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Attorneys for Plaintiffs Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, and

BIOTECHNOLOGY INNOVATION ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as Governor of the State of Nevada, and

RICHARD WHITLEY, in his official capacity as Director of the Nevada Department for Health and Human Services,

Defendants.

Case No.:

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Innovation Organization ("BIO") (together, "Plaintiffs"), on behalf of themselves and their members, for their Complaint against Brian Sandoval, in his official capacity as Governor of the State of Nevada (the "State"), and Richard Whitley, in his official capacity as Director of the Nevada Department of Health and Human Services (together, "Defendants"), allege as follows:

INTRODUCTION

1. Plaintiffs bring this action to block an unprecedented and unconstitutional Nevada law that interferes with the federal patent and trade-secret laws, deprives manufacturers of their property interest in their trade secrets, and improperly overrides the regulatory choices of every other state. Because the new Nevada statute violates multiple provisions of the United States Constitution, this Court has subject matter jurisdiction under 28 U.S.C. § 1331.

2. Nevada recently enacted Senate Bill No. 539 ("SB 539" or the "Act," attached as Exhibit A), a statute novel in its scope, ambition, and nationwide effect. As a penalty for exercising rights protected under the U.S. patent laws, SB 539 strips pharmaceutical manufacturers of trade-secret protection for confidential, competitively sensitive, proprietary information regarding the advertising, cost, marketing, pricing, and production of their patented diabetes medicines. The Act then compels manufacturers to disclose this information to the Nevada Department of Health and Human Services (the "Department"), which must publish at least some of the information on its website and may disseminate the rest as it pleases.

3. By extinguishing trade-secret protection for manufacturers' confidential, proprietary information, burdening the lawful exercise of longstanding federal patent rights, and interfering with the national market for diabetes medicines, the Act violates the U.S. Constitution in at least four ways.

4. *First*, SB 539 violates the Supremacy Clause because it conflicts with federal patent law, including the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. The federal patent laws allow a patent holder to exclude others from making, using, or selling new inventions. The Hatch-Waxman Act adapts this system to pharmaceuticals through a comprehensive federal scheme to provide broad access to affordable medicines while

offering economic incentives sufficiently potent to motivate innovators to shoulder the enormous costs and risks to develop pioneering new treatments. SB 539 upsets this legislative balance by burdening a patent holder's right to price its product in a manner reflecting the economic incentives the federal patent laws are intended to ensure.

5. *Second*, SB 539 also conflicts with, and is therefore preempted by, federal trade-secret law. Recognizing that protection of trade secrets is critical to the success of U.S. businesses, Congress enhanced existing state-law safeguards by enacting the Defend Trade Secrets Act of 2016 ("DTSA"). The DTSA sets a federal baseline for trade-secret protection. SB 539 does not merely fall below this baseline. It effectively nullifies federal protection for valuable trade secrets, undermining innovation and competition in the American pharmaceutical industry.

6. *Third*, SB 539 violates the Takings Clause of the Fifth Amendment by depriving affected manufacturers of trade-secret protection for their confidential information, forcing them to disclose it to the State, and ensuring that much of it is disseminated on the Internet, including to third-party payers and competitors. Before SB 539, these materials qualified as trade secrets under the laws of every state, including Nevada. Trade secrets are property. SB 539 destroys the value of that property without recompense. It thus deprives manufacturers of their property "without just compensation," in violation of the Takings Clause.

7. *Fourth*, SB 539 violates the dormant Commerce Clause because the penalty it imposes in Nevada impedes commerce in other states. By tying penalties to the national list price for a drug, SB 539 affects drug prices throughout the country, even for drugs bought and sold entirely outside of Nevada. The Act also eviscerates trade-secret protection not only in Nevada, but in every other state as well. Requiring disclosures, rescinding trade-secret protection for the information disclosed, and mandating its publication on the Internet destroys its confidentiality. Such disclosures cannot be undone—information cannot be undisclosed. SB 539 overrides the protections of other states that treat the information as trade secrets, including states where the affected manufacturers reside, pay taxes, and employ thousands of workers. Whatever purported local benefit SB 539 might seek for Nevada purchasers of diabetes medicines is far less substantial than the displacement of the laws of every other state in the Union. Only Congress has the authority

to override state trade-secret law or to impose national economic policies. Nevada cannot do so unilaterally.

8. SB 539's constitutional infirmities led Governor Brian Sandoval to veto a substantially similar bill—Senate Bill 265 ("SB 265")—just three months ago. Governor Sandoval warned that provisions of the earlier bill "could be challenged under theories of federal preemption, the Fifth Amendment's prohibition on uncompensated takings, and the Dormant Commerce Clause." Veto Letter from Gov. Brian Sandoval to Sen. Maj. Leader Aaron Ford 3 (June 2, 2017) ("Veto Letter," attached as Exhibit B). The Governor was right, but SB 539 did not alleviate the defects he identified.

9. Governor Sandoval further recognized that, beyond these constitutional defects, SB 265 could seriously harm Nevada residents suffering from diabetes. The bill, in the Governor's view, posed "serious risks of unintended and potentially detrimental consequences for Nevada's consumer patients, not the least of which is the possibility that access to critical care will become more expensive, more restricted, and less equitable." *Id.* at 2. He cautioned that the bill "could cause more harm than good for Nevada's families." *Id.* "Before I support a bill [this] uncertain," he wrote, "which deals so directly and extensively with the health and well-being of countless Nevadans, there must be compelling evidence that the benefits are worth the risks." *Id.* at 3. There was no such evidence, and the Legislature did not remedy that deficit in adopting SB 539.

10. Accordingly, Plaintiffs seek a declaration that the challenged provisions of SB 539 are preempted by federal law and also violate the Takings Clause and the dormant Commerce Clause. Plaintiffs also seek an injunction prohibiting the defendants from implementing or enforcing those provisions.

PARTIES

11. PhRMA is a non-profit corporation organized under Delaware law, with its headquarters in Washington, D.C. PhRMA serves as the pharmaceutical industry's principal public policy advocate, representing the interests of its members before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. Among other objectives, PhRMA seeks to advance public policies that foster continued medical innovation and to educate the public about the

process for discovering and developing new drugs. PhRMA members are the leading research-based pharmaceutical and biotechnology companies in America, devoted to discovering and developing new medications that allow people to live longer, healthier, and more productive lives.[1]

12. BIO is the world's largest trade association representing more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.[2]

13. Defendant Brian Sandoval is the Governor of the State of Nevada and is sued in his official capacity only. As Governor, Defendant Sandoval is responsible for the execution of SB 539.

14. Defendant Richard Whitley is the Director of the Department and is sued in his official capacity only. As Director of the Department, Defendant Whitley is responsible for the implementation and execution of SB 539, including the promulgation of rules and the assessment of administrative penalties authorized by the Act. *See* SB 539, 2017 Leg., 79th Sess. §§ 7–8 (Nev. 2017).

JURISDICTION AND VENUE

15. Plaintiffs' causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court thus has jurisdiction under 28 U.S.C. § 1331.

16. Venue is proper in this district under 28 U.S.C. § 1391(b) because Plaintiffs' claims arise in this judicial district and because Defendants reside and perform their official duties in this district.

17. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201, and this Court has the authority to grant declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201 and 2202.

[1] A list of PhRMA members is available at *Members*, http://www.phrma.org/about/members.

[2] A list of BIO members is available at *BIO Member Directory*, http://www.bio.org/bio-member-directory.

BACKGROUND

Plaintiffs' Members Devote Billions of Dollars Each Year to Developing Innovative Diabetes Medicines in Reliance on Patent and Trade-Secret Law

18. Diabetes is an epidemic in the United States, with more than 30 million Americans diagnosed with either Type 1 or Type 2 diabetes. Type 1 diabetes is an autoimmune disease in which the immune system attacks the insulin-producing cells of the pancreas, and the body as a result produces too little insulin, the principal hormone regulating the body's absorption of glucose (sugar) from the blood. In Type 2 diabetes, the body resists the effects of insulin and, although the pancreas produces abnormally high levels of insulin to overcome this resistance, blood glucose rises to higher levels than normal. About 5 to 10% of diabetes diagnoses are Type 1, and 90 to 95% are Type 2. *See What Is Diabetes?*, Nat'l Inst. of Diabetes & Digestive & Kidney Diseases, Nat'l Insts. of Health, https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes. High levels of glucose in the blood can result in a number of complications, including vision loss, kidney disease, and cardiovascular disease. *Id.*

19. Diabetes is the seventh leading cause of death in the United States. In addition to the 30 million Americans diagnosed with the disease itself, another 84 million have pre-diabetes—abnormally high blood sugar levels that increase the risk of developing diabetes in the future. All told, over half the adults in the United States have either diabetes or pre-diabetes. *See* A. Menke et al., *Prevalence of and Trends in Diabetes Among Adults in the United States, 1988-2012*, 314 JAMA 1021 (2015), www.jamanetwork.com/journals/jama/fullarticle/2434682.

20. For a century, Plaintiffs' members have been at the forefront of the fight against diabetes, starting with the mass production of early animal-based insulins by Eli Lilly in 1922. Before the discovery of insulin as a diabetes treatment, a diagnosis of diabetes was a swift death sentence. Even with a strict diet, a patient typically survived "no more than three or four years." Diabetes Que., *Treating Diabetes: 1921 to the Present Day* (Nov. 2016), http://www.diabete.qc.ca/en/understand-diabetes/all-about-diabetes/history-of-diabetes/treating-diabetes-1921-to-the-present-day. In 1897, the average life expectancy of a 10-year-old child diagnosed with diabetes was just one year and, for a 30-year-old, only four years. *See* Dawn

Swidorski, *Diabetes History*, Defeat Diabetes Found. (Jan. 22, 2014), https://www.defeatdiabetes.org/diabetes-history. Their quality of life was also poor. Blood vessel or nerve damage resulted in dizziness and fainting, frequent urination, blindness, kidney failure, and infections leading to amputation.

21. While the disease "is still associated with a reduced life expectancy, the outlook for patients with th[e] disease has improved dramatically," Kenneth S. Polonsky, *The Past 200 Years in Diabetes*, 367 New Eng. J. Med. 1332, 1332 (2012), http://www.nejm.org/doi/full/10.1056/NEJMra1110560, owing significantly to the enormous investments by Plaintiffs' members in research and development of innovative diabetes treatments. Many innovative treatments have broken new scientific ground and significantly improved patients' life expectancy and quality of life.

22. In 1921, a pair of scientists discovered that they could reverse diabetes in dogs by injecting them with an extract—insulin—from the pancreatic islets of healthy dogs. *See* Brian Wu, *History of Diabetes: Past Treatments and New Discoveries*, Med. News Today (May 2017), http://www.medicalnewstoday.com/articles/317484.php. The following year, Eli Lilly began mass producing animal-based insulin and, in 1925, Novo Nordisk gained the rights to produce insulin outside North America, allowing diabetes patients across the world to better manage their condition. *Id.*; Novo Nordisk, *The Founders*, www.novonordisk.com/about-novo-nordisk/novo-nordisk-history/the-founders.html.

23. Since then, pharmaceutical manufacturers have devoted very substantial resources to improving insulin treatment and otherwise controlling diabetes. For example:

- In 1936, a scientist discovered that adding protamine prolonged the effects of injected insulin.
- In 1950, Novo Nordisk introduced Neutral Protamine Hagedorn ("NPH") Insulin, a drug so important in treating diabetes that it is on the World Health Organization model list of essential medicines. *See* WHO Model List of Essential Medicines, World Health Org. (20th ed.) (Mar. 2017), http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017.pdf.
- In 1964, the Ames Company, a subsidiary of the Dr. Miles Medical Company that later merged into Bayer AG, introduced the first strips for testing blood

glucose, which allowed diabetes patients to monitor and regulate their glucose levels frequently and conveniently. *See* Am. Diabetes Ass'n, *75th Anniversary Timeline*, http://www.diabetes.org/about-us/75th-anniversary/timeline.html ("75th Anniversary Timeline"). By 1981, the Ames Company introduced home glucose meters, allowing patients to accurately check their own blood glucose levels without having to visit a doctor's office. S.F. Clarke & J.R. Foster, *A History of Blood Glucose Meters and Their Role in Self-Monitoring of Diabetes Mellitus*, 69 Brit. J. of Biomed. Sci. 83, 86 (2012).

- In 1982, FDA approved Eli Lilly's Humulin, the first human insulin product, freeing the world's supply of insulin from its supply using animal sources. *See* Lawrence K. Altman, *A New Insulin Given Approval for Use In U.S.*, N.Y. Times, Oct. 30, 1982, http://www.nytimes.com/1982/10/30/us/a-new-insulin-given-approval-for-use-in-us.html?mcubz=0.
- In 1985, Novo Nordisk developed, introduced, and marketed the first insulin pen, which allows patients to vary the injected dose and to administer insulin discreetly. Since 1985, innovators have made significant investments into designing insulin pens that improve patient satisfaction and safety.
- In 1994, Bristol Myers Squibb became the first company to secure FDA approval for the drug metformin, an oral biguanide that prevents glucose production in the liver. Press Release, U.S. Food & Drug Admin., FDA Approves New Diabetes Drug (Dec. 30, 1994), https://web.archive.org/web/20070929152824/http://www.fda.gov/bbs/topics/ANSWERS/ANS00627.html. Metformin is the recommended first line of treatment for Type 2 diabetes after diet and exercise. *See* Randy Dotinga, *Metformin Still Best as First Type 2 Diabetes Treatment*, WebMD (Jan. 2, 2017), http://www.webmd.com/diabetes/news/20170102/metformin-still-best-choice-for-first-type-2-diabetes-treatment.
- In 2000, Aventis Pharmaceuticals, a predecessor company of Sanofi U.S., received FDA approval for Lantus, the first FDA approved long-acting (basal) recombinant human insulin analog with a once-daily administration. *See* 75th Anniversary Timeline. With Lantus, the reduced risk of nighttime hypoglycemia and the flexibility of once-daily dosing made insulin a more acceptable option for patients to start insulin earlier and intensify their insulin sooner, leading to long-term improvements and reducing complications in diabetes.
- In 2005, FDA approved the first patient-use continuous glucose monitoring system, which automatically reads blood sugar levels every 5 to 15 minutes and can detect trends and patterns. *See id.*
- Also in 2005, Eli Lilly and Amylin Pharmaceuticals received FDA approval for Byetta, a first-in-class glucagon-like peptide-1 (GLP-1) receptor agonist that improves glycemic control and delays or reduces the need for insulin in patients with Type 2 diabetes. *Id.* Significant innovation in the GLP-1 space has continued since, including, for example, the development of once-weekly agents that can significantly increase patient adherence.
- In 2006, Merck & Co. received FDA approval for Januvia, a first-in-class dipeptidyl peptidase 4 (DPP-4) inhibitor that enhances the body's ability to lower

elevated blood sugar by increasing incretin levels, thereby inhibiting glucagon release and decreasing blood glucose levels. *Id.*

- In 2013, Janssen, a Johnson & Johnson subsidiary, secured FDA approval for Invokana, a first-in-class sodium/glucose cotransporter 2 (SGLT-2) inhibitor that prevents the kidneys from reabsorbing glucose back into the blood, allowing them to lower blood glucose levels and remove excess blood glucose through urination. *Id.*
- Also in 2013, Takeda Pharmaceuticals obtained FDA approval for Nesina, a new "DPP-4 inhibitor" that allows the pancreas to secrete insulin and better manage blood glucose levels. *See* Press Release, Takeda Receives FDA Approval for Three New Type 2 Diabetes Therapies, Takeda (Jan. 26, 2013), http://www.takeda.us/newsroom/press_release_detail.aspx?year=2013&id=269.
- In 2015, Novo Nordisk and Sanofi U.S. received FDA approval for Tresiba and Toujeo, respectively, which are ultra-long-acting insulins. These latest advances offer a more stable delivery of insulin and afford patients more flexibility in dosing. *See* Press Release, Novo Nordisk Receives FDA Approval for Tresiba® (insulin degludec injection) for Adults with Type 1 and Type 2 Diabetes, Novo Nordisk (Sept. 25, 2015), http://press.novonordisk-us.com/2015-09-25-Novo-Nordisk-Receives-FDA-Approval-for-Tresiba-insulin-degludec-injection-for-Adults-with-Type-1-and-Type-2-Diabetes; Press Release, Sanofi Receives FDA Approval of Once-Daily Basal Insulin Toujeo®, Sanofi (Feb. 25, 2015), http://www.news.sanofi.us/2015-02-25-Sanofi-Receives-FDA-Approval-of-Once-Daily-Basal-Insulin-Toujeo.

24. All told, FDA has approved 39 diabetes medicines since 2000. These 39 medicines are the product of decades of investment in research and development, including both successes and failures. As shown in the chart below, Plaintiffs' members were responsible for developing the vast majority of these medicines.

Drug name	Type of drug	Manufacturer	Approval year
Adlyxin	Glucagon-like peptide	Sanofi U.S.	2016
Soliqua	Injectable combination therapy	Sanofi U.S.	2016
Xultophy	Injectable combination therapy	Novo Nordisk	2016
Basaglar	Long-acting insulin	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2015
Tresiba	Long-acting insulin	Novo Nordisk	2015

Ryzodeg	Combination insulin	Novo Nordisk	2015
Toujeo	Long-acting insulin	Sanofi U.S.	2015
Glyxambi	Combination SGLT-2 inhibitor and DPP-4 inhibitor	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2015
Trulicity	Glucagon-like peptide	Eli Lilly	2014
Invokamet	Combination SGLT-2 inhibitor and biguanide	Janssen Pharmaceuticals	2014
Jardiance	SGLT-2 inhibitor	Boehringer Ingelheim Pharmaceuticals	2014
Afrezza Inhalation Powder	Inhaled insulin	Sanofi U.S. and MannKind	2014
Tanzeum	Glucagon-like peptide	GlaxoSmithKline	2014
Xigduo XR	Combination Dapagliflozin and Metformin	AstraZeneca	2014
Farxiga	SGLT-2 inhibitor	AstraZeneca and Bristol-Myers Squibb	2014
Invokana	SGLT-2 inhibitor	Janssen Pharmaceuticals	2013
Nesina	DPP-4 inhibitor	Takeda Pharmaceuticals	2013
Janumet XR	DPP-4 inhibitor	Merck	2012
Jentadueto	Combination DPP-4 inhibitor and biguanide	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2012
Bydureon	Glucagon-like peptide	Amylin Pharmaceuticals and Alkermes PLC	2012
Juvisync	Combination statin and	Merck	2011

	DPP-4 inhibitor		
Tradjenta	DPP-4 inhibitor	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2011
Kombiglyze XR	Combination DPP-4 inhibitor and biguanide	AstraZeneca and Bristol-Myers Squibb	2010
Victoza	Glucagon-like peptide	Novo Nordisk	2010
Onglyza	DPP-4 inhibitor	AstraZeneca and Bristol-Myers Squibb	2009
PrandiMet	Combination repaglinide and biguanide	Sciele Pharma and Novo Nordisk	2008
Janumet	DPP-4 inhibitor and Biguanide	Merck	2007
Januvia	DPP-4 inhibitor	Merck	2006
Duetact	Combination pioglitazone (directly targets insulin resistance) and sulfonylurea (increases amount of insulin produced by pancreas)	Takeda Pharmaceuticals	2006
ACTOplus met	Combination pioglitazone and biguanide	Takeda Pharmaceuticals	2005
Levemir	Long-acting insulin	Novo Nordisk	2005
Byetta	Glucagon-like peptide	Amylin Pharmaceuticals and Eli Lilly	2005

Symlin	Antihyperglycemic drug	Amylin Pharmaceuticals	2005
Apidra	Rapid-acting insulin	Aventis Pharmaceuticals	2004
Metaglip	Combination glipizide and biguanide	Bristol-Myers Squibb	2002
Avandamet	Combination rosiglitazone and biguanide	GlaxoSmithKline	2002
Novolog 70/30	Combination insulin	Novo Nordisk	2001
Lantus	Long-acting insulin	Aventis Pharmaceuticals	2000
Novolog	Rapid-acting insulin	Novo Nordisk	2000

See U.S. Food & Drug Admin., *FDA-Approved Diabetes Medicines*, https://www.fda.gov/forpatients/illness/diabetes/ucm408682.htm.

25. Although there have been substantial advances in diabetes treatments, 1.7 million people are newly diagnosed with diabetes in the United States every year. Developing innovative new diabetes treatments and improving existing treatments requires continuing research. To that end, Plaintiffs' members invest billions each year. *See, e.g.*, *2016 Biopharmaceutical Research Industry Profile*, PhRMA (April 2016), phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf; David Thomas & Chad Wessel, *Emerging Therapeutic Company Investment and Deal Trends*, BIO (June 2017), https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf. In 2016 alone, more than 170 medicines for diabetes and related conditions were in development. *See Medicines in Development for Diabetes: A Report on Diabetes and Related Conditions*, PhRMA (2016), phrma-docs.phrma.org/files/dmfile/medicines-in-development-report-diabetes.pdf. The vast majority of drugs in development are potentially "first-in-class medicines" that offer a new approach to fighting the disease. *See, e.g.*, Genia Long, Analysis Grp., *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development* (July 2017), http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the_biopharmaceutical_pi

peline_report_2017.pdf (noting that 69% of diabetes drugs in development were potential first-in-class medicines).

26. Among the approximately 170 medicines in the development pipeline, innovations include a potential first-in-class oral medicine that provides a new way for addressing Type 1 and Type 2 diabetes; a fully recombinant monoclonal antibody that treats patients with newly diagnosed Type 1 diabetes; and a medicine for diabetic nephropathy, damage to the kidneys from Type 1 or 2 diabetes. Many new innovations improve the convenience of dosing and thus increase adherence, which helps patients with diabetes avoid emergency room visits and hospitalizations, and could save the healthcare system as much as $8.3 billion annually. Ashish Jha et al., *Greater Adherence to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly $5 Billion Annually*, 31 Health Aff. 1836, 1836 (2012). For instance, oral versions of both insulin and GLP-1 agents are included in the development pipeline of several manufacturers, and these have the potential to significantly increase adherence to these much needed diabetes therapies for millions of patients in the U.S. New diabetes therapies have also had beneficial secondary effects, including weight loss, a reduction in cardiovascular disease, and improved renal function. *See* A. Kuhn et al., *Intensifying Treatment Beyond Monotherapy in Type 2 Diabetes Mellitus: Where Do Newer Therapies Fit?*, Current Cardiology Reports (March 2017).

27. Another emphasis in diabetes research and development is prevention: researchers at top universities, hospitals, and pharmaceutical companies devote significant time and resources to developing a vaccine that could teach the immune system not to react to and attack beta cells (the cells in the pancreas that produce insulin), thus preventing the onset of Type 1 diabetes. In fact, a trial at a Massachusetts General Hospital lab is aimed not only at preventing Type 1 diabetes, but also reversing it in patients who have had the disease for under 5 years. *See* Andrew Curry, *Pathways to a Type 1 Vaccine*, Diabetes Forecast (July 2016), http://www.diabetesforecast.org/2016/jul-aug/vaccines.html. Congress recognized the importance of prevention and adherence in the Affordable Care Act by establishing Diabetes Prevention Programs that offer lifestyle interventions for individuals at risk for diabetes, providing grants to states for prevention activity initiatives, and requiring the U.S. Department of Health and Human

Services to prepare a biannual diabetes report card that assesses quality of care indicators, including adherence, in each state.[3]

28. Many potentially first-in-class medicines may reach the market in the next few years. Sanofi and Lexicon are developing sotagliflozin, a SGLT-1/SGLT-2 dual inhibitor, which has shown promising Phase 2 and 3 results in Type 1 diabetes. The drug advanced into Phase 3 trials for Type 2 diabetes in March 2017. Merck and Pfizer are developing ertugliflozin, an SGLT-2 inhibitor. Novo Nordisk is developing semaglutide, a GLP-1 receptor agonist, in a once-weekly, injected formulation and a once-daily oral formulation that are both active in lowering glucose and improving weight loss for Type 2 diabetes patients. And researchers at the University of North Carolina are working on developing glucose-responsive "smart" insulin, which is an injection that releases insulin only when glucose levels are too high. *See* John B. Buse & Mark Harmel, *New Diabetes Drugs in Development*, Medscape (Mar. 10, 2017), www.medscape.com/viewarticle/876853.

29. Meanwhile, costly and labor-intensive research continues to lay the groundwork for the next generation of treatments. Researchers at the Harvard Stem Cell Institute discovered a hormone that can stimulate insulin-secreting pancreatic cells to reproduce at up to 30 times the normal rate in mice. *See* Harvard Stem Cell Inst., *From Stem Cells to Billions of Human Insulin-Producing Cells* (Oct. 9, 2014), https://hsci.harvard.edu/news/stem-cells-billions-human-insulin-producing-cells. Recreating this effect in diabetes patients could lead to the body's natural regulation of insulin as the new cells produce insulin only as needed. *Id.*

30. The cost of developing these innovative diabetes medicines is staggering. On average, a manufacturer spends between 10 and 15 years—and $2.6 billion—developing a new medicine. Developing diabetes medicines is particularly costly, as all new medicines must comply

[3] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 4108, 4202, 10407, 10501, 124 Stat. 119 (2010); Nat'l Conference of State Legislatures, *Federal Health Reform Provisions Related to Diabetes* (May 2011), http://www.ncsl.org/portals/1/documents/health/DiabetesinHR511.pdf; Ctr. for Disease Control & Prevention, *Diabetes 2014 Report Card* (2014), https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2014.pdf.

with FDA's 2008 guidance requiring new diabetes medicines to undergo costly testing on cardiovascular risk that other new medicines need not undergo. These costs are all the more daunting given the very small success rate. Between 1988 and 2014, on average only 12% of drug candidates that entered clinical testing were approved for use. From May 27 to December 29, 2016, ten different advanced drug candidates for FDA approval in different drug product areas experienced setbacks ranging from manufacturing issues, FDA requirements to conduct new trials, failing Phase II or Phase III trials altogether, and patient deaths during trial. *See* Lisa M. Jarvis, *The Year in New Drugs*, Chem. & Eng'g News (Jan. 30, 2017), http://cen.acs.org/content/cen/articles/95/i5/year-new-drugs.html.

31. Even when a product reaches the market, there is no guarantee that the manufacturer will earn back the cost of research and development. In 2015, for example, FDA approved Afrezza, the only available inhalable insulin, manufactured by Sanofi in partnership with another pharmaceutical company. Press Release, Sanofi and MannKind Announce Afrezza®, the Only Inhaled Insulin, Now Available in the U.S., Sanofi (Feb. 3, 2015), en.sanofi.com/images/38264_20150203_Afrezza_en.pdf. However, Afrezza appealed only to a small segment of the market and suffered from lackluster sales. Ed Silverman, *Breathe Deeply: Sanofi Will No Longer Market Afrezza Inhaled Insulin*, Stat (Jan. 6, 2016), https://www.statnews.com/pharmalot/2016/01/05/insulin-sanofi-diabetes/. It is unlikely that Afrezza will ever generate enough revenue to cover the cost of its development.

32. Pharmaceutical manufacturers can invest these billions of dollars each year in research and development only if they have an appropriate opportunity to recoup that investment through the sales of the small fraction of products that ultimately make it to market. Patents are especially important to the biotechnology industry, as they are often the sole or the most valuable asset of a start-up venture. *See* Charles W. Wessner, *Capitalizing on New Needs and New Opportunities: Government-Industry Partnerships in Biotechnology and Information Technologies* 40 (2001), https://www.ncbi.nlm.nih.gov/books/NBK208686/pdf/Bookshelf_NBK208686.pdf.

Overview of Nevada Senate Bill 539

33. Like all states, Nevada over the past 20 years has seen a marked increase in the number of adults living with diabetes. In 1995, the estimated diabetes rate in Nevada was 4.7%. Today, an estimated 12.4% of Nevada's adult population—281,355 people—have diabetes. An additional 787,000 people in Nevada, 38.5% of Nevada's adult population, have pre-diabetes, with abnormally high blood glucose levels, but not at a level warranting a diabetes diagnosis.

34. SB 265, introduced in the Nevada Senate in February 2017, "sought to lower the cost of certain essential diabetes drugs, such as insulin, by requiring companies that manufacture them [to] report the costs of producing and marketing the drug along with any rebates that they provide for the drugs." Megan Messerly, *Sandoval Vetoes Major Pharmaceutical Transparency Legislation Citing Concerns Over "Nascent, Unproven and Disruptive" Changes*, Nev. Indep., (June 2, 2017, 10:12 PM), https://thenevadaindependent.com/article/sandoval-vetoes-major-pharmaceutical-transparency-legislation-citing-concerns-over-nascent-unproven-and-disruptive-changes. SB 539 later incorporated many of SB 265's provisions.

35. As the legislative history of SB 265 shows, the State's primary focus was on controlling the list prices of insulin and other patented diabetes medicines. At the very outset of the first Senate hearing on SB 265, its author cited a putative class action lawsuit charging insulin manufacturers with antitrust violations. *Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 33 (Nev. Mar. 29, 2017) ("Mar. 29 Mins.") (statement of Sen. Yvanna D. Cancela). Proponents repeatedly criticized the prices of patented diabetes drugs as the main target of the bill, complaining that "competition has not led to lower [insulin] prices" and asserting that manufacturers would simply "tweak" insulin "to keep it under patent status, so the patent does not expire and become eligible for generic versions." *Id.* at 36 (statement of Bobette Bond, Exec. Dir., Nev. Healthcare Policy, Unite Here Health); *see also id.* at 58–60 (discussion of patent protection). In reference to the patented diabetes medicines Janumet and Jardiance, one proponent argued that he "should not [have to] depend on [manufacturer] coupons on the Internet to offset the cost of diabetic medications." *Id.* at 45 (statement of Ruben R. Murillo, Nev. State Educ. Ass'n). As another explained, the bill was designed to "hit directly to the root of the problem" of

high diabetes drug prices because "pharma will react accordingly with rebate dollars and trying to unwind what has been done" in order to "meet the terms of what [SB 265] puts out." *Id.* at 37 (testimony of Kevin Hooks, a managed care clinical pharmacist).

36. SB 265 sought to achieve these goals in several ways. First, SB 265 directed the Department to compile a list of prescription drugs "essential" for treating diabetes. SB 265, 2017 Leg., 79th Sess. § 6 (Nev. 2017). It then compelled the manufacturers of those drugs to submit to the Department a report disclosing certain cost and pricing information for each of their essential diabetes drugs. *Id.* § 7(1). SB 265 excluded this cost and pricing information from the definition of "trade secret" under Nevada law, *id.* § 27.5(5), and it required the Department to compile and publish on its website a report concerning the prices of essential diabetes drugs and the effect of those prices on overall spending on health care in Nevada, *id.* § 7(2). SB 265 also required manufacturers to provide the Department with 90 days' notice of any planned increase in the national list price, also known as the wholesale acquisition cost or "WAC," of any essential diabetes drug. *Id.* § 8.

37. On May 16, 2017, a second bill targeting list price increases for diabetes drugs was introduced, SB 539. Originally a "complement" to SB 265, *see Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 3 (Nev. May 26, 2017) ("May 26 Mins."), SB 539 added requirements that "Pharmacy Benefit Managers" (PBMs)—intermediaries between manufacturers and payers—disclose, among other things, the amount of rebates received from manufacturers during the preceding calendar year. *See id.* at 5. The author of SB 539 justified the legislation on the ground that the "retail price [of prescription diabetes medicine] paid by patients is unpredictable and can escalate to unaffordable levels over short periods." *Id.* at 3.

38. On May 19, 2017, the Nevada State Senate passed the first bill, SB 265. On May 25, 2017, the Nevada State Assembly passed SB 265 and sent the bill to the Governor for approval.

39. On June 2, 2017, Nevada Governor Brian Sandoval vetoed SB 265. His explanation acknowledged that SB 265 was "well-intentioned," but concluded that the bill "poses serious risks of unintended and potentially detrimental consequences for Nevada's consumer patients, not the least of which is the possibility that access to critical care will become more expensive, more

restricted, and less equitable." Veto Letter at 2. The bill, he wrote, "could cause more harm than good for Nevada's families." *Id.*

40. Governor Sandoval also concluded that "constitutional and other legal concerns" rendered the bill "problematic." *Id.* at 3. He found the bill vulnerable to "challenge[s] under theories of federal preemption, the Fifth Amendment's prohibition on uncompensated takings, and the Dormant Commerce Clause." *Id.* at 2.

41. On June 5, 2017, just three days after Governor Sandoval vetoed SB 265, both the Nevada Senate and the Nevada State Assembly passed SB 539, which, as amended, included almost all the same provisions as SB 265. With respect to the drug pricing and reporting provisions, the primary exception was the 90-day notice period for increasing the WAC of an essential diabetes drug, to which Governor Sandoval had objected on the ground that it could lead to purchasers stockpiling drugs that they knew would have price increases in 90 days. *See id.*

42. Aside from the lack of the 90-day notice period, SB 539 essentially replicated SB 265. Even though SB 539 did not remedy the constitutional problems that Governor Sandoval had identified, he signed the bill on June 15, 2017.

43. Like SB 265, SB 539 directs the Department to compile, by February 1 of each year, "[a] list of prescription drugs . . . essential for treating diabetes." SB 539 § 3.6(1). The Act does not define "essential," but the list "must include, without limitation, all forms of insulin and biguanides marketed for sale in this State." *Id.*[4]

44. In August 2017, the Nevada State Primary Care Office distributed a draft list of "essential diabetes drugs" with 46 major drug products, including Afrezza, Byetta, Duetact, Farxiga, Humulin, Invokana, Janumet, Januvia, Jardiance, Lantus, Nesina, Novolog, PrandiMet, Trulicity, and others. *See* Exhibit C, Draft List of Essential Diabetes Drugs.

[4] Both insulin and biguanides seek to lower blood glucose levels. Insulin injections replace the insulin that the body would produce naturally in patients with diabetes who do not produce enough insulin. Biguanides, such as metformin, lower blood sugar by decreasing the amount of sugar produced by the liver, increasing the amount of sugar absorbed by muscle cells, and decreasing the body's need for insulin. *See Biguanides (Metformin) for Prediabetes and Type 2 Diabetes*, WebMD, http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes.

45. Once the Department releases its final list of "essential" diabetes drugs, Section 3.8 of the Act requires manufacturers of those drugs to "prepare and submit to the Department," by April 1 of each year, a "report which must include":

- "[t]he costs of producing the drug";
- "marketing and advertising costs" associated with the drug;
- profit "earned from the drug" and "the percentage of the manufacturer's total profit . . . attributable to the drug";
- the amount spent on "patient prescription assistance program[s]";
- "[t]he cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs";
- the "wholesale acquisition cost of the drug," defined as "the manufacturer's list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing date";
- "[a] history of any increases in the wholesale acquisition cost of the drug over the 5 years immediately preceding the date on which the report is submitted, including the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective any explanation for the increase";
- "[t]he aggregate amount of all rebates" in Nevada; and
- "[a]ny additional information prescribed by regulation . . . for the purpose of analyzing the cost of prescription drugs . . . on the list."

Id. § 3.8.

46. Beyond these disclosures, any manufacturer that increases the WAC of an "essential" diabetes drug by more than the "Consumer Price Index, Medical Care Component" ("CPI") during the preceding year, or by double the percentage increase in the CPI for Medical Care over the previous two years, must make additional disclosures pursuant to Section 4 of the Act. These disclosures include:

- "[a] list of each factor that has contributed to the increase";
- "[t]he percentage of the total increase that is attributable to each factor";
- "[a]n explanation of the role of each factor"; and
- "[a]ny other information prescribed by regulation."

Id. §§ 3.6(2), 4.

47. For many manufacturers, the types of information that must be disclosed under Sections 3.8 and 4 are generally factors relevant to pricing decisions for *all* of their pharmaceutical products, not just the essential diabetes medicines they produce.

48. By tying these disclosures to the CPI for Medical Care, the Act penalizes those manufacturers whose diabetes drug prices exceed the index. This penalty is especially harsh, as the CPI for Medical Care includes the list prices of not only pharmaceutical products, but also professional and hospital services. Successful diabetes therapies improve the convenience and efficacy of treatment, which reduces doctor and hospital visits, which, in turn, lowers the costs factored into the CPI for Medical Care. Thus, the more successful a product is at reducing or preventing medical costs, the lower the prices the manufacturer can charge and still avoid the penalty of disclosing its confidential information. While the CPI for Medical Care is a useful benchmark for certain purposes relating to overall health care spending, it is not an appropriate measuring stick for imposing penalties on manufacturers for price increases on drug products.

49. Once manufacturers have submitted the disclosures required by Sections 3.8 and 4, the Department must, by June 1 of each year, "analyze the information submitted . . . and compile a report on the price of the prescription drugs that appear on the most current lists . . . , the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State." *Id.* § 4.3.

50. The Department must post the report on its website, *id.* § 6(a)(5), "organized so that each individual . . . manufacturer . . . has its own separate entry," *id.* § 6(b).

51. Critically, SB 539 does not prevent the Department from publishing the information, sharing it with other entities, or using it for other purposes such as the Department's own rebate negotiations with manufacturers.

52. What is more, SB 539 expressly eliminates trade-secret protection for all information manufacturers must disclose concerning "essential" diabetes drugs. *Id.* § 4.3. Specifically, the Act alters the definition of "trade secret" in NRS 600A.030 to exclude "any information that a

manufacturer is required to report pursuant to section 3.8 or 4 of [the Act], . . . to the extent that such information is required to be disclosed by [that] section[]." *Id.* § 9(5)(b).[5]

53. Any manufacturer that fails to disclose the required information is subject to "an administrative penalty of not more than $5,000 for each day of such failure." *Id.* § 8(2).

54. The provisions of SB 539 relevant to this lawsuit "become effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on October 1, 2017, for all other purposes." *Id.* § 28(3). Thus, while the Department has until February 1, 2018 to publish its first list of "essential" diabetes drugs, it could publish the list as early as October 1, 2017, and, in fact, the Department has represented that it intends to publish the list on October 15, 2017.

SB 539's Harm to Plaintiffs' Members and Innovation of Diabetes Treatments

55. SB 539, if implemented, will seriously harm Plaintiffs' members, including the largest U.S. manufacturers of insulin and other diabetes medicines. Several of Plaintiffs' members produce drugs that appear on the Department's draft list of "essential" diabetes drugs. None of these companies is headquartered in Nevada.

56. For example, Eli Lilly and Company manufactures the diabetes drugs Basaglar (a long-acting insulin), Glyxambi (a combination drug of SGLT-2 inhibitor and DPP-4 inhibitor), Humalog, Humulin, Jardiance (a SGLT-2 inhibitor), Jentadueto (a combination DPP-4 inhibitor with metformin), Synjardy, Tradjenta (a DPP-4 inhibitor), and Trulicity (a glucagon-like peptide). The drugs Glyxambi, Jardiance, Jentadueto, Synjardy, Tradjenta, and Trulicity are patented. Patients administer Humalog and Humalin using a patented device. And the clinical testing for Basalgar and Trulicity is protected by test data exclusivity—*i.e.*, because this information is costly to produce, FDA maintains its confidentiality for a number of years to prevent competitors from benefitting at Lilly's expense. Eli Lilly is headquartered in Indianapolis, Indiana and employs

[5] By contrast, every other state to legislate on pharmaceutical price transparency has acknowledged the trade-secret status of the information to be disclosed, erecting safeguards to prevent its dissemination. *See, e.g.*, Vt. Stat. Ann., tit. 18, § 4635(e); H.B. 631, Gen. Assemb., 437th Sess. § 1, 2-803(F) (Md. 2017).

approximately 12,600 people in Indiana. Indiana law confers trade-secret protection for the confidential information concerning advertising, cost, marketing, pricing, and production that SB 539 requires Eli Lilly to disclose. *See Hydraulic Exch. & Repair, Inc. v. KM Specialty Pumps, Inc.*, 690 N.E.2d 782, 786 (Ind. Ct. App. 1998) (holding that customer and pricing information, including compilations of profits and sales, were trade secrets under Indiana Uniform Trade Secrets Act); *Ackerman v. Kimball Int'l, Inc.*, 634 N.E.2d 778, 783 (Ind. Ct. App. 1994) (affirming trial court conclusion that pricing information was a trade secret).

57. Johnson & Johnson manufactures the diabetes drugs Invokamet (a combination SGLT-2 inhibitor with metformin), Invokamet XR (extended release), and Invokana (an SGLT-2 inhibitor). The drugs Invokamet, Invokamet XR, and Invokana are patented. Johnson & Johnson is headquartered in New Brunswick, New Jersey and employs approximately 9,300 people in New Jersey. New Jersey law confers trade-secret protection for the confidential information that SB 539 requires Johnson & Johnson to disclose. *See Commc'ns Workers of Am. v. Rousseau*, 9 A.3d 1064, 1076 (N.J. Super. Ct. App. Div. 2010) ("A trade secret may also include pricing and marketing techniques."); *Lamorte Burns & Co. v. Walters*, 770 A.2d 1158, 1166 (N.J. 2001) (citing with approval treatise stating that "information relating to customers, merchandising, costs, and pricing may be considered trade secrets" (citing 1 Roger M. Milgrim, *Milgrim on Trade Secrets* § 2.09 (1995))).

58. Merck Sharp & Dohme Corp. manufactures the diabetes drugs Januvia (sitagliptin) (a dipeptidyl peptidase 4 (DPP-4) inhibitor), Janumet (sitagliptin and metformin HCI) and Janumet XR (sitagliptin and metformin HCI extended release). The drugs Januvia, Janumet, and Janumet XR are patented. Merck is headquartered in Kenilworth, New Jersey and employs approximately 5,200 people in New Jersey. As noted, New Jersey law confers trade-secret protection for the confidential information that SB 539 requires Merck to disclose.

59. Novo Nordisk Inc. markets, sells, and distributes the diabetes drugs Levemir (insulin detemir, a long-acting recombinant human insulin analog), Victoza (liraglutide, a long-acting, acylated glucagon-like peptide-1 (GLP-1) analog), Tresiba (insulin degludec, an ultralong-acting basal human insulin analog), Ryzodeg 70/30 (insulin degludec and insulin aspart injection, a

combination of a long-acting basal human insulin analog and a fast-acting human insulin analog), and Xultophy 100/3.6 (insulin degludec and liraglutide injection, a combination of an ultralong-acting basal human insulin analog and a long-acting, acylated glucagon-like peptide-1 (GLP-1) analog). The drugs Levemir, Victoza, Tresiba, Ryzodeg 70/30 and Xultophy 100/3.6 have U.S. patent protection. Novo Nordisk Inc. is headquartered in Plainsboro, New Jersey. As noted, New Jersey law confers trade-secret protection for the confidential information that SB 539 requires Novo Nordisk to disclose.

60. Sanofi U.S. markets, sells, and distributes the diabetes drugs Lantus (insulin glargine, a long acting human insulin analog), Apidra (insulin glulisine, a fast acting, mealtime insulin), Toujeo (insulin glargine, a long acting human insulin analog), Adlyxin (lixisenatide, a GLP-1 receptor agonist) and Soliqua 100/33 (insulin glargine and lixisenatide injection, a combination of long acting insulin and GLP-1). The drugs Lantus, Apidra, Toujeo, Adlyxin and Soliqua 100/33 are patented. Sanofi U.S. is headquartered in Bridgewater, New Jersey and employs approximately 2,500 people in New Jersey. As noted, New Jersey law confers trade-secret protection for the confidential information that SB 539 requires Sanofi to disclose.

61. Section 3.8 of SB 539 requires these manufacturers and other PhRMA and BIO members that manufacture "essential" diabetes medicines to report advertising, cost, marketing, pricing, and production information related to those drugs to the Department. The required disclosures include information that qualifies as trade secret under federal law and the law of every state—including Nevada until SB 539 takes effect.

62. These companies face additional reporting requirements under Section 4 of SB 539 if the list prices for the diabetes drugs they manufacture increased during the prior year by a percentage greater than the CPI for Medical Care, or increased over the last two years by a percentage more than twice the two-year increase for that index. The additional disclosures required under Section 4 of the Act include information that qualifies as a trade secret under federal law and the law of every state—including Nevada until SB 539 takes effect.

63. Plaintiffs' members zealously guard the secrecy and confidentiality of the trade-secret information that SB 539 requires them to disclose. Among other things, Plaintiffs' members

require their employees to sign confidentiality agreements and nondisclosure agreements requiring them to hold this information in confidence. These companies also use a variety of security measures to ensure that such information is kept secret, including video camera monitoring, restricting access to their facilities, limiting computer system access, marking documents that reflect such information as confidential or proprietary, training their employees on the importance of not disclosing such information, adopting policies that prohibit employees from removing such information from company property, and imposing other internal controls.

64. Plaintiffs' members expend significant resources determining how to allocate their resources and set prices for their products. This information would be extremely valuable to competitors, who could use the information to allocate their own resources and set their own prices without expending the same level of resources. As a consequence, the companies that lost trade-secret protection would suffer serious competitive harm. This harm would undermine competition involving non-diabetes products as well, because manufacturers consider similar factors manufacturers in setting prices for non-diabetes products.

65. Similarly, third-party payers who learn how a manufacturer prices its diabetes drugs would gain an advantage over the manufacturer in purchase or rebate negotiations for all of the manufacturer's products.

66. The economic harm from SB 539 will spread to the entire Nation. Because the WAC is a national list price, SB 539's effective cap on a drug's WAC will apply throughout the country. And because drug prices and the way manufacturers set them generally apply nationally, the information disclosed under SB 539 will affect a company's negotiations and competitive positioning nationwide. Similarly, because trade-secret protection is moot in every state once the information becomes public in Nevada, the impact of SB 539 will extend across the Nation.

67. The competitive harm arising from SB 539's punitive and coercive effects will undermine the incentives that trade secret and patent law provides for Plaintiffs' members to invest in developing innovative diabetes medicines. Absent judicial intervention, SB 539 could force innovators into the unfortunate position of having to review and revise their research and development priorities for diabetes products, including projects underway.

SB 539'S CONSTITUTIONAL DEFECTS

The Constitution Vests Congress With Sole Authority To Establish Patent Policy

68. The Framers of the Constitution understood Congress's paramount role in setting national patent policy. Article I vests Congress with the power to "secur[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. The stated objective of this clause is to "promote the Progress of Science and useful Arts." *Id.* As James Madison observed in The Federalist:

> The utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals. The States cannot separately make effectual provisions for either of the cases, and most of them have anticipated the decision of this point, by laws passed at the instance of Congress.

The Federalist No. 43 (James Madison).

69. "From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). The patent laws achieve this balance first by granting an inventor the exclusive right to make, use, and sell its patented invention for a limited period of time. 35 U.S.C. § 154. Then, once the exclusivity period expires, others may enter the market and compete with the patent holder, driving down the cost of the patented product and, in turn, stimulating further innovation in the search for greater returns. Critically here, Congress has long recognized that "the right to exclude others from making, using, or selling an invention . . . enable[s] innovators to obtain greater profits than could have been obtained if direct competition existed," and that "[t]hese profits act as incentives for innovative activities." H.R. Rep. No. 98-857(I), at 17 (June 21, 1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 (Committee on Energy and Commerce).

70. During the exclusivity period, a patent holder may set the price for its product in a manner that takes into account the patent holder's ability to preclude others from marketing an infringing product. The United States Court of Appeals for the Federal Circuit has described the

increased return on innovation investment due to the patent holder's legal monopoly as the "carrot" that incentivizes would-be inventors to expend the substantial resources and to take the significant research and development risks required to invent a new product. *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). As the Federal Circuit has noted, "the only limitation on the size of the carrot should be the dictates of the marketplace." *Id.*

71. Patent protection is particularly necessary to promote the research and development of pharmaceutical products because it is extraordinarily difficult, costly, and rare to discover a successful new drug. By one estimate focusing on the most prolific developers of new drugs, "95% of the experimental medicines that are studied in humans fail to be both effective and safe. . . . [B]ecause so many drugs fail, large pharmaceutical companies . . . spend $5 billion per new medicine." Matthew Herper, *The Cost of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change*, Forbes.com (Aug. 11, 2013, 11:10 AM), http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine. Even drugs that are ultimately approved cost billions of dollars to research and develop. *See* Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, Chem. & Eng'g News (Nov. 20, 2014), http://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html (study found that "developing a prescription drug that gains market approval [costs] $2.6 billion, a 145% increase" from 2003).

72. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585 (1984). In light of the unique economic challenges to pharmaceutical research and development, the Hatch-Waxman Act extended the patent term for pharmaceuticals to "create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18; *see also Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1373 (Fed. Cir. 2007). President Reagan reiterated this goal when he signed the bill into law: "The bill will promote medical breakthroughs and drug innovation by granting drug companies up to 5 more years of patent protection for new drugs. And

this extension will help compensate for the years of patent life lost due to the time-consuming, but essential, testing required by the Food and Drug Administration." Presidential Statement on Signing S. 1538 Into Law, 20 Weekly Comp. Pres. Doc. 1359 (Sept. 24, 1984).

73. Balancing consumer access to affordable medication against the critical need for sufficient economic incentives to invest in innovation, the Hatch-Waxman Act allows other manufacturers to sell generic versions of an innovator's drug after the period of patent exclusivity expires. This carefully crafted framework provides substantial incentives for innovators to invest in research and development of new life-saving and life-enhancing treatments that will benefit patients while also "'get[ting] generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Lab., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

74. Congress, moreover, has bestowed patent protection on "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. Thus, the federal patent system, including the Hatch-Waxman Act, encourages not only the discovery of new pharmacological compounds, but also new methods of manufacturing or improving the effectiveness of existing drugs.

75. Under the Supremacy Clause of the United States Constitution, federal statutes are "the supreme Law of the Land." U.S. Const. art. IV, cl. 2. And under settled principles of federal "conflict" preemption, no state law may "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

76. State laws penalizing patent holders for exercising the right to set prices that the patent affords and coercing them to forgo those rights "stand as an obstacle to the federal patent law's balance of objectives as established by Congress" and thus are invalid under the Supremacy Clause. *BIO*, 496 F.3d at 1374. In *BIO*, the Federal Circuit struck down a District of Columbia statute that prohibited pharmaceutical manufacturers from selling or supplying a "patented prescription drug that results in the prescription drug being sold in the District for an excessive price." *Id.* at 1365. The court held that the statute was a "clear attempt to restrain . . . excessive

[drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers." *Id.* at 1374. Because Congress—and Congress alone—is the "promulgator of patent policy," federal law preempted the District's attempt to "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1373–74.

77. Just like the District of Columbia statute invalidated in *BIO*, SB 539 "attempt[s] to restrain . . . excessive [essential diabetes drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to [Nevada] drug consumers." *Id.* at 1374. In purpose and effect, the Act punishes manufacturers for the price of their "essential" diabetes drugs as well as for list price increases by more than the "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." SB 539 §§ 3.6(2), 4. If an essential diabetes drug's list price increases by more than these benchmarks, then the Act compels the manufacturer to report to the Department additional confidential, competitively sensitive, proprietary information about that price increase, including a list of "factors" that contributed to the increase and an "explanation" of the role of each factor. *Id.* § 4. The Act also strips trade-secret protection for that information. *Id.* § 9. The only way a manufacturer can avoid forfeiting trade-secret protection for the "factors" of a price increase is by limiting its list prices to the Act's effective cap. SB 539 thus restrains patent holders from setting list prices in a manner that the federal patent laws secure in order to incentivize innovation.

78. Further, the Act impermissibly burdens the federal patent rights of diabetes drug manufacturers by requiring disclosure of trade secrets associated with these patented products—and hence it eliminates trade-secret protection in retaliation for pricing diabetes drugs as the patent laws specifically allow. *See BIO*, 496 F.3d at 1374 (holding invalid District of Columbia law that had the effect of "diminishing the reward" federal law grants to patentees). The mandatory disclosures chill the exercise of patent rights by penalizing past exercises and forcing manufacturers either to charge less than the patent laws permit or to furnish their proprietary information to third-party payers and competitors and thereby suffer significant economic loss.

79. As a result of SB 539, innovators cannot raise list prices without being stripped of valuable trade-secret protection for their confidential, proprietary information. SB 539 thus interferes with the objectives of the patent laws by undermining, if not defeating altogether, affected manufacturers' ability to recover the enormous up-front costs to research and develop diabetes medicines.

80. The Act's burdens on federal patent rights will discourage research and development of new diabetes drugs—a chilling of innovation itself. *See, e.g.*, *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1351–53 (Fed. Cir. 2014) (Newman, J., dissenting) (quoting *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757 (2014)) (burdening patentees who file infringement claims with threat of antitrust liability chills innovation); *In re Microsoft Corp. Antitrust Litig.*, 274 F. Supp. 2d 743, 745 (D. Md. 2003) (finding that "to require one company to provide its intellectual property to a competitor would significantly chill innovation").

81. The Nevada Legislature jettisoned concerns that "transparency in prescription drug pricing will stifle innovation." Mar. 29 Mins. at 34. They chose to elevate other, insular considerations over the law's interference with federal innovation incentives. But whether the Nevada Legislature's judgment is right or wrong is beside the point. The policy choice of whether the benefits of innovation in the treatment of diabetes justify the prices of existing drugs is reserved exclusively to the United States Congress, not to the State of Nevada. *See BIO*, 496 F.3d at 1374; H.R. Rep. 98-857(I), at 17–18. Congress exercised that choice through the patent laws. Nevada cannot unilaterally displace it.

SB 539 Conflicts with Federal Trade-Secret Law

82. Federal and state trade-secret laws play a similarly important role in fueling the American economy. Legal protection for trade secrets "encourage[s] invention in areas where patent law does not reach, and . . . prompt[s] the independent innovator to proceed with the discovery and exploitation of his invention." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 485 (1974). "Competition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention." *Id.*

83. Every state in the nation protects trade secrets. Initially, the common law provided safeguards "for the advantage of the public, to encourage and protect invention and commercial enterprise." *Peabody v. Norfolk*, 98 Mass. 452, 457 (1868). "Traditionally defined as relating to technical matters in the production of goods, trade secrets now encompass non-technical aspects of a business including, customer lists, price codes economic studies, costs reports, customer tracking and marketing strategies." *First Mfg. Co. v. Young*, 3 N.Y.S.3d 284, at *3 (Sup. Ct. 2014).

84. In evaluating whether information is a trade secret under the common law, courts consider, among other things, "[1] the extent of measures taken by the employer to guard the secrecy of the information; [2] the value of the information to the employer and to his competitors; [3] the amount of effort or money expended by the employer in developing the information; and [4] the ease or difficulty with which the information could be properly acquired or duplicated by others." *Jet Spray Cooler, Inc. v. Crampton*, 385 N.E.2d 1349, 1355 n.9 (Mass. 1979) (citation omitted); *Frantz v. Johnson*, 999 P.2d 351, 358–59 (Nev. 2000) ("Factors to be considered include: (1) the extent to which the information is known outside of the business and the ease or difficulty with which the acquired information could be properly acquired by others; (2) whether the information was confidential or secret; (3) the extent and manner in which the [company] guarded the secrecy of the information; and (4) . . . whether this information is known by the [company's] competitors.").

85. Forty-eight states, including Nevada, have adopted, with slight variations in some states, the Uniform Trade Secrets Act ("UTSA"), which "codifie[d] the common law elements of misappropriation of confidential information." *Frantz*, 999 P.2d at 357–58. The UTSA defines a "trade secret" as:

> [I]nformation, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

UTSA, § 1(4).

86. Courts in UTSA jurisdictions routinely hold that confidential information concerning advertising, cost, marketing, pricing, and production constitutes a trade secret. *See, e.g.*, *Finkel v. Cashman Prof'l, Inc.*, 270 P.3d 1259, 1263 (Nev. 2012) (holding that "confidential pricing structures and marketing plans" were trade secrets); *Frantz*, 999 P.2d at 359 (holding pricing information was trade secret because "its secrecy was guarded, and it was not readily available to others because the plastic gaming card industry is highly specialized"); *Aerodynamics Inc. v. Ceasars Entm't Operating Co.*, No. 2:15-CV-01344, 2015 WL 5679843, at *8 (D. Nev. Sept. 24, 2015) (a company's "confidential pricing information, . . . marketing strategies, . . . exact pricing for [certain] bid[s], payment terms, and credits and discounts provided" are trade secrets); *accord In re Dana Corp.*, 574 F.3d 129, 152 (2d Cir. 2009) (recognizing that under New York law, "[c]onfidential proprietary data relating to pricing, costs, systems, and methods are protected by trade secret law"); *S.I. Handling Sys., Inc. v. Heisley*, 753 F.2d 1244, 1260 (3d Cir.1985) (same under Pennsylvania law); *Burbank Grease Servs., LLC v. Sokolowski*, 693 N.W.2d 89, 96 (Wis. App. 2005) ("Generally, it appears that when prices are based on complicated or unique formulas that the customers do not know about, courts conclude the information meets the standard embodied in [the UTSA]."), *aff'd in part, rev'd in part*, 717 N.W.2d 781 (Wis. 2006); *Whyte v. Schlage Lock Co.*, 101 Cal. App. 4th 1443, 1455 (2002) ("[P]ricing, profit margins, costs of production, pricing concessions, promotional discounts, advertising allowances, volume rebates, marketing concessions, payment terms and rebate incentives" have independent economic value as trade secrets).

87. In 2016, Congress enacted the Defend Trade Secrets Act ("DTSA"), creating for the first time a federal private right of action for misappropriation of trade secrets "related to a product or service used in, or intended for use in, interstate or foreign commerce." Pub. L. No. 114-153, 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)).

88. Congress enacted the DTSA because "trade secrets are increasingly becoming the foundation of businesses across the country, with one estimate placing the value of trade secrets in the United States at $5 trillion. . . . With so much at stake, it is absolutely vital . . . [to] include strong protections against theft of trade secrets." 162 Cong. Rec. H2028-01, H2033 (Apr. 27, 2016)

(comments of Rep. Nadler). "By improving trade secret protection," Congress intended the DTSA to "incentivize future innovation while protecting and encouraging the creation of American jobs." S. Rep. No. 114-220, at 3 (2016).

89. Although every state protects confidential and proprietary advertising, cost, marketing, pricing, and production information, Congress intended the DTSA to provide businesses engaged in interstate commerce with a uniform remedy for misappropriation. Congress expressed concerns that "state laws vary in a number of ways and contain built-in limitations that make them not wholly effective in a national and global economy." H.R. Rep. No. 114-529, at 4 (Apr. 26, 2016) (Committee on the Judiciary). Congress acknowledged that "trade secret cases often require swift action by courts across state lines to preserve evidence." *Id.* "[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist." 162 Cong. Rec. H2034 (comments of Rep. Jackson Lee). Thus, the DTSA allows businesses "to move quickly to Federal court . . . to stop trade secrets from winding up being disseminated and losing their value." H.R. Rep. No. 114-529, at 6; *accord* S. Rep. No. 114-220, at 3. The primary goal was to create "remedies that, first, halt the misappropriator's use and dissemination of the . . . trade secret." H.R. Rep. No. 114-529, at 13.

90. Congress likewise modeled the DTSA definition of "trade secret" on the UTSA, as did Nevada—that is, until SB 539. *Compare* UTSA § 1, *with* 18 U.S.C. § 1839(4), *and* Nev. Rev. Stat. § 600A.030(5) (1999); *see also* H.R. Rep. 114-529, at 14 ("[T]he Committee does not intend for the definition of a trade secret to be meaningfully different from the scope of that definition as understood by courts in States that have adopted the UTSA."). Reflecting Congress's intention to provide a uniform remedy, the DTSA makes information related to advertising, cost, marketing, pricing, and production a protectable trade secret, just as it is in UTSA jurisdictions. *See supra*, ¶ 86.

91. SB 539 compels manufacturers to disclose to the Department confidential and proprietary advertising, cost, marketing, pricing, and production information that derives independent value from not being generally known to third parties and competitors. This valuable

information constitutes a trade secret under the DTSA—and also under Nevada law until SB 539 takes effect.

92. Further, the Act amends Nevada's trade-secret statute expressly to eliminate trade-secret protection for all information "that a manufacturer is required to report" to the Department. SB 539 § 9. Thus, the manufacturer loses trade-secret protection the moment the Department issues its annual list of "essential" diabetes drugs, even before the manufacturer actually turns the information over to the State.

93. Furthermore, the Act places no restriction on how the Department may use or disseminate the information disclosed. To the contrary, SB 539 affirmatively requires the Department to publish a report on its website that identifies the information belonging to each manufacturer. *Id.* § 6(a)(5), (b). Once published on the Internet or otherwise publicly disseminated under the authority of SB 539, the information no longer constitutes a trade secret under either the UTSA or the DTSA. *See, e.g.*, 18 U.S.C. § 1839. As a practical matter, even if there were some residual trade-secret protection from the laws of other states, it would be ineffective once the previously protected information is in the public domain for all to see.

94. The destruction of trade-secret protection in Nevada will thwart the ability of manufacturers subject to the Act's disclosure requirements to sue for misappropriation in any jurisdiction, including in federal court under the DTSA.

95. In effect, SB 539 alters the operation of the DTSA—and the laws of every other jurisdiction in the nation—to eliminate trade-secret protection for confidential advertising, cost, marketing, pricing, and production information associated with diabetes drugs. This, in turn, undercuts both of Congress's goals in enacting the DTSA—to "incentivize future innovation while protecting and encouraging the creation of American jobs." S. Rep. No. 114-220, at 3.

96. Thus, SB 539 "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. Indeed, the Act jeopardizes the $5 trillion worth of trade secrets that Congress enacted the DTSA to protect.

SB 539's Uncompensated Elimination of Trade-Secret Protection for Valuable Information Violates the Fifth Amendment Takings Clause

97. The Fifth Amendment provides that "private property [shall not] be taken for public use, without just compensation." U.S. Const. amend. V. This proscription applies to the states through the Fourteenth Amendment.

98. Government regulation of private property can constitute a taking. *See Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992). "Private property" includes not only tangible property, but also intangible property, such as trade secrets. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984). A state's "failure to provide adequate protection to assure [a trade secret's] confidentiality, when disclosure is compelled . . . , can amount to an unconstitutional taking of property by destroying [the trade secret], or by exposing it to the risk of destruction by public disclosure or by disclosure to competitors." *St. Michael's Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981) (alteration omitted) (quoting *Wearly v. FTC*, 462 F. Supp. 589, 598 (D.N.J. 1978)).

99. There are two kinds of regulatory takings: (1) categorical and (2) noncategorical. *See Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005). A categorical taking occurs where a state statute "denies all economically beneficial or productive use" of property. *Lucas*, 505 U.S. at 1015. By contrast, a noncategorical taking may occur where a regulation "fall[s] short of eliminating *all* economically beneficial use," *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001), yet still goes "too far" for purposes of the Fifth Amendment, *Lucas*, 505 U.S. at 1014–15 (quoting *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)). To determine whether a noncategorical regulatory taking goes "too far," courts apply the three-part test articulated in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978), and its progeny. That test assesses: "[1] the character of the governmental action, [2] its economic impact, and [3] its interference with reasonable investment-backed expectations." *Ruckelshaus*, 467 U.S. at 1005.

100. SB 539 works as a categorical taking of property rights. "With respect to a trade secret, the right to exclude others is central to the very definition of the property interest." *Id.* at 1011. SB 539 does not merely "expos[e] [manufacturers' trade secrets] to the *risk* of destruction by

public disclosure or by disclosure to competitors." *St. Michael's*, 643 F.2d at 1374 (emphasis added). Rather, the Act strips trade-secret protection and *mandates* public disclosure of manufacturers' confidential advertising, cost, marketing, pricing, and production information on the Department's website, *see* SB 539 §§ 6(a)(5), 9, thus destroying for all time any trade-secret protection for the information disclosed. The normal operation of the Act ensures that manufacturers lose any claim of confidentiality, the *sine qua non* of what makes a trade secret valuable. *See Ruckelshaus*, 467 U.S. at 1011–12; *see also* 162 Cong. Rec. H2034 ("[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist." (comments of Rep. Jackson Lee in support of DTSA)).

101. In the alternative, even if SB 539 did not work a categorical taking by destroying manufacturers' property interests in their trade secrets, the Act would still constitute an impermissible regulatory taking under the three-part test articulated in *Penn Central*.

102. First, the "character" of Nevada's legislative action weighs heavily against sustaining the Act. It prevents pharmaceutical manufacturers from "exclud[ing] others from their trade secrets," causing the trade secrets to "lose all value." *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir. 2002) (en banc) (citing this aspect of state disclosure statute's "character" to show a regulatory taking). "Therefore, if the [pharmaceutical manufacturers] comply with the requirements of [SB 539], their property right will be extinguished." *Id.* at 42. "[T]his is precisely what the Takings Clause is designed to prevent." *Id.* at 43.

103. Second, eliminating trade-secret protection for confidential advertising, cost, marketing, pricing, and production information relating to diabetes drugs will have a devastating "economic impact" not only on manufacturers subject to the disclosure requirements, but also on the market for diabetes drugs. *See Penn Cent.*, 438 U.S. at 124. Manufacturers forced to disclose such information will be at a severe disadvantage against competing diabetes-drug manufacturers not subject to the Act. These competitors will be able to obtain the information that Sections 3.8 and 4 of the Act require to be disclosed, and will gain a competitive advantage by knowing how the manufacturer allocates its resources and sets its prices. Because manufacturers consider similar factors in setting prices for non-diabetes products, disclosure of pricing information under SB 539

will also impair the ability of the affected manufacturers to compete with regard to non-diabetes products. Similarly, the Act disadvantages affected manufacturers in their dealings with third-party payers, who will be able to use the manufacturer's pricing information against it in negotiations.

104. These adverse effects are not confined to Nevada, but rather will be nationwide. A trade secret published in Nevada may be used in New York, Ohio, Florida, or any other state, as a trade secret must in fact be "secret" to be protected. *See, e.g.*, UTSA § 1(4) (restricting definition of "trade secret" to information "not . . . generally known" or "readily ascertainable by proper means"); 18 U.S.C. § 1839(3) (same). Thus, losing trade-secret protection anywhere means losing it everywhere. This substantial competitive harm increases the penalty for Plaintiffs' members who exercise their patent rights to set prices on their diabetes products, thereby diminishing the incentive to invest in the development of diabetes drugs. *See supra* ¶¶ 77–81.

105. Third, manufacturers investing in diabetes treatments had the reasonable "investment-backed expectation" that their confidential and proprietary information would remain secret. *See Penn Cent.*, 438 U.S. at 124. For many years Nevada has treated confidential advertising, cost, marketing, pricing, and production information as entitled to trade-secret protection without any exception for manufacturers of diabetes drugs, as has virtually every other state. *See, e.g.*, Nev. Rev. Stat § 600A.030 (1987); *Finkel*, 270 P.3d at 1263; *Frantz*, 999 P.2d at 359. Manufacturers thus had reasonable investment-backed expectations in the secrecy of this information, because of longstanding trade-secret protection and because no state has ever required such intrusive disclosures. *See Reilly*, 312 F.3d at 40. Manufacturers did not expect and could not reasonably have expected the economic impact detailed above, or the erosion of the anticipated returns on their investments in researching, developing, and marketing their diabetes drugs, in reliance on the protection of their valuable trade secrets.

106. Thus, under any Takings analysis, SB 539's disclosure requirements destroy valuable trade secrets related to diabetes drugs without any compensation, let alone just compensation, in violation of the Takings Clause. U.S. Const. amends. V, XIV.

SB 539 Violates the Commerce Clause by Overriding the Laws of Every Other State

107. The Constitution grants Congress the power "[t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause "reflect[s] a central concern of the Framers . . . : the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation." *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979).

108. Thus, the Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This is the "so-called 'dormant' aspect of the Commerce Clause." *Id.*

109. When a state "directly regulates" interstate commerce, the Supreme Court has "generally struck down the statute without further inquiry." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see also Edgar v. MITE Corp.*, 457 U.S. 624, 640 (1982) ("The Commerce Clause, however, permits only *incidental* regulation of interstate commerce by the States; direct regulation is prohibited."). By contrast, when a state law directly regulates only *intra*state commerce, the regulation will not survive scrutiny if "the burden imposed on [*inter*state] commerce is clearly excessive in relation to the putative local benefits" of the statute. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

110. SB 539 imposes a burden on interstate commerce that "is clearly excessive in relation to [its] putative local benefits." *Id*. The Act strips trade-secret protection for broad categories of proprietary information belonging to "essential" diabetes drug manufacturers, *none* of whom is headquartered in Nevada. By doing so, the Act directly negates the trade-secret laws of every other state and the federal government. The extraterritorial effects of SB 539 are substantial and unavoidable because the market for diabetes drugs—especially "essential" diabetes drugs—is inherently national. *See Nat'l Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir. 2012) ("[S]ignificant burdens on interstate commerce generally result from inconsistent regulation of activities that are inherently national or require a uniform system of regulation."). SB

539 will prevent manufacturers from protecting and enforcing their trade secrets in every state. This in turn will impose significant burdens on other states that host a substantial part of these manufacturers' operations. Those jurisdictions have a legitimate interest in promoting the economic success of these manufacturers by protecting their trade secrets. *See Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336–37 (1989); *Rocky Mtn. Farmers Union v. Corey*, 730 F.3d 1070, 1101 (9th Cir. 2013).

111. Take, for example, Eli Lilly—one of the major manufacturers of diabetes drugs. Eli Lilly is headquartered in Indianapolis, Indiana. It has *no* offices or operations in Nevada. The State of Indiana and the other states where Eli Lilly has operations protect Eli Lilly's trade secrets—including its pricing and cost information for essential diabetes drugs. *See, e.g.*, *Hydraulic Exch. & Repair*, 690 N.E.2d at 786. These states have an interest in protecting Eli Lilly's trade secrets in order to promote the company's growth, which creates local jobs and fuels the local economy. SB 539, however, overthrows the protection these other states provide by compelling Eli Lilly to disclose the information that the other states protect as trade secrets. By enacting SB 539, Nevada legislators have told legislators in every other state that Nevada knows best, and its decision controls, when balancing the interest in protecting trade secrets against the interest in price transparency. The dormant Commerce Clause does not tolerate such efforts by one state to impose its preferred regulation on every other state.

112. Furthermore, because WAC is a national list price, SB 539's effective cap on a drug's WAC will apply throughout the country, including to drugs that are bought and sold outside of Nevada. A manufacturer of essential diabetes drugs based in New York selling to a purchaser in California will not be able to raise list prices without having the state of *Nevada* stripping the New York manufacturer of its valuable trade secrets.

113. These substantial effects on interstate commerce will clearly exceed any putative local benefit to the residents of Nevada. While the purpose of the Act is apparently to control prices for diabetes drugs, neither the Act nor its legislative history explain how transparency will lower prices apart from impermissibly burdening manufacturers' lawful exercise of federal patent rights. The Act is precisely the kind of attempt by a state to "extend [its] police power beyond its

jurisdictional bounds" that offends the dormant Commerce Clause. *C & A Carbone*, 511 U.S. at 393.

114. In fact, SB 539's publication of competitively sensitive price and cost information may lead to unintended anticompetitive effects that prevent drug prices from falling as quickly as they would have without the Act. "Too much transparency can harm competition in any market, including in health care markets. . . . [W]hen information disclosures allow competitors to figure out what their rivals are charging, [it] dampens each competitor's incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices." Tara Isa Koslov & Elizabeth Jex, *Price Transparency or TMI?*, Fed. Trade Comm'n (July 2, 2015, 2:31 PM), https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi. The Congressional Budget Office has found that compelled disclosure of drug pricing information, specifically rebates, "could set in place conditions for tacit collusion, as manufacturers would find it more difficult to set prices below their competitors' without detection." Cong. Budget Office, *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals* 6 (June 5, 2008), https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf.

115. The Federal Trade Commission has also explained, "If, for example, pharmaceutical manufacturers know the precise details of rebate arrangements offered by their competitors, then tacit collusion among them may be more feasible. Absent such knowledge, manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment may yield increased sales. Unprotected disclosures thus may raise the price that . . . consumers pay for pharmaceutical coverage by undermining competition among pharmaceutical companies for preferred formulary treatment." Letter from James Cooper, Pauline M. Ippolito, & David P. Wales of the Fed. Trade Comm'n to Hon. James L. Seward (Mar. 31, 2009), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.

116. In sum, the Act excessively burdens interstate commerce without a commensurate local benefit. The Constitution entrusts national economic policy to Congress precisely to avoid such outcomes. U.S. Const. art. I, § 8, cl. 3.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 539 Is Preempted By Federal Patent Law In Violation Of The Supremacy Clause Of The U.S. Constitution)

117. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

118. Under the Supremacy Clause of the United States Constitution, federal statutes are "the supreme Law of the Land." U.S. Const. art. IV, cl. 2. No state law may "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67.

119. The federal patent laws embody "a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats*, 489 U.S. at 146. Federal patent laws, including the Hatch-Waxman Act, grant an inventor the exclusive right to make, use, and sell his patented invention for a limited period of time. During this exclusivity period, a patent holder may set the price for its product in a manner that takes into account the patent holder's ability to preclude others from marketing an infringing product. *See BIO*, 496 F.3d at 1373–74. This protection extends to "[whom]ever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. By this means, the federal patent system, including the Hatch-Waxman Act, encourages not only the discovery of new pharmacological compounds, but also new methods of manufacturing or improving the effectiveness of drugs already discovered.

120. Federal patent law preempts SB 539 because the Act stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the federal law. The Act impermissibly burdens the federal patent rights of diabetes drug manufacturers by requiring the

disclosure of trade secrets associated with these patented products if manufacturers raise the list prices of those patented drugs.

121. Accordingly, the Act constitutes an impermissible and "clear attempt to restrain . . . excessive [drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to [Nevada] drug consumers." *BIO*, 496 F.3d at 1374.

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – SB 539 Is Preempted By Federal Trade-Secret Law In Violation Of The Supremacy Clause Of The U.S. Constitution)

122. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

123. SB 539 violates the Supremacy Clause for the independent reason that eliminating trade-secret protection for the information disclosed by manufacturers stands as an obstacle to the accomplishment and execution of the full purposes and objectives of, and is therefore preempted by, the federal Defend Trade Secrets Act of 2016.

124. SB 539 compels manufacturers to disclose to the Department confidential and proprietary advertising, cost, marketing, pricing, and production information that derives independent value from not being generally known to third-party payers and competitors. These categories of information are "trade secrets" under the DTSA. SB 539, however, removes trade-secret protection from these categories of information by requiring their disclosure and by amending Nevada's trade-secret statute expressly to eliminate trade-secret protection for all information "that a manufacturer is required to report." SB 539 § 9. These provisions stand as an obstacle to the purposes and objectives of the DTSA.

125. Although the DTSA provides that it "shall not be construed to preempt or displace any other remedies . . . provided by . . . [s]tate . . . law for the misappropriation of a trade secret," 18 U.S.C. § 1838, that provision has no applicability here. SB 539 does not merely provide a *different* remedy for the misappropriation that must be disclosed. Rather, SB 539 *eliminates all remedies*, not only in Nevada, but throughout the Nation. Thus, the rule of construction set forth in Section 1838 does not save SB 539 from federal preemption.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The Act Works A Taking Without Just Compensation In Violation Of The Fifth And Fourteenth Amendments To The U.S. Constitution)

126. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

127. The Fifth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, provides that "private property [shall not] be taken for public use, without just compensation."

128. SB 539 constitutes a categorical taking of Plaintiffs' members' intellectual property rights because it guarantees public disclosure of their trade secrets, which in turn negates the value of those trade secrets.

129. Alternatively, the Act works a regulatory taking under the three-part test set out in *Penn Central*. First, SB 539 has the "character" of a total interference with manufacturers' property rights in their trade secrets. *Penn Cent.*, 438 U.S. at 124–25. Second, eliminating all trade-secret protection for the confidential advertising, cost, marketing, pricing, and production information for diabetes drugs will have a devastating "economic impact" not only on manufacturers subject to the disclosure requirements, but also on the market for diabetes drugs. *Id.* at 124. Third, manufacturers invest in diabetes treatments with the reasonable "investment-backed expectation" that their confidential and proprietary information will remain a secret. *Id.* at 124, 127.

130. Thus, SB 539's disclosure requirements destroy valuable trade secrets related to diabetes drugs without any compensation, let alone just compensation, in violation of the Takings Clause. U.S. Const. amends. V, XIV.

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The Act Imposes An Excessive Burden On Interstate Commerce In Violation Of The Commerce Clause Of The U.S. Constitution)

131. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

132. The Constitution grants Congress the power "[t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause places an implicit restraint, known as the dormant Commerce Clause, on state laws that are inimical to national commerce.

133. SB 539 violates the dormant Commerce Clause because the burden it imposes on interstate commerce is clearly excessive in relation to any putative local benefits. Because WAC is a national list price, SB 539's effects will be felt throughout the country. SB 539 also will prevent manufacturers from protecting and enforcing their trade secrets in every state. These other jurisdictions, especially those in which manufacturers reside, have a legitimate interest in promoting the economic success of manufacturers. These substantial effects on interstate commerce clearly exceed any putative local benefit to the residents of Nevada. While the purpose of the Act is to control prices for diabetes drugs, neither the Act nor its legislative history explain how transparency will lower prices apart from impermissibly burdening manufacturers' lawful exercise of federal patent rights. The Constitution entrusts national economic policy to Congress precisely to avoid such outcomes. U.S. Const. art. I, § 8, cl. 3.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiffs request a judgment in their favor against Defendants as follows:

1. A declaration that Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of SB 539 are unconstitutional and void;
2. A preliminary and permanent injunction preventing Defendants from implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of SB 539;
3. That Plaintiffs be awarded attorneys' fees and costs, plus interest accruing thereon, in their favor at the maximum rate allowed by law; and

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4. That the Court award such other and further relief as it may deem appropriate.

DATED this 1st day of September, 2017.

Respectfully submitted,

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EXHIBIT A – SB 539

EXHIBIT A – SB 539

EMERGENCY REQUEST of Senate Minority Leader

Senate Bill No. 539–Senators Roberson, Gansert; Atkinson, Cancela, Cannizzaro, Denis, Farley, Ford, Goicoechea, Harris, Manendo, Parks, Ratti, Segerblom, Settelmeyer, Spearman and Woodhouse

CHAPTER.....

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

Legislative Counsel's Digest:

Existing law requires the organization with the largest membership in this State which represents the interests of retail merchants to prepare a list of not less than 100 prescription drugs most commonly prescribed to residents of this State. (NRS 439.905) Existing law also requires the Department of Health and Human Services to place on the Internet website maintained by the Department certain information reported by pharmacies concerning the prices charged by the pharmacies for drugs that appear on that list. (NRS 439.915) **Section 3.6** of this bill requires the Department to compile: (1) a list of prescription drugs that the Department

determines to be essential for treating diabetes in this State; and (2) a list of such prescription drugs that have been subject to a significant price increase within the immediately preceding 2 calendar years. **Section 3.8** of this bill requires the manufacturer of a prescription drug included on the list of essential diabetes drugs to submit to the Department an annual report that contains certain information concerning the cost of the drug. **Section 4** of this bill requires the manufacturer of a drug included on the list of essential diabetes drugs that have undergone a substantial cost increase to submit to the Department a report concerning the reasons for the cost increase. **Section 4.2** of this bill requires a pharmacy benefit manager to report certain information concerning essential diabetes drugs to the Department. **Section 9** of this bill provides that any information that a manufacturer of an essential diabetes drug, a pharmacy benefit manager or a pharmaceutical sales representative is required to report is not a trade secret. **Section 4.3** of this bill requires the Department to analyze the information submitted by such manufacturers and compile a report concerning the reasons for and effect of the pricing of essential diabetes drugs.

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

Section 4.6 of this bill requires a manufacturer to provide to the Department a list of each pharmaceutical sales representative who markets prescription drugs to providers of health care, pharmacies, medical facilities and insurers in this State on behalf of the manufacturer. **Section 4.6** also prohibits a person who is not included on such a list from marketing prescription drugs on behalf of a manufacturer to providers of health care, pharmacies, medical facilities and insurers. Additionally, **section 4.6** requires each pharmaceutical sales representative who is included on such a list to submit an annual report to the Department. Finally, **section 4.6** requires the Department to compile an annual report based on the information submitted by pharmaceutical sales representatives. **Section 8** of this bill authorizes the Department to impose an administrative penalty against a manufacturer, pharmacy benefit manager, nonprofit organization or pharmaceutical sales representative who fails to provide the information required by **sections 3.8, 4, 4.2, 4.6 and 4.9**.

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

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

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

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

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

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

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

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

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

Sec. 3.4. ***"Wholesale acquisition cost" means the manufacturer's list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing data.***

Sec. 3.6. ***On or before February 1 of each year, the Department shall compile:***

1. A list of prescription drugs that the Department determines to be essential for treating diabetes in this State and the wholesale

acquisition cost of each such drug on the list. The list must include, without limitation, all forms of insulin and biguanides marketed for sale in this State.

2. A list of prescription drugs described in subsection 1 that have been subject to an increase in the wholesale acquisition cost of a percentage equal to or greater than:

(a) The percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding calendar year; or

(b) Twice the percentage increase in the Consumer Price Index, Medical Care Component during the immediately preceding 2 calendar years.

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

1. The costs of producing the drug;

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

3. The profit that the manufacturer has earned from the drug and the percentage of the manufacturer's total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug;

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

5. The cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs;

6. The wholesale acquisition cost of the drug;

7. A history of any increases in the wholesale acquisition cost of the drug over the 5 years immediately preceding the date on which the report is submitted, including the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective and any explanation for the increase;

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

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

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

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

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

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

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

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

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

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

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

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

(1) Recipients of Medicare;

(2) Recipients of Medicaid;

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

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

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

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

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

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

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

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

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

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

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

4. On or before March 1 of each year, each person who was included on a list of pharmaceutical sales representatives submitted pursuant to subsection 1 at any time during the

immediately preceding calendar year shall submit to the Department a report, which must include, for the immediately preceding calendar year:

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

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

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

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

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

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

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

6. As used in this section:

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

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

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

Sec. 4.9. ***1. On or before February 1 of each year, a nonprofit organization that advocates on behalf of patients or funds medical research in this State and has received a payment, donation, subsidy or anything else of value from a manufacturer, third party or pharmacy benefit manager or a trade or advocacy group for manufacturers, third parties or pharmacy benefit managers during the immediately preceding calendar year shall:***

(a) Compile a report which includes:

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

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

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

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

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

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

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

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

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

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

439.900 As used in NRS 439.900 to 439.940, inclusive, ***and sections 2 to 4.9, inclusive, of this act,*** unless the context otherwise requires, ~~["pharmacy" means every store or shop licensed by the State Board of Pharmacy where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or~~

~~dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed. The term does not include an institutional pharmacy as defined in NRS 639.0085.~~] ***the words and terms defined in sections 2 to 3.4, inclusive, of this act have the meanings ascribed to them in those sections.***

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

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

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

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

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

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

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

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

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

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

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

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

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

2. If a pharmacy is part of a larger company or corporation or a chain of pharmacies or retail stores, the Department may present the

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

3. The Department may establish additional or alternative procedures by which a consumer who is unable to access the Internet or is otherwise unable to receive the information described in subsection 1 in the manner in which it is presented by the Department may obtain that information:

(a) In the form of paper records;

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

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

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

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

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

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

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

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

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

1. Notice to consumers stating that:

(a) Although the Department will strive to ensure that consumers receive accurate information regarding pharmacies,

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

(b) If a consumer follows an Internet link from the Internet website maintained by the Department to an Internet website ***not*** maintained by ~~[a pharmacy,]~~ ***the Department,*** the Department is unable to guarantee the accuracy of any information made available on ~~[the]~~ ***that*** Internet website ***;*** ~~[maintained by the pharmacy;]~~ and

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

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

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

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

(b) Nonprofit organizations and advocacy groups;

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

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

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

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

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

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

10. Standards and criteria pursuant to which the Department may remove from its Internet website information regarding a pharmacy or an Internet link to the Internet website maintained by a pharmacy, or both, if the Department determines that the pharmacy has:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Any other person as a result of exposure to or injury caused by needles, medical devices or other medical waste from

the self-administration of medication by a pupil pursuant to this section.

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

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

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

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

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

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

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

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

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

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

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

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

10. As used in this section:

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

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

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

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

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

1. "Improper means" includes, without limitation:

(a) Theft;

(b) Bribery;

(c) Misrepresentation;

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

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

(f) Espionage through electronic or other means.

2. "Misappropriation" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Does not include any information that a manufacturer is required to report pursuant to section 3.8 or 4 of this act, information that a pharmaceutical sales representative is required to report pursuant to section 4.6 of this act or information that a pharmacy benefit manager is required to report pursuant to section 4.2 of this act, to the extent that such information is required to be disclosed by those sections.

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

Sec. 11. (Deleted by amendment.)

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

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

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

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

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

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

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

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

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

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

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

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

2. A plan described in subsection 1 may, by contract, require a pharmacy benefit manager that manages the coverage of prescription drugs under the plan to comply with the requirements of sections 12 to 21, inclusive, of this act and any regulations adopted by the Commissioner pursuant thereto.

Sec. 18. (Deleted by amendment.)

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

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

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

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

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

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

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

Secs. 21-26. (Deleted by amendment.)

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

689A.405 1. An insurer that offers or issues a policy of health insurance which provides coverage for prescription drugs shall include with any summary, certificate or evidence of that coverage provided to an insured, notice of whether a formulary is used and, if so, of the opportunity to secure information regarding the formulary from the insurer pursuant to subsection 2. The notice required by this subsection must:

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

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

(c) If a formulary is used, include:

(1) An explanation of:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) On or before July 1, 2018:

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

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

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

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

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

2. As used in this section:

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

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

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

2. As used in this section:

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

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

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

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

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

3. Sections 1 to 6.5, inclusive, 7.5, 8, 9 and 26.6 of this act become effective upon passage and approval for the purpose of adopting regulations and performing any other administrative tasks that are necessary to carry out the provisions of this act and on October 1, 2017, for all other purposes.

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

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

EXHIBIT B – Veto Letter

EXHIBIT B – Veto Letter

ONE HUNDRED ONE NORTH CARSON STREET
CARSON CITY, NEVADA 89701
OFFICE: (775) 684-5670
FAX NO.: (775) 684-5683

555 EAST WASHINGTON AVENUE, SUITE 5100
LAS VEGAS, NEVADA 89101
OFFICE: (702) 486-2500
FAX NO.: (702) 486-2505

Office of the Governor

June 2, 2017

The Honorable Aaron Ford
Nevada State Senate Majority Leader
The Nevada Legislature
401 South Carson Street
Carson City, NV 89701

RE: Senate Bill 265 of the 79th Legislative Session

Dear Leader Ford:

I am herewith forwarding to you, for filing within the constitutional time limit and without my approval, Senate Bill 265 ("SB 265"), which is entitled:

> AN ACT relating to prescription drugs; requiring the Department of Health and Human Services to compile a list of prescription drugs essential for treating diabetes in this State; requiring the manufacturer of a prescription drug included on the list to report certain information to the Department; requiring a manufacturer to notify the Department in advance of planned price increases for such drugs; requiring a manufacturer of prescription drugs to submit a list of each pharmaceutical sales representative who markets prescription drugs to certain persons in this State; prohibiting a pharmaceutical sales representative who is not included on such a list from marketing prescription drugs on behalf of a manufacturer; requiring each pharmaceutical sales representative included on such a list to report certain information to the Department; requiring certain nonprofit organizations to report to the Department certain information concerning contributions received from drug manufacturers, insurers and pharmacy benefit managers or trade and advocacy groups for such entities; requiring the Department to place certain information on its Internet website; authorizing the Department to impose an administrative penalty in certain circumstances; requiring a private school to allow a pupil to keep and self-administer certain drugs; requiring certain insurers to provide

certain notice to insureds; providing a penalty; and providing other matters properly relating thereto.

SB 265 contains provisions that are well-intentioned relating to legitimate concerns regarding access to affordable health care. Health care costs for patients with chronic diseases, particularly diabetes, are escalating, and in many cases prohibitively so. Rising costs mean that fewer Nevadans have access to critical—even lifesaving—health care options, threatening to diminish the quality of life for families across our State. To be clear, I support efforts to slow these rising costs, and share the belief that greater transparency in the marketplace can be a contributing factor to more affordable care options and can support other public policy goals.

While certain aspects of this bill are laudable, including provisions benefiting students suffering from diabetes, SB 265 also poses serious risks of unintended and potentially detrimental consequences for Nevada's consumer patients, not the least of which is the possibility that access to critical care will become more expensive, more restricted, and less equitable. SB 265 fails to account for market dynamics that are inextricably linked to health care delivery and access to prescription drugs. This failure cannot be overlooked, and it could cause more harm than good for Nevada's families.

For example, SB 265 requires a manufacturer of certain prescription drugs, such as insulin, to provide a public, 90-day notice of any potential increase in the price of diabetes drugs. By requiring an advance notice of a change in price before the change is effective, this bill may create a perverse incentive for some market participants to manipulate supply in order to maximize profits. SB 265 would inevitably provide purchasers, wholesalers, and secondary distributors of health care products an even greater financial motivation to restrict access to health care products. This could potentially lead to stockpiling of drugs or other artificial mechanisms for adjusting the supply of medication based on the guarantee of higher profits in the future. In short, SB 265 risks creating a "buy-low, sell-high" culture with regard to diabetes medication, which will only serve to exacerbate access-to-care challenges in Nevada.

The price-increase notice requirements in SB 265 will also spur the growth of the so-called "gray market" in health care products. In that gray market, the choice to sell critical shortage drugs to the highest bidder will be all the more attractive, particularly when states with less stringent rules and regulations are involved. This scenario could leave more Nevadans with higher costs, fewer choices, and less access to the medicine they need. For these reasons, SB 265 threatens to create undesirable incentives that could result in drug stockpiling, artificially inflated drug prices, and an expanded gray market for prescription drugs, thereby perpetuating the very problems SB 265 was meant to solve.

Moreover, SB 265 wholly ignores the role of pharmacy benefit managers (PBMs) and other participants along the prescription drug supply chain. SB 265 focuses exclusively on increasing transparency at the first stage of a complex process and not the others. By excluding other relevant participants from its requirements to publish pricing information, the bill provides an incomplete pricing picture for patient consumers. Complete transparency would shed light on every stage of the prescription drug supply process, and require all participants to share the

same disclosure responsibility. The selective and narrow approach reflected in this bill is unlikely to achieve sound public policy solutions for patients in Nevada.

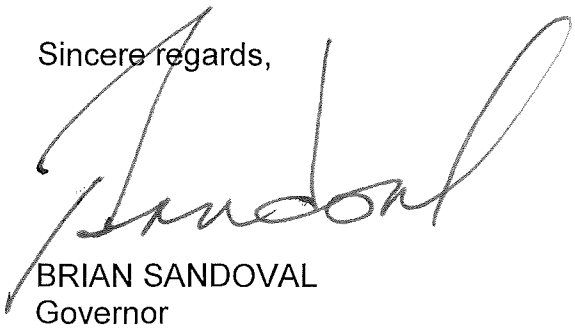
In addition, constitutional and other legal concerns have been raised that render the bill problematic. Among other issues, SB 265 could be challenged under theories of federal preemption, the Fifth Amendment's prohibition on uncompensated takings, and the Dormant Commerce Clause. And while the ultimate disposition of any legal claim challenging SB 265 would be for the courts to decide, lengthy and expensive litigation and legal uncertainty could destabilize the market for diabetes drugs and jeopardize a now secure supply of these drugs.

Finally, there is insufficient evidence that SB 265 will in fact lead to lower drug costs. While other states are considering policies similar to those reflected in this bill, the results to date are inconclusive. Before I support a bill as uncertain as SB 265, which deals so directly and extensively with the health and well-being of countless Nevadans, there must be compelling evidence that the benefits are worth the risks. No convincing evidence has been offered to justify SB 265's nascent, unproven, and disruptive change to public health policy.

Having reviewed the legislative record, testimony from committee hearings, and hundreds of constituent calls and letters, it is clear that there are others with deep concerns regarding this bill. In addition, many groups have opposed SB 265, including the Epilepsy Foundation, the Nevada Cancer Research Foundation, the Biotechnology Innovation Organization, and the Neuropathy Action Foundation.

For these reasons, I veto SB 265 and return it without my signature or approval.

Sincere regards,



BRIAN SANDOVAL
Governor

Enclosure

cc: *The Honorable Mark Hutchison, President of the Senate (without enclosure)*
The Honorable Jason Frierson, Speaker of the Nevada Assembly (without enclosure)
The Honorable Barbara Cegavske, Nevada Secretary of State (without enclosure)
Claire J. Clift, Secretary of the Senate (without enclosure)
Susan Furlong, Chief Clerk of the Assembly (without enclosure)
Brenda Erdoes, Esq., Legislative Counsel (without enclosure)

EXHIBIT C – Draft List of Essential Diabetes Drugs

EXHIBIT C – Draft List of Essential Diabetes Drugs

	Generic Name	Brand Name
2	Acarbose	Precose
3	Albiglutide	Tanzeum
4	Alogliptin	Nesina
5	Bromocriptine	Cycloset
6	Canagliflozin	Invokana
7	Colesevelam	Welchol
8	Dapagliflozin	Farxiga
9	Dulaglutide	Trulicity
10	Empagliflozin	Jardiance
11	Exenatide, Exenatide ER	Byetta, Bydureon
12	Glimepiride	Amaryl
13	Glipizide	Glucotrol, Glucotrol XL, Glipizide XL
14	Glyburide	DiaBeta
15	Insulin Aspart	Novolog, Novolog FlexPen, Novolog PenFill
16	Insulin Detemir	Levemir, Levemir Flex Touch
17	Insulin Glargine	Lantus, Lantus SoloStar, Toujeo SoloStar
18	Insulin Glulisine	Apidra, Apidra SoloStar
19	Insulin Lispro	HumaLog, HumaLog KwikPen
20	Linagliptin	Tradjenta
21	Liraglutide	Victoza, Saxenda
22	Metformin	Glucophage, Glucophage XR, Fortamet, Glumetza, Riomet Liquid
23	Metformin & Alogliptin	Kazano
24	Metformin & Canagliflozin	Invokamet
25	Metformin & Dapagliflozin	Xigduo XR
26	Metformin & Glipizide	Metaglip
27	Metformin & Glyburide	Glucovance
28	Metformin & Linagliptin	Jentadueto
29	Metformin & Piolgitazone	Actoplus Met, Actoplus Met XR
30	Metformin & Repaglinide	PrandiMet
31	Metformin & Rosiglitazone	Avandamet
32	Metformin & Saxagliptin	Kombiglyze
33	Metformin & Sitagliptin	Janumet
34	Miglitol	Glyset
35	Nateglinide	Starlix
36	NPH insulin or Intermediate insulin	HumuLIN N, NovoLin N
37	Pioglitazoe & Alogliptin	Oseni
38	Pioglitazone	Actos
39	Pioglitazone & Glimepride	Duetact
40	Pramlintide	SymlinPen 60, SymlinPen 120
41	Regular Insulin	Afrezza – inhaled
42	Regular Insulin	HumuLin R, Novolin R
43	Repaglinide	Prandin
44	Rosiglitazone	Avandia
45	Rosiglitazone & Glimepiride	Avandaryl
46	Sitagliptin	Januvia

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, and BIOTECHNOLOGY INNOVATION ORGANIZATION

(b) County of Residence of First Listed Plaintiff District of Columbia
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Pat Lundvall, MCDONALD CARANO LLP, 2300 West Sahara Avenue, Suite 1200, Las Vegas, NV 89102, (702) 873-4100

DEFENDANTS
BRIAN SANDOVAL, in his official capacity as Governor of the State of Nevada, and RICHARD WHITLEY, in his official capacity as Director of the Nevada Department for Health and Human Services

County of Residence of First Listed Defendant Carson City, Nevada
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
42 U.S.C. Section 1983

Brief description of cause:
Supremacy Clause; Takings Clause; Dormant Commerce Clause (Declaratory Relief; Injunctive Relief)

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:

JUDGE _____ DOCKET NUMBER _____

DATE
09/01/2017

SIGNATURE OF ATTORNEY OF RECORD
Pat Lundvall

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Nevada

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, and BIOTECHNOLOGY INNOVATION ORGANIZATION,

Plaintiff(s)

v.

BRIAN SANDOVAL, in his official capacity as Governor of the State of Nevada, and RICHARD WHITLEY, in his official capacity as Director of the Nevada Department for Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Brian Sandoval
State Capitol Building
101 N. Carson Street
Carson City, NV 89701

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Pat Lundvall
MCDONALD CARANO LLP
2300 West Sahara Avenue, Suite 1200
Las Vegas, NV 89102
Telephone: (702) 873-4100

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 09/01/2017

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Nevada

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, and BIOTECHNOLOGY INNOVATION ORGANIZATION,

Plaintiff(s)

v.

BRIAN SANDOVAL, in his official capacity as Governor of the State of Nevada, and RICHARD WHITLEY, in his official capacity as Director of the Nevada Department for Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Richard Whitley
Nevada Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City, NV 89706

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Pat Lundvall
MCDONALD CARANO LLP
2300 West Sahara Avenue, Suite 1200
Las Vegas, NV 89102
Telephone: (702) 873-4100

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 09/01/2017

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: