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 ANSWERING BRIEF

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April 26, 2021

NRAP 26.1 DISCLOSURE STATEMENT

Pursuant to Nevada Rule of Appellate Procedure 26.1, Respondent Sanofi-Aventis U.S. LLC submits this Disclosure Statement:

The undersigned counsel of record certifies that the following are persons and entities as described in NRAP 26.1(a) and must be disclosed. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. Sanofi-Aventis U.S. LLC hereby discloses that it is an indirect, wholly owned subsidiary of Sanofi, a publicly held corporation. No other publicly held company owns ten (10) percent or more of Sanofi-Aventis U.S. LLC's stock.

2. The law firm of Bailey❖Kennedy represented Sanofi-Aventis U.S. LLC in the underlying action and continues to represent them for the purposes of this appeal.

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3. Sanofi-Aventis U.S. LLC is not using a pseudonym for the purposes of this appeal.

DATED this 26th day of April, 2021.

BAILEY❖KENNEDY

By: */s/ John R. Bailey*
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I. ROUTING STATEMENT

Respondent Sanofi-Aventis U.S. LLC ("Sanofi") disagrees with Appellant The Nevada Independent's ("TNI") Routing Statement to the extent that: (i) it fails to define the alleged principal issue of statewide public importance; and (ii) it fails to explain why the alleged issue is of statewide public importance. (Opening Br. ("O.B.") at VII:16-19.) Sanofi contends that this appeal concerns an issue of statewide public importance because TNI seeks to invalidate regulations properly promulgated by the Nevada Department of Health and Human Services ("Department"), with the participation and approval of the Nevada Legislature, in order to obtain trade secrets and confidential information that prescription drug manufacturers are required by law to provide to the State, in order to assist the State in promoting affordable medical care to Nevada residents and ensuring a competitive market for such medical care. Specifically, the Department enacted regulations which allow prescription drug manufacturers and pharmacy benefit managers ("PBMs") to request confidentiality for any trade secrets they provide to the Department pursuant to NRS 439B.635, NRS 439B.640, or NRS 439B.645. If this protection is invalidated many manufacturers may choose to cease offering their

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prescription drugs in Nevada, to safeguard their trade secrets from public disclosure. Therefore, this appeal concerns an issue of statewide public importance and should be retained by the Nevada Supreme Court for determination.

II. STATEMENT OF ISSUES PRESENTED FOR REVIEW

First, Sanofi believes that the issues on appeal can be more accurately described as follows:

1. Whether the District Court erred in determining that NAC 439.735 and NAC 439.740 protect trade secrets included in reports submitted by prescription drug manufacturers or PBMs to the Department pursuant to NRS 439B.635, NRS 439B.640, and NRS 439B.645 from public disclosure and requests for public records pursuant to NRS 239.010?

2. Whether the District Court erred in determining that the Department possessed the authority to adopt NAC 439.735 and NAC 439. 740?

3. Whether the District Court erred in determining that there is no conflict between either NAC 439.735 or NAC 439.740 and NRS 439B.600-NRS 439B.695 or NRS 600A.030(5)(b)?

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4. Whether the District Court erred in determining that the Department's disclosure of trade secrets in the reports submitted by prescription drug manufacturers or PBMs pursuant to NRS 439B.635, NRS 439B.640, and NRS 439B.645 could constitute misappropriation of a trade secret for which a court could award relief pursuant to the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836?

Second, Sanofi contends that TNI does not have standing to raise one of the issues presented for review in its Opening Brief. Specifically, TNI has defined one of the issues in this appeal as whether "[t]he District Court abused its discretion in failing to strike the Declaration of James Borneman." (*Id.* at VII:26-27.) However, TNI has not appealed from an order denying its motion to strike the Borneman Declaration.

Pursuant to NRAP 3(c)(1)(B), a notice of appeal must "designate the judgment, order, or part thereof being appealed." *See also Collins v. Union Fed. Sav. & Loan Ass'n*, 97 Nev. 88, 89-90, 624 P.2d 496, 497 (1981) ("It is the general rule that a judgment or order which is not included in the notice of appeal will not be considered on appeal.") TNI's Notice of Appeal, filed on September 22, 2020, only specifies that TNI seeks to appeal "from the final

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judgment entered in this action on the 4th day of September, 2020." (IVJ.A.[1] at 000999:23-001000:1.) The "September 4, 2020 Order" referenced in the Notice of Appeal (which was actually entered on September 9, 2020), is the Order Denying Petition for Writ of Mandamus, and it does not pertain, in any manner, to the Declaration of James Borneman or a motion to strike his Declaration. (IVJ.A. at 000985-000998.)

This Court typically will not dismiss an appeal due to a deficient notice of appeal "where the intention to appeal from a specific judgment may be reasonably inferred from the text of the notice [of appeal] and where the defect has not materially misled the respondent." *Collins*, 97 Nev. at 90, 624 P.2d at 497. However, nothing in TNI's Notice of Appeal provides any notice from which an intent to appeal from an order denying TNI's Motion to Compel Testimony of James Borneman, or in the Alternative, to Strike His Declaration ("Motion to Strike"), can be inferred.

Moreover, no written order denying the Motion to Strike has been entered in the underlying action. To date, the Court has only entered a Minute Order denying the motion. (IVJ.A. at 000921-000922.) It is well-settled that

[1] For citations to the Joint Appendix, Sanofi will refer to "J.A." The number preceding "J.A." refers to the applicable volume of the Joint Appendix.

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"only a written judgment may be appealed," and a minute order is "ineffective for any purpose and cannot be appealed." *Rust v. Clark Cnty. Sch. Dist.*, 103 Nev. 686, 689, 747 P.2d 1380, 1382 (1987). Therefore, TNI's second issue presented for review, (O.B. at VII:26-27), should be dismissed.

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III. STATEMENT OF FACTS

A. New Statutory Scheme for the Reporting of Information Relating to Prescription Drugs.

1. Senate Bill 265.

On March 14, 2017, Senate Bill 265 was introduced in the Nevada Senate. The bill was "intended to address the rapidly increasing cost of diabetes care in Nevada." *Hr'g on S.B. 265 Before the S. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. at 33 (March 29, 2017) (statement of Sen. Yvanna D. Cancela). To that end, Senate Bill 265 required prescription drug manufacturers to reimburse the purchasers of its essential diabetes drug if: (i) the wholesale acquisition cost ("WAC")[1] of the drug exceeded the highest price paid for the drug in certain foreign countries; or (ii) the manufacturer increased the ("WAC") of the drug by more than a prescribed amount during a calendar year. S.B. 265, 2017 Leg., 79th Sess. § 6 (original draft). The bill also required manufacturers of essential diabetes drugs to notify insurers ninety (90) days before a planned price increase if the

[1] The WAC is the "manufacturer's list price" for a drug to wholesalers and direct purchasers, which does not include "discounts, rebates, or reductions in price." NRS 439B.620.

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increase was going to be larger than a prescribed amount. *Id.* at § 8. Finally, Senate Bill 265 required manufacturers of essential diabetes drugs to provide the Department with an annual report concerning the costs of research and development, production, and marketing and advertising for the drug, along with the profits earned from the drug, the financial assistance provided for patients, the cost of consumer coupons, the WAC, and the prior five-year history of WACs of the drug. *Id.* at § 7.

Ultimately, on June 2, 2017, Governor Brian Sandoval vetoed Senate Bill 265, stating that it "pose[d] serious risks of unintended and potentially detrimental consequences for Nevada's consumer patients, not the least of which is the possibility that access to critical care will become more expensive, more restricted, and less equitable." S. JOURNAL, 2017 Leg., 79th Sess., GOVERNOR'S MESSAGE ACCOMPANYING VETO OF SB 265, at 15 (June 5, 2017). The Governor further noted that "constitutional and other legal concerns have [also] been raised that render the bill problematic" including challenges for "federal preemption, the Fifth Amendment's prohibition on uncompensated takings, and the Dormant Commerce Clause." *Id.* at 16.

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2. Assembly Bill 215.

Assembly Bill 215 was also introduced in the 2017 legislative session. This bill required manufacturers of non-generic medications to provide to the Department certain information regarding the drugs, including production costs, profits earned, financial assistance provided to patients, and the WACs. A.B. 215, 2017 Leg., 79th Sess. § 2 (original draft). The Department was then required to compile non-confidential information from these manufacturer reports into a new report which would be posted online for public review. *Id.* at § 3.

However, Assembly Bill 215 was not designed to target diabetes medications. Rather, it was meant to apply to all "brand" medications that exceeded a certain price increase threshold. *Id.* at § 2. Thus, Assembly Bill 215 was eventually withdrawn, and some of its language was integrated into Senate Bill 265, before that bill was vetoed. *See Hr'g on S.B. 265 Before the S. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 3-4 (May 3, 2017).

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3. Senate Bill 539.

Senate Bill 539 was first introduced to the Nevada Senate on May 16, 2017. As originally drafted, the bill was intended, primarily, to serve as a complement to its counterpart, Senate Bill 265, by eliminating the "gag rule" which "preclude[d] pharmacists from working with patients to identify the best price for life-saving medications." *Hr'g on S.B. 539 Before the S. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 3 (May 26, 2017) (statement of Sen. Heidi S. Gansert). It also provided for regulation of PBMs. *Id*. at 4. Finally, Senate Bill 539 also included a different reporting requirement for prescription drug manufacturers. Rather than reporting on the manufacturing costs of the drug, as required by Senate Bill 265, this bill required manufacturers to submit a report explaining why there was an increase in the WAC of their drug. S.B. 539, 2017 Leg., 79th Sess. § 4 (original draft).

On June 4, 2017, two days after Governor Sandoval vetoed Senate Bill 265, Senate Bill 539 was amended to include the prescription drug manufacturer reporting requirements from Senate Bill 265. S.B. 539, 2017 Leg., 79th Sess. § 3.8 (1st Amend.). On June 8, 2017, the newly amended

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Senate Bill 539 was enrolled, and on June 15, 2017, Governor Sandoval approved and signed the bill. The reporting requirements specified in Senate Bill 539 and discussed in more detail in Subsection 4, *infra*, became "effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that [we]re necessary to carry out the provisions of this act," and they became effective for all other purposes on October 1, 2017. S.B. 539, 2017 Leg., 79th Sess. § 28.

4. NRS 439B.600-NRS 439B.695.

While it was originally intended that a significant portion of Senate Bill 539 would be enacted into NRS Ch. 439, *id.* at § 1, it was actually enacted into NRS Ch. 439B, as NRS 439B.600 to NRS 439B.695. The new reporting requirements included in NRS Ch. 439B which are relevant to this matter are summarized as follows.

NRS 439B.630 states that on February 1st of each year, the Department must compile a list of prescription drugs that it determines are "essential for treating asthma and diabetes," along with the WAC of each drug ("Essential Drug List"). NRS 439B.630(1). That same day, the Department is also required to compile a second list ("Price Increase List")

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of all drugs from the Essential Drug List that had an increase in the WAC of a percentage equal to or greater than: (i) the percentage increase in the Medical Care Component of the Consumer Price Index during the prior calendar year; or (ii) twice the percentage increase of the Medical Care Component of the Consumer Price Index during the prior two calendar years. NRS 439B.630(2).

By April 1st of each year, the manufacturers of the drugs in the Essential Drug List must submit a report ("Manufacturers' Cost Report") to the Department which includes:

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;

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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 [Essential Drug List], trends in those costs and rebates available for such drugs.

NRS 439B.635.

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In addition, if a manufacturer's drug is included in the Price Increase List, then by April 1st of that year, the manufacturer must submit a second report ("Manufacturers' Price Increase Report") to the Department explaining the reasons for the increase in the WAC, including:

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.

NRS 439B.640.

NRS 439B.645 requires PBMs to submit a report ("PBMs' Rebate Report")[2] to the Department by April 1st of each year. Specifically, the PBMs must report certain information pertaining to rebates for prescription drugs included in the Essential Drug List. *Id.*

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[2] The Manufacturers' Cost Report, the Manufacturers' Price Increase Report, and the PBMs' Rebate Report are hereinafter collectively referred to as the "Reports."

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The Department then reviews the Reports and compiles a separate report ("Department Price Increase Report") by June 1st of each year detailing: (i) the price of the drugs on the Essential Drug List; (ii) the reason for any increase in these prices; and (iii) the effect of these prices on overall spending on prescription drugs in Nevada. NRS 439B.650. This report may also include information regarding "opportunities" to lower the cost of asthma and diabetes drugs while still "maintaining access to such drugs." *Id.*

There are four additional reports that must be submitted to the Department. First, pursuant to NRS 439B.655, pharmacies are required to report ("Pharmacy Report") to the Department "[i]nformation that a consumer may use to locate, contact, or otherwise do business with the pharmacy," such as the name, physical address, and phone number of the pharmacy. NRS 439B.655(1)(a). Second, manufacturers are also required to provide the Department with a list ("Manufacturers' Pharmaceutical Sales Representative List") of each pharmaceutical sales representative who markets their prescription drugs to health care providers, pharmacies, and medical facilities in Nevada. NRS 439B.660(1). Third, each identified pharmaceutical sales representative must then submit a report

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("Compensation/Sample Report") to the Department by March 1st of each year detailing the health care providers, pharmacies, and medical facilities to whom he or she provided any compensation which exceeded $10 in value (or total compensation which exceeded $100 in value in aggregate) along with the name and manufacturer of each prescription drug for which he or she provided a free sample to a health care provider, pharmacy, or medical facility. NRS 439B.660(4). Fourth, by February 1st of each year, any nonprofit organization that advocates on behalf of patients or funds medical research in Nevada, that has received a payment, donation, subsidy or anything else of value from a manufacturer, PBM, or other third party during the prior calendar year, must submit a report ("Nonprofit Report") which includes the amount of each contribution, the identity of the contributor, and the percentage of the nonprofit's total gross income which is attributable to the contribution. NRS 439B.665.

Finally, the Department posts the Pharmacy Report, Nonprofit Report, Essential Drug List, Price Increase List, Department Price Increase Report, Manufacturers' Pharmaceutical Sales Representative List, and Compensation/Sample Report on its website. NRS 439B.670(1)(a).

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However, the only information from the Manufacturers' Cost Report disclosed on the Department's website is the WAC, and no information from the Manufacturers' Price Increase Report is disclosed by the Department publicly or otherwise. *Id.*

5. NRS 600A.030(5)(b).[3]

Senate Bill 539 also amended the definition of a trade secret. Specifically, NRS 600A.030 was amended to provide that the phrase "trade secret" "[d]oes not include any information that a manufacturer is required to report pursuant to NRS 439B.635 [the Manufacturers' Cost Report] or 439B.640 [the Manufacturers' Price Increase Report], information that a pharmaceutical sales representative is required to report pursuant to NRS 439B.660 [the Compensation/Sample Report] or information that a pharmacy benefit manager is required to report pursuant to NRS 439B.645 [the PBMs' Rebate Report], to the extent that such information is required to be disclosed by those sections." This was further modified as discussed below.

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[3] NRS 439B.600 to NRS 439B.695 and NRS 600A.030(5)(b) are hereinafter collectively referred to as "Prescription Drug Reporting Statutes."

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B. The PhRMA Litigation.

On September 1, 2017, one month before the reporting requirements set forth in Section A(4), *supra*, were to become effective, Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Innovation Organization ("BIO") filed a federal action (the "PhRMA Litigation") against the Governor of Nevada and the Director of the Department seeking declarative and injunctive relief relating to Senate Bill 539. (IIIJ.A. at 000582-000625.) Sanofi is a member of both PhRMA and BIO. (IIIJ.A. at 000628:13-14, 18-19.)

In the PhRMA Litigation, PhRMA and BIO alleged that Section 3.8 of Senate Bill 539, which pertains to the Manufacturers' Cost Report, and Section 4, which pertains to the Manufacturers' Price Increase Report, require disclosure of "information that qualifies as a trade secret under federal law and the law[s] of every state — including Nevada until SB 539 takes effect." (IIIJ.A. at 000604:16-26.) PhRMA and BIO further asserted that the statutes enacted and/or amended by Senate Bill 539:

> [S]trip[] pharmaceutical manufacturers of trade secret protection for confidential, competitively sensitive, proprietary information regarding the advertising, cost, marketing, pricing, and

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> production of their patented diabetes medicines. The Act then compels manufacturers to disclose this information to the [Department], which must publish at least some of the information on its website and may disseminate the rest as it pleases.

(IIIJ.A. at 000583:12-19.) Thus, PhRMA and BIO alleged that Senate Bill 539 was unconstitutional because it: (1) violated the Supremacy Clause of the U.S. Constitution by conflicting with the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the Hatch-Waxman Act); (2) violated the Takings Clause of the 5th Amendment by depriving manufacturers of trade-secret protection for their confidential information; and (3) violated the dormant Commerce Clause by 'tying penalties to the national list price for a drug." (*Id.* at 000583:20-000585:2.) PhRMA and BIO also alleged that Senate Bill 539 conflicted with the Defend Trade Secrets Act of 2016 (18 U.S.C. §1836) ("DTSA"). (*Id.* at 000584:5-10.)

1. The Legislature's Intent With Regard to Trade Secrets Under Senate Bill 539.

On September 26, 2017, the Nevada Legislature — not the Legislative Counsel Bureau, as asserted by the Culinary Workers Union Local 226 ("Culinary Union") in its *Amicus Curiae* Brief — moved to intervene in the

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PhRMA Litigation. (IR.A.2 at 32-52; *see also Amicus Curiae* Br. ("A.C.B.") at 22:10-12.)[4] The Legislature was granted the right to intervene on October 3, 2017. (IIIJ.A. at 000638:18-19.)

PhRMA and BIO filed a motion for temporary restraining order and preliminary injunction, seeking to enjoin implementation and enforcement of several provisions of Senate Bill 539. (IIIJ.A. at 000640-000674.) In the Legislature's opposition to this motion, it repeatedly emphasized that Senate Bill 539 did ***not*** require manufacturers to disclose trade secrets:

> - 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***. (IR.A.3 at 55:23-56:3 (emphasis added).)
>
> - "[T]o the extent that manufacturers believe they cannot satisfy their disclosure requirements without revealing trade-secret

[4] For citations to Respondent Sanofi-Aventis U.S. LLC's Supplement to the Joint Appendix, Sanofi will refer to "R.A." The number preceding "R.A." refers to the applicable volume of the Appendix, and the number succeeding "R.A." refers to the applicable tab number.

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information, manufacturers may enter into confidentiality agreements with [the Department] ***to provide the trade-secret information confidentially to the agency without losing its protected trade-secret status***. (*Id.* at 61:16-62:4 (emphasis added) (citing § 7 of Senate Bill 539, which authorizes the Department "to adopt regulations prescribing the 'form and manner' in which manufacturers are to provide the necessary information" to the Department, and NRS 600A.070(5), which recognizes 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'").)

- [A]lthough the challenged provisions amend the definition of "trade secret" in the UTSA [Uniform Trade Secret Act], ***the Legislature's intent was <u>not</u> 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 Department]; or (2) providing the trade-secret information in their reports to [the Department] under the terms of a confidentiality agreement. (*Id.* at 63:6-10 (emphasis added).)

- [T]he ***Legislature's objective*** . . . was to require manufacturers to provide [the Department] with as much business

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> information as possible about the factors contributing to the cost of diabetes drugs ***while also protecting some proprietary information from disclosure***. (*Id.* at 65:21-66:2 (emphasis added).)
>
> - [I]t 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***. (*Id.* at 66:21-24 (emphasis added).)

The Nevada Legislature continued to make substantially similar statements in its Motion for Summary Judgment. (*See e.g.*, IR.A.4 at 128:4-6, 134:19-135:7, 136:9-13, 139:3-6, 140:1-4.)

The Department also adopted the Legislature's assertion that Senate Bill 539 did not require manufacturers to disclose trade secrets. (1R.A.5 at 152:17-18, 157:7-9, 161:7-10.) Moreover, as early as September 2017, the Department was considering adopting regulations to address the trade secret concerns of the manufacturers. Specifically, in the Department's response to PhRMA and BIO's motion for preliminary injunction, the Department

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acknowledged that while it could not alter NRS 600A.030 by regulation, it "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***." (IR.A.1 at 6:22-26 (emphasis added).) Because it was not realistically possible to fully comply with the reporting requirements without disclosing trade secrets, and confidentiality agreements were not a sufficient safeguard in this instance,[5] it was determined that adopting regulations addressing the confidentiality of the trade secrets was the most efficient and expedient way to effectuate the Legislature's intent.

2. The Confidentiality Regulations.

In January 2018, the Department issued public notice of draft regulations that were designed to protect the confidentiality of trade secrets submitted in the Reports. (1R.A.6 at 173-188.) Originally, the Department proposed that if manufacturers believed any information provided in the Reports met the standard of a trade secret under the DTSA, then the manufacturers could request that this information be declared confidential

[5] TNI claims that an agency's promise to keep records confidential may not hold up in a public records request action. (O.B. at 29:9-18.)

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and could provide a detailed description of why the data qualified as a trade secret. (*Id.* at 180.) This description would be made available to the public upon request. (*Id.*) Then, the Department would notify manufacturers of any public records requests which sought the information for which the manufacturers had requested confidentiality. (*Id.*) The manufacturers would then be given thirty (30) days to take legal action under the DTSA before the Department would release the requested information. (*Id.*)

BIO objected that the proposed regulations would essentially cause manufacturers to "be in federal court perpetually every year" fighting public records requests for the trade secrets the manufacturers are required to disclose in the Reports. (1R.A.7 at 194.) BIO asserted that this would "harm innovation and clinical trials in the State of Nevada" and "would overly burden small biotechnology firms who would not only be overwhelmed with reporting requirements, but they would also be forced to spend money on unwarranted litigation under the DTSA every year." (*Id.* at 194-195.) Similarly, PhRMA contended that the Department should model its regulations on the existing procedures under the Freedom of Information Act and the Nevada Public Records Act and allow manufacturers to request

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confidentiality by marking the information they submit to the Department with a confidentiality legend. (*Id.* at 198-199.) The Department would then determine if the information qualified for confidential treatment. (*Id.* at 199.) Any party disagreeing with the Department's determination (whether manufacturer or a member of the public) could then file the appropriate legal action. (*Id.*)

While the proposed regulations went through several rounds of revision and public comment, the ***Nevada Legislature*** moved for leave to supplement its motion for summary judgment to inform the Court that "as the agency charged with administering and enforcing the challenged provisions, [the Department] intends to adopt regulations which will provide manufacturers with reasonable procedures to safeguard the confidentiality of information included in their reports if the manufacturers reasonably believe that public disclosure of the information would constitute misappropriation of a trade secret" under the DTSA. (2R.A.8 at 236:11-16.) Specifically, the Legislature disclosed that the Department intended to adopt regulations which:

> (1) authorize[] a manufacturer to request that [the Department] keep information included in their

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> reports confidential as a trade secret under the federal DTSA; and (2) establish[] procedures for [the Department] to follow when it receives a request for public records under state law seeking disclosure of information for which a manufacturer has submitted a request for confidentiality.

(*Id.* at 238:3-10.) As the Legislature rationalized, "[b]ecause the procedures that [the Department] will follow under its proposed regulations are similar to the procedures that federal agencies have been following for decades under federal law, the proposed regulations will provide manufacturers with reasonable procedures to safeguard the confidentiality of information included in their reports if the manufacturers reasonably believe that public disclosure of the information would constitute misappropriation of a trade secret under the federal DTSA." (*Id.* at 241:6-10.)

On May 16, 2018, the Legislative Commission approved the Department's proposed regulations for protecting trade secrets included in the Reports. (2R.A.9 at 264:2-3.) The following regulations were subsequently adopted by the Department and became effective on May 31, 2018:

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Under NAC 439.735, if a manufacturer or PBM reasonably believes that public disclosure of information submitted to the Department pursuant to NRS 439B.635, NRS 439B.640, or NRS 439B.645 "would constitute misappropriation of a trade secret for which a court may award relief" pursuant to the DTSA, "the manufacturer or [PBM] may submit to the Department a request to keep the information confidential." NAC 439.735(1). A request for confidentiality must: (i) "describe, with particularity, the information sought to be protected from public disclosure," NAC 439.735(2)(a); (ii) "include an explanation of the reasons why public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief" pursuant to the DTSA, NAC 439.735(2)(b). This first portion of the request will not be publicly disclosed unless the Department receives a public records request, denies the manufacturer's or PBM's request for confidentiality, and the manufacturer or PBM either fails to seek an injunction enjoining the disclosure or the court denies the injunction. NAC 439.735(2)(a), (5), (6). The second portion of the request will be publicly disclosed if the Department receives a public records request. NAC 439.735(2)(b).

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If the Department receives a public records request for any information for which a manufacturer or PBM has submitted a request for confidentiality, the Department must provide the manufacturer or PBM with written notice and a copy of the public records request. NAC 439.735(3)(a). The Department must also "[u]ndertake an initial review to determine whether the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the [DTSA]." NAC 439.735(3)(b). As part of this initial review, "the Department will consider, as persuasive authority, the interpretation and application given to the term "trade secrets" in Exemption 4 of the federal Freedom of Information Act." *Id.*

If, after undertaking its initial review regarding confidentiality, "the Department reasonably believes that public disclosure of the information would constitute misappropriation of a trade secret for which a court may award relief pursuant to the [DTSA]," the Department must, pursuant to the requirements of NRS 239.0107, provide the public records requester with written notice that the Department is denying the request "on the basis that the information is confidential pursuant to the [DTSA]." NAC

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439.735(4)(a). The Department must also provide written notice to the manufacturer or PBM that the public records request was denied, along with a copy of the written notice that the Department provided to the public records requester. NAC 439.735(4)(b).

On the other hand, if, after undertaking its initial review regarding confidentiality, "the Department reasonably believes that public disclosure of the information would not constitute misappropriation of a trade secret for which a court may award relief pursuant to the [DTSA]," the Department must, pursuant to the requirements of NRS 239.0107, provide the public records requester with written notice that the Department intends to disclose the requested information. NAC 439.735(5)(a). However, the written notice must also explain that the Department cannot disclose the requested information "until 30 days have elapsed following the date on which such written notice was sent to the requester." NAC 439.735(5)(a)(1). Moreover, the written notice must state that if the manufacturer or PBM "commences an action within the 30-day period" to enjoin the Department from disclosing the requested information, "the Department will not be able to

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disclose the information" unless and until disclosure is permitted by the court. NAC 439.735(5)(a)(2).

In addition to the written notice to the public records requester, the Department must also send written notice to the manufacturer or PBM stating that the Department intends to disclose the requested information, along with a copy of the written notice that the Department sent to the public records requester. NAC 439.735(5)(b). If, during the 30-day period following the Department's notice to the public records requester, the manufacturer or PBM fails to commence an action pursuant to the DTSA to enjoin the Department from disclosing the information, then the Department is free to disclose the requested information to the public records requester. NAC 439.735(6)(a). However, if the manufacturer or PBM does commence an action pursuant to the DTSA, the Department cannot disclose the requested information until final resolution of the litigation, including any appeals. NAC439.735(6)(b). If the court enjoins the disclosure of any trade secrets, "the Department will not disclose the information so long as the information retains its status as a trade secret." NAC 439.735(6)(b)(1). If the court does not enjoin disclosure of the requested information, then the

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Department will disclose the information to the public records requester "as soon as reasonably practicable." NAC 439.735(6)(b)(2).

The Department also adopted and approved two additional regulations designed to remedy the issues and concerns raised in the PhRMA Litigation. First, the Department confirmed that in the Department Price Increase Report, pursuant to NRS 439B.650, the Department would only include "aggregated data that does not disclose the identity of any drug, manufacturer, or [PBM]," along with a "description of trends concerning the prices of prescription drugs" on the Essential Drug List and Price Increase List, pursuant to NRS 439B.630, "and an explanation of how those prices and trends may affect the prevalence and severity of diabetes" in Nevada. NAC 439.740. Second, the Department confirmed that it would make available on the Internet the forms that manufacturers, PBMs, and pharmaceutical sales representatives must use to comply with the reporting requirements of Senate Bill 539. NAC 439.730.[6]

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[6] NAC 439.730, NAC 439.735, and NAC 439.740 will be collectively referred to as the "Confidentiality Regulations."

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3. Resolution of the PhRMA Litigation.

After the Confidentiality Regulations became effective, the parties to the PhRMA Litigation resolved their dispute. Thus, on June 28, 2018, PhRMA, BIO, the Department, and the Nevada Legislature filed a Joint Status Report to inform the court of the resolution. (IIIJ.A. at 000676-000692.) The Report stated:

- "The parties ***agree and acknowledge*** that, under SB 539, the Department may acquire manufacturer trade secrets, such as a manufacturer's costs of production and other internal costs, '***under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret***.'" (*Id.* at 000678:11-14 (emphasis added).)

- "[T]he parties ***agree and acknowledge*** that, so long as such trade secrets continue to satisfy the definition of 'trade secret' in 18 U.S.C. §1839, if the Department were to disclose such trade secrets to any third party or use such trade secrets, ***such disclosure or use would constitute 'misappropriation' for which a court may award relief pursuant to the DTSA***." (*Id.* at 000678:14-17 (emphasis added).)

- "These protections are intended to ***afford an opportunity*** to manufacturers that submit trade secrets to the Department to seek to ***safeguard their interests in the confidentiality of those trade secrets***." (*Id.* at 000678:17-19 (emphasis added).)

- "In [the ***Department's and Legislature's view***], the now-effective regulation . . . resolves the alleged facial constitutional issues with respect to the challenged provisions of SB 539." (*Id.* at 000678:19-21 (emphasis added).)

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Thus, in reliance on the Confidentiality Regulations, PhRMA and BIO agreed to file a motion for the voluntary dismissal of the PhRMA Litigation. *Id.* at 000679:7-9.) The court granted the motion without prejudice on June 28, 2018. (IIIJ.A. at 000694-000699.)

C. Sanofi Submitted the Required Reports to the Department Along With Requests for Confidentiality.

Sanofi-Aventis U.S. LLC is the United States affiliate of Sanofi, a global life sciences company committed to improving access to healthcare and supporting the people it serves throughout the continuum of care. (IIIJ.A. at 000575:10-12.) Specifically, Sanofi transforms scientific innovation into healthcare solutions in human vaccines, rare diseases, multiple sclerosis, oncology, immunology, infectious disease, diabetes and cardiovascular, consumer healthcare, established prescription products, and generics. (*Id.* at 000575:12-14.) Some of the drugs that Sanofi manufactures include Adlyxin, Admelog, Amaryl, Apidra, Diaβeta, Lantus, Soliqua, and Toujeo, which are all FDA-approved for the treatment of diabetes. (IIIJ.A. at 000576:3-5.)

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On October 31, 2017, the Department issued its first Essential Drug List pursuant to NRS 439B.630. (IIIJ.A. at 000701-000706.) The List included the following Sanofi products: Diaβeta, Amaryl Glimepiride, Basaglar, Lantus, Toujeo, Soliqua, and Apidra. (*Id.*) Similarly, on February 1, 2019, the Department issued its second Essential Drug List, which included Adlyxin, Admelog, Amaryl, Apidra, Lantus, Soliqua, and Toujeo. (IIIJ.A. at 000708-000730.)

In reliance upon the Department's new Confidentiality Regulations, Sanofi submitted the required Manufacturers' Cost Reports, pursuant to NRS 439B.635, and Manufacturers' Price Increase Reports, pursuant to NRS 439B.640, on January 15, 2019 and April 1, 2019, along with a subsequent August 7, 2019 supplemental submission under these statutes. (IIIJ.A. at 000576:9-12.) In the Manufacturers' Cost Reports, Sanofi reported trade secrets regarding its diabetes drugs in response to the following categories of information:

- The total cost of producing the drug;
- Total administrative expenditures relating to the drug;

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- Profit [Sanofi] earned from the drug;
- Percentage of [Sanofi's] total profit attributed to the [drug] during marketing period for drug sale;
- Total amount of financial assistance provided through patient Prescription Assistance Programs;
- Cost associated with consumer coupons for consumer Copayment Assistance Programs;
- [Sanofi's] cost attributable to redemption of consumer coupons and use of consumer Copayment Assistance Program; and
- Aggregate amount of all rebates [Sanofi] provided to PBMs for drug sales in Nevada . . . .

(IIIJ.A. at 000576:13-24.) Similarly, in the Manufacturer Price Increase Reports, Sanofi reported trade secrets regarding the WAC increases for Adlyxin, Apidra, Lantus, Soliqua, and Toujeo in response to the following categories of information:

- A list of factors that has contributed to the increase;
- The explanation for the percent increase attributable to each factor; and

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- An explanation of the role each factor played in the increase.

(IIIJ.A. at 000577:1-6.)

With the submission of each of these reports, Sanofi also submitted a request for confidentiality for its trade secret information ("Requests for Confidentiality"). (IIIJ.A. at 000732-000734, 000736-000738.) Sanofi's Requests for Confidentiality state that Sanofi "reasonably believes that public disclosure of the Sanofi Confidential Information to any person or entity outside of the Department[,] including to state legislators, would constitute misappropriation of a trade secret for which a court may award relief pursuant to the [DTSA]." (IIIJ.A. at 000732, 000736.) The Requests for Confidentiality also state that Sanofi was submitting the Requests "in reliance upon" the June 28, 2018 Joint Status Report filed in the PhRMA Litigation, "in which the State of Nevada and the Department agreed that if the Department were to disclose trade secrets of Sanofi to any third party or use such trade secrets, such disclosure or use would constitute misappropriation for which a court may award relief to Sanofi pursuant to the DTSA." (*Id.*) Sanofi's Requests for Confidentiality also included an

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explanation of the "[r]ationale for [t]rade [s]ecret [p]rotection [u]nder the DTSA." (*Id.* at 000733, 000737.) Specifically, Sanofi stated that its trade secrets were "of substantial independent value" and that public disclosure of this information "would cause significant harm" to Sanofi. (*Id.*) Sanofi further explained that, pursuant to 18 U.S.C. § 1839(3)(A), it has taken "reasonable measures" to maintain the secrecy of its trade secrets, such as: (i) not sharing the information publicly; (ii) restricting access to the information internally within Sanofi; (iii) sharing the information internally within Sanofi on a need-to-know basis; (iv) requiring Sanofi employees to maintain the secrecy of the information by signing non-disclosure agreements; and (v) subjecting Sanofi employees to discipline, including termination, for the unauthorized disclosure of the information. (*Id.*)

Finally, Sanofi's Requests for Confidentiality detailed the harm it would suffer from public disclosure of its trade secrets:

> The customers and competitors of [Sanofi] would gain an unfair competitive advantage if they were to obtain [Sanofi's trade secrets] through a public records request pursuant to NRS 239.010. In particular, [Sanofi's] competitors and customers would receive the details of [Sanofi's] cost structure, marketing and advertising costs, rebate strategies and profit information, which in turn

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> provides insight into [Sanofi's] pricing. This information could be used against [Sanofi] in negotiations with insurers and other intermediaries in the healthcare system. This could put [Sanofi] at a significant disadvantage, especially if [its] competitors do not make a diabetes drug and thus are not subject to SB 539's disclosure requirements. Disclosure of [Sanofi's trade secrets] could prejudice [Sanofi] in competition involving non-diabetes products as well, given that [Sanofi] considers the same or similar factors when establishing pricing, advertising and rebate strategies for its other therapeutic products.

(*Id.*)

D. <u>TNI's Public Records Request.</u>

Just two days after Sanofi submitted its Request for Confidentiality to the Department, on January 17, 2019, TNI sent the Department a public records request. (IJ.A. at 000024-000026.) TNI requested the annual reports submitted by any manufacturer pursuant to NRS 439B.635 and/or NRS 439B.640, specifically naming ninety-eight (98) manufacturers, including Sanofi. (*Id.* at 000024-000025.) TNI also requested the annual reports submitted by PBMs pursuant to NRS 439B.645, specifically naming 7 PBMs. (*Id.* at 000025-000026.) Finally, TNI requested any written

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opinions that the attorney general's office provided to the Department "relating to the implementation" of Senate Bill 539. (*Id.* at 000026.)

On April 3, 2019, the Department responded to TNI's records request and informed TNI that the "source reports" it sought were subject to Requests for Confidentiality made by the manufacturers and PBMs. (IJ.A. at 000028.) The Department confirmed that it had reviewed the information provided by the manufacturers and PBMs and their related Requests for Confidentiality, and it determined that certain information was confidential and protected from disclosure pursuant to the DTSA. (*Id.*) Thus, the Department informed TNI that it would only publicly disclose the following, non-confidential information:

- From the Manufacturers' Cost Reports pursuant to NRS 439B.635:
    - Drug manufacturer name;
    - Nonproprietary prescription drug name;
    - Proprietary prescription drug name;
    - National Drug Code (NDC);
    - WAC price history;
    - Increase in WAC unit price; and

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- Date of increase in WAC price.

- From the Manufacturers' Price Increase Reports pursuant to NRS 439B.640:
  - Drug manufacturer name;
  - Non-proprietary drug name;
  - Proprietary drug name; and
  - NDC.
- From the PBMs' Rebate Reports pursuant to NRS 439B.645:
  - A list of PBMs that submitted reports.

(IJ.A. at 000028, 000031.)

On June 11, 2019, TNI submitted a second public records request to the Department. (IJ.A. at 000033-000035.) In this request, TNI sought the second annual reports submitted by manufacturers pursuant to NRS 439B.635 and/or NRS 439B.640; however, this time TNI only specifically named seventy-two (72) manufacturers, including Sanofi. (*Id.* at 000033-000034.) TNI also requested the second annual reports submitted by PBMs pursuant to NRS 439B.645, specifically naming the same seven (7) PBMs. (*Id.* at 000034.) In this request, TNI did not request any attorney general opinions. (*Id.*)

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On June 24, 2019, the Department responded to TNI's second records request, and, again, the Department informed TNI that the "source reports" sought in the request were subject to Requests for Confidentiality submitted by the manufacturers and PBMs. (IJ.A. at 000037.) Just as with the first request, the Department confirmed that, based on its review of the information and the Requests for Confidentiality, it had determined that some of the requested information was confidential and exempt from disclosure pursuant to the DTSA. (*Id.*) Again, the Department provided TNI with a list of the specific, non-confidential information that would be disclosed, and the list included the same information as set forth in the Department's response to TNI's first records request in January 2019. (*Id.* at 000040.)

E. TNI's Petition for Writ of Mandamus in the District Court.

1. Challenge to the Borneman Declaration.

On August 8, 2019, TNI filed a Petition for Writ of Mandamus ("Petition") directing the Department to provide copies of the records it had requested. (IJ.A. at 000001-JA000014.) Sanofi filed a Response to the Petition on December 23, 2019, after its motion to intervene was granted.

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(IIIJ.A. at 000549-000553, 000554-000738.) Sanofi relied upon the Declaration of James Borneman, in support of its Response. (IIIJ.A. at 000575-000580.)

Mr. Borneman is the Vice-President and Head of Diabetes and Primary Care Sales for Sanofi, and he formerly served as Sanofi's Vice President of Strategic Pricing and Contract Management and as the Head of Customer Engagement & Insight. (*Id.* at 000575:3-6.) Based on these roles, Mr. Borneman "was responsible for and . . . knowledgeable about the establishment of all gross and net pricing strategies for all [Sanofi] pharmaceutical products." (*Id.* at 000575:6-8.)

Mr. Borneman's Declaration included information about Sanofi's diabetes drugs, the confidential information and trade secrets included in Sanofi's Reports, Sanofi's Requests for Confidentiality, details about the steps taken to safeguard Sanofi's trade secrets, and the harm Sanofi would suffer if its trade secrets were publicly disclosed. (IIIJ.A. at 000575-000580.) Mr. Borneman's Declaration was also made under the penalty of perjury under the laws of both Nevada and New Jersey. (*Id.* at 000580:12-13.)

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In TNI's Reply in support of its Petition, TNI never objected to the Borneman Declaration or disputed any of the information set forth therein. (IIIJ.A. at 000739-000750; IVJ.A. at 000751-000758.) Because the issues presented by the Petition were primarily questions of law, not fact, Sanofi filed a notice that it did not intend to call any affirmative witnesses for the evidentiary hearing on the Petition. (IVJ.A. at 000762-000764.)

Despite the passage of over three months between the filing of Sanofi's Response to the Petition and the hearing on the Petition, TNI waited until the eve of the hearing on the Petition to challenge the Borneman Declaration with the Motion to Strike. (IIIJ.A. at 000554-000738; IVJ.A. at 000820:20-000821:17.)

The District Court found that, it had the discretion, pursuant to NRCP 56(e), to "consider all pleadings and supporting documents in the context of the [Petition] as a whole," and to give the "entire record" the "weight of credibility it is due" when deciding the Petition. (IVJ.A. at 000921-000922.) The Court also found that there were insufficient "reasonable grounds" to compel Mr. Borneman to testify, given that Sanofi did not bear the burden of proof on the issues raised in the Petition. (*Id.* at 000922.)

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2. Denial of the Petition.

On September 4, 2020, the District Court denied TNI's Petition. (IVJ.A. at 000974-000984.) The District Court found that regulations created by state agencies, like the Confidentiality Regulations, are presumed to be valid. (IVJ.A. at 000969, 000980:16-20.) The District Court also deferred to the Department's reasonable interpretation of the statutes it was charged with enforcing. (IVJ.A. at 000971, 000980:20-22.) The District Court found that the Department had "broad discretion to implement regulations to foster efficient enforcement of codified legislation," and that if the Department had not adopted the Confidentiality Regulations, "the courts would [have] become inundated with cases in which the compelled disclosing parties claim[ed] they did not have the opportunity to protect their trade secrets from mass disclosures." (IVJ.A. at 000972, 000980:26-000981:3.) Finally, the District Court determined that the information in the Reports fell "squarely under" confidentiality protection based on the DTSA's definition of trade secrets. (IVJ.A. at 000972, 000981:15-25.)

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IV. SUMMARY OF ARGUMENT

The District Court did not abuse its discretion in denying TNI's Petition or its Motion to Strike. Moreover, upon this Court's *de novo* review of the statutory interpretation of the Prescription Drug Reporting Statutes, the Confidentiality Regulations, and the Nevada Public Records Act, this Court should affirm the District Court's denial of the Petition and the Motion to Strike.

The public is permitted access to "all public books and public records of a governmental entity" unless such records are specifically and statutorily exempted from disclosure or are "otherwise declared by law to be confidential." NRS 239.010(1). Here, the issue as to whether certain information disclosed to the Department in the Reports is exempt from public disclosure is quite simple. Information included within these Reports can be declared confidential and exempt from public disclosure pursuant to the Confidentiality Regulations based on their qualifications as a "trade secret" under the DTSA.

The Department was duly authorized to adopt the Confidentiality Regulations through enabling legislation in the Prescription Drug Reporting

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Statutes. *See* NRS 439B.685(6). Moreover, the Confidentiality Regulations were drafted and adopted prior to the effective date of the Prescription Drug Reporting Statutes as a means of resolving a legal challenge to the constitutionality of the Statutes.

Not only do the Confidentiality Regulations not conflict with the plain language of the Prescription Drug Reporting Statutes, but the Legislature has expressly stated that the Regulations properly implement the legislative intent for the Statutes. Specifically, the Legislature has stated that the Prescription Drug Reporting Statutes were not designed or intended to require public disclosure of the manufacturers' or PBMs' trade secrets to the extent such information was submitted to the Department in compliance with the Statutes.

Because certain information submitted in the Reports qualifies as a "trade secret" under the DTSA, and the Confidentiality Regulations protect the confidentiality of this information, the Department could be liable for misappropriation of trade secrets under the DTSA if such information were disclosed pursuant to a public records request. This is because the Department acquired the trade secrets under circumstances which gave rise

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to a duty to maintain their secrecy. *See* 18 U.S.C. § 1839(5)(B)(ii)(II). Because disclosure of the trade secrets would not have constituted a "lawful activity," the Department and its employees could be potentially liable for misappropriation under the DTSA if a manufacturer or PBM sought injunctive relief. *See* 18 U.S.C. § 1833(a)(1); *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 73 (1996). Thus, it is clear that the Confidentiality Regulations strike a balance between allowing the Department to collect necessary information regarding prescription drug pricing to assist the State in restraining the costs of healthcare, while also ensuring that the Department does not violate the DTSA and become subjected to countless legal disputes seeking to enjoin public disclosure of trade secrets.

Notably, TNI and the Culinary Union avoid any discussion of the history of the Confidentiality Regulations because the Legislature's participation in the creation and adoption of these Regulations sets this case apart from traditional public records request challenges. This is a unique instance in which it is undisputed that the Department had the authority to adopt the Confidentiality Regulations and that such Regulations are in harmony with the plain language, spirit, and legislative intent of the statutes

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they were designed to implement. Therefore, the denial of the Petition and the Motion to Strike should be affirmed.

V. STANDARD OF REVIEW

Sanofi agrees with TNI's brief statement of the standard of review — abuse of discretion for denial of the Petition and *de novo* review for statutory interpretation. (O.B. at 6:22-26.) However, to the extent this Court reviews the issue concerning the denial of the Motion to Strike (which it should not), the Court's review should be for an abuse of discretion. *M.C. Multi-Family, L.L.C. v. Crestdale Assocs., Ltd.*, 124 Nev. 901, 913, 193 P.3d 536, 544 (2008) (holding that a district court's decision to admit or exclude evidence is reviewed for abuse of discretion); *State ex rel. Dep't of Highways v. Nev. Aggregates & Asphalt Co.*, 92 Nev. 370, 376, 551 P.2d 1095, 1098 (1976).

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VI. ARGUMENT

A. The District Court Did Not Abuse Its Discretion in Denying TNI's Petition.

1. The Trade Secrets in the Reports Were Declared Confidential Under the Confidentiality Regulations and Were Exempted From Public Disclosure.

It is well settled that under the NPRA, "all public records generated by government entities are public information and are subject to public inspection unless otherwise declared to be confidential." *Reno Newspapers, Inc. v. Haley*, 126 Nev. 211, 214, 234 P.3d 922, 924 (2010). While NRS 239.010 includes numerous statutes which exempt certain categories of information from the NPRA, "[t]his [C]ourt has held that regulations need not be expressly mentioned in NRS 239.010 to grant confidentiality and exemption from the NPRA." *City of Sparks v. Reno Newspapers, Inc.*, 133 Nev. 398, 402-03, 399 P.3d 352, 356-57 (2017). This is because NRS 239.010 provides that the NPRA also does not apply to government records "otherwise declared by law to be confidential." NRS 239.010(1).

When an administrative agency properly adopts regulations, such regulations have the force of law. NRS 233B.040(1). Therefore, a category

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of government records will be exempt from public disclosure under the NPRA if either a statute — or a regulation — expressly and unequivocally makes the records confidential. *Reno Newspapers, Inc. v. Haley*, 126 Nev. 211, 214-15, 234 P.3d 922, 924-25 (2010).

TNI repeatedly asserts that because the DTSA does not expressly and unequivocally designate any specific categories of documents as confidential or trade secrets, the Reports were not exempt from disclosure under the NPRA. (*See, e.g.,* O.B. at 7:1-19, 15:22-26.) However, TNI misses the point. While the DTSA does not expressly bestow confidentiality as to a specific type of records, it does provide a means for determining what information qualifies as a trade secret under federal law, *see* 18 U.S.C. § 1839(3), and the Confidentiality Regulations then bestow confidentiality on these trade secrets and protect them from disclosure under the NPRA.

Specifically, to the extent that information qualifies as a trade secret under the DTSA, (*see* Section VI(A)(5), *infra*), NAC 439.735 expressly and unequivocally makes trade secrets submitted to the Department in the Reports confidential. As such, any trade secrets included in these Reports, for which a manufacturer or PBM has submitted a Request for

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Confidentiality, and for which the Department has approved the Request, has been "otherwise declared by law to be confidential" for the purpose of the NPRA.

TNI and the Culinary Union contend that agency regulations cannot "limit the NPRA" or serve as a "line-item veto over the NPRA." (O.B. at 38:1-5, 18-28 (citing *Clark Cnty. Sch. Dist. v. Las Vegas Review-Journal*, 134 Nev. 700, 704, 429 P.3d 313, 317-18 (2018) and *Comstock Residents Ass'n v. Lyon Cnty. Bd. of Comm'rs*, 134 Nev. 142, 147, 414 P.3d 318, 322 (2018)); A.C.B. at 20:3-15 (same).) However, the cases upon which TNI and the Culinary Union rely involve an agency's attempt to bestow confidentiality by designating the requested documents "nonrecord materials" pursuant to NAC 239.051 or contending that the documents were not within the "legal custody" of the agency pursuant to NAC 239.041. *Clark Cnty. Sch. Dist.*, 134 Nev. at 703-04 & n.2, 429 P.3d at 317-18 & n.2; *Comstock Residents Ass'n*, 134 Nev. at 147-48, 414 P.3d at 322-23. Both of these cases are inapposite and irrelevant, as they involve attempts to avoid the NPRA using the public records management practices in NAC Ch. 239. In contrast, in this action, the Department exempted the trade secrets from

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the scope of the NPRA based on duly authorized and approved agency regulations concerning the confidentiality of specific categories of agency records.

TNI also objects to the Confidentiality Regulations providing an exemption to the NPRA because they "invit[e] unelected members of the executive branch to make judicial determinations regarding confidentiality." (O.B. at 40:17-19.) However, it is irrelevant that the trade secrets in these Reports may only be considered confidential upon request to and approval by the Department. Some of the statutes which are expressly acknowledged to exempt certain categories of information from the NPRA under NRS 239.010 also bestow confidentiality only upon a request to and approval by an administrative agency or other government entity. *See, e.g.*, NRS 231.1473; NRS 388A.247. Moreover, to the extent that either the public records requester, the manufacturer, or the PBM has reason to believe that the "unelected members of the executive branch" erred in their confidentiality determination, an action can always be filed seeking a judicial determination as to confidentiality. NAC 439.735(5), (6).

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2. The Department Possessed the Requisite Authority to Adopt the Confidentiality Regulations.

TNI asserts that the Confidentiality Regulations "must be stricken, as they were not authorized by the Legislature." (O.B. at 38:1-4.) While TNI acknowledges that NRS 439B.685 authorizes the Department to "adopt such regulations as it determines to be necessary or advisable to carry out the provisions of NRS 439B.600 to 439B.695, inclusive," TNI seemingly ignores the non-exclusive list of regulations that the Legislature determined that the Department must adopt. (O.B. at 39:23-40:2.) Specifically, the Legislature specified that "[s]uch regulations must provide for, ***without limitation***[,] . . . [t]he ***form and manner*** in which manufacturers [and PBMs] are to provide" the Reports to the Department. NRS 439B.685(6), (7) (emphasis added).

Thus, the plain language of these enabling provisions authorized the Department to adopt the Confidentiality Regulations. *See Nev. Power Co. v. Haggerty*, 115 Nev. 353, 366, 989 P.2d 870, 878 (1999) ("'When the language of a statute is plain and unambiguous, a court should give that language its ordinary meaning and not go beyond it.'") (quoting *City*

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Council of Reno v. Reno Newspapers, 105 Nev. 886, 891, 784 P.2d 974, 977 (1989)). When the PhRMA Litigation threatened to invalidate several provisions of the Prescription Drug Reporting Statutes as unconstitutional, the Department was duly authorized to adopt the Confidentiality Regulations as a means of resolving the constitutional challenge.

To the extent NRS 439B.685 is ambiguous as to the Department's authority to adopt the Confidentiality Regulations, and an examination of legislative intent is necessary, the Legislature has unequivocally confirmed that the Department possessed the necessary authorization to adopt the Regulations. *See City of Sparks v. Reno Newspapers, Inc.*, 133 Nev. 398, 402, 399 P.3d 352, 356 (2017) ("If the statutory language is ambiguous . . . 'this court will construe a statute by considering reason and public policy to determine legislative intent.'") (quoting *D.R. Horton, Inc. v. Eighth Jud. Dist. Ct. ex rel. Cnty. of Clark*, 125 Nev. 449, 456, 215 P.3d 697, 702 (2009)). In the PhRMA Litigation, the Legislature expressly stated that the Department was the agency charged with "administering and enforcing" NRS 439B.635, NRS 439B.640, and NRS 439B.645, (2R.A.8 at 236:11-16); that it had approved the Confidentiality Regulations, (2R.A.9 at 264:2-3);

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and that it believed the Confidentiality Regulations resolved the constitutional issues raised as to the challenged provisions, (IIIJ.A. at 000678:19-21). Given the Legislature's close involvement with the drafting and adoption of the Confidentiality Regulations, it is expected that if the Legislature believed that the Department was acting in excess of its authority, the Legislature would have informed the court in the PhRMA Litigation and/or otherwise taken steps to invalidate the Confidentiality Regulations. It never did so.

TNI also contends that NRS 439B.685 does not authorize the Department to adopt the Confidentiality Regulations because this provision "substantially predates S.B. 539" and was added to NRS Ch. 439B in 2007. (O.B. at 39:16-22.) Again, TNI seemingly ignores the history of NRS 439B.685 which demonstrates that the statute was "[a]mended by Laws 2017, c. 592, § 7," which was effective May 1, 2018, and was "[s]ubstituted in 2017 revision for NRS 439.930." The 2017 amendment was Senate Bill 539, and § 7 of the Senate Bill stated that NRS 439.930 was to be amended to include the enabling provision that is now NRS 439B.685.

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Finally, TNI and the Culinary Union contend that NRS 439B.685 does not authorize the Department to adopt the Confidentiality Regulations because the enabling provision did not clearly and explicitly outline the Legislature's desire for the subject information to be exempted from the NPRA. (O.B. at 39:1-13 (citing NRS 453A.370(5) and *City of Sparks v. Reno Newspapers, Inc.*, 133 Nev. 398, 401-02, 399 P.3d 352, 355-56 (2017)); A.C.B. at 21:3-16 (same).) However, TNI has pointed to no legal authority which states that a government entity is only authorized to adopt regulations making certain records or information confidential if the Legislature explicitly provides the Department with that specific authority. In fact, there are several administrative regulations which provide confidentiality for certain categories of government records or information based entirely on enabling provisions similar to NRS 439B.685. *See, e.g.,* NRS 482A.100 & NAC 482A.060; NRS 513.063(5) & NAC 513.070; NRS 522.040 & NAC 522.728(5)-(7).

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3. The Confidentiality Regulations Do Not Conflict With the Prescription Drug Reporting Statutes.

(a). The Confidentiality Regulations do not conflict with the legislative intent for the Prescription Drug Reporting Statutes.

The Prescription Drug Reporting Statutes are ambiguous as to whether trade secrets in the Reports must be publicly disclosed in response to a public records request. This ambiguity arises because of a conflict in the plain language of NRS 600A.030(5)(b) and the plain language of the rest of the Prescription Drug Reporting Statutes. *Nev. Att'y for Injured Workers v. Nev. Self-Insurers Ass'n*, 126 Nev. 74, 84, 225 P.3d 1265, 1271 (2010) (quoting *Allstate Ins. Co. v. Fackett*, 125 Nev. 132, 138, 206 P.3d 572, 577 (2009)) ("Whenever possible, we interpret 'statutes within a statutory scheme harmoniously with one another to avoid an unreasonable or absurd result.'").)

Specifically, NRS 600A.030(5)(b) provides that a trade secret "[d]oes not include any information that a manufacturer is ***required to report*** pursuant to NRS 439B.635 or 439B.640, information that a pharmaceutical sales representative is ***required to report*** pursuant to NRS 439B.660 or

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information that a [PBM] is ***required to report*** pursuant to NRS 439B.645, to the extent that such information is ***required to be disclosed by those sections***." (Emphasis added). However, neither NRS 439B.635, NRS 439B.640, nor NRS 439B.645 require the information in the Reports to be "disclosed" in any manner.[7] In fact, nothing in the plain language of any of the NRS Ch. 439B Prescription Drug Reporting Statutes requires the information in the Reports to be publicly disclosed. Rather, these Reports are to be submitted to the Department, and the Department then prepares a separate report — the Department Price Increase Report pursuant to NRS 439B.650 — regarding the price of essential prescription drugs, the reasons for the increase in these prices, and the effect of the prices on overall spending on prescription drugs in Nevada.

Further, the only non-government-prepared reports that the Department is required to publicly disclose on its website are the Pharmacy Report pursuant to NRS 439B.655 and the Nonprofit Report pursuant to

[7] Moreover, NRS 439B.660(5) expressly provides that when the Department compiles its report on activities of pharmaceutical sales representatives, the Department must report the information received from pharmaceutical sales representatives in the Compensation/Sample Report (pursuant to NRS 439B.660(4)) in the ***aggregate***, so as not to disclose the identity of any person or entity. Thus, this provision is in ***direct contradiction*** to NRS 600A.030(5)(b).

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NRS 439B.665. NRS 439B.670(1)(a)(1)-(2). The Department is not required to publicly disclose the Manufacturers' Cost Report on its website; rather, NRS 439B.670(1)(a)(4) merely requires the Department to post the WAC of each prescription drug included in the Manufacturers' Costs Reports. However, the WAC is not confidential, as demonstrated by the fact that the Department properly disclosed this information in response to TNI's public records requests. (IJ.A. at 000031; IJ.A. at 000040.)

Therefore, this Court should examine the Legislature's intent with respect to the Prescription Drug Reporting Statutes to determine if the Confidentiality Regulations conflict with the statutes they were designed to implement. As set forth in detail in Section III(B), *supra*, the Legislature repeatedly stated in the PhRMA Litigation that despite its amendment to the definition of "trade secret" in NRS 600A.030, its intent was ***not*** to strip trade secret protection from the manufacturers and the PBMs. (1R.A.3 at 63:6-10; *see also id.* at 66:21-24 (stating that "***there is nothing in the plain language or legislative history of the challenged provisions to indicate that the Legislature intended to unwind . . . 150 years of trade secret law***") (emphasis added).)

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Once it became clear that the manufacturers and PBMs did not believe they could fully comply with their reporting obligations without disclosing some trade secrets to the Department, and that the manufacturers and PBMs were not willing to rely solely on confidentiality agreements to protect their trade secrets from public records requests, the Department began drafting the Confidentiality Regulations as a means of addressing the manufacturers' and PBMs' concerns with Senate Bill 539. (*See* Section III(B)(2), *supra*.) The Legislature had prior knowledge that the Department was drafting the Confidentiality Regulations, as it informed the Court in the PhRMA Litigation that the Department intended to "adopt regulations which w[ould] provide manufacturers with reasonable procedures to safeguard the confidentiality of information included in their reports if the manufacturers reasonably believe that public disclosure of the information would constitute misappropriation of a trade secret under the" DTSA. (2R.A.8 at 236:12-16.)

The Legislature never objected that the Department lacked the authority to adopt such regulations, nor took any actions to block the Department from adopting the regulations. In fact, the Legislative Commission approved the proposed regulations on May 16, 2018. (2R.A.9

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at 264:2-3.) Moreover, the Legislature expressly and unequivocally stated in the PhRMA Litigation, after the adoption of the Confidentiality Regulations, that it agreed and acknowledged that:

- Under the Prescription Drug Reporting Statutes, the Department may acquire manufacturers' trade secrets under circumstances which give rise to a duty to maintain the secrecy or limit the use of the information;
- If the Department were to disclose the manufacturers' trade secrets to a third party, the disclosure would constitute a misappropriation for which a court could award relief pursuant to the DTSA; and
- The Confidentiality Regulations resolved the constitutional challenges to the Prescription Drug Reporting Statutes.

(IIIJ.A. at 000678:11-21.)

Therefore, despite the fact that Senate Bill 539 was intended to increase transparency regarding the prices of prescription diabetes drugs in Nevada, it is clear that the Legislature never intended for this goal of increased transparency to eliminate protections for manufacturers' and PBMs' trade secrets.

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(b). <u>The Confidentiality Regulations do not conflict with the plain language of the Prescription Drug Reporting Statutes.</u>

To the extent that this Court finds no conflict or other ambiguity between the language in NRS 600A.030(5)(b) and the rest of the Prescription Drug Reporting Statutes, Sanofi contends that there is no conflict between the Confidentiality Regulations and the plain language of the Prescription Drug Reporting Statutes. First, as set forth above, nothing in the NRS Ch. 439B Prescription Drug Reporting Statutes requires public disclosure of the trade secrets in the Reports. In fact, the only information from these Reports that must be disclosed under the Statutes is the non-confidential WAC of these drugs. NRS 439B.670(1)(a)(4).

Similarly, there is no conflict between the plain language of the Confidentiality Regulations and NRS 600A.030. If the Legislature had intended for the information in the Reports to lose trade secret protections for all purposes, it should have, and would have, omitted the phrase "to the extent that such information is required to be disclosed by those sections" from NRS 600A.030(5)(b). This phrase is completely unnecessary and mere surplusage under the interpretation advanced by TNI and the Culinary

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Union, as the language preceding this phrase expressly and unequivocally would exclude the Reports from the definition of a trade secret. Thus, the only reasonable interpretation of NRS 600A.030(5)(b) which gives effect to each word and phrase in the statute is that manufacturers and PBMs cannot claim trade secret protection to avoid their reporting requirements in the NRS Ch. 439B Prescription Drug Reporting Statutes but may claim trade secret protection for this same information in the face of a public records request or other attempted public disclosure. *Davis v. Beling*, 128 Nev. 301, 311, 278 P.3d 501, 508 (2012) ("In examining the plain meaning of a statute, we read the provisions as a whole and give effect to each of its words and phrases."); *see also S. Nev. Homebuilders Ass'n v. Clark Cnty.*, 121 Nev. 446, 449, 117 P.3d 171, 173 (2005) (holding that a statute should be construed by "considering [the] provisions as a whole so as to read them in a way that would not render words or phrases superfluous or make a provision nugatory") (internal quotations omitted).

This interpretation of NRS 600A.030(5)(b) is consistent with the fact that this Court has repeatedly held that a court considering a claim of confidentiality in response to a public records request "'begin[s] with the

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presumption that all ***government-generated records*** are open to disclosure.'" *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 266 P.3d 623, 628 (2011) (emphasis added); *see also Reno Newspapers, Inc. v. Haley*, 126 Nev. 211, 214, 234 P.3d 922, 924 (2010) ("Under the Nevada Public Records Act . . . all public records ***generated by government entities*** are public information and are subject to public inspection unless otherwise declared to be confidential.") (emphasis added). Here, the Reports are generated by the manufacturers and PBMs, not the government; therefore, these Reports are not subject to disclosure through public records requests. *See e.g., Donrey of Nev., Inc. v. Bradshaw*, 106 Nev. 630, 631-32, 798 P.2d 144, 145 (1990) (concerning a request for a police investigative report); *DR Partners v. Bd. of Cnty. Comm'rs of Clark Cnty.*, 116 Nev. 616, 619, 6 P.3d 465, 467 (2000) (concerning a request for Clark County's phone records); *Reno Newspapers, Inc. v. Haley*, 126 Nev. 211, 213, 234 P.3d 922, 923-24 (2010) (concerning firearms permits); *Pub. Employees' Ret. Sys. of Nev. v. Reno Newspapers, Inc.*, 129 Nev. 833, 834-35, 313 P.3d 221, 222-23 (2013) (concerning government employee personnel files); *Clark Cnty. Sch. Dist. v. Las Vegas Review Journal*, 134 Nev. 700, 701, 429 P.3d 313, 315-16

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(2018) (concerning Clark County School District's internal investigative records).

TNI has failed to cite to any authority demonstrating that the NPRA is a tool that allows the public to obtain access to private entities' confidential information and/or trade secrets in reports prepared by the private entities and submitted to administrative agencies as required by law (as opposed to voluntarily submitted[8] to the government in a bid proposal or a license application). Therefore, there is no conflict between the plain language of the Confidentiality Regulations and the Prescription Drug Reporting Statutes.

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[8] The Culinary Union asserts that the "NPRA is regularly applied to records that were not generated by the government, but are in the government's possession." (A.C.B. at 9:15-10:5.) However, each case cited by the Culinary Union involved emails using government-provided email addresses, logs of phone calls from public phones maintained by a government contractor, and information in government-provided licenses. Moreover, the statute at issue in the Nevada Attorney General Opinion referenced by the Culinary Union as an example of a privately-generated report containing confidential information becoming a public document when submitted to a government entity, was repealed in 2019. *See* NRS 690B.260.

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(c). TNI Never Sought Disclosure of the Reports Prepared by the Department Pursuant to NRS 439B.650.

TNI claims that NAC 439.740 "directly conflicts with the overall intent of S.B. 539 of creating transparency in an otherwise opaque market." (O.B. at 40:4-16.) However, NAC 439.740 concerns the Department Price Increase Report pursuant to NRS 439B.650. TNI's public records requests never sought copies of this Report. (IJ.A. at 000024-000026; IJ.A. at 000033-000035.) Thus, this issue is not ripe for decision.

(d). The Confidentiality Regulations do not conflict with the NPRA.

Finally, with respect to NAC 439.735, TNI contends that the regulation conflicts with the NPRA by "delaying production of public records[] because it requires [the Department] to offer pharmaceutical manufacturers or PBMs 30 days in which to respond to requests [the Department] receives under the NPRA, or alternatively to commence a court action." (O.B. at 40:19-41:8 (suggesting that NAC 439.735 violates NRS 239.0107 which "require[s] governmental entities to assist requestors to access public records 'as expeditiously as possible'").) However, NAC

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439.735 expressly requires the Department to provide a response to a public records requester "[w]ithin the time prescribed by NRS 239.0107." NAC 439.735(4)(a), (5)(a). Therefore, NAC 439.735 does not delay responses to public records requests and cannot be invalidated on that basis.

4. TNI Never Challenged Whether the Manufacturers or PBMs Properly Requested Confidentiality Protections for Their Trade Secrets Pursuant to NAC 439.735.

In its Petition and its Supplemental Brief in support of the Petition, TNI failed to assert that the Department had improperly withheld information from the Reports for manufacturers or PBMs who had failed to submit a Request for Confidentiality. (I.J.A. at 000001-000013; 1J.A. at 000235-000246.) Similarly, TNI failed to assert in either its Petition or its Supplemental Brief thereto that the Department had improperly determined that the information subject to the manufacturers' and PBMs' Requests for Confidentiality did, in fact, constitute trade secrets. (*Id.*)

Thus, it is undisputed that Sanofi submitted Requests for Confidentiality to protect the trade secrets in each of its Reports submitted to the Department. (IIIJ.A. at 000732-000734, 000736-000738.) It is also undisputed that Sanofi's Requests for Confidentiality provided information

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regarding: (i) the reasonable measures it takes to maintain the secrecy of its trade secrets and confidential information; (ii) the harm it would suffer from public disclosure of its trade secrets; and (iii) and an explanation why disclosure of its trade secrets would constitute misappropriation under the DTSA. (*Id.*; *see also* Section III(C), *supra*.) Thus, it is undisputed that Sanofi (and the other manufacturers and PBMs submitting Requests for Confidentiality) properly complied with NAC 439.735(2).

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5. The Department Properly Determined That It Could Have Been Liable for Misappropriation Pursuant to the DTSA If It Had Publicly Disclosed the Manufacturers' or PBMs' Trade Secrets in Response to TNI's Records Request.

(a). The information in the Reports constitutes a trade secret pursuant to the DTSA.

The DTSA provides a federal, private right of action for the misappropriation of a trade secret if the trade secret is related to products or services used or intended for use in interstate or foreign commerce. 18 U.S.C. § 1836(b)(1). The DTSA defines "trade secret" as "all forms and types of financial, business, scientific, technical, economic, or engineering information" that "the owner thereof has taken reasonable measures to

keep . . . secret" and which "derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person, who can obtain economic value from the disclosure or use of the information." 18 U.S.C. § 1839(3).

As set forth in Section VI(A)(4), *supra*, TNI's Petition and Supplemental Brief in support of the Petition failed to assert that the information withheld from the Department's public records response did not constitute a trade secret under the DTSA. However, in its Opening Brief, TNI now contends for the first time that the withheld information does not qualify as a trade secret because it provides no economic benefit to the manufacturers or PBMs. (O.B. at 24:10-19.) Essentially, TNI asserts that because two insulin products have the same price, "no economic advantage is enjoyed by any particular manufacturer." (*Id.* at 24:20-25:2.)

Even if it were assumed that every diabetes manufacturer charged the same price for diabetes drugs, the manufacturers could still be earning their "economic advantage" over their competitors in other areas, like costs and expenses in producing or marketing the drug or in the sale of other

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therapeutic products. As Sanofi explained in its Requests for Confidentiality, the Reports contain a multitude of information that would be useful and economically beneficial to competitors, such as "details of [Sanofi's] cost structure, marketing and advertising costs, rebate strategies, profit information." (IIIJ.A. at 000733, 000737.) The information in the Reports can also be beneficial to Sanofi's competitors for non-diabetes products, because Sanofi "considers the same or similar factors when establishing pricing, advertising, and rebate strategies for its other therapeutic products." (*Id.*) Thus, the assertion that some manufacturers may charge the same price for their products fails to refute the manufacturers' claims that the information in the Reports is a trade secret under the DTSA.

TNI also contends that the Department could not be liable for misappropriation under the DTSA because the DTSA does not preempt or "displace state trade secret law," and "the law of the State of Nevada is determinative as to what is and is not a trade secret in the State of Nevada." (O.B. at 23:1-7.) However, the Nevada Legislature has already stated, expressly and unequivocally, that its amendment to NRS 600A.030 was not

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intended to eliminate trade secret protections for the trade secrets included in the Reports. (*See* Section III(B), *supra*.)

TNI further contends that to the extent the information in the Reports constitute trade secrets, the information lost any trade secret protections when the manufactures and PBMs disclosed the Reports to the Department without any guarantee of confidentiality. (O.B. at 26:9-27:9.) This is patently incorrect. As set forth in Section III(B), *supra*, the manufacturers' and PBMs' representatives sued the Department seeking to enjoin enforcement of the Prescription Drug Reporting Statutes and/or to have them stricken as unconstitutional because they required reporting of trade secrets without any express guarantee that the Department would maintain and protect the confidentiality of the trade secrets. It was only upon the adoption of the Confidentiality Regulations, and the Nevada Legislature's express acknowledgement and agreement that the secrecy and confidentiality of the trade secrets submitted to the Department in the Reports would be maintained upon request, that the manufacturers and PBMs submitted their Reports to the Department in compliance with the Prescription Drug Reporting Statutes. (*See* Section III(B), (C), *supra*.) The fact that the Department is not mandated

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to protect the secrecy of the trade secrets in the Reports, but rather, must determine whether a manufacturer's or PBM's information qualifies as a trade secret under the DTSA is irrelevant. As set forth in Section VI(A)(1), *supra*, several of the statutes which the Legislature has acknowledged as providing an express and unequivocal exemption from the NPRA also require a governmental entity to consider whether or not to grant a request for confidentiality.

Finally, both TNI and the Culinary Union rely on *Amgen Inc. v. Health Care Servs.*, 260 Cal. Rptr. 3d 873 (Cal. Ct. App. 2020), to suggest that the manufacturers' and PBMs' submission of trade secrets to the Department in compliance with the Prescription Drug Reporting Statutes waived any trade secret protections that may have existed for the information in the Reports. (O.B. at 27:11-22; A.C.B. at 7:12-18.) Specifically, TNI claims that the Department "in its role administering Medicaid in Nevada, is a major buyer of the drugs tracked under S.B. 539"; therefore, when the manufacturers and PBMs disclosed their trade secrets to the Department, they disclosed them to their opponent at the negotiating table and waived any confidentiality for the trade secrets. (O.B. at 27:11-

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22.) Similarly, the Culinary Union refers to *Amgen* as an example of "price-increase notices [being] subject to disclosure under California's Public Records Act, notwithstanding claims of trade secrecy." (A.C.B. at 7:12-18.) However, the *Amgen*, case and the statutory scheme at issue in California is quite different from this case. In *Amgen*, the court reasoned that the relevant California statute required numerous disclosures but did not provide for specific statutory or contractual protections for the confidential information. *Amgen*, 260 Cal. Rptr. 3d at 887-88. In contrast, Nevada provides for just a single disclosure to the Department and allows for a Request for Confidentiality that, as conceded by the Nevada Legislature, creates a duty to maintain the confidentiality of the trade secrets or limit their use. (IIIJ.A. at 000678:11-14, 000732-000734, 000736-000738.) Therefore, the Department is subject to potential liability under the DTSA if the trade secrets were released pursuant to a public records request ***or*** if the Department were to use the trade secrets to obtain negotiating and bargaining power over the manufacturers and PBMs. As such, the *Amgen* case is inapposite and fails to demonstrate that the information in Sanofi's

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(and the other manufacturers' and PBMs') Reports are not trade secrets that should be kept confidential.

(b). Disclosure of the trade secrets in the Reports would constitute misappropriation pursuant to the DTSA.

Given the evidence of the Legislature's intent in amending NRS 600A.030, and its express statements upon resolving the PhRMA Litigation after the adoption of the Confidentiality Regulations, it is undisputed that the Department would have engaged in a misappropriation of trade secrets if it had fully disclosed all records sought in TNI's public records request. The DTSA defines "misappropriation," in part, as "disclosure or use of a trade secret of another without express or implied consent by a person who . . . at the time of disclosure of use, knew or had reason to know that the knowledge of the trade secret was . . . acquired under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret." 18 U.S.C. § 1839(5)(B)(ii)(II).

It is undisputed that the manufacturers and PBMs expressly did not consent to public disclosure of their trade secrets, as evidenced by the fact that they did not submit any Reports to the Department until after the

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adoption of the Confidentiality Regulations, and the fact that they submitted the Reports with Requests for Confidentiality. (IIIJ.A. at 000732-000734, 000736-000738.) Moreover, the Legislature has expressly and unequivocally stated that it never intended for Senate Bill 539 to eliminate trade secret protections for the trade secrets included in the Reports submitted to the Department. (*See* Section III(B), *supra*.) In fact, the Legislature originally envisioned that the reporting requirements could be complied with without having to disclose any trade secrets or that the Reports would be subject to confidentiality agreements with the Department. (*Id.*). Thus, even before the Confidentiality Regulations were adopted, it was anticipated that the Department would have acquired trade secrets "under circumstances giving rise to a duty to maintain secrecy." Third, upon the adoption of the Confidentiality Regulations, the Legislature acknowledged and agreed that manufacturers and PBMs provided the Department with trade secret information under circumstances giving rise to a duty to maintain the secrecy of the trade secrets or to limit the use of the trade secrets. (IIIJ.A. at 000678:11-14.) Finally, the Legislature acknowledged and agreed that if the Department had disclosed the

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manufacturers' or PBMs' trade secrets to TNI or any other third party, the disclosure would have constituted misappropriation under the DTSA. (*Id*. at 000678:14-17.)

The Culinary Union contends that the DTSA cannot preempt or override the NPRA because the DTSA does not apply to "lawful activity conducted by a governmental entity." 18 U.S.C. § 1833(a)(1); *see also* A.C.B. at 2:5-13. However, a governmental entity's disclosure of trade secrets pursuant to a public records request is only considered lawful if the trade secrets are not expressly exempted from disclosure under NPRA or otherwise declared by law to be confidential. NRS 239.010; *City of Sparks v. Reno Newspapers, Inc*, 133 Nev 398, 402-03, 399 P.3d 352, 356-47 (2017). Here, the trade secrets at issue were declared by law to be confidential by the Confidentiality Regulations. Therefore, if the Department disclosed the trade secrets to TNI in response to its public records request, the Department's actions would not be lawful, and the Department would have been liable for misappropriation under the DTSA.

Further, TNI contends that neither the Department nor its Director could have been held liable for misappropriation under the DTSA because

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they were immune under the Eleventh Amendment. (O.B. at 20:6-22:7.) However, the United States Supreme Court found an exception to this immunity in *Ex parte Young*, 209 U.S. 123 (1908). *Ex parte Young* "ensures that state officials do not employ the Eleventh Amendment as a means of avoiding compliance with federal law." *P.R. Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 146 (1993). Specifically, the *Ex parte Young* doctrine applies to "a suit against a state official when that suit seeks only prospective injunctive relief in order to 'end a continuing violation of federal law.'" *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 73 (1996) (quoting *Green v. Mansour*, 474 U.S. 64, 68 (1985)). In determining whether this doctrine applies, "'a court need only conduct a straightforward inquiry into whether [the] complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective.'" *Va. Office for Prot. & Advocacy v. Stewart*, 563 U.S. 247, 255 (2011) (quoting *Verizon Md. Inc. v. Pub. Serv. Comm'n of Md.*, 535 U.S. 635, 645 (2002)).

In this case, it is unknown whether a manufacturer or PBM could state a claim against the Department or its Director for misappropriation of trade secrets under the DTSA, as no violation of the statute has yet occurred. In

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addition to media, like TNI, it is likely that individuals paying for their own diabetes drugs, healthcare providers, insurers, competitors, unions, and many others would submit public records requests for the Reports each year. If the Department provided the manufacturers' and PBMs' trade secrets in response to each such request, it is likely that a manufacturer or PBM could demonstrate an ongoing misappropriation of trade secrets under the DTSA for which Eleventh Amendment immunity would not apply. *See Kazee, Inc. v. Callender*, No. 4:19-CV-31-SDJ, 2020 WL 994832, at *1 (E.D. Tex. Mar. 2, 2020) (denying motion to dismiss on the basis of Eleventh Amendment immunity in a DTSA action). Therefore, it was proper for the Department to take precautions to avoid liability for the misappropriation of trade secrets pursuant to the DTSA, particularly given the Legislature's intent to continue to protect such trade secrets.

B. The District Court Did Not Err or Abuse Its Discretion in Denying TNI's Motion to Strike.

As set forth in Section II, *supra*, Sanofi objects to the issue TNI has presented concerning the denial of its Motion to Strike the Borneman

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Declaration. However, to the extent that this Court allows TNI to raise this issue on appeal, Sanofi will briefly address TNI's arguments.

Because Sanofi produced evidence (the Borneman Declaration) in the District Court proceedings to demonstrate the reasonable steps it takes to safeguard its trade secrets, and also to demonstrate the harm it would suffer if its trade secrets in the Reports were publicly disclosed, TNI sought to strike such evidence on the eve of the evidentiary hearing for its Petition. (IVJ.A. at 000776-000815.) The District Court did not err or abuse its discretion in denying TNI's motion. (IVJ.A. at 000921-000922.) First, Sanofi submitted the Borneman Declaration in support of its Response to the Petition, which it first served on TNI in conjunction with its Motion to Intervene in the District Court action. (IIJ.A. at 000292-000297.) Thus, TNI had knowledge of the Borneman Declaration for over three months (since October 21, 2019), before it moved, on the eve of the evidentiary hearing, to challenge the evidence. (*Id.* at 000257; IVJ.A. at 000776; IVJ.A. at 000820:20-000821:17.)

Second, the Borneman Declaration is based on personal knowledge of "the establishment of all gross and net pricing strategies" for Sanofi's pharmaceutical products, as well as Sanofi's "pricing and contracting for its

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prescription drugs, including its diabetes therapies." (IIIJ.A. at 000575:6-9.) Mr. Borneman gained this knowledge in his role as the Vice President and Head of Diabetes and Primary Care Sales for Sanofi, and his former roles as Sanofi's Vice President of Strategic Pricing and Contract Management and Head of Customer Engagement & Insights. (*Id.* at 000575:3-6.) Thus, the Borneman Declaration complied with NRS 50.025(1)(a), EDCR 2.21, and NRCP 56(c)(4).

TNI challenges the Borneman Declaration because portions of the Declaration are identical to information that can be found on Sanofi websites and testimony of Sanofi employees/officers before Congress. (O.B. at 35:10-22.) Of course it is! The fact that Sanofi is consistent in its statements about the general background and history of its company, the safeguards it takes to protect its trade secrets, or the harm it will suffer from the disclosure of its trade secrets only serves to bolster — not weaken — the veracity of these facts and provides additional support for the assertion that these facts are within Mr. Borneman's personal knowledge.

TNI also objects to the Borneman Declaration because two months after he stated that Sanofi had a "long-standing commitment" to diabetes research

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and that there was much research and work still to be done with diabetes treatments, Sanofi's parent company announced that it was discontinuing its diabetes research. (O.B. at 35:23-36:12.) However, there is no evidence that Mr. Borneman's statement was not accurate at the time his Declaration was made or that he had knowledge that Sanofi's parent company intended to change its position on diabetes research two months later.

Thus, there is no evidence to support TNI's contention that the District Court abused its discretion in denying TNI's Motion to Strike the Borneman Declaration. The District Court properly held that it would give the Declaration — like the rest of the record for the Petition — the "weight of credibility it [wa]s due." (IVJ.A. at 000922.)

VII. CONCLUSION

For the foregoing reasons, Sanofi respectfully requests that this Court affirm the District Court's Order Denying TNI's Petition for Writ of Mandamus. Further, if this Court entertains the issue TNI has raised as to its

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Motion to Strike the Borneman Declaration, Sanofi respectfully requests that this Court also affirm the District Court's denial of that motion.

DATED this 26th day of April, 2021.

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NRAP 32(a)(9) CERTIFICATE OF COMPLIANCE

1. I hereby certify that this Answering Brief complies with the formatting requirements of NRAP 32(a)(4), the typeface requirements of NRAP 32(a)(5), and the type-style requirements of NRAP 32(a)(6) because:

[x] This Answering Brief has been prepared in a proportionally spaced typeface using Microsoft Word for Office 365 in Times New Roman font 14.

2. I further certify that this Brief complies with the page- or type-volume limitations of NRAP 32(a)(7) because, excluding the parts of the brief exempted by NRAP 32(a)(7)(C), it is proportionally spaced, has a typeface of 14 points or more, and contains 13,870 words.

3. I further hereby certify that I have read this Answering Brief, and to the best of my knowledge, information, and belief, it is not frivolous or interposed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation. I further certify that this Answering Brief complies with all applicable Nevada Rules of Appellate Procedure, in particular NRAP 28(e)(1), which requires every assertion in the Brief regarding matters in the record to be supported by a

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reference to the page and volume number, if any, of the appendix where the matter relied on is to be found.

I understand that I may be subject to sanctions in the event that the accompanying Answering Brief is not in conformity with the requirements of the Nevada Rules of Appellate Procedure.

DATED this 26th day of April, 2021.

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CERTIFICATE OF SERVICE

I certify that I am an employee of BAILEY❖KENNEDY and that on the 26th day of April, 2021, service of the foregoing **RESPONDENT SANOFI-AVENTIS U.S. LLC'S ANSWERING BRIEF and RESPONDENT SANOFI-AVENTIS U.S. LLC'S SUPPLEMENT TO JOINT APPENDIX, VOLUMES 1 through 2,** was made by electronic service through Nevada Supreme Court's electronic filing system and/or by depositing a true and correct copy in the U.S. Mail, first class postage prepaid, and addressed to the following at their last known address:

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ADDENDUM

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