

1 Pat Lundvall
2 Nevada Bar No. 3761
3 McDONALD CARANO LLP
4 2300 West Sahara Avenue, Suite 1200
5 Las Vegas, NV 89102
6 Telephone: (702) 873-4100
7 plundvall@mcdonaldcarano.com

8 Robert N. Weiner
9 Pending Admission *Pro Hac Vice*
10 Jeffrey L. Handwerker
11 Pending Admission *Pro Hac Vice*
12 R. Stanton Jones
13 Pending Admission *Pro Hac Vice*
14 ARNOLD & PORTER KAYE SCHOLER LLP
15 601 Massachusetts Avenue, NW
16 Washington, DC 20001
17 Telephone: (202) 942-5000
18 robert.weiner@apks.com
19 jeffrey.handwerker@apks.com
20 stanton.jones@apks.com

21 *Attorneys for Plaintiffs Pharmaceutical*
22 *Research and Manufacturers of America and*
23 *Biotechnology Innovation Organization*

24 **UNITED STATES DISTRICT COURT**
25 **DISTRICT OF NEVADA**

26 PHARMACEUTICAL RESEARCH AND
27 MANUFACTURERS OF AMERICA, and
28 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**

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

6 INTRODUCTION

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

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

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

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

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

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

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

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

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

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

10 9. Governor Sandoval further recognized that, beyond these constitutional defects, SB
11 265 could seriously harm Nevada residents suffering from diabetes. The bill, in the Governor’s
12 view, posed “serious risks of unintended and potentially detrimental consequences for Nevada’s
13 consumer patients, not the least of which is the possibility that access to critical care will become
14 more expensive, more restricted, and less equitable.” *Id.* at 2. He cautioned that the bill “could
15 cause more harm than good for Nevada’s families.” *Id.* “Before I support a bill [this] uncertain,”
16 he wrote, “which deals so directly and extensively with the health and well-being of countless
17 Nevadans, there must be compelling evidence that the benefits are worth the risks.” *Id.* at 3. There
18 was no such evidence, and the Legislature did not remedy that deficit in adopting SB 539.

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

23 **PARTIES**

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

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

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

9 13. Defendant Brian Sandoval is the Governor of the State of Nevada and is sued in his
10 official capacity only. As Governor, Defendant Sandoval is responsible for the execution of SB
11 539.

12 14. Defendant Richard Whitley is the Director of the Department and is sued in his
13 official capacity only. As Director of the Department, Defendant Whitley is responsible for the
14 implementation and execution of SB 539, including the promulgation of rules and the assessment of
15 administrative penalties authorized by the Act. *See* SB 539, 2017 Leg., 79th Sess. §§ 7–8 (Nev.
16 2017).

17 JURISDICTION AND VENUE

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

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

23 17. An actual controversy exists between the parties within the meaning of 28 U.S.C.
24 § 2201, and this Court has the authority to grant declaratory and injunctive relief pursuant to 28
25 U.S.C. §§ 2201 and 2202.

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

27 ² A list of BIO members is available at *BIO Member Directory*, [http://www.bio.org/bio-member-](http://www.bio.org/bio-member-directory)
28 [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*

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

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

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

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

- 22 • In 1936, a scientist discovered that adding protamine prolonged the effects of
 23 injected insulin.
- 24 • In 1950, Novo Nordisk introduced Neutral Protamine Hagedorn (“NPH”) Insulin,
 25 a drug so important in treating diabetes that it is on the World Health
 26 Organization model list of essential medicines. *See* WHO Model List of
 27 Essential Medicines, World Health Org. (20th ed.) (Mar. 2017),
 28 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

1 glucose, which allowed diabetes patients to monitor and regulate their glucose
2 levels frequently and conveniently. See Am. Diabetes Ass'n, *75th Anniversary*
3 *Timeline*, <http://www.diabetes.org/about-us/75th-anniversary/timeline.html>
4 ("75th Anniversary Timeline"). By 1981, the Ames Company introduced home
5 glucose meters, allowing patients to accurately check their own blood glucose
6 levels without having to visit a doctor's office. S.F. Clarke & J.R. Foster, *A*
7 *History of Blood Glucose Meters and Their Role in Self-Monitoring of Diabetes*
8 *Mellitus*, 69 Brit. J. of Biomed. Sci. 83, 86 (2012).

- 9 • In 1982, FDA approved Eli Lilly's Humulin, the first human insulin product,
10 freeing the world's supply of insulin from its supply using animal sources. See
11 Lawrence K. Altman, *A New Insulin Given Approval for Use In U.S.*, N.Y.
12 Times, Oct. 30, 1982, [http://www.nytimes.com/1982/10/30/us/a-new-insulin-](http://www.nytimes.com/1982/10/30/us/a-new-insulin-given-approval-for-use-in-us.html?mcubz=0)
13 [given-approval-for-use-in-us.html?mcubz=0](http://www.nytimes.com/1982/10/30/us/a-new-insulin-given-approval-for-use-in-us.html?mcubz=0).
- 14 • In 1985, Novo Nordisk developed, introduced, and marketed the first insulin pen,
15 which allows patients to vary the injected dose and to administer insulin
16 discreetly. Since 1985, innovators have made significant investments into
17 designing insulin pens that improve patient satisfaction and safety.
- 18 • In 1994, Bristol Myers Squibb became the first company to secure FDA approval
19 for the drug metformin, an oral biguanide that prevents glucose production in the
20 liver. Press Release, U.S. Food & Drug Admin., FDA Approves New Diabetes
21 Drug (Dec. 30, 1994),
22 [https://web.archive.org/web/20070929152824/http://www.fda.gov/bbs/topics/ANS-](https://web.archive.org/web/20070929152824/http://www.fda.gov/bbs/topics/ANSWERS/ANS00627.html)
23 [WERS/ANS00627.html](https://web.archive.org/web/20070929152824/http://www.fda.gov/bbs/topics/ANSWERS/ANS00627.html). Metformin is the recommended first line of treatment
24 for Type 2 diabetes after diet and exercise. See Randy Dotinga, *Metformin Still*
25 *Best as First Type 2 Diabetes Treatment*, WebMD (Jan. 2, 2017),
26 [http://www.webmd.com/diabetes/news/20170102/metformin-still-best-choice-](http://www.webmd.com/diabetes/news/20170102/metformin-still-best-choice-for-first-type-2-diabetes-treatment)
27 [for-first-type-2-diabetes-treatment](http://www.webmd.com/diabetes/news/20170102/metformin-still-best-choice-for-first-type-2-diabetes-treatment).
- 28 • 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

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

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

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

25 Drug name	26 Type of drug	27 Manufacturer	28 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

1	Ryzodeg	Combination insulin	Novo Nordisk	2015
2	Toujeo	Long-acting insulin	Sanofi U.S.	2015
3	Glyxambi	Combination SGLT-2	Eli Lilly and Boehringer	2015
4		inhibitor and DPP-4	Ingelheim	
5		inhibitor	Pharmaceuticals	
6	Trulicity	Glucagon-like peptide	Eli Lilly	2014
7	Invokamet	Combination SGLT-2	Janssen Pharmaceuticals	2014
8		inhibitor and biguanide		
9	Jardiance	SGLT-2 inhibitor	Boehringer Ingelheim	2014
10			Pharmaceuticals	
11	Afrezza Inhalation	Inhaled insulin	Sanofi U.S. and	2014
12	Powder		MannKind	
13	Tanzeum	Glucagon-like peptide	GlaxoSmithKline	2014
14	Xigduo XR	Combination	AstraZeneca	2014
15		Dapagliflozin and		
16		Metformin		
17	Farxiga	SGLT-2 inhibitor	AstraZeneca and Bristol-	2014
18			Myers Squibb	
19	Invokana	SGLT-2 inhibitor	Janssen Pharmaceuticals	2013
20	Nesina	DPP-4 inhibitor	Takeda Pharmaceuticals	2013
21	Janumet XR	DPP-4 inhibitor	Merck	2012
22	Jentadueto	Combination DPP-4	Eli Lilly and Boehringer	2012
23		inhibitor and biguanide	Ingelheim	
24			Pharmaceuticals	
25	Bydureon	Glucagon-like peptide	Amylin Pharmaceuticals	2012
26			and Alkermes PLC	
27	Juvisync	Combination statin and	Merck	2011
28				

1		DPP-4 inhibitor		
2	Tradjenta	DPP-4 inhibitor	Eli Lilly and Boehringer Ingelheim Pharmaceuticals	2011
3				
4				
5	Kombiglyze XR	Combination DPP-4 inhibitor and biguanide	AstraZeneca and Bristol- Myers Squibb	2010
6				
7	Victoza	Glucagon-like peptide	Novo Nordisk	2010
8	Onglyza	DPP-4 inhibitor	AstraZeneca and Bristol- Myers Squibb	2009
9				
10	PrandiMet	Combination repaglinide and biguanide	Sciele Pharma and Novo Nordisk	2008
11				
12	Janumet	DPP-4 inhibitor and Biguanide	Merck	2007
13				
14	Januvia	DPP-4 inhibitor	Merck	2006
15	Duetact	Combination pioglitazone (directly targets insulin resistance) and sulfonylurea (increases amount of insulin produced by pancreas)	Takeda Pharmaceuticals	2006
16				
17				
18				
19				
20				
21				
22	ACTOplus met	Combination pioglitazone and biguanide	Takeda Pharmaceuticals	2005
23				
24				
25	Levemir	Long-acting insulin	Novo Nordisk	2005
26	Byetta	Glucagon-like peptide	Amylin Pharmaceuticals and Eli Lilly	2005
27				
28				

1	Symlin	Antihyperglycemic drug	Amylin Pharmaceuticals	2005
2	Apidra	Rapid-acting insulin	Aventis Pharmaceuticals	2004
3	Metaglip	Combination glipizide	Bristol-Myers Squibb	2002
4		and biguanide		
5	Avandamet	Combination	GlaxoSmithKline	2002
6		rosiglitazone and		
7		biguanide		
8	Novolog 70/30	Combination insulin	Novo Nordisk	2001
9	Lantus	Long-acting insulin	Aventis Pharmaceuticals	2000
10	Novolog	Rapid-acting insulin	Novo Nordisk	2000

11 See U.S. Food & Drug Admin., *FDA-Approved Diabetes Medicines*,

12 <https://www.fda.gov/forpatients/illness/diabetes/ucm408682.htm>.

13 25. Although there have been substantial advances in diabetes treatments, 1.7 million
14 people are newly diagnosed with diabetes in the United States every year. Developing innovative
15 new diabetes treatments and improving existing treatments requires continuing research. To that
16 end, Plaintiffs' members invest billions each year. See, e.g., *2016 Biopharmaceutical Research*
17 *Industry Profile*, PhRMA (April 2016), [phrma-](http://docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf)
18 docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf; David Thomas &
19 Chad Wessel, *Emerging Therapeutic Company Investment and Deal Trends*, BIO (June 2017),
20 [https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report](https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf)
21 [%202007-2016.pdf](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
22 were in development. See *Medicines in Development for Diabetes: A Report on Diabetes and*
23 *Related Conditions*, PhRMA (2016), [phrma-docs.phrma.org/files/dmfile/medicines-in-](http://phrma-docs.phrma.org/files/dmfile/medicines-in-development-report-diabetes.pdf)
24 [development-report-diabetes.pdf](http://phrma-docs.phrma.org/files/dmfile/medicines-in-development-report-diabetes.pdf). The vast majority of drugs in development are potentially “first-
25 in-class medicines” that offer a new approach to fighting the disease. See, e.g., Genia Long,
26 *Analysis Grp., The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development*
27 (July 2017),
28 http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/the_biopharmaceutical_pi

1 pipeline_report_2017.pdf (noting that 69% of diabetes drugs in development were potential first-in-
2 class medicines).

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

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

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

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

14 29. Meanwhile, costly and labor-intensive research continues to lay the groundwork for
15 the next generation of treatments. Researchers at the Harvard Stem Cell Institute discovered a
16 hormone that can stimulate insulin-secreting pancreatic cells to reproduce at up to 30 times the
17 normal rate in mice. See Harvard Stem Cell Inst., *From Stem Cells to Billions of Human Insulin-*
18 *Producing Cells* (Oct. 9, 2014), [https://hsci.harvard.edu/news/stem-cells-billions-human-insulin-](https://hsci.harvard.edu/news/stem-cells-billions-human-insulin-producing-cells)
19 [producing-cells](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
20 regulation of insulin as the new cells produce insulin only as needed. *Id.*

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

24
25 ³ See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 4108, 4202, 10407,
26 10501, 124 Stat. 119 (2010); Nat’l Conference of State Legislatures, *Federal Health Reform*
27 *Provisions Related to Diabetes* (May 2011),
28 <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>.

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

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

20 32. Pharmaceutical manufacturers can invest these billions of dollars each year in
21 research and development only if they have an appropriate opportunity to recoup that investment
22 through the sales of the small fraction of products that ultimately make it to market. Patents are
23 especially important to the biotechnology industry, as they are often the sole or the most valuable
24 asset of a start-up venture. See Charles W. Wessner, *Capitalizing on New Needs and New*
25 *Opportunities: Government-Industry Partnerships in Biotechnology and Information Technologies*
26 40 (2001), https://www.ncbi.nlm.nih.gov/books/NBK208686/pdf/Bookshelf_NBK208686.pdf.

1 **Overview of Nevada Senate Bill 539**

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

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

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

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

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

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

23 38. On May 19, 2017, the Nevada State Senate passed the first bill, SB 265. On May 25,
24 2017, the Nevada State Assembly passed SB 265 and sent the bill to the Governor for approval.

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

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

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

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

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

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

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

24 _____
25 ⁴ Both insulin and biguanides seek to lower blood glucose levels. Insulin injections replace the
26 insulin that the body would produce naturally in patients with diabetes who do not produce enough
27 insulin. Biguanides, such as metformin, lower blood sugar by decreasing the amount of sugar
28 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>.

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

- 4 • “[t]he costs of producing the drug”;
- 5 • “marketing and advertising costs” associated with the drug;
- 6 • profit “earned from the drug” and “the percentage of the manufacturer’s total
7 profit . . . attributable to the drug”;
- 8 • the amount spent on “patient prescription assistance program[s]”;
- 9 • “[t]he cost associated with coupons provided directly to consumers and for
10 programs to assist consumers in paying copayments, and the cost to the
11 manufacturer attributable to the redemption of those coupons and the use of those
12 programs”;
- 13 • the “wholesale acquisition cost of the drug,” defined as “the manufacturer’s list
14 price for a prescription drug to wholesalers or direct purchasers in the United
15 States, not including any discounts, rebates or reductions in price, as reported in
16 wholesale price guides or other publications of drug pricing date”;
- 17 • “[a] history of any increases in the wholesale acquisition cost of the drug over the
18 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”;
- 19 • “[t]he aggregate amount of all rebates” in Nevada; and
- 20 • “[a]ny additional information prescribed by regulation . . . for the purpose of
analyzing the cost of prescription drugs . . . on the list.”

21 *Id.* § 3.8.

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

26 These disclosures include:

- 27 • “[a] list of each factor that has contributed to the increase”;
- 28 • “[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.”

1 *Id.* §§ 3.6(2), 4.

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

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

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

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

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

25 52. What is more, SB 539 expressly eliminates trade-secret protection for all information
26 manufacturers must disclose concerning “essential” diabetes drugs. *Id.* § 4.3. Specifically, the Act
27 alters the definition of “trade secret” in NRS 600A.030 to exclude “any information that a
28

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

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

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

11 ***SB 539’s Harm to Plaintiffs’ Members and Innovation of Diabetes Treatments***

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

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

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

1 approximately 12,600 people in Indiana. Indiana law confers trade-secret protection for the
2 confidential information concerning advertising, cost, marketing, pricing, and production that SB
3 539 requires Eli Lilly to disclose. *See Hydraulic Exch. & Repair, Inc. v. KM Specialty Pumps, Inc.*,
4 690 N.E.2d 782, 786 (Ind. Ct. App. 1998) (holding that customer and pricing information, including
5 compilations of profits and sales, were trade secrets under Indiana Uniform Trade Secrets Act);
6 *Ackerman v. Kimball Int'l, Inc.*, 634 N.E.2d 778, 783 (Ind. Ct. App. 1994) (affirming trial court
7 conclusion that pricing information was a trade secret).

8 57. Johnson & Johnson manufactures the diabetes drugs Invokamet (a combination
9 SGLT-2 inhibitor with metformin), Invokamet XR (extended release), and Invokana (an SGLT-2
10 inhibitor). The drugs Invokamet, Invokamet XR, and Invokana are patented. Johnson & Johnson is
11 headquartered in New Brunswick, New Jersey and employs approximately 9,300 people in New
12 Jersey. New Jersey law confers trade-secret protection for the confidential information that SB 539
13 requires Johnson & Johnson to disclose. *See Commc'ns Workers of Am. v. Rousseau*, 9 A.3d 1064,
14 1076 (N.J. Super. Ct. App. Div. 2010) (“A trade secret may also include pricing and marketing
15 techniques.”); *Lamorte Burns & Co. v. Walters*, 770 A.2d 1158, 1166 (N.J. 2001) (citing with
16 approval treatise stating that “information relating to customers, merchandising, costs, and pricing
17 may be considered trade secrets” (citing 1 Roger M. Milgrim, *Milgrim on Trade Secrets* § 2.09
18 (1995))).

19 58. Merck Sharp & Dohme Corp. manufactures the diabetes drugs Januvia (sitagliptin)
20 (a dipeptidyl peptidase 4 (DPP-4) inhibitor), Janumet (sitagliptin and metformin HCl) and Janumet
21 XR (sitagliptin and metformin HCl extended release). The drugs Januvia, Janumet, and Janumet
22 XR are patented. Merck is headquartered in Kenilworth, New Jersey and employs approximately
23 5,200 people in New Jersey. As noted, New Jersey law confers trade-secret protection for the
24 confidential information that SB 539 requires Merck to disclose.

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

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

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

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

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

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

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

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

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

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

24 67. The competitive harm arising from SB 539's punitive and coercive effects will
25 undermine the incentives that trade secret and patent law provides for Plaintiffs' members to invest
26 in developing innovative diabetes medicines. Absent judicial intervention, SB 539 could force
27 innovators into the unfortunate position of having to review and revise their research and
28 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

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

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

20 72. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration
21 Act of 1984, commonly known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585
22 (1984). In light of the unique economic challenges to pharmaceutical research and development,
23 the Hatch-Waxman Act extended the patent term for pharmaceuticals to “create a significant, new
24 incentive which would result in increased expenditures for research and development, and
25 ultimately in more innovative drugs.” H.R. Rep. No. 98-857(I), at 18; see also *Biotech. Indus. Org.*
26 *v. District of Columbia (“BIO”)*, 496 F.3d 1362, 1373 (Fed. Cir. 2007). President Reagan reiterated
27 this goal when he signed the bill into law: “The bill will promote medical breakthroughs and drug
28 innovation by granting drug companies up to 5 more years of patent protection for new drugs. And

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

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

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

17 75. Under the Supremacy Clause of the United States Constitution, federal statutes are
18 “the supreme Law of the Land.” U.S. Const. art. IV, cl. 2. And under settled principles of federal
19 “conflict” preemption, no state law may “stand[] as an obstacle to the accomplishment and
20 execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U.S. 52, 67
21 (1941).

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

1 [drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to
2 District drug consumers.” *Id.* at 1374. Because Congress—and Congress alone—is the
3 “promulgator of patent policy,” federal law preempted the District’s attempt to “re-balance the
4 statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* at
5 1373–74.

6 77. Just like the District of Columbia statute invalidated in *BIO*, SB 539 “attempt[s] to
7 restrain . . . excessive [essential diabetes drug] prices, in effect diminishing the reward to patentees
8 in order to provide greater benefit to [Nevada] drug consumers.” *Id.* at 1374. In purpose and effect,
9 the Act punishes manufacturers for the price of their “essential” diabetes drugs as well as for list
10 price increases by more than the “percentage increase in the Consumer Price Index, Medical Care
11 Component during the immediately preceding calendar year; or . . . [t]wice the percentage increase
12 in the Consumer Price Index, Medical Care Component during the immediately preceding 2
13 calendar years.” SB 539 §§ 3.6(2), 4. If an essential diabetes drug’s list price increases by more
14 than these benchmarks, then the Act compels the manufacturer to report to the Department
15 additional confidential, competitively sensitive, proprietary information about that price increase,
16 including a list of “factors” that contributed to the increase and an “explanation” of the role of each
17 factor. *Id.* § 4. The Act also strips trade-secret protection for that information. *Id.* § 9. The only
18 way a manufacturer can avoid forfeiting trade-secret protection for the “factors” of a price increase
19 is by limiting its list prices to the Act’s effective cap. SB 539 thus restrains patent holders from
20 setting list prices in a manner that the federal patent laws secure in order to incentivize innovation.

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

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

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

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

21 ***SB 539 Conflicts with Federal Trade-Secret Law***

22 82. Federal and state trade-secret laws play a similarly important role in fueling the
23 American economy. Legal protection for trade secrets “encourage[s] invention in areas where
24 patent law does not reach, and . . . prompt[s] the independent innovator to proceed with the
25 discovery and exploitation of his invention.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 485
26 (1974). “Competition is fostered and the public is not deprived of the use of valuable, if not quite
27 patentable, invention.” *Id.*

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

7 84. In evaluating whether information is a trade secret under the common law, courts
8 consider, among other things, “[1] the extent of measures taken by the employer to guard the
9 secrecy of the information; [2] the value of the information to the employer and to his competitors;
10 [3] the amount of effort or money expended by the employer in developing the information; and [4]
11 the ease or difficulty with which the information could be properly acquired or duplicated by
12 others.” *Jet Spray Cooler, Inc. v. Crampton*, 385 N.E.2d 1349, 1355 n.9 (Mass. 1979) (citation
13 omitted); *Frantz v. Johnson*, 999 P.2d 351, 358–59 (Nev. 2000) (“Factors to be considered include:
14 (1) the extent to which the information is known outside of the business and the ease or difficulty
15 with which the acquired information could be properly acquired by others; (2) whether the
16 information was confidential or secret; (3) the extent and manner in which the [company] guarded
17 the secrecy of the information; and (4) . . . whether this information is known by the [company’s]
18 competitors.”).

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

23 [I]nformation, including a formula, pattern, compilation, program, device, method,
24 technique, or process, that: (i) derives independent economic value, actual or
25 potential, from not being generally known to, and not being readily ascertainable by
26 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.”

27 UTSA, § 1(4).

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

21 87. In 2016, Congress enacted the Defend Trade Secrets Act (“DTSA”), creating for the
22 first time a federal private right of action for misappropriation of trade secrets “related to a product
23 or service used in, or intended for use in, interstate or foreign commerce.” Pub. L. No. 114-153,
24 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)).

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

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

4 89. Although every state protects confidential and proprietary advertising, cost,
5 marketing, pricing, and production information, Congress intended the DTSA to provide businesses
6 engaged in interstate commerce with a uniform remedy for misappropriation. Congress expressed
7 concerns that “state laws vary in a number of ways and contain built-in limitations that make them
8 not wholly effective in a national and global economy.” H.R. Rep. No. 114-529, at 4 (Apr. 26,
9 2016) (Committee on the Judiciary). Congress acknowledged that “trade secret cases often require
10 swift action by courts across state lines to preserve evidence.” *Id.* “[U]nlike patents, once this
11 information is disclosed it instantly loses its value and the property right itself ceases to exist.” 162
12 Cong. Rec. H2034 (comments of Rep. Jackson Lee). Thus, the DTSA allows businesses “to move
13 quickly to Federal court . . . to stop trade secrets from winding up being disseminated and losing
14 their value.” H.R. Rep. No. 114-529, at 6; *accord* S. Rep. No. 114-220, at 3. The primary goal was
15 to create “remedies that, first, halt the misappropriator’s use and dissemination of the . . . trade
16 secret.” H.R. Rep. No. 114-529, at 13.

17 90. Congress likewise modeled the DTSA definition of “trade secret” on the UTSA, as
18 did Nevada—that is, until SB 539. *Compare* UTSA § 1, with 18 U.S.C. § 1839(4), and Nev. Rev.
19 Stat. § 600A.030(5) (1999); *see also* H.R. Rep. 114-529, at 14 (“[T]he Committee does not intend
20 for the definition of a trade secret to be meaningfully different from the scope of that definition as
21 understood by courts in States that have adopted the UTSA.”). Reflecting Congress’s intention to
22 provide a uniform remedy, the DTSA makes information related to advertising, cost, marketing,
23 pricing, and production a protectable trade secret, just as it is in UTSA jurisdictions. *See supra*,
24 ¶ 86.

25 91. SB 539 compels manufacturers to disclose to the Department confidential and
26 proprietary advertising, cost, marketing, pricing, and production information that derives
27 independent value from not being generally known to third parties and competitors. This valuable
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1 information constitutes a trade secret under the DTSA—and also under Nevada law until SB 539
2 takes effect.

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

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

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

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

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

1 ***SB 539’s Uncompensated Elimination of Trade-Secret Protection for Valuable***
2 ***Information Violates the Fifth Amendment Takings Clause***

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

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

15 99. There are two kinds of regulatory takings: (1) categorical and (2) noncategorical.
16 *See Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005). A categorical taking occurs where a
17 state statute “denies all economically beneficial or productive use” of property. *Lucas*, 505 U.S. at
18 1015. By contrast, a noncategorical taking may occur where a regulation “fall[s] short of
19 eliminating *all* economically beneficial use,” *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001),
20 yet still goes “too far” for purposes of the Fifth Amendment, *Lucas*, 505 U.S. at 1014–15 (quoting
21 *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)). To determine whether a noncategorical
22 regulatory taking goes “too far,” courts apply the three-part test articulated in *Penn Central*
23 *Transportation Co. v. City of New York*, 438 U.S. 104 (1978), and its progeny. That test assesses:
24 “[1] the character of the governmental action, [2] its economic impact, and [3] its interference with
25 reasonable investment-backed expectations.” *Ruckelshaus*, 467 U.S. at 1005.

26 100. SB 539 works as a categorical taking of property rights. “With respect to a trade
27 secret, the right to exclude others is central to the very definition of the property interest.” *Id.* at
28 1011. SB 539 does not merely “expos[e] [manufacturers’ trade secrets] to the *risk* of destruction by

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

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

13 102. First, the “character” of Nevada’s legislative action weighs heavily against sustaining
14 the Act. It prevents pharmaceutical manufacturers from “exclud[ing] others from their trade
15 secrets,” causing the trade secrets to “lose all value.” *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41
16 (1st Cir. 2002) (en banc) (citing this aspect of state disclosure statute’s “character” to show a
17 regulatory taking). “Therefore, if the [pharmaceutical manufacturers] comply with the requirements
18 of [SB 539], their property right will be extinguished.” *Id.* at 42. “[T]his is precisely what the
19 Takings Clause is designed to prevent.” *Id.* at 43.

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

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

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

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

24 106. Thus, under any Takings analysis, SB 539's disclosure requirements destroy
25 valuable trade secrets related to diabetes drugs without any compensation, let alone just
26 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

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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).

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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.*

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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 *intrastate* commerce, the regulation will not survive scrutiny if “the burden imposed on [*interstate*] 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).

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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

1 539 will prevent manufacturers from protecting and enforcing their trade secrets in every state.
2 This in turn will impose significant burdens on other states that host a substantial part of these
3 manufacturers' operations. Those jurisdictions have a legitimate interest in promoting the economic
4 success of these manufacturers by protecting their trade secrets. *See Healy v. Beer Inst., Inc.*, 491
5 U.S. 324, 336–37 (1989); *Rocky Mtn. Farmers Union v. Corey*, 730 F.3d 1070, 1101 (9th Cir.
6 2013).

7 111. Take, for example, Eli Lilly—one of the major manufacturers of diabetes drugs. Eli
8 Lilly is headquartered in Indianapolis, Indiana. It has *no* offices or operations in Nevada. The State
9 of Indiana and the other states where Eli Lilly has operations protect Eli Lilly's trade secrets—
10 including its pricing and cost information for essential diabetes drugs. *See, e.g., Hydraulic Exch. &*
11 *Repair*, 690 N.E.2d at 786. These states have an interest in protecting Eli Lilly's trade secrets in
12 order to promote the company's growth, which creates local jobs and fuels the local economy. SB
13 539, however, overthrows the protection these other states provide by compelling Eli Lilly to
14 disclose the information that the other states protect as trade secrets. By enacting SB 539, Nevada
15 legislators have told legislators in every other state that Nevada knows best, and its decision
16 controls, when balancing the interest in protecting trade secrets against the interest in price
17 transparency. The dormant Commerce Clause does not tolerate such efforts by one state to impose
18 its preferred regulation on every other state.

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

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

1 jurisdictional bounds” that offends the dormant Commerce Clause. *C & A Carbone*, 511 U.S. at
2 393.

3 114. In fact, SB 539’s publication of competitively sensitive price and cost information
4 may lead to unintended anticompetitive effects that prevent drug prices from falling as quickly as
5 they would have without the Act. “Too much transparency can harm competition in any market,
6 including in health care markets. . . . [W]hen information disclosures allow competitors to figure
7 out what their rivals are charging, [it] dampens each competitor’s incentive to offer a low price, or
8 increases the likelihood that they can coordinate on higher prices.” Tara Isa Koslov & Elizabeth
9 Jex, *Price Transparency or TMI?*, Fed. Trade Comm’n (July 2, 2015, 2:31 PM),
10 <https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi>.
11 The Congressional Budget Office has found that compelled disclosure of drug pricing information,
12 specifically rebates, “could set in place conditions for tacit collusion, as manufacturers would find it
13 more difficult to set prices below their competitors’ without detection.” Cong. Budget Office,
14 *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals* 6 (June 5,
15 2008), [https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-](https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf)
16 [pricetransparency.pdf](https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf).

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

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

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

6 SECOND CLAIM FOR RELIEF

7 **(Declaratory/Injunctive Relief – SB 539 Is Preempted By Federal Trade-Secret Law 8 In Violation Of The Supremacy Clause Of The U.S. Constitution)**

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

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

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

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

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(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.

1 133. SB 539 violates the dormant Commerce Clause because the burden it imposes on
2 interstate commerce is clearly excessive in relation to any putative local benefits. Because WAC is
3 a national list price, SB 539's effects will be felt throughout the country. SB 539 also will prevent
4 manufacturers from protecting and enforcing their trade secrets in every state. These other
5 jurisdictions, especially those in which manufacturers reside, have a legitimate interest in promoting
6 the economic success of manufacturers. These substantial effects on interstate commerce clearly
7 exceed any putative local benefit to the residents of Nevada. While the purpose of the Act is to
8 control prices for diabetes drugs, neither the Act nor its legislative history explain how transparency
9 will lower prices apart from impermissibly burdening manufacturers' lawful exercise of federal
10 patent rights. The Constitution entrusts national economic policy to Congress precisely to avoid
11 such outcomes. U.S. Const. art. I, § 8, cl. 3.
12

13 **PRAYER FOR RELIEF**

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

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

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

2 DATED this 1st day of September, 2017.

3 Respectfully submitted,

4 /s/ Pat Lundvall

5 Pat Lundvall
6 Nevada Bar No. 3761
7 McDONALD CARANO LLP
8 2300 West Sahara Avenue, Suite 1200
9 Las Vegas, NV 89102
10 Telephone: (702) 873-4100
11 plundvall@mcdonaldcarano.com

12 Robert N. Weiner
13 Pending Admission *Pro Hac Vice*
14 Jeffrey L. Handwerker
15 Pending Admission *Pro Hac Vice*
16 R. Stanton Jones
17 Pending Admission *Pro Hac Vice*
18 ARNOLD & PORTER KAYE SCHOLER LLP
19 601 Massachusetts Avenue, NW
20 Washington, DC 20001
21 Telephone: (202) 942-5000
22 robert.weiner@apks.com
23 jeffrey.handwerker@apks.com
24 stanton.jones@apks.com

25 Attorneys for Plaintiffs *Pharmaceutical Research*
26 *and Manufacturers of America and Biotechnology*
27 *Innovation Organization*
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