

SB 539 PUBLIC WORKSHOP

DRAFT MINUTES

February 15, 2018

9:00 a.m.

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

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

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

Great Basin College
1500 College Parkway
Elko, NV 89801

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

Carson City Location:

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

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

Elko Location:

Joseph Tucker, Primary Care Office (PCO)

Las Vegas Location:

Scott Jones, Manager, Primary Care Office (PCO)

Carson City Location:

Veronica Sheldon, Primary Care and Health Workforce Development Office
Margot Chappel, Primary Care and Health Workforce Development Manager

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

1. Phone Etiquette

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

2. Process Items

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

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

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

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

3. Public Comment

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

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

4. Adjournment

The meeting adjourned at 9:07AM.

Public comment
received for SB 539
Public Workshop



VIA ELECTRONIC DELIVERY

February 15, 2018

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

Re: Draft Regulations to Implement SB 539 Transparency Provisions

Dear Deputy Director Kotchevar:

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

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

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

Further, the innovative side of the biopharmaceutical marketplace is strong, but challenges exist. The cost of developing a new drug has increased exponentially since the 1970s. A recent study conducted by the Tufts Center for the Study of Drug Development found that developing a drug that gains market approval can take 10-years or longer, and

¹ Association for Accessible Medicines, *2017 Generic Drug Access & Savings in the U.S.* available at: <http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>

cost roughly \$2.6 billion.² There is a high failure rate in biopharmaceuticals research and development (R&D), so investments must take into account the funds spent on products that never make it to market. Furthermore, biopharmaceutical development is increasingly relying on outside private and public market capital as an investment source. Investors, however, have a range of diverse industries to choose from when making capital allocation decisions. Issues like government-imposed price regulations are significant detractions for the investment community when evaluating investment options. Small and emerging companies are responsible for 70% of the global clinical pipeline and 84% of all products in the pipeline are orphan designated programs. Many of these companies work for years, even decades, without products on the market but continue investing millions upon millions in research and development. In fact, 92% of publicly traded biotech companies in the US operate on a negative net income.³ Reports of overall profit margin are misleading.

The enormous resources required to sustain and drive forward the innovation ecosystem is reflected in the reality that the pharmaceutical industry spends significantly more than almost every other industry on R&D. On average, pharmaceutical companies spend 18.5 percent of revenue on R&D; when looking just at the U.S., one study found that, in 2013, 23.4 percent of domestic sales went to domestic R&D.⁴ Complementing this research is data that demonstrates the pharmaceutical industry spent not only the most on domestic R&D annually but also globally, averaging \$150 billion globally in 2015. When looking at a company's profit, it should be measured in the return on equity. When looking at all other industries, the biopharmaceutical industry ranks 45th, yet it is time and again ranked first on investment in R&D. The entire budget for the National Institutes of Health (NIH) was \$30 billion.⁵ The direct and indirect economic impact in the State of Nevada is approximately \$2.4 billion.⁶ The biopharmaceutical industry alone is currently conducting nearly 650 clinical trials recruiting or in progress within the State of Nevada.⁷ In short, while the innovation necessary to drive development of new treatments continues, the process is increasingly more difficult – and more expensive. But hope for patients with previously untreatable diseases continues to rise as evidenced by the vast pipeline emphasizing unmet needs.

Section 1: Drug Transparency does not focus on patients, is not holistic, and does not enhance the innovative healthcare ecosystem

BIO believes firmly that any transparency provisions should focus on what matters most for patients, including lowering out of pocket costs and improving patient access. This transparency law is fundamentally flawed. More focus should be placed in areas that will directly help consumers, including ensuring that they know what their actual cost-sharing obligations are, how plans are using manufacturers' rebates, and what drugs are available on their health plan's formulary. More transparency is needed to understand how health plans and other middlemen are using these rebates and discounts and whether these savings are being passed on to consumers, as that is the kind of information helpful to patients and consumers.

² Lamberti M. and Getz, K. Profiles of New Approaches to Improving the Efficiency and Performance of Pharmaceutical Drug Development. Tufts Center for the Study of Drug Development. May 2015.

³ Factset, BIO Industry Analysis, January 2016

⁴ Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA annual membership survey. Washington, DC: PhRMA; 2015, as reported here: http://phrma-docs.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf (last accessed March 10, 2017).

⁵ NIH Website and EvaluatePharma Report, 2015.

⁶ The Economic Impact of the US Bio-Pharmaceutical Industry: National and State Estimates, May 2016.

⁷ www.clinicaltrials.gov Search performed: February 12, 2018.

Moreover, we believe that this law will have a negative impact on small, emerging biotechnology companies. If a small company is developing new innovative drugs for Diabetes that would likely end up on the list or they will already have a drug included on the list of “essential diabetes drugs,” it will be overly burdened by the reporting requirements currently included in the law, ultimately impacting patients with unmet needs. Small, emerging companies must use their limited resources as efficiently as possible to continue to supply the therapies patients need and to invest in future innovation. Any reporting requirements that force researchers and scientists to incorporate burdensome accounting measures into their laboratory practices risk diverting the scarce resources of these companies. Patients are ultimately the ones who suffer, since resources would be diverted away from innovative research and drug development.

While BIO appreciates the Department’s efforts to maintain the information reported in aggregate, we are concerned that there are not enough confidentiality protections in the law or in the regulations. While certain information may be in aggregate form in the report included on the internet, if a company were to only have one drug on the list of Essential Diabetes Drugs, specific data will be much easier for the public to determine rebate and cost data unless the term “aggregate” included rebate dollars of all companies together rather than simply by company. We believe this is an important distinction; one which should be reflected in regulation.

Section 2. Prescription Drug Manufacturers—Trade Secret Protections are Not Consistent with Federal Law

Section 2 of the draft regulation appears to use the terms “request” and “requester” interchangeably with manufacturers and a possible request from the public for information that should be protected under the federal Defend Trade Secrets Act (DTSA).⁸ BIO believes there should be greater clarity in the draft that indicates the difference between a request to keep information confidential under the DTSA by the manufacturer under 2(2)(a), and what appears to be a request for disclosure by the general public in 2(2)(d).

BIO is pleased that the Department seemingly intends to protect trade secret information as provided for under the DTSA. However, we believe the requirements in Section 2, are not consistent with federal requirements. In the DTSA, information is a trade secret if it has commercial value, and the company or person has taken reasonable steps to ensure its security. The DTSA gives the holder of trade secrets, the power to implement strict policies maintaining confidentiality of trade secrets to prevent litigation. However, the DTSA does provide for a remedy in federal courts.

Nevertheless, one major difficulty BIO has with this regulation, is that the state assumes the information is not protected unless the manufacturer requests it remain confidential. The manufacturer would then need to challenge it in the courts, but the information is being disclosed to the state based upon passage of the law, regardless of the steps the manufacturer has taken to keep it confidential. The draft regulation would grant the manufacturer 30 days to challenge the disclosure and take legal action. While each company may be different, because companies maintain that much of this information is confidential trade secrets, then it would stand to assume companies would automatically be in federal court perpetually every year. This is not a positive business environment and could stand to harm innovation and clinical trials in the State of Nevada. Moreover, these requirements would overly burden small biotechnology firms who would not only be

⁸ 18 U.S.C. § 1836, et seq.

overwhelmed with reporting requirements, but they would also be forced to spend money on unwarranted litigation under the DTSA every year.

Thank you for the opportunity to comment on the draft regulations to implement SB 539. Should you have any questions regarding our comments, please do not hesitate to contact me at 202-962-9200.

Sincerely,

/s/

Jack Geisser
Director, Healthcare Policy,
Medicaid, and State
Initiatives



February 15, 2018

Attention: DHHS

drugtransparency@dhhs.nv.gov

Subject: Proposed Regulations regarding SB539

Thank you for the opportunity to participate in the regulation setting process for SB539.

Unite HERE Health, through the Culinary Health Fund, has actively supported this first-in-nation legislation to make more transparent the process of setting and increasing pricing for essential diabetic medications. We are following the implementation of this legislation with great interest and hope that it becomes, as intended, a step forward in understanding prescription pricing and patient impact in Nevada. Through the filings submitted on our behalf concerning PhRMA and BIO's current lawsuit to oppose implementation of this legislation, DHHS is already aware of our concerns regarding these regulations.

Briefly, we support the full implementation of this statute. We find the current lawsuit by PhRMA and BIO to be meritless and a distraction from full implementation. We find it unfortunate that the proposed regulations purport to permit regulated drug manufacturers to withhold information from the public about their pricing decisions based on the federal Defend Trade Secrets Act ("DTSA"). The DTSA does not preempt state trade-secrets laws and, by its terms, does not apply to a state government's "otherwise lawful activity"—including its disclosure of information pursuant to state law. 18 U.S.C. § 1833(a). The DTSA provides no support for adopting regulations that are clearly contrary to SB 539.

If DHHS nonetheless adopts regulations that permit regulated drug manufacturers to mark information as confidential, it should make clear that the regulations are temporary and may be superseded based on the outcome of PhRMA's lawsuit. DHHS should not promise to maintain the confidentiality of reports if a court subsequently determines that PhRMA's challenge to SB 539 is without basis.

Such temporary regulations, should they be adopted, must also be far clearer on the basis on which a regulated manufacturer may claim confidentiality. The proposed regulations state: "If a manufacturer believes that a data element in the report meets the standard of the Defend Trades Secret Act (DTSA), a request to have the element declared confidential may be submitted." It is unclear what the phrase "meets the standard of the Defend Trades Secret Act" means. The DTSA contains a definition of a trade secret, but not all use of a trade secret constitutes "misappropriation" under that statute. *See* 18 U.S.C. § 1839(5). Even under DHHS's misguided interpretation of the DTSA's scope, it is not enough that certain information "qualifies as a trade secret under the DTSA" for DHHS to withhold information from the public. Only if DHHS is affirmatively precluded by federal law from disclosing information that SB 539 commands it to make public may DHHS withhold this information.

Section 2(2) of the proposed regulation should therefore read: “If a manufacturer believes that public disclosure of a data element in the report by DHHS would constitute the misappropriation of a trade secret under the Defend Trade Secrets Act, 18 U.S.C. § 1836 *et seq.* sufficient to confer jurisdiction under 18 U.S.C. § 1836(b), a request to have the element declared confidential may be submitted.”
Section 2(2)(a) should read: “The request must include a detailed description of why disclosure of the data element by DHHS would constitute the misappropriation of a trade secret under the DTSA.”
Section 2(2)(d) should read: “The requester will be notified of the 30-day period and will be provided the detailed description provided by the manufacturer to assert that disclosure of the data elements would constitute the misappropriation of a trade secret under the DTSA.”

We request that the State return to regulation setting and create new regulations that implement SB 539 as it was adopted and signed by Governor Sandoval at the conclusion of PhRMA’s lawsuit. As this letter makes clear, the Culinary Health Fund disagrees with DHHS’s interpretation of the law. These comments and the Culinary Health Fund’s participation in the adoption of temporary regulations should not be construed to prejudice the Fund’s positions in PhRMA’s pending lawsuit in any way.

Sincerely,



Bobbette Bond
Policy Director, Unite HERE Health

February 14, 2018

BY E-MAIL

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

Re: Draft Regulations Implementing Senate Bill 539

Dear Ms. Sheldon:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) appreciates the opportunity to comment regarding the Department of Health and Human Services’ (“Department”) draft regulations implementing Senate Bill 539 of the 2017 Legislative Session. PhRMA is a voluntary, non-profit association that represents the country’s leading pharmaceutical research and biotechnology companies. PhRMA members are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives, including essential diabetes medicines. Since 2000, PhRMA’s member companies have invested more than half a trillion dollars in the search for new treatments and cures, with members investing \$65.5 billion in 2016 in the discovery and development of new medicines.

As the Department is aware, PhRMA has filed a lawsuit in federal court challenging the constitutionality of various provisions of SB 539. The Department has drafted the proposed regulations in part to address PhRMA’s concern in the litigation that SB 539 impermissibly requires the disclosure of manufacturer trade secrets. While PhRMA commends the Department for recognizing the constitutional problems that would arise if it fails to safeguard trade secrets, we remain concerned that the proposed regulations do not establish a process that adequately ensures the protection required. Below, we outline some of our legal and policy concerns with the regulations.

I. Section 1: Drug Transparency Report and Section 2: Prescription Drug Manufacturers

The draft regulations suffer from several flaws that PhRMA fears will render them unworkable in practice absent significant revisions.

First, the prescribed process for challenging a request for confidential information—a manufacturer-initiated lawsuit under the Defend Trade Secrets Act of 2016 (“DTSA”)—will impose significant burdens and costs on all parties. Instead, the Department should model its

regulations on existing procedures under the Freedom of Information Act (“FOIA”), 5 U.S.C. §§ 552, *et seq.*, and the Nevada Public Records Act (“Public Records Act”), Nev. Rev. Sta. 239.010. Those laws allow a party submitting information to request that it be treated confidentially, by marking it with a confidentiality legend. The government agency then must determine in the first instance whether the information requested qualifies as confidential and thus exempt from disclosure. A party who disagrees with the government agency’s position can begin legal action. This well-established procedure is less expensive, less burdensome, and more predictable.

Second, the proposed regulations are unclear as to what specific information manufacturers must disclose under §§ 3.8 and 4 of SB 539. The regulations would require manufacturers to disclose “costs,” “profits,” and “administrative expenditures,” without any definition of those terms. Without further guidance, manufacturers could adopt different definitions, resulting in reports that are not helpful to the Department and raising fairness concerns if and when the terms are defined after the fact.

Third, the regulations should affirm that the Department will not post manufacturer-specific information in the “Drug Transparency Report” on the Department’s website. The regulation as written appears to contemplate that the Department will not include such information, as it provides that the report will include only “aggregated information.” To ensure that the Department does not later adopt a different interpretation and disclose trade secrets in the report, the regulation should make this point crystal clear.

Fourth, the regulations should correct what appears to be a clerical error and track the statutory requirement that manufacturers’ initial report pursuant to § 3.8 is due on July 1, 2018, not April 1, 2018. *See* SB 539 § 26.9. The regulations should also confirm that because the Department has not published the list of essential diabetes medicines required by § 3.6(2), no reporting required by § 4 is due until April 1, 2019. *See id.*

We address each of these issues in further detail below.

A. Process Concerns Regarding Protecting Trade Secret Information

The Department has argued in federal court against invalidation of SB 539 because it remained conceivable that the Department could “adopt regulations to address the protection of trade secrets.”¹ PhRMA appreciates the Department’s acknowledgement that trade secrets must be protected from public disclosure. While the Department’s proposed regulations seek to bring SB 539 in line with federal trade secret law, the proposed process falls short and should track other Federal and Nevada state laws more closely. The process discussed below would serve to protect trade secrets while working efficiently for all parties involved.

The proposed regulations attempt to afford trade secret protection by setting forth a process whereby manufacturers can seek to prevent the disclosure of information they deem to be confidential. In doing so, manufacturers must first submit a request to the Department that includes a “detailed description of why the data element qualifies as a trade secret.” *See* Draft

¹ *See* Defs.’ Opp’n to Pls.’ Mot. for Summ. J., *Pharm Research & Mfrs. of Am. v. Sandoval*, No. 17-cv-02315-JCM-CWH (D. Nev. Nov. 17, 2017), ECF No. 74.

Regulations, § 2(a). The regulations propose that the detailed description “will be available upon request to the public.” *Id.* If a party then seeks, through a public-records request, any data element noted as confidential, the Department would “notify the manufacturer of [the] request” and “allow the manufacturer thirty days to take legal action under the DTSA prior to releasing the information.” *Id.* §§ (b)-(c). The requestor would be notified of the 30-day period and would be given the manufacturers’ detailed description explaining why the data qualifies as a trade secret. *Id.* § (d).

The proposed process suffers from a number of flaws. In our view, the Department’s final regulations should adopt a process for resolving requests for information that both protects the confidentiality of the materials required to be reported under SB 539 and imposes minimal burden and cost on the parties and the courts. To that end, PhRMA proposes the following revisions to the draft regulations.

1. **Requiring Legal Action Under the DTSA**

Under the proposed regulations, a manufacturer is required to bring a new lawsuit under the DTSA every time that a private party requests information that the manufacturer deems to be confidential. This process will be incredibly time-consuming and expensive. Trade-secret litigation is especially costly, with one study estimating that the median cost for a trade-secret lawsuit with \$1 million to \$10 million at risk is \$925,000.² The median civil litigation in federal court in Nevada takes 42.3 months to go to trial.³ Nevada’s Culinary Health Fund has already vowed to seek the information that manufacturers are required to report under SB 539, ensuring that manufacturers will bear these litigation costs if the proposed regulations are adopted as written. Such an unchecked, repetitive, legal process could have the unnecessary effect of adding to the costs of bringing diabetes medicines to market and thus exacerbate the concern PhRMA has raised in the litigation that SB 539’s publication of competitively sensitive price and cost information may lead to unintended effects that prevent drug prices from falling as quickly as they would without the Act. Further, it would impose unnecessary burdens on the courts.

Rather than requiring a manufacturer to initiate a DTSA lawsuit every time a private party requests their confidential information, the Department should model its review process after the Freedom of Information Act or Nevada’s own Public Records Act. Under FOIA, it is the government agency—not the courts—that decides in the first instance whether the requested information falls within the FOIA exemption for “trade secrets and commercial or financial information obtained from a person and privileged or confidential.” 5 U.S.C. § 552(b)(4). If the agency withholds the requested information on the ground that it qualifies for the exemption, then the requester may file a challenge to that agency determination in federal court. *Id.* § 552(a)(4)(B). Alternatively, if the agency decides that the requested information is not protected and could be made public, the party that originally submitted the information to the agency may itself bring a “reverse FOIA” action in federal court to prevent disclosure. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 285 (1979).

² *See* American Intellectual Property Law Association, 2015 Report of the Economic Survey at I-171.

³ United States District Courts National Judicial Caseload Profile, http://www.uscourts.gov/sites/default/files/data_tables/fcmts_na_distprofile0930.2017.pdf.

Similarly, under the Nevada Public Records Act, a governmental entity must make public records available unless “declared by law to be confidential.” Nev. Rev. Stat. § 239.010. The governmental entity decides in the first instance whether the public record is “confidential.” *Id.* § 239.0107(d). If the entity concludes that the record is confidential and withholds it on that basis, the requester “may apply to the district court in the county in which the book or record is located for an order” requiring disclosure. *Id.* § 239.011. The governmental entity bears the burden of proving by a preponderance of the evidence that the public record is confidential. *Newspapers, Inc. v. Gibbons*, 266 P.3d 623, 628 (Nev. 2011).

There are several reasons why the government should determine in the first instance whether information is subject to a confidentiality exemption. First, it reduces litigation costs by providing the parties with a neutral evaluation of the confidentiality of the information before the parties decide whether to litigate the issue. A party that would otherwise opt to file suit might be less likely to do so after the agency has determined that the information at issue is or is not confidential. Accordingly, the amount of litigation for all parties, including the Department, may be reduced. Second, it apportions the responsibility for initiating litigation more equitably on the party against whom the agency decides. Third, if the Department were to decide these requests in the first instance, it would likely develop expertise in dealing with these issues, which in turn could lead to decisions that are more timely, consistent, and well-reasoned. Leaving each individual ruling up to the court system could lead to different judges’ making different decisions.

Delegating to the Department the responsibility to decide whether to disclose information in the first instance is also particularly appropriate here, where nearly all of the information that SB 539 requires manufacturers to disclose constitutes a trade secret under well-established law from jurisdictions throughout the country.⁴ As PhRMA has explained in detail in its briefing in its pending challenge to SB 539, numerous court decisions have held that the advertising, cost, marketing, pricing, and production information that SB 539 requires manufacturers to disclose is a trade secret.⁵ It would be improper to require manufacturers to bring legal action to defend these trade secrets in full-blown litigation every time a party submits a public-records request. It would be far less burdensome, consistent with other trade secret regimes, and respectful of the sensitivity of trade secrets for the Department to decide, once, whether it believes that the

⁴ The only exception is the wholesale acquisition cost (WAC) of the drug. *See* SB 539 § 3.8(6).

⁵ *See, e.g., Aerodynamics Inc. v. Caesars Entm’t Operating Co.*, No. 2:15-CV-01344, 2015 WL 5679843, at *8 (D. Nev. Sept. 24, 2015) (“confidential pricing information, . . . marketing strategies, . . . exact pricing for [certain] bid[s], payment terms, and credits and discounts provided” held trade secrets under state law); *Finkel v. Cashman Prof’l, Inc.*, 270 P.3d 1259, 1263 (Nev. 2012) (holding that “confidential pricing structures and marketing plans” were trade secrets); *In re Dana Corp.*, 574 F.3d 129, 152 (2d Cir. 2009) (recognizing that under New York law, “[c]onfidential proprietary data relating to pricing, costs, systems, and methods are protected by trade secret law”); *S.I. Handling Sys., Inc. v. Heisley*, 753 F.2d 1244, 1260 (3d Cir. 1985) (same under Pennsylvania law); *Burbank Grease Servs., LLC v. Sokolowski*, 693 N.W.2d 89, 96 (Wis. App. 2005) (“Generally, it appears that when prices are based on complicated or unique formulas that the customers do not know about, courts conclude the information meets the standard embodied in [the UTSA].”), *aff’d in part, rev’d in part*, 717 N.W.2d 781 (Wis. 2006); *Whyte v. Schlage Lock Co.*, 101 Cal. App. 4th 1443, 1455 (2002) (“[P]ricing, profit margins, costs of production, pricing concessions, promotional discounts, advertising allowances, volume rebates, marketing concessions, payment terms and rebate incentives” have independent economic value as trade secrets).

information constitutes a trade secret, with an opportunity for the aggrieved party to file a challenge to that determination in court.

2. The “Detailed Description” Requirement

The proposed regulations also depart from standard records-request procedures in requiring manufacturers to support their request for confidentiality with a “detailed description” as to why the information qualifies as a trade secret. Neither FOIA nor the Public Records Act imposes such a requirement.⁶ The requirement also appears to serve no purpose under the regulations as drafted, as, under the regulations, the Department plays no role in deciding whether particular information is a trade secret. Thus, it is unclear why the proposed regulations require manufacturers to justify their confidentiality designations to the Department. It is even less clear why this detailed description would be made “available upon request to the public.”

Even if the Department were to revise the regulations so that the Department decides in the first instance whether to disclose the requested information, there would still be no reason for a “detailed description” requirement. As noted, the requirement is absent from other transparency laws, including FOIA and the Public Records Act. Instead, under FOIA, for example, companies typically label information as “confidential” if they believe that it satisfies a confidentiality exemption from disclosure. Some companies may also—voluntarily—provide additional explanation to the agency as to why the information qualifies for an exemption to bolster the administrative record. But there is no *requirement* under FOIA or the Public Records Act that companies justify their confidentiality designations when they are submitted.

If the Department retains the “detailed description” requirement, it should, at a minimum, be revised to make clear that the “detailed description” need not include information that is itself a trade secret. Otherwise, the requirement would obviously itself run afoul of the DTSA. Alternatively, the final regulations could provide that the “detailed description” will be available in the first instance only to the Department and would enjoy the same protections from disclosure as the underlying information itself.

3. The 30-Day Notice Period

The proposed regulations provide that, after a party has requested information that a manufacturer has designated confidential, “the Department will allow the manufacturer thirty days to take legal action under the DTSA prior to releasing information.” Draft Regulations, § 2(c). As noted above, PhRMA believes that the Department should follow the standard practice and decide in the first instance whether information requested by third parties is exempt from disclosure. However, if the final regulations instead require manufacturers to take legal action without any initial decision by the Department, the regulations should make clear that the Department will not release the requested information until litigation has concluded. In this instance, the release of the information at issue should be stayed until either (i) an appellate court has finally decided the legal challenge and the appellate court’s mandate has issued or (ii) a district court has finally decided the challenge and the time for a party to file a notice of appeal has elapsed.

⁶ See 5 U.S.C. § 552; Nev. Rev. Stat. § 239.010.

Without this clarity, the regulation could be interpreted to suggest that the Department might still release the information even if a manufacturer has brought legal action under the DTSA. Such an interpretation would force manufacturers to seek a temporary restraining order or preliminary injunction every time they challenge a request for disclosure, which would impose even greater costs on the manufacturers who would have to bring such claims, the Department who would have to defend the claims, and the courts who would have to hear and decide them. Regulations that virtually guarantee such frequent emergency litigation would be unfair, unsound, and unworkable.

If the Department retains the notice period structure, PhRMA requests that the Department consider extending the notice period to 60 days to provide manufacturers with adequate time to evaluate the request, retain counsel, and prepare the relevant legal filings.

4. Other Procedural Safeguards

The final regulations also should ensure that manufacturers have a meaningful opportunity to challenge a request for information through the judicial process. To prove a claim under the DTSA, a moving party must establish that disclosure would constitute (i) “misappropriation” of (ii) a “trade secret.” 18 U.S.C. § 1836.

To prove “misappropriation,” a manufacturer must show that the Department was planning to disclose the trade secret “without express or implied consent” from the manufacturer and that the Department “knew or had reason to know that the knowledge of the trade secret was . . . acquired under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret.” 18 U.S.C. § 1839(5)(B)(ii)(II).⁷ To ensure that the DTSA provides manufacturers with a meaningful opportunity for judicial review, the Department should revise the proposed regulations to underscore that the Department acquires manufacturers’ trade secrets “under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret.” *Id.*

To prove that the information is a “trade secret,” a manufacturer must show, among other things, that it “has taken reasonable measures to keep such information secret.” *Id.* § 1839(3)(A). Again, the final regulations should confirm that, by complying with SB 539’s mandatory reporting provisions and requesting that certain information be treated as confidential, manufacturers have “taken reasonable measures to keep such information secret.” *Id.*

B. Implementation Concerns

In addition to the legal process concerns identified above, PhRMA is also concerned that the proposed regulations offer no clarity to manufacturers as to what precise information they must disclose. The statute requires manufacturers to disclose information regarding “costs,”

⁷ Alternatively, a misappropriation occurs where the trade secret is acquired through “improper means,” “accident,” or “mistake.” *Id.* § 1839(5)(A), (B)(i), (B)(iii). However, none of these would seem applicable in these circumstances.

“profits,” and “administrative expenditures,” but those terms are reasonably susceptible to multiple interpretations,⁸ and the proposed regulations make no attempt to define them.

For example, under the proposed regulations, manufacturers are required to report a “number” that reflects the “cost of producing the drug.” The regulations do not define “cost” or explain which costs (*i.e.*, research and development, manufacturing, distributing, etc.) should be included in manufacturers’ calculation of the “cost of producing the drug.” The regulations do not even specify a relevant time period. Without further guidance, manufacturers inevitably will report different “costs” from other companies, resulting in an apples-to-oranges compilation that will be unhelpful to the Department. The same is true of terms such as “administrative expenditures,” “profit,” and “financial assistance,” all of which are undefined and could reasonably be interpreted differently by manufacturers, the Department, and others.

Regardless of how the Department defines these terms, manufacturers will incur significant costs to comply with these new reporting obligations, as all manufacturers will need to train employees and implement new systems (which for certain manufacturers may lead to significant costs) to compile this information. The Department will likely be asking for information that some manufacturers cannot readily extract from their records as maintained in the ordinary course of business. For some companies, the information will likely reside in different business entities across different levels of the production and distribution system, perhaps different geographic areas. Some companies likely do not analyze and maintain this type of data state-by-state, and the Department may view aggregated data as less informative to Nevada constituents. To minimize the compliance costs in building systems and processes—and to ensure that the Department receives information that is meaningful—it is essential that the Department define, as precisely as possible and as quickly as possible, the information that manufacturers must disclose.

C. Drug Transparency Report

The regulations also provide that the Department will publish a “Drug Transparency Report” on its website, which will include “aggregated information” from manufacturers and “describe the trends related to drug pricing and how those costs may impact the diabetes burden and health system within Nevada.” *See Id.* § 1(a). This regulation appears to respond to a concern raised by PhRMA in the federal litigation that § 6 of SB 539 would appear to require the Department to post manufacturer-specific information on its website, which would be preempted by federal law to the extent that the Department disclosed an individual manufacturer’s trade secrets.

The Department should clarify that the “Drug Transparency Report” described in § 1 of the proposed regulations will not include information that is manufacturer-specific or that can be reverse-engineered to identify the originating company. The regulations appear to contemplate that the Department will not include such information, as they provide that the report will include

⁸ *See, e.g., Cost*, OXFORD DICTIONARY OF ACCOUNTING (5th ed. 2016) (“There are a number of different ways of defining cost, the major ones being average cost, first-in first-out cost, historical cost, last-in first-out cost, and replacement cost. *See also* FIXED COST; MARGINAL COST; OPPORTUNITY COST.”).

“aggregated information.” The final regulations should state expressly, however, that the Department will publish only aggregated information.

D. Deadline for Initial Manufacturer Reports

Section 26.9 of SB 539 provides that, in 2018, the reports required under § 3.8 will be due on July 1, 2018. In subsequent years, the report is due on April 1. *See* SB 539 §§ 3.8, 4. The proposed regulations, however, simply state that drug manufacturers must submit the report “by April 1st,” without reference to the July 1 deadline for the first manufacturer report in 2018. The final regulations should make clear that, consistent with the statute, manufacturers’ initial § 3.8 report is not due until July 1, 2018. The U.S. District Court’s decision regarding PhRMA’s motion for a preliminary injunction was premised on a July 1, 2018 reporting date. If the Department now adopts an April 1 deadline, PhRMA may need to ask the Court to consider a renewed preliminary injunction motion.

Section 26.9 also provides that “[o]n or before November 1, 2017, the Department . . . shall place on the Internet website maintained by the Department the information prescribed by section 3.6 of this act.” Although the Department has published the list of essential diabetes medicines pursuant to § 3.6(1), the Department has *not* yet published the list of essential diabetes medicines pursuant to § 3.6(2), *i.e.*, those medicines whose WAC has increased by more than “[t]he percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year” or “[t]wice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years.” Only manufacturers whose drugs appear on the § 3.6(2) list must submit the report contemplated by § 4. Because the Department did not publish the § 3.6(2) list by November 1, 2017 as required (and indeed, still has not published the § 3.6(2) list), the Department should confirm that no § 4 reporting will be due this year on July 1, 2018. The seven-month period that the Legislature required between the initial § 3.6(2) list and the § 4 report is essential to providing manufacturers adequate lead time to prepare their initial § 4 reports. The Department should thus confirm that no § 4 reporting will be due until at the earliest April 1, 2019 (the date on which § 4 reporting is due in 2019 and subsequent years).

II. Section 4: Pharmaceutical Sales Representative

The proposed regulations require registered pharmaceutical sales representatives to submit a report described in section 4.6(4) of SB 539 to the Department on a proposed form by March 1. Section 4.6(4)(a)(1) and (2) describe types of compensation that must be included in the reports, but does not contain a clear definition of “compensation.” PhRMA requests that the Department clarify the definition of “compensation” and suggests that the Department consider the definition of “payment or transfer of value” that was adopted in regulations and guidance promulgated and issued pursuant to the federal Physician Payments Sunshine Act.

III. Conclusion

PhRMA appreciates the opportunity to comment on these important regulations. We commend the Department for recognizing that trade secrets must be safeguarded, as failure to do so would raise the serious constitutional problems noted in PhRMA’s complaint and litigation

briefs. For the reasons explained above, however, we do not believe that the regulations as currently drafted provide adequate protections for manufacturer trade secrets. In addition, the vagueness of the regulations will multiply the burdens on manufacturers. PhRMA looks forward to working with the Department on these issues at the upcoming workshop and throughout the notice-and-comment process.

Respectfully submitted,



Joanne Chan
Assistant General Counsel
Law



February 13, 2018

Veronica Sheldon, Management Analyst
Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City NV 89706

Via email: drugtransparency@health.nv.gov

Re: Proposed Amendments to the Nevada Administrative Code Chapter 439: Drug Transparency Reporting

Dear Ms. Sheldon:

The Pharmaceutical Care Management Association (PCMA) submits the following comment in response to the Department's proposed rules to implement SB 539 (2017) relating to drug price transparency. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through large and small employers, state governments, health insurance plans, labor unions, Medicaid managed care, Medicare Part D, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide feedback on the proposed rules. First, PCMA appreciates the Department's acknowledgment that certain proprietary price information is protected by the federal Defend Trade Secrets Act and appreciates that the Department has outlined a process to address those protections as the issues arise.

PCMA has two comments on the draft regulation and the PBM data collection form.

1. Section 3(2)(b) of the proposed rule states "The Department will notify the pharmacy benefit manager of any request for data elements marked as confidential and will provide the manufacturer a copy of the written request for those records." We believe that the use of "manufacturer" was inadvertently used in place of "pharmacy benefit manager." PCMA requests that this language be clarified in the following way:

The Department will notify the pharmacy benefit manager of any request for data elements marked as confidential and will provide the ~~manufacturer~~ pharmacy benefit manager a copy of the written request for those records.

2. The proposed data collection form includes a box to report rebates negotiated for the purchase of drugs for use by recipients of Medicare. However, Medicare is a federal program, and any state law "with respect to" a Part D plan offered by a Part D sponsoring organization is preempted. No requirement for a finding that a state law is *inconsistent* with a Part D standard is needed. All standards established under the Part D program "shall supersede any State law or regulation...with respect to [Part D] plans



which are offered by [Part D plan sponsors].¹ Only state laws governing licensure and solvency are saved from preemption.² In its final rules implementing the Medicare Advantage and Part D programs, the Centers for Medicare and Medicaid Services (CMS) noted that Congress had clearly enacted broad preemption language in the Medicare Modernization Act (MMA), and that state requirements that derive from case law are also preempted.³ The courts have also recognized the broad scope of preemption under the MMA, looking at whether there is an established federal standard (i.e., a statute or rule codified in the Code of Federal Regulations), and whether the state statute is a law with respect to that standard (and therefore preempted unless it is a law of general applicability or a minimum plan licensure or solvency).⁴

Under the Medicare Part D (prescription drug program) statute, the Part D plans are required to provide the Centers for Medicare and Medicaid Services with information about prescription drug price concessions and rebates.⁵ The terms of SB 539 “relate to” this federal requirement because it requires similar reporting by the same, federally-regulated entities (Part D plans). SB 539 is not a state licensure or solvency standard that is saved from preemption, and its terms are not generally applicable to any type of business in the state—it is the very fact that rebates are negotiated and purchased for Medicare recipients that triggers this provision of the state statute. Thus, federal Medicare law preempts the state law and the proposed data collection form, as they relate to rebates negotiated for the purchase of drugs for used by Medicare recipients. PCMA requests that this data element be stricken from the form.

We appreciate the opportunity to provide comments on this proposed rule and we welcome the opportunity to speak with you about our concerns. Please do not hesitate to contact me at 202-756-5743 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "April C. Alexander".

April C. Alexander
Assistant Vice President, State Affairs

cc: Margot Chappel, MS, Manager, Primary Care and Health Workforce Development Office,
Department of Health and Human Services

¹ Social Security Act § 1856(b)(3), 42 U.S.C. § 1395w-26(b)(3). *See also*, Social Security Act § 1860D-12(g), applying Medicare Advantage preemption standards to Part D.

² *Id.* *See also*, 70 Fed. Reg. 4588, 4663-66 (Jan. 28, 2005). CMS cites, as an example, a state requirement that a plan file Articles of Incorporation with the Secretary of State’s office as a permissible state regulation.

³ 70 Fed. Reg. 4588, 4663-66.

⁴ *Pacificare v. Rogers*, 127 Nev. Adv. Rep. 71 (2011); *Uhm v. Humana*, 620 F.3d 1134, 1149, n.20 (9th Cir. 2010)

⁵ 42 USC § 1395w-102(d)(2).

Pfizer Inc
235 East 42nd Street
New York NY 10017-5755



February 15, 2018

VIA E-MAIL AND FEDERAL EXPRESS

Attn: Veronica Sheldon
Nevada Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City, NV 89706

drugtransparency@dhhs.nv.gov

Re: Comment on SB 539 Drug Transparency Draft Regulations

Dear Ms. Sheldon,

Thank you for providing stakeholders the opportunity to comment on the SB 539 Drug Transparency Draft Regulations (the "Regulations") issued by the Nevada Department of Health and Human Services (the "Department") on January 4, 2018. We understand that the laws implemented by 2017 Nevada Senate Bill 539 ("SB 539") are currently being challenged in litigation. Without waiving any claims or rights and remedies in litigation with respect to SB 539, Pfizer Inc. ("Pfizer") is submitting this letter to the Department to comment on the Regulations.

Pfizer is commenting on both the timing and the contents of the reports manufacturers need to submit under Nev. Rev. Stat. SB 539, §§ 3.8 and 4. Pfizer has several very serious concerns that the Regulations, as currently drafted, would both force the disclosure of Pfizer's trade secrets and strip those trade secrets of legal protection.

I. Confirmation that State Does Not Intend to Implement SB 539 Before July 1, 2018

Section 2 of the Regulations states "Drug manufacturers must submit a report in the format listed on the Department website by April 1st for the previous calendar ~~year~~."

Although the Regulations reference an April 1 date for manufacturers to report under SB 539, Pfizer notes that the State of Nevada (the "State") has consistently referred to a July 1, 2018 date in the pending litigation with the Pharmaceutical Research and Manufacturers of America's ("PhRMA") and the Biotechnology Innovation Organization's ("BIO"), *PhRMA v. Sandoval*, 2:17-cv-02315 (D. Nev.). As such, Pfizer believes that the July 1, 2018 date reflects the State's actual position.

In the hearing on PhRMA's motion for a preliminary injunction, to support the State's position that an injunction in October 2017 was not warranted due to a lack of imminent harm to manufacturers, the State's attorneys stated that manufacturers would not have to report under SB 539 until July 1, 2018. *See* Transcript of Proceedings from Motion for Preliminary Judgement at 15, *PhRMA v. Sandoval*, 2:17-cv-02315 (D. Nev.) (“No actual report is going to be filed by a manufacturer before July 1, 2018.”).

Further, the Legislature's response to the motion for preliminary injunction stated “. . . SB 539 contains a transitory section that *adjusts the reporting deadlines for the first reporting period*, so the affected manufacturers *do not have to file their first reports until July 1, 2018.*” Nevada Legislature's Opposition to Plaintiffs Motion for Preliminary Injunction at 5, *PhRMA v. Sandoval*, 2:17-cv-02315 (D. Nev.) (emphasis added).

Additionally, the July 1, 2018 reporting date was used in the Attorney General's response to the motion for a preliminary injunction to argue SB 539's reporting provisions did not pose imminent harm to manufacturers. *See* Opposition to Motion for Preliminary Injunction at 5, *PhRMA v. Sandoval*, 2:17-cv-02315 (D. Nev.) (“The Department is unable to place any information, create any reports, or impose any penalties until *after that deadline of July 1, 2018 when manufacturers must report*. Therefore, any harm to trade secret that may be disclosed in these reports *is not imminent.*”) (emphasis added).

Lastly, the Court itself stated that manufacturers would not need to begin reporting until July 1, 2018. *See* Transcript of Proceedings from Motion for Preliminary Judgement at 4-5, *PhRMA v. Sandoval*, 2:17-cv-02315 (D. Nev.) (quoting Judge James C. Mahan, “This will all take *effect in July . . .* so it's not like we need a preliminary injunction today to prevent this all from *taking effect next July . . .*”) (emphasis added).

Pfizer, like many other manufacturers, has relied upon the July 1, 2018 reporting date represented by the State to the Court during the hearing on PhRMA and BIO's motion for a preliminary injunction.

Accordingly, Pfizer requests that the Department clarify the reporting date in the Regulations and align that date with the date represented by the State to the Court. If not, the State should correct its representation made to the Court.

II. Section 2 of the Regulations Forces the Disclosure of Trade Secrets and Strips Them of Trade Secret Protection

The State, in addressing the critical issue of trade secrets by statute, by proposed regulation, and in its court filings, has failed to provide any clear and consistent position on the critical question of trade secret protection of manufacturer information¹

¹ The Regulations directly contradict the State's own arguments in the pending litigation, as well as Nevada's rules of statutory interpretation. The State asserts in its Motion for Summary Judgement in *PhRMA v. Sandoval* that “as properly interpreted under Nevada's rules of statutory interpretation, the challenged provisions *do not require manufacturers to disclose trade secrets.*” Defendant's Motion for Summary Judgement, *PhRMA v. Sandoval*, 2:17-cv-02315 at 1 (D. Nev.) (emphasis added).

Section 2 of the Regulations currently state “if a manufacturer believes that a data element in the report meets the standards of the Defend Trade Secrets Act (DTSA), a request to have the element declared confidential may be submitted [T]he request must include a detailed description of why the data element qualifies as a trade secret under the DTSA.”

Section 2 of the Regulations indisputably requires manufacturers to disclose trade secrets to comply with Nev. Rev. Stat. SB 539 §§ 3.8 and 4, including, information that relates to costs, profits, pricing, and advertising and marketing strategies associated with a manufacturer's specific drugs.² This mandated information derives independent economic value from not being generally known to third-party payers and competitors, and is unquestionably a trade secret under the Defend Trade Secrets Act of 2016 (“DTSA”), as well as Nevada law- unless SB 539 takes effect. *See, e.g., Aerodynamics Inc. v. Caesars Entm't Operating Co.*, No. 2:15-CV-01344, 2015 WL 5679843, at *8 (D. Nev. Sept. 24, 2015 (“confidential pricing information. . . . marketing strategies . . . exact pricing for [certain] bid[s], payment terms, and credits and discounts provided” held trade secrets under state law.); *Finkel v. Cashman Prof'l, Inc.* 270 P.3d 1259, 1263 (Nev. 2012) (“confidential pricing structures and marketing plans” were trade secrets).

Because Section 2 of the Regulations compels manufacturers to report all information requested by Nev. Rev. Stat. §§ 3.8 and 4, even if that information is a trade secret, the Regulations raise numerous, serious concerns. First, the Regulations do not contain any protections for trade secrets compelled under SB 539. Second, the Regulations would strip reported trade secrets of trade secret protection, nullifying a manufacturer's trade secret protection not just in Nevada, but nationwide. Finally, the Regulations facilitate third party acquisition of manufacturer trade secrets and fail to provide manufacturers with meaningful remedies to protect their trade secrets.

Further, the State asserts in its Response to PhRMA and BIO's motion for summary judgement that “. . . the plain language and the legislative history of the challenged provisions - along with reason and public policy - amply demonstrate that the provisions are much narrower in scope and *do not require manufacturers to disclose trade secrets.*” Defendant's Response to Plaintiff's Motion for Summary Judgement, *PhRMA v. Sandoval*. 2:17-cv-02315 at 2 (D. Nev.) (emphasis added).

Pfizer is extremely concerned that the regulatory scheme detailed in Section 2 of the Regulations, by demanding manufacturers disclose trade secrets to comply with SB 539, contradict the State's own arguments in the pending litigation. Further, Pfizer is concerned that the Regulations, as currently drafted, are inconsistent with SB 539's legislative history, public policy, and Nevada's rules of statutory interpretation.

² *See* Nev. Rev. Stat. SB 539 § 3.8 (requiring manufacturers whose drugs are listed by the Department under Nev. Rev. Stat. SB 539 § 3.6(1) to report to the Department detailed information related to the listed drug' s pricing including, amongst other things, the listed drug's production costs, marketing and advertising costs, profitability, and rebates paid to pharmacy benefit managers); *see also* Nev. Rev. Stat. SB 539 § 4 (requiring manufacturers whose drugs are listed by the Department under Nev. Rev. Stat. SB 539 § 3.6(2) to report to the Department detailed information related to the listed drug' s price increases, including, amongst other things, a list of factors contributing to a price increase and an explanation of the role the factor played in the price increase.).

a. Regulations Do Not Contain Protections for Reported Trade Secrets

First, the Regulations do not contain any protections for trade secrets compelled under SB 539. Fundamental to the definition of a trade secret is that it remains confidential. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984) ("Because of the intangible nature of a trade secret, the extent of the property right therein is defined by the extent which the owner of the secret protects his interest from disclosure to others."). Indeed, once a trade secret is public, trade secret protection is gone forever.

Because a trade secret's economic value is dependent on its secrecy, any disclosures involving trade secrets necessitate protections in order to preserve secrecy. For example, in court cases involving trade secrets, trade secret information is only disclosed under a Protective Order and/or is filed under seal. Likewise, trade secret disclosures to third parties, such as a government entity, are and should be accompanied with confidentiality agreements or non-disclosure agreements. Additionally, trade secret disclosures mandated by certain statutes often contain statutory language that indicates the information reported to the government is confidential and not subject to public disclosure. *See* 18 Vt. Stat. Ann. §4635(e) ("Information provided to the Office of the Attorney General ... is exempt from public inspection and copying under the Public Records Act and shall not be released in a manner . . . that is likely to compromise the financial, competitive, or proprietary nature of the information.").

SB 539 and the Regulations offer no protections to ensure a manufacturer's trade secrets will be kept confidential or provide any guarantees against further dissemination once disclosed to the Department. Nothing in SB 539 or the Regulations limit what the Department can do with reported trade secrets. Specifically, while the Regulations require manufacturers to request information be deemed confidential, the Regulations do not indicate (1) if the Department will decide if the manufacturer's request for confidentiality is granted or (2) what the Department will do to ensure information is kept confidential in the meantime. In short, while the Regulations force manufacturers to disclose trade secrets under SB 539, the Regulations do not offer any of the trade secret protections that typically accompany disclosure of trade secret information in court proceedings or to government entities.

Consequently, Pfizer has serious concerns that SB 539 and the Regulations, as drafted, would nullify trade secret protection not just in Nevada, but nationwide, for all information manufacturers are forced to disclose.

b. Regulations Strip Reported Trade Secrets of Trade Secret Protection

Second, SB 539 and the Regulations not only mandate public disclosure of trade secrets, but they seek to eliminate trade secret status for all information manufacturers must disclose. Specifically, the Regulations demand that manufacturers report trade secrets to comply with Nev. Rev. Stat. SB 539 §§ 3.8 and 4. However, § 9 of SB 539 amended the definition of "trade secret" under Nevada law so that "trade secrets", by law, "does not include any information that a manufacturer is required to report pursuant to section 3.8 or 4 of this act . . ." Nev. Rev. Stat. § 600A.030(5).

Taken together, SB 539 and the Regulations eviscerate a manufacturer's property interest in its trade secrets. This compelled destruction of trade secrets, with no mechanism for compensation, will have a significant, detrimental economic impact. At a minimum, manufacturers of essential diabetes drugs will be at a severe disadvantage vis-a-vis competitors not subject to SB 539, as well as in their dealing with third-party payers, who will be given a manufacturer's once commercially sensitive trade secrets to use in negotiations.

c. Regulations Are Ambiguous Regarding Third-Party Access to Trade Secrets and Fail to Provide Meaningful Remedies

Third, the Regulations are ambiguous regarding third-party access to trade secrets and fail to provide manufacturers with meaningful remedies.

Section 2 of the Regulations state "The Department will notify the manufacturer of any request for data elements marked as confidential . . . [T]he Department will allow the manufacturers thirty days to take legal action under DTSA prior to releasing the information . . ."

Section 2 of the Regulations indicate third parties can request information manufacturers submit to the Department under Nev. Rev. Stat. Ann. §§ 3.8 and 4. However, the Regulations are both vague as to the identity of the requesters and what information will be given to requesters. Accordingly, as drafted, the Regulations currently permit any third party, including a manufacturer's competitors or other sophisticated business entities, to request and gain access to the detailed information a manufacturer submits to the Department under SB 539.

Additionally, the Regulations do not limit the information the Department provides requesters even in the event a manufacturer takes legal action under the DTSA. In fact, as drafted, the Regulations indicate that the Department will release all information a manufacturer provides to the Department, including information the manufacturers requests be declared confidential, to requesters after 30 days. The only remedy the Regulations provide is the 30 day grace period for the manufacturer to protect its trade secrets under the DTSA.

Nevertheless, the Regulations purported remedy of providing manufacturers 30 days to protect their trade secrets under the DTSA is no remedy at all. The DTSA provides a federal cause of action for trade secrets misappropriated, *i.e.* the wrongful acquisition, disclosure or use of trade secrets. The DTSA does not provide a mechanism for challenging the Department's mandate that a manufacturer hand over its trade secrets. Nor does it provide an avenue that would allow a manufacturer to somehow censor or recover trade secrets that were provided to a government entity and/or were otherwise disseminated to the public.

Even if the DTSA offered some way to address the Department's forced disclosure of trade secrets, requiring a manufacturer to file a federal lawsuit anytime someone requests access to its trades secrets is an unworkable, unfair burden that will undermine trade secret protection that has been part of our nation's public policy for over a hundred years.

III. Detailed Description Required by Regulations May Itself Force the Disclosure of Trade Secret

Section 2 of the Regulations currently require manufacturers who “request to have [a reportable data element] declared confidential” to submit “a detailed description of why the data element qualifies as a trade secret under the DTSA. This detailed description asserting trade secret protection will be available upon request to the public.”

Providing a “detailed description” of why the data element is a trade secret may itself require a manufacturer to disclose portions of its trade secrets, particularly those relating to its pricing strategy. As such, the “detailed description” required by Section 2 of the Regulations itself could force a manufacturer to disclose a trade secret that in turn would be “available upon request to the public.”

At a minimum, Pfizer suggests the Department replace “detailed description” with “description” in Section 2 of the Regulations given the public nature of the Regulation’s required description and the resulting trade secret concerns.

IV. Effect on Pending Litigation

As you know, SB 539 is being challenged in court by PhRMA, in which PhRMA asserts (1) SB 539 is preempted by federal patent laws, including the Hatch-Waxman Act, (2) SB 539 is preempted by the federal Defend Trade Secrets Act of 2016, (3) SB 539 violates the Takings Clause of the Fifth Amendment as a regulatory taking, and (4) SB 539 imposes an excessive burden on interstate commerce in violation of the Commerce Clause of the U.S. Constitution.

The Regulation, as indicated above, does not resolve the many issues raised in the PhRMA litigation. We urge the State to take the necessary regulatory steps to eliminate the statutory defects that are the subject of the litigation. In the absence of a regulatory process that adequately resolves those issues, pharmaceutical manufacturers may be forced to reserve or limit their statements under the statute until the Court has resolved those concerns.

* * *

As currently drafted, the Regulations raise serious concerns for manufacturers who may be forced to disclose and lose valuable trade secrets. The Regulations also contradict numerous positions taken by the State in the pending litigation concerning SB 539.

One way the State may be able to better align the Regulations with the State’s own litigation positions and with Nevada’s rules of statutory interpretation is to limit information reported under Nev. Rev. Stat. SB 539 §§ 3.8 and 4 to information that is publicly available or otherwise in the public domain. This is an approach being employed by the State of California under its own prescription drug price transparency law, 2017 California Senate Bill 17, to address trade secret protections. *See* Cal. Health & Safety Code§ 127679 (b) (“The manufacturer may limit the information reported ... to that which is otherwise in the public domain or publicly available.”); *see also* Cal. Health & Safety Code§ 127681(c) (“The manufacturer may limit the information reported ... to that which is otherwise in the public domain or publicly available.”).

Pfizer requests that the Department revise the proposed Regulations to address the concerns raised in this letter and then afford stakeholders an opportunity to comment on the revised Regulations before finalizing any such Regulations. Given the necessary level of revisions to these proposed Regulations, if stakeholders are not afforded an opportunity to comment on the revised Regulations, they will not have been afforded sufficient notice to comment on the revised Regulations.

* * *

Thank you for providing Pfizer this opportunity to comment on the Regulations and for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura Chenoweth". The signature is written in a cursive, flowing style.

Laura Chenoweth Senior
Vice President &
Deputy General Counsel

Drug Transparency

From: Clair Irwin [REDACTED]
Sent: Tuesday, February 6, 2018 1:05 PM
To: Drug Transparency
Subject: concern regarding draft regulations for SB539

February 6, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a patient with diabetes, I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies often argue increasing prices are necessary for R&D, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics. The monthly cost of insulin and supplies equals the cost of all my other monthly bills—over \$1500 a month, a cost that has only been manageable due to subsidization by my university. People with diabetes are expected to pay rent on our bodies, and we are paying ever-increasing amounts for the insulin we need to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. One of the bill's sponsors, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem." According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual." Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "[t]he transparency is very essential in my mind. That's what we need for the consumer in this case to receive the benefits of this particular drug [insulin]..." Senator Heidi Gansert summarized it well: "Over the last few years, the news has highlighted unprecedented increases in drug prices without information to support the increases. Transparency is required in order to help address this issue."

When signing SB539 into law, Governor Sandoval opined that SB539 "was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients." Indeed, Nevada's diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information,

please contact me at _____ or at _____

Sincerely,

A handwritten signature in cursive script that reads "Clair E. Irwin".

Clair E. Irwin

Drug Transparency

From: mike lawson [REDACTED]
Sent: Tuesday, February 6, 2018 11:42 AM
To: Drug Transparency
Subject: Help Protect Insulin Transparency!

Hey, Mr. Whitley!

I have been living with diabetes for over a decade. I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will in practice, work to prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-sustaining medication. Companies often argue increasing prices are necessary for research and development, but the insulin market has not seen a truly innovative product since the early 80s. Insulin was discovered almost a century ago, yet there are no generics and a single vial that lasts a week or two costs over \$300 at the pharmacy. Patients are paying ever-increasing amounts for the insulin we need to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. Once the bills' sponsor, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem." [1] According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual." [2] Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "the transparency is very essential in my mind. That's what we need for the consumer in his case to receive the benefits of this particular drug [insulin]..." [3] Senator Heidi Gansert summarized it well: "Over the last few years, the news has highlighted unprecedented increases in drug prices without information to support the increases. Transparency is required in order to help address the issue." [4]

When signing SB539 into law, Governor Sandoval opined that SB539 "was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients." [5] Indeed, Nevada's diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent:
transparency f
provide any ad
[REDACTED]

Best,
or patients and payors. Thank you for your time. If you have any questions or believe I can
ditional helpful information, please contact me at: [REDACTED] on the phone at

^[1] “Nevada Bill to Limit Diabetes Drug Prices Headed to the Governor,” Ed Silverman, STAT News, at <https://www.statnews.com/pharmalot/2017/05/25/nevada-bill-diabetes-drug-prices/>.

² “Nevada Senate Passes Insulin-Price Bill Tough on Drugmakers,” Alison Noon, U.S. News & World Report, at <https://www.usnews.com/news/best-states/nevada/articles/2017-05-19/nevada-senate-passes-insulin-price-bill-tough-on-drugmakers>.

^[3] Id.

^[4] Nevada Senate Committee Hearing on Health and Human Services regarding SB539, May 26, 2017. Text from: Minutes available at <https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1272.pdf>.

^[5] “Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits,” Mike Akers, Las Vegas Sun, at <https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/>.

Drug Transparency

From: Brandon . [REDACTED]
Sent: Wednesday, February 7, 2018 5:44 AM
To: Drug Transparency
Subject: SB539 Concerns
Attachments: Nevada HHS Form Letter re Insulin Transparency Regs - Final - 5-Feb-2018 (1).docx

I am the father of a 7 year old Type-1 diabetic. I live in Missouri but I am a native Nevadan. Last year I celebrated as I found that my home state was leading the way in drug transparency in order to bring drug prices down. Recently I found that there may be unintended changes made to the law. Please see my attached letter voicing my concerns. Please feel free to reach out to me with questions.

With Regards,
Brandon Porath

February 15, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a parent of a child with diabetes I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies often argue increasing prices are necessary for R&D, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics and a single vial that lasts a week or two costs over \$300 at the pharmacy. In sum, patients are paying ever-increasing amounts for the insulin that is needed to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. One of the bill's sponsor, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem."¹ According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual."² Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "[t]he transparency is very essential in my mind. That's what we need for the consumer in this case to receive the benefits of this particular drug [insulin]..."³ Senator Heidi Gansert summarized it well: "Over the last few years, the news has highlighted unprecedented increases in drug prices without information to support the increases. Transparency is required in order to help address this issue."⁴

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³ [Id.](#)

⁴ Nevada Senate Committee Hearing on Health and Human Services regarding SB539, May 26, 2017. Text from: [Minutes](https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1272.pdf) available at <https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1272.pdf>.

When signing SB539 into law, Governor Sandoval opined that SB539 “was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients.”⁵ Indeed, Nevada’s diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I therefore strongly urge your department to reconsider the draft regulations alongside the law’s intent: transparency for patients and payors. Thank you for your time.

Sincerely,

Brandon Porath

⁵ “Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits,” Mike Akers, Las Vegas Sun, at <https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/>.

February 15, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley:

As a parent of a child with diabetes, I am grateful that Nevada is leading the way to improved understanding of diabetes related costs with its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers. I write with concern that the draft regulations for SB539 will prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from understanding all the factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies argue price increases are necessary to cover costs of research and development, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics and a single vial that lasts a week or two costs over \$300 at the pharmacy. Patients pay ever-increasing amounts for the insulin needed to live with no justification from the manufacturers or pharmacy benefit managers. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

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I strongly urge your department to reconsider the draft regulations alongside the law’s intent: transparency for patients and payors. If you have any questions or I can provide any additional information, please contact me at [REDACTED] or at [REDACTED]

Sincerely,

Melinda Wedding

⁵ “Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits,” Mike Akers, [Las Vegas Sun](https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/), at <https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/>.

Drug Transparency

From: [REDACTED]
Sent: Tuesday, February 6, 2018 3:04 PM
To: Drug Transparency
Subject: Insulin pricing

February 6, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@health.nv.gov

Dear Mr. Whitley,

As a [patient with diabetes ,I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies often argue increasing prices are necessary for R&D, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics and a single vial that lasts a week or two costs over \$300 at the pharmacy. In sum, patients are paying ever-increasing amounts for the insulin we need to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. One of the bill's sponsor, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem." According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual." Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "[t]he transparency is very essential in my mind. That's what we need for the consumer in this case to receive the benefits of this particular drug [insulin]..." Senator Heidi Gansert summarized it well: "Over the last few years, the news has highlighted unprecedented increases in drug prices without information to support the increases. Transparency is required in order to help address this issue."

When signing SB539 into law, Governor Sandoval opined that SB539 "was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients." Indeed, Nevada's diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information, please contact me at [your contact information [REDACTED]]

Sincerely,

Sara Stock

February 22, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a Type One Diabetic, I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies often argue increasing prices are necessary for R&D, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics and a single vial that lasts a week or two costs over \$300 at the pharmacy. In sum, patients are paying ever-increasing amounts for the insulin we need to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

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² "Nevada Senate Passes Insulin-Price Bill Tough on Drugmakers," Alison Noon, [U.S. News & World Report](https://www.usnews.com/news/best-states/nevada/articles/2017-05-19/nevada-senate-passes-insulin-price-bill-tough-on-drugmakers), at <https://www.usnews.com/news/best-states/nevada/articles/2017-05-19/nevada-senate-passes-insulin-price-bill-tough-on-drugmakers>.

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I therefore strongly urge your department to reconsider the draft regulations alongside the law’s intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information, please contact me at 

Sincerely,

Robert Frisk

⁵ “Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits,” Mike Akers, Las Vegas Sun, at <https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/>.

February 22, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a patient with diabetes I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by more than 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

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I therefore strongly urge your department to reconsider the draft regulations alongside the law’s intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information, please contact me at [REDACTED]

Sincerely,

Paul Clements
[REDACTED]

⁵ “Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits,” Mike Akers, Las Vegas Sun, at <https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/>.

February 22, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706
drugtransparency@dhhs.nv.gov

Dear Mr. Whitley,

As a patient with diabetes, I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

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I therefore strongly urge your department to reconsider the draft regulations alongside the law’s intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information, please contact me at [REDACTED]

Sincerely,

Christopher Lockett MA

⁵ “Nevada Forces Drugmakers to Reveal Insulin Pricing, Profits,” Mike Akers, Las Vegas Sun, at <https://lasvegassun.com/news/2017/jun/15/sandoval-signs-insulin-pricing-transparency-bill/>.

Drug Transparency

From: Angela Lautner [REDACTED]
Sent: Wednesday, February 7, 2018 10:03 AM
To: Drug Transparency
Subject: Call to protect insulin price transparency in Nevada

February 7, 2018

Richard Whitley
Director of the Department of Health and Human Services
State of Nevada
4126 Technology Way, Suite 100
Carson City, NV 89706

Dear Mr. Whitley,

As a person who has lived with Type 1 diabetes for the past 18 years and as an advocate for insulin price transparency in Kentucky, I am grateful that Nevada is leading the way through its first-in-the-nation diabetes transparency law. Since 1996, the list price of a single vial of insulin has risen by over 1200% and patients deserve to know why. I thank you for working to give patients answers, but I write with concern that the draft regulations for SB539 will, in practice, work to prevent the transparency for patients that is the crux of the law's intent.

Currently, patients are shielded from all factors affecting the price of insulin, and thus only learn of price increases when we go to the pharmacy to pick up our life-saving medication. Companies often argue increasing prices are necessary for R&D, but the insulin market has not seen a truly "innovative" product since the early 1980s. Despite insulin's discovery almost a century ago, there are no generics and a single vial that lasts a week or two costs over \$300 at the pharmacy. In sum, patients are paying ever-increasing amounts for the insulin we need to live with no justification from the manufacturers or pharmacy-benefit managers as to why. The vast majority of these drugs are decades old and long off-patent, yet the pharmaceutical companies seek to continue to block all transparency into costs, pricing, and rebates, on the basis of "trade secret protection." These companies are going to extreme lengths to prevent transparency, by suing the Nevada Attorney General and now attempting to subvert the intent of Nevada's legislature to bring diabetes drug pricing transparency to patients.

Patient transparency is the undisputed purpose of SB539. One of the bill's sponsor, Senator Yvanna Cancela, summarized the importance of transparency for patients by stating, "We can talk about pricing in the abstract, but without real data, we can't as a state make decisions to address the problem." According to Cancela, "in the process of disclosure, patients will be equipped with information to push back and ask questions related to price gouging and to what happens between the time a drug is with a manufacturer and the time that it gets to an individual." Senator Cancela's Republican colleagues echoed this sentiment, Senator Scott Hammond stating, "[t]he transparency is very essential in my mind. That's what we need for the consumer in this case to receive the benefits of this particular drug [insulin]...." Senator Heidi Gansert summarized it well: "Over the last few years, the news has highlighted unprecedented increases in drug prices without information to support the increases. Transparency is required in order to help address this issue."

When signing SB539 into law, Governor Sandoval opined that SB539 "was a bill that was very hard fought and debated in the legislative session and very meaningful for diabetes patients." Indeed, Nevada's diabetes transparency law is the most meaningful legislative initiative undertaken to date to shed light through the purposeful complexity of diabetes drug prices. Armed with this data, patients will be able to push Nevada, other states, and the federal government for a true fix to this uniquely-American insulin pricing crisis.

I therefore strongly urge your department to reconsider the draft regulations alongside the law's intent: transparency for patients and payors. Thank you for your time. If you have any questions or I can provide any additional information, please contact me at [REDACTED]

Sincerely,

Angela Lautner

Drug Transparency

From: Donna Robinson [REDACTED]
Sent: Tuesday, February 6, 2018 3:44 PM
To: Drug Transparency
Subject: Re: RE:

My family tree is rife with Type 1 diabetes, a daughter, a sister, a brother. My grandchildren have grandparents and aunts and uncles with Type 1 on both sides of their family tree.

Insulin is the only thing keeping our loved ones alive. It is important to recognize that if insulin is unaffordable some will die. I have heard of people rationing their insulin prescriptions due to lack of funds.

Our health care system is broken and our politicians seem incapable of fixing it. It is imperative that we hold corporations accountable for their actions even as our elected officials fumble and bumble their way to no solution.

People are dying while our representatives hem and haw and pocket hefty campaign contributions from various interests.

Do they know, or even care, that their inaction and cowardice are hurting real people? I support your drug transparency bill in the hope that it will hold drug companies accountable for their insulin drug pricing.

Sincerely,

Donna Robinson

P.S. feel free to include in public comments.

On Feb 6, 2018, at 5:37 PM, Drug Transparency <DrugTransparency@dhhs.nv.gov> wrote:

Good afternoon Ms. Robinson,

I am unable to open your attachment. Would you please re-send it?

Do you want this included in the public comment for the upcoming workshop?

Thank you in advance.

Best Regards,

 **Drug Transparency Nevada**
Director's Office
Department of Health and Human Services
4126 Technology Way, Suite 100 | Carson City, NV 89706
www.dhhs.nv.gov

Drug Transparency

From: [Redacted]
Sent: Monday, July 12, 2018 2:22 PM
To: Drug Transparency
Subject: Draft Regulations for SB539

Dear Mr. Whitley,

I leading have lived the way with with a\}t the oimmune Type first-in-the-nation 1 diabetes diabetes for 42 drug years. tra I am nsparency very gratlaw. I eful have that the followed State of that legiNevada sla is tion (including unchanged the since failed the disclawsuit overy filed in 19against 21, and it yet filed by prices the have drug seen industry)prices . The exceeding price for 1000% insulin, over which the last is few largely years. Pricing transparency is something the pharmaceutical industry is fighting. Jorgensen

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do He told business, Reuters for "If instance, the tranif we sparency have to bills pulead blicly to a share disclowhat sure is in level our that contris actoo ts." excessive, it becomes difficult to Indeed, industry the trade Pharmaceutical organization that Research sued and Nevada last Manufacturers year, of spent a America staggering (better \$39.4 known million as to PhRMfight A), a one ballot of the also initiative showed in Ohio that a vast known maas jothe rity of Drug that Price money Relief came Act, also directly known from a as subOhio sidiary ballot of Issue PhRMA. 2. In Reports the to end, the all state the industry. spending There mainly is news succeeded of in industry confusing increasing voters, state although lobbying that was significasufficient ntly in for 2018the . pharmaceutical

I patients write with and the concern State that of the Nevada draft that's regulations the crux for of SBthe 539 law's will, intent. in practice, work to prevent the transparency for The without law's real original data, we sponsor, can't Seas a ntator state make Yvamma decisions Cancela to said address "We the can talk problem. about She pricing added in " ... the in abthe stract, process but of and to disclosure, what patients happens will between be the equipped time with a drug informais with tion a to push manufacturer back and and ask the time questions it gets to related an to price individual."

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was Other fought legislahard tors in and the debated state, in in botlegislah tive political session parties, and very echoed this meaningful sentiment. to diabetes Governor patientsSa ." ndoval said the bill

I me, thepatients please refore and urge contact payers. your me at Thankdepartment for to our time; reconsider if you the r have draft by any phone regl atations questions or alongside wish for the any law's intent: additional trainsight nsparency from for

Sincerely
C. Scott Strumello

[Redacted signature block]