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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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