request for confidentiality is granted or (2) what the Department will do to ensure information is kept confidential in the meantime. In short, while the Regulations force manufacturers to disclose trade secrets under SB 539, the Regulations do not offer any of the trade secret protections that typically accompany disclosure of trade secret information in court proceedings or to government entities.

Consequently, Pfizer has serious concerns that SB 539 and the Regulations, as drafted, would nullify trade secret protection not just in Nevada, but nationwide, for all information manufacturers are forced to disclose.

b. Regulations Strip Reported Trade Secrets of Trade Secret Protection

Second, SB 539 and the Regulations not only mandate public disclosure of trade secrets, but they seek to eliminate trade secret status for all information manufacturers must disclose. Specifically, the Regulations demand that manufacturers report trade secrets to comply with Nev. Rev. Stat. SB 539 §§ 3.8 and 4. However, § 9 of SB 539 amended the definition of "trade secret" under Nevada law so that "trade secrets", by law, "does not include any information that a manufacturer is required to report pursuant to section 3.8 or 4 of this act . . ." Nev. Rev. Stat. § 600A.030(5).

Taken together, SB 539 and the Regulations eviscerate a manufacturer's property interest in its trade secrets. This compelled destruction of trade secrets, with no mechanism for compensation, will have a significant, detrimental economic impact. At a minimum, manufacturers of essential diabetes drugs will be at a severe disadvantage vis-a-vis competitors not subject to SB 539, as well as in their dealing with third-party payers, who will be given a manufacturer's once commercially sensitive trade secrets to use in negotiations.

c. Regulations Are Ambiguous Regarding Third-Party Access to Trade Secrets and Fail to Provide Meaningful Remedies

Third, the Regulations are ambiguous regarding third-party access to trade secrets and fail to provide manufacturers with meaningful remedies.

Section 2 of the Regulations state "The Department will notify the manufacturer of any request for data elements marked as confidential . . . [T]he Department will allow the manufacturers thirty days to take legal action under DTSA prior to releasing the information . . ."

Section 2 of the Regulations indicate third parties can request information manufacturers submit to the Department under Nev. Rev. Stat. Ann.§§ 3.8 and 4. However, the Regulations are both vague as to the identity of the requesters and what information will be given to requesters. Accordingly, as drafted, the Regulations currently permit any third party, including a manufacturer's competitors or other sophisticated business entities, to request and gain access to the detailed information a manufacturer submits to the Department under SB 539.

Additionally, the Regulations do not limit the information the Department provides requesters even in the event a manufacturer takes legal action under the DTSA. In fact, as drafted, the Regulations indicate that the Department will release all information a manufacturer provides to the Department, including information the manufacturers requests be declared confidential, to requesters after 30 days. The only remedy the Regulations provide is the 30 day grace period for the manufacturer to protect its trade secrets under the DTSA.

Nevertheless, the Regulations purported remedy of providing manufacturers 30 days to protect their trade secrets under the DTSA is no remedy at all. The DTSA provides a federal cause of action for trade secrets misappropriated, *i.e.* the wrongful acquisition. disclosure or use of trade secrets. The DTSA does not provide a mechanism for challenging the Department's mandate that a manufacturer hand over its trade secrets. Nor does it provide an avenue that would allow a manufacturer to somehow censor or recover trade secrets that were provided to a government entity and/or were otherwise disseminated to the public.

Even if the DTSA offered some way to address the Department's forced disclosure of trade secrets, requiring a manufacturer to file a federal lawsuit anytime someone requests access to its trades secrets is an unworkable, unfair burden that will undermine trade secret protection that has been part of our nation' s public policy for over a hundred years.

III. Detailed Description Required by Regulations May Itself Force the Disclosure of Trade Secret

Section 2 of the Regulations currently require manufacturers who "request to have [a reportable data element] declared confidential" to submit "a detailed description of why the data element qualifies as a trade secret under the DTSA. This detailed description asserting trade secret protection will be available upon request to the public."

Providing a "detailed description" of why the data element is a trade secret may itself require a manufacturer to disclose portions of its trade secrets, particularly those relating to its pricing strategy. As such, the "detailed description" required by Section 2 of the Regulations itself could force a manufacturer to disclose a trade secret that in turn would be "available upon request to the public."

At a minimum, Pfizer suggests the Department replace "detailed description" with "description" in Section 2 of the Regulations given the public nature of the Regulation's required description and the resulting trade secret concerns.

IV. Effect on Pending Litigation

As you know, SB 539 is being challenged in court by PhRMA, in which PhRMA asserts (1) SB 539 is preempted by federal patent laws, including the Hatch-Waxman Act, (2) SB 539 is preempted by the federal Defend Trade Secrets Act of 2016, (3) SB 539 violates the Takings Clause of the Fifth Amendment as a regulatory taking, and (4) SB 539 imposes an excessive burden on interstate commerce in violation of the Commerce Clause of the U.S. Constitution.

The Regulation, as indicated above, does not resolve the many issues raised in the PhRMA litigation. We urge the State to take the necessary regulatory steps to eliminate the statutory defects that are the subject of the litigation. In the absence of a regulatory process that adequately resolves those issues, pharmaceutical manufacturers may be forced to reserve or limit their statements under the statute until the Court has resolved those concerns.

* * *

As currently drafted, the Regulations raise serious concerns for manufacturers who may be forced to disclose and lose valuable trade secrets. The Regulations also contradict numerous positions taken by the State in the pending litigation concerning SB 539.

One way the State may be able to better align the Regulations with the State's own litigation positions and with Nevada's rules of statutory interpretation is to limit information reported under Nev. Rev. Stat. SB 539 §§ 3.8 and 4 to information that is publicly available or otherwise in the public domain. This is an approach being employed by the State of California under its own prescription drug price transparency law, 2017 California Senate Bill 17, to address trade secret protections. *See* Cal. Health & Safety Code§ 127679 (b) ("The manufacturer may limit the information reported ... to that which is otherwise in the public domain or publicly available."); *see also* Cal. Health & Safety Code§ 127681(c) ("The manufacturer may limit the information reported ... to that which is otherwise in the public domain or publicly available.").

Pfizer requests that the Department revise the proposed Regulations to address the concerns raised in this letter and then afford stakeholders an opportunity to comment on the revised Regulations before finalizing any such Regulations. Given the necessary level of revisions to these proposed Regulations, if stakeholders are not afforded an opportunity to comment on the revised Regulations, they will not have been afforded sufficient notice to comment on the revised Regulations.

* * *

Thank you for providing Pfizer this opportunity to comment on the Regulations and for your attention to this matter.

Sincerely,

Laura Chenoweth Senior
Vice President &
Deputy General Counsel

Drug Transparency

From: Clair Irwin [redacted]
Sent: Tuesday, February 6, 2018 1:05 PM
To: Drug Transparency
Subject: concern regarding draft regulations for SB539

February 6, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a patient with diabetes, I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

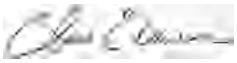
Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies often argue increasing prices are necessary for R&D, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics. The monthly cost of insulin and supplies equals the cost of all my other monthly bills-—over $1500 a month, a cost that has only been manageable due to subsidization by my university. People with diabetes are expected to pay rent on our bodies, and we are paying ever-increasing amounts for the insulin we need to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. One of the bill's sponsors, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem." According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual." Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "[t]he transparency is very essential in my mind. That's what we need for the consumer in this case to receive the benefits of this particular drug [insulin]...." Senator Heidi Gansert summarized it well: "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."

When signing SB539 into law, Governor Sandoval opined that SB539 "was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients." Indeed, Nevada's diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information,
please contact me at or at

Sincerely,



Clair E. Irwin

Drug Transparency

From: mike lawson [redacted]
Sent: Tuesday, February 6, 2018 11:42 AM
To: Drug Transparency
Subject: Help Protect Insulin Transparency!

Hey, Mr. Whitley!

I have been living with diabetes for over a decade. I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will in practice, work to prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-sustaining medication. Companies often argue increasing prices are necessary for research and development, but the insulin market has not seen a truly innovative product since the early 80s. Insulin was discovered almost a century ago, yet there are no generics and a single vial that lasts a week or two costs over $300 at the pharmacy. Patients are paying ever-increasing amounts for the insulin we need to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. Once the bills' sponsor, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem." [1] According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual." [2] Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "the transparency is very essential in my mind. That's what we need for the consumer in his case to receive the benefits of this particular drug [insulin]..." [3] Senator Heidi Gansert summarized it well: "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 the issue." [4]

When signing SB539 into law, Governor Sandoval opined that SB539 "was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients." [5] Indeed, Nevada's diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency f
provide any adc
[redacted]

Best, or patients and payors. Thank you for your time. If you have any questions or believe I can ditional helpful information, please contact me at: [redacted] on the phone at

Mike Lawson
[redacted]

[1] "Nevada Bill to Limit Diabetes Drug Prices Headed to the Governor," Ed Silverman, STAT News, at https://www.statnews.com/pharmalot/2017/05/25/nevada-bill-diabetes-drug-prices/.
2 "Nevada Senate Passes Insulin-Price Bill Tough on Drugmakers," Alison Noon, U.S. News & World Report, at https://www.usnews.com/news/best-states/nevada/articles/2017-05-19/nevada-senate-passes-insulin-price-bill-tough-on-drugmakers.
[3] Id.
[4] Nevada Senate Committee Hearing on Health and Human Services regarding SB539, May 26, 2017. Text from: Minutes available at https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1272.pdf.
[5] "Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits," Mike Akers, Las Vegas Sun, at https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/.

Drug Transparency

From: Brandon [redacted]
Sent: Wednesday, February 7, 2018 5:44 AM
To: Drug Transparency
Subject: SB539 Concerns
Attachments: Nevada HHS Form Letter re Insulin Transparency Regs - Final - 5-Feb-2018 (1).docx

I am the father of a 7 year old Type-1 diabetic. I live in Missouri but I am a native Nevadan. Last year I celebrated as I found that my home state was leading the way in drug transparency in order to bring drug prices down. Recently I found that there may be unintended changes made to the law. Please see my attached letter voicing my concerns. Please feel free to reach out to me with questions.

With Regards,
Brandon Porath

February 15, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a parent of a child with diabetes I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies often argue increasing prices are necessary for R&D, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics and a single vial that lasts a week or two costs over $300 at the pharmacy. In sum, patients are paying ever-increasing amounts for the insulin that is needed to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. One of the bill's sponsor, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem."[1] According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual."[2] Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "[t]he transparency is very essential in my mind. That's what we need for the consumer in this case to receive the benefits of this particular drug [insulin]…."[3] Senator Heidi Gansert summarized it well: "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."[4]

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[1] "Nevada Bill to Limit Diabetes Drug Prices Headed to the Governor," Ed Silverman, STAT News, at https://www.statnews.com/pharmalot/2017/05/25/nevada-bill-diabetes-drug-prices/.
[2] "Nevada Senate Passes Insulin-Price Bill Tough on Drugmakers," Alison Noon, U.S. News & World Report, at https://www.usnews.com/news/best-states/nevada/articles/2017-05-19/nevada-senate-passes-insulin-price-bill-tough-on-drugmakers.
[3] Id.
[4] Nevada Senate Committee Hearing on Health and Human Services regarding SB539, May 26, 2017. Text from: Minutes available at https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1272.pdf.

When signing SB539 into law, Governor Sandoval opined that SB539 "was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients."[5] Indeed, Nevada's diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time.

Sincerely,

Brandon Porath

[5] "Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits," Mike Akers, Las Vegas Sun, at https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/.

February 15, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley:

As a parent of a child with diabetes, I am grateful that Nevada is leading the way to improved understanding of diabetes related costs with its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers. I write with concern that the draft regulations for SB539 will prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from understanding all the factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies argue price increases are necessary to cover costs of research and development, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics and a single vial that lasts a week or two costs over $300 at the pharmacy. Patients pay ever-increasing amounts for the insulin needed to live with no justification from the manufacturers or pharmacy benefit managers. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. One of the bill's sponsors, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem."[1] According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual."[2] Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "[t]he transparency is very essential in my mind. That's what we need for the consumer in this case to receive the benefits of this particular drug [insulin]…."[3] Senator Heidi Gansert summarized it well: "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."[4]

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[1] "Nevada Bill to Limit Diabetes Drug Prices Headed to the Governor," Ed Silverman, STAT News, at https://www.statnews.com/pharmalot/2017/05/25/nevada-bill-diabetes- drug-prices/.

[2] "Nevada Senate Passes Insulin-Price Bill Tough on Drugmakers," Alison Noon, U.S. News & World Report, at https://www.usnews.com/news/best-states/nevada/articles/2017-05-19/nevada-senate-passes-insulin-price-bill-tough-on-drugmakers.

[3] Id.

[4] Nevada Senate Committee Hearing on Health and Human Services regarding SB539, May 26, 2017. Text from: Minutes available at https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1272.pdf.

When signing SB539 into law, Governor Sandoval opined that SB539 "was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients."[5] Indeed, Nevada's diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. If o e any questions or I can rovide any additional information, please contact me at [redacted] or at [redacted]

Sincerely,

Melinda Wedding

[5] "Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits," Mike Akers, Las Vegas Sun, at https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/.

[redacted]arenc

From: [redacted]
Sent: uesday, ebruary 8, 2018 3:04 PM
To: Drug Transparency
Subject: Insulin pricing

February 6, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@health.nv.gov

Dear Mr. Whitley,

As a [patient with diabetes ,I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

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I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If you have an uestions or I can provide any additional information, please contact me at [your contact information [redacted]
Sincerely,

Sara Stock

February 22, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a Type One Diabetic, I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

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I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information, please contact me at [redacted]

Sincerely,

Robert Frisk

[5] "Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits," Mike Akers, Las Vegas Sun, at https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/.

February 22, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a patient with diabetes I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by more than 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

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I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If ou have an questions or I can provide any additional information, please contact me [redacted]

Sincerely,

Paul Clements

[5] "Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits," Mike Akers, Las Vegas Sun, at https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/.

February 22, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

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I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If ou have an s or I can provide any additional information, please contact me a[redacted]

Sincerely,

Christopher Luckett MA

[5] "Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits," Mike Akers, Las Vegas Sun, at https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/.

Drug Transparency

From: Angela Lautner [redacted]
Sent: Wednesday, February 7, 2018 10:03 AM
To: Drug Transparency
Subject: Call to protect insulin price transparency in Nevada

February 7, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706

Dear Mr. Whitley,

As a person who has lived with Type 1 diabetes for the past 18 years and as an advocate for insulin price transparency in Kentucky, I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

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I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information, please contact me at [redacted]

Sincerely,

Angela Lautner

Drug Transparency

From: Donna Robinson [redacted]
Sent: Tuesday, February 6, 2018 3:44 PM
To: Drug Transparency
Subject: Re: RE:

My family tree is rife with Type 1 diabetes, a daughter, a sister, a brother. My grandchildren have grandparents and aunts and uncles with Type 1 on both sides of their family tree.

Insulin is the only thing keeping our loved ones alive. It is important to recognize that if insulin is unaffordable some will die. I have heard of people rationing their in ng prescriptions due to lack of funds.

Our health care system is broken and our politicians seem incapable of fixing it. It is imperative that we hold corporations accountable for their actions even as our elected officials fumble and bumble their way to no solution.

People are dying while our representatives hem and haw and pocket hefty campaign contributions from various interests.
Do they know, or even care, that their inaction and cowardice are hurting real people? I support your drug transparency bill in the hope that it will hold drug companies accountable for their insulin drug pricing.

Sincerely,

Donna Robinson

P.S. feel free to include in public comments.

On Feb 6, 2018, at 5:37 PM, Drug Transparency <DrugTransparency@dhhs.nv.gov> wrote:

> Good afternoon Ms. Robinson,
>
> I am unable to open your attachment. Would you please re-send it?
>
> Do you want this included in the public comment for the upcoming workshop?
>
> Thank you in advance.
>
> Best Regards,

<image001.png>

Drug Transparency Nevada
Director's Office
Department of Health and Human Services
4126 Technology Way, Suite 100 | Carson City, NV 89706
www.dhhs.nv.gov

Drug Transparency

From: [redacted]
Sent: Mo u ry 12, 2018 2:22 PM
To: Drug Transparency
Subject: Draft Regulations for SB539

Dear Mr. Whitley,

I leading have lived the way with with a\ł the oimmune Type first-in-the-nation 1 diabetes diabetes for 42 drug years. tra I am nsparency very gratlaw. I eful have that the followed State of that legiNevada sla is tion (including unchanged the since failed the disclawsuit overy filed in 19against 21, and it yet filed by prices the have drug seen industry)prices . The exceeding price for 1000% insulin, over which the last is few largely years. Pricing transparency is something the pharmaceutical industry is fighting. Jorgensen Last felt November, the need the to CEO warn of Novo investors Nordisk about (one more of and the more largest leginsulin islation to sellers in increase the U.S.) clarity Lars around Fruergaardprices. do He told business, Reuters for "If instance, the tranifwe sparency have to bills pulead blicly to a share disclowhat sure is in level our that contris actoo ts." excessive, it becomes difficult to Indeed, industry the trade Pharmaceutical organization that Research sued and Nevada last Manufacturers year, of spent a America staggering (better $39.4 known million as to PhRMfight A), a one ballot of the also initiative showed in Ohio that a vast known maas jothe rity of Drug that Price money Relief came Act, also directly known from a as subOhio sidiary ballot of Issue PhRMA. 2. In Reports the to end, the all state the industry. spending There mainly is news succeeded of in industry confusing increasing voters, state although lobbying that was significasufficient ntly in for 2018the . pharmaceutical I patients write with and the concern State that of the Nevada draft that's regulations the crux for of SBthe 539 law's will, intent. in practice, work to prevent the transparency for The without law's real original data, we sponsor, can't Seas a ntator state make Yvamma decisions Cancela to said address "We the can talk problem. about She pricing added in " ... the in abthe stract, process but of and to disclosure, what patients happens will betweeb be the equipped time with a drug informais with tion a to push manufacturer back and and ask the time questions it gets to related an to price individual." gouging was Other fought legislahard tors in and the debated state, in in botlegislah tive political session parties, and very echoed this meaningful sentiment. to diabetes Governor patientsSa ." ndoval said the bill I me, thepatients please refore and urge contact payers. your me at Thankdepartment for to our time; reconsider if you the r have draft by any phone regl atations questions or alongside wish for the any law's intent: additional trainsight nsparency from for

Sincerely
C. Scott Strumello
[redacted]