IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Pharmaceutical Research and Manufacturers of America, Plaintiff, v. Stuart Williams, Stacey Jassey, Mary Phipps, Andrew Behm, James Bialke, Amy Paradis, Rabih Nahas, Samantha Schirmer, and Kendra Metz, in their official capacities as members of the Minnesota Board of Pharmacy; and Nate Clark, Peter Benner, Suyapa Miranda, David Fisher, Jodi Harpstead, Phil Norrgard, Stephanie Stoffel, and Andrew Whitman, in their official capacities as members of the Board of MNsure, Defendants.	Case No. **COMPLAINT**

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") brings this action for declaratory and injunctive relief against the members of the Minnesota Board of Pharmacy (the "Board of Pharmacy") and the members of the Board of MNsure in their official capacities ("Defendants") and states as follows:

INTRODUCTION

1. In the newly enacted Alec Smith Insulin Affordability Act (the "Act"), Minnesota chose to address a matter of public concern in an unconstitutional way.

2. The public concern is the high out-of-pocket costs that some patients must pay for insulin, often because these individuals lack health insurance coverage for prescription medications, or because their insurance requires significant out-of-pocket payments for their medications. Minnesota could have taken various lawful steps to address this concern. What Minnesota chose to do, however, is to order pharmaceutical manufacturers to give insulin to state residents, on the state's prescribed terms, at no charge to the recipients and without compensating the manufacturers in any way.

3. A state cannot simply commandeer private property to achieve its public policy goals. The Takings Clause of the Fifth Amendment of the U.S. Constitution prohibits states from attempting to solve societal problems in this draconian manner. Because the Act takes private property for public use without paying just compensation, it is unconstitutional and should be enjoined.

4. PhRMA and its members believe that no one living with diabetes should be forced to go without life-saving insulin because they cannot afford it. Indeed, before Minnesota enacted its confiscatory law, three of PhRMA's members that collectively manufacture most of the insulin sold in the United States were already committing significant resources to provide insulin to those in need, so that individuals living with diabetes are not forced to ration or forgo life-saving insulin because they cannot afford it. All three manufacturers have affordability programs

that provide discounts and co-payment assistance to significantly reduce patients' out-of-pocket costs, and the manufacturers also provide free insulin (directly or through charitable organizations) to a great number of patients. The manufacturers and charitable organizations operate these programs in all 50 states. And the manufacturers devote considerable resources and attention to adapting the terms and benefits of these programs to respond to new financial challenges patients face—including, most recently, challenges sparked by the COVID-19 pandemic.

5. Despite these extensive voluntary efforts on the part of insulin manufacturers, Minnesota has enacted an extraordinary law that *compels* manufacturers to give their insulin away for free to thousands of Minnesota residents. Manufacturers that fail to give away their products as the state demands are subject to substantial and increasing fines. The Act makes no provision to compensate manufacturers for this compulsory appropriation of their property for public use. Nor does the Act cover any of the substantial costs manufacturers must incur to create and operate Minnesota-specific programs (separate from the national programs noted above) to provide products according to the state's mandates—including processing Minnesota residents' claims for free insulin, determining claimants' eligibility under the Act, and arranging to distribute insulin to such individuals.

6. Minnesota has imposed these requirements, burdens, and penalties solely on manufacturers even though patients' out-of-pocket costs for insulin often

depend on the actions and determinations of health insurance plans, pharmacies and other entities over whom the manufacturers have no control. In fact, the Act specifically allows pharmacies to charge eligible individuals a co-payment for dispensing the very insulin that manufacturers are required to give away for free.

7. The Act's implications are staggering. If Minnesota can appropriate privately manufactured insulin for distribution to its residents without paying any compensation—let alone just compensation—to the manufacturers, states can compel manufacturers to dispense other medications for free as well. And, if a state's compulsory appropriation of medicine is permissible, there is no reason a state cannot commandeer other products for its residents as the state sees fit to advance its public policy goals.

8. The Takings Clause was adopted precisely to prevent such uncompensated appropriations of private property. If Minnesota believes that, despite the insulin manufacturers' affordability programs, there is a need for further action to help some Minnesota residents obtain insulin, it could have created a state-run program in which it purchases insulin from PhRMA's members and distributes it to residents in need. But instead of using public funds to address a matter of public concern, Minnesota chose to enact a law that effects *per se* takings of the manufacturers' property without compensation, so that the state can achieve its policy objectives at no expense to its taxpayers. While it may be expedient for a state simply to

take private property for use in pursuing its objectives, the Takings Clause prohibits forcing "some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960).

9. Because the Act effects a repeated and continuous series of unconstitutional *per se* takings, includes no mechanism to compensate manufacturers for those takings, and, by its very design and purpose, forecloses any compensation, its enforcement should be enjoined.

PARTIES

Plaintiff

10. PhRMA is a nonprofit corporation organized under Delaware law, with its headquarters in Washington, D.C. PhRMA represents the country's leading innovative pharmaceutical companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

11. Since 2000, PhRMA's member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone. These investments were responsible for much of the innovation that led the U.S. Food and Drug Administration ("FDA") to approve more than 550 new drugs over the past two decades.

12. PhRMA serves as the pharmaceutical industry's principal public policy advocate, representing the interests of its members before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. Among other objectives, PhRMA seeks to advance public policies that encourage the discovery of important new medicines for patients by pharmaceutical research companies.[1]

13. PhRMA brings this suit on behalf of itself and its members. The Act's unconstitutional taking of insulin manufacturers' products is of vital concern to PhRMA and its members, and several of PhRMA's members are subject to and directly harmed by the Act. This suit seeks to protect interests that are germane to PhRMA's purpose because the Act directly affects PhRMA's core goals of advocating for public policies that encourage investment in pharmaceutical innovation and addressing distortions in the market for medicines. Three of PhRMA's members—Eli Lilly and Company ("Lilly"), Novo Nordisk Inc., and Sanofi—manufacture most of the insulin sold in the United States, including in Minnesota, and are subject to the Act.

14. Neither the claims asserted nor the relief sought in the Complaint requires the participation of any individual member of PhRMA.

[1] A full list of PhRMA's members is available at http://www.phrma.org/about/members.

Defendants

15. The Defendants, named only in their official capacities, are the members of the Board of Pharmacy and the Board of MNsure charged with enforcing the Act.

16. Defendant Stuart Williams is President of the Board of Pharmacy.

17. Defendant Stacey Jassey is Vice-President of the Board of Pharmacy.

18. Defendant Mary Phipps is a member of the Board of Pharmacy.

19. Defendant Andrew Behm is a member of the Board of Pharmacy.

20. Defendant James Bialke is a member of the Board of Pharmacy.

21. Defendant Amy Paradis is a member of the Board of Pharmacy.

22. Defendant Rabih Nahas is a member of the Board of Pharmacy.

23. Defendant Samantha Schirmer is a member of the Board of Pharmacy.

24. Defendant Kendra Metz is a member of the Board of Pharmacy.

25. Defendant Nate Clark is CEO of the Board of MNsure.

26. Defendant Peter Benner is Chair of the Board of MNsure.

27. Defendant Suyapa Miranda is Vice Chair of the Board of MNsure.

28. Defendant David Fisher is a member of the Board of MNsure.

29. Defendant Jodi Harpstead is a member of the Board of MNsure.

30. Defendant Phil Norrgard is a member of the Board of MNsure.

31. Defendant Stephanie Stoffel is a member of the Board of MNsure.

32. Defendant Andrew Whitman is a member of the Board of MNsure.

JURISDICTION AND VENUE

33. Subject matter jurisdiction is founded on 28 U.S.C. §§ 1331 and 1343 because this case arises under the Constitution and laws of the United States.

34. The Court has authority under 42 U.S.C. § 1983 and the doctrine of *Ex Parte Young*, 209 U.S. 123 (1908), to enjoin enforcement of the Act, and to grant declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202.

35. Venue lies in this district under 28 U.S.C. § 1391(b) because the Act was enacted in this district and will be enforced by each Defendant in the course of the performance of his or her official duties in this district.

FACTUAL BACKGROUND

Development of Insulin Products to Treat Diabetes

36. More than 30 million Americans, including approximately 330,000 Minnesotans, suffer from diabetes.[2] Diabetes is a chronic disease caused by insufficient insulin production or development of resistance to insulin. Insulin is a hormone produced by the pancreas that signals the body's cells to absorb glucose from the blood for energy. Without insulin, cells are unable to absorb glucose. If not treated, diabetes can damage a number of organ systems in the body.

[2] Minnesota Dept. of Health, *Diabetes in Minnesota*, https://bit.ly/2WnlQBO.

37. There are two types of diabetes. Type 1 diabetes is caused when a person's pancreas does not produce insulin. Type 2 diabetes is caused when a person's pancreas produces insulin, but the body develops a resistance to it, such that the body needs more insulin than the pancreas can produce to regulate blood sugar effectively.

38. Diabetes is often treated with injectable insulin, which takes the place of or supplements insulin naturally produced in the body.

39. Before insulin was discovered in 1921, people with diabetes did not live long. A child diagnosed with type 1 diabetes at age 10 typically died within three years.

40. After insulin was discovered, pharmaceutical manufacturers, including some that are members of PhRMA today, began developing and producing injectable insulin products that extended the life expectancy of people with diabetes. The early forms of injectable insulin were extracted from animal tissue, and they extended the average life expectancy for people living with type 1 diabetes into their early 40s.

41. In the late 1970s, the first genetically engineered synthetic insulin was produced. This led to the development of bioengineered insulin products that are more effective at treating diabetes and more closely resemble the insulin release that naturally occurs in the body.

42. Three of PhRMA's members have long invested in the development of insulin products and manufacture most of the insulin products sold in the United States today. The companies (and their insulin products) are: Lilly (Basaglar®, Humalog®, and Humulin®); Novo Nordisk (Tresiba®, Levemir®, Fiasp®, NovoLog Mix 70/30®, NovoLog®, and Novolin®); and Sanofi (Admelog®, Apidra®, Lantus®, and Toujeo®).

43. These manufacturers' decades of work to develop improved insulin products has led to an increase in life expectancy for people with type 1 diabetes by more than 20 years, into their late 60s. Similarly, these manufacturers' innovations have enabled people with type 2 diabetes to better manage their diabetes with additional treatment options, and have helped reduce the occurrence of certain comorbid conditions that are associated with diabetes.

44. PhRMA's members are actively researching and developing new insulins and other diabetes treatments to help people with diabetes live longer and healthier lives. PhRMA's members have recently introduced a new rapid acting insulin and also are working on new inhalable insulin and insulin with more convenient dosing directly before and after meals, rather than in anticipation of meals. PhRMA's members have also released treatments, and continue to work on new products, that encourage the body to produce more insulin and that further reduce the risk from comorbid conditions.

45. Manufacturers use revenue from the sale of existing medicines to finance the research and development of new medicines, which is a lengthy and costly process. PhRMA estimates that it takes a manufacturer an average of 10 to 15 years to develop a new medicine from discovery through approval by the FDA. Less than 12% of the candidate medicines that make it into Phase 1 clinical trials are approved by the FDA. *See* PhRMA, *Biopharmaceuticals In Perspective* 33 (Chart Pack, Summer 2019), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2019_ChartPack_Final.pdf.

46. Over the past decade, the average research and development cost required to develop a new FDA-approved drug was estimated to be $2.6 billion (in 2013 dollars). *See id.* at 33, 41. This is a substantial increase over research and development costs in the 1990s to early 2000s, when the cost to develop an FDA-approved drug was approximately $1 billion. *Id.* at 41.

The Cost of Insulin to Consumers

47. Pharmaceutical products, including insulin, are sold and distributed to patients through an interstate distribution system involving a number of participants. Pharmaceutical manufacturers primarily sell their products to wholesalers at a price based on the drug's Wholesale Acquisition Cost ("WAC"). Federal law defines WAC as "the manufacturer's list price" to "wholesalers or direct purchasers," "not including prompt pay or other discounts, rebates or reductions in price." 42 U.S.C. § 1395w-3a(c)(6)(B). In accordance with the statutory definition, WAC is

a national list price that manufacturers charge their wholesale customers for their products.

48. The out-of-pocket cost that patients typically pay at the pharmacy for a particular medication is often lower—indeed, often much lower—than WAC. This is because most patients are covered by commercial insurance or governmental health insurance programs.

49. In addition, manufacturers pay rebates and offer discounts that ultimately lower the cost paid for the medication by these insurers. Pharmacy Benefit Managers ("PBMs") are retained by insurance companies to manage their commercial prescription drug programs. PBMs decide which medications will be covered by an insurance plan (a list called the plan's "formulary"), and on what terms. Formularies typically have multiple tiers that determine the cost-sharing terms between the insurer and its covered members, with medicines in preferred tiers carrying lower co-payment obligations for members. If a medication is excluded from these formularies or placed in a disfavored reimbursement tier on the formulary, patients may be required to pay the full retail cost of the medication or a larger share of the cost (through higher co-payments or coinsurance percentages). That, in turn, can reduce demand for, and use of, the medication. As a result, for manufacturers, securing preferred placement for a medication on a formulary can be important to ensuring that insured patients have access to that medication.

50. PBMs' control over formulary design can give them leverage when negotiating with manufacturers. PBMs are often able to use that leverage to extract substantial rebates or discounts from the manufacturer in exchange for placement of the product on the plan's formulary in a preferred tier.

51. PBMs also work with insurers and negotiate with pharmacies to determine the amounts that the insurance plan will pay the pharmacy and that the patient must pay the pharmacy out-of-pocket when the prescription is filled. For patients with private insurance, therefore, the out-of-pocket cost they pay for insulin depends on the terms of their insurance plan and whether drug coverage is subject to a deductible, co-payment, and/or coinsurance requirement. Insulin manufacturers play no role in establishing these requirements of private plans.

52. There has been a trend in the design of large employer health plans toward greater use of coinsurance and higher out-of-pocket deductibles for prescription drugs. As a result, patient out-of-pocket costs in these plans grew faster between 2006 and 2016 than the overall cost of all benefits covered by the plans during this period. *See* PhRMA, *Biopharmaceuticals In Perspective* at 81. To address this problem, Minnesota enacted a law that took effect on January 1, 2020 and requires insurers that impose cost-sharing requirements on beneficiaries to limit out-of-pocket payments for insulin to the net price the insurer pays—"including any rebates or discounts received by or accrued directly or indirectly to the health plan

company from a drug manufacturer or pharmacy benefit manager." Minn. Stat. § 62Q.48, subdiv. (2)(e), (3). But this law allows insurers to recover the costs of the insulin for which they provide coverage—unlike the Act's requirement that manufacturers recover nothing for insulin they are compelled to provide.

53. The amount that Medicaid beneficiaries must pay for prescription medication is determined by the federal and state laws and regulations that establish and govern that program. Manufacturers are required by federal law to enter into a standard National Drug Rebate Agreement with the federal government, on behalf of participating states, if they want their medications to be covered by Medicaid, and to pay rebates to the states on covered outpatient medications dispensed to the states' Medicaid beneficiaries. *See* 42 U.S.C. § 1396r-8.

54. Individuals who are not covered by public or private insurance pay the price set by the pharmacy for the medication. Although it varies by pharmacy, the retail price at the pharmacy can approximate WAC. However, as discussed below, the manufacturers have adopted various affordability programs to enable individuals to obtain insulin at a price that is lower than WAC or the retail pharmacy price.

55. Ironically, the net price realized by a manufacturer can decline while its product's WAC remains the same, because of the discounts offered by the manufacturer to individual purchasers and the rebates paid to PBMs and other payors.

Manufacturers Have Adopted Programs to Make Insulin Accessible and Affordable

56. PhRMA's members recognize that, as patients' out-of-pocket costs for medications increase, some patients may be unable to afford to fill all of their prescriptions. To address that problem for patients taking insulin, Lilly, Novo Nordisk, and Sanofi all have programs, and undertake other significant voluntary efforts, to enable patients to obtain their medications at lower out-of-pocket costs, or even for free. The manufacturers have implemented these voluntary initiatives in all 50 states. The particulars of each manufacturer's affordability offerings vary, and the manufacturers refine their initiatives and programs over time to address new market conditions or causes of patient needs.

57. Lilly has undertaken multiple programs to improve access to insulin for those living with diabetes, which can be accessed directly at https://www.insulinaffordability.com. People with diabetes can also call the Lilly Diabetes Solution Center, a hotline staffed by medical professionals who connect patients to various affordability options based on individual circumstances. By calling the Solution Center, patients with an urgent need can access an immediate supply of their Lilly insulin. In response to the COVID-19 crisis, Lilly recently launched the Lilly Insulin Value Program, which allows U.S. residents—with any type of commercial insurance or no insurance at all—to purchase their monthly Lilly insulin prescrip-

tions for $35 with a co-payment card. And, separate from co-pay cards, Lilly provides automatic savings to commercially insured patients at retail pharmacies. When a patient with commercial insurance fills a prescription for a Lilly insulin product at a retail pharmacy, the individual generally will pay only $95 for a month's supply, subject to local and state regulations and quantity limits.

58. In addition to the affordability programs that it administers, Lilly donates vast amounts of product to separate charitable organizations, such as the Lilly Cares Foundation, that provide free medicine, including insulin, directly to patients who qualify. Under the Lilly Cares Foundation's current eligibility criteria, patients who use Lilly insulins, have no insurance or Medicare Part D coverage, and have a household annual adjusted gross income of up to 400% of the federal poverty level, can qualify to obtain donated insulin at no cost.

59. Novo Nordisk has likewise developed a number of programs to provide both long-term support and more immediate assistance to individuals with diabetes, and has established a centralized location where patients can find information about all Novo Nordisk affordability programs at Novocare.com. For example, through its Patient Assistance Program, Novo Nordisk provides free insulin and other diabetes medications to eligible patients whose annual income is at or below 400% of the federal poverty level. Further, patients using Novo Nordisk insulin who have lost health insurance coverage because of a change in job status due to

COVID-19 are eligible for enrollment in the program and to receive insulin free-of-charge for 90 days.

60. Additionally, through partnerships with national pharmacies, including Walmart and CVS, patients can purchase Novo Nordisk human insulin—an effective and affordable diabetes treatment—for about $25 per vial. Novo Nordisk also offers a program through which eligible commercially insured patients with a valid prescription can take advantage of co-payment cards. Separately, Novo Nordisk's "My$99Insulin" program allows patients with a valid prescription to purchase a 30-day supply (up to 3 vials or 2 packs of pens) of any of Novo Nordisk's insulins for $99. Among other programs, Novo Nordisk also offers a free one-time 30-day supply (up to three vials or two packs of pens) of its insulins for individuals with diabetes at risk of rationing insulin.

61. Sanofi similarly operates an assortment of affordability programs, and provides information about these programs at teamingupfordiabetes.com/sanofidiabetes-savings-program and sanofipatientconnection.com. For instance, the patient-assistance component of Sanofi's Patient Connection program provides free insulin to qualified patients whose income is below 400% of the federal poverty level, and who either lack insurance or have insurance that does not cover Sanofi's insulin products. Sanofi recently expanded this program in response to the COVID-19 pandemic, allowing patients experiencing a recent financial hardship to

receive an immediate 30-day supply of insulin even while their application to the program is pending. Additionally, Sanofi's Insulins Valyou Savings Program enables all uninsured patients—regardless of income—to receive up to 10 boxes of pens and/or 10 mL vials of a Sanofi insulin product (or a combination of products, as needed) for $99 per 30-day supply.

62. Sanofi also offers all commercially insured patients—again, regardless of income—co-payment assistance for its insulin products. This program caps patients' co-payment for Lantus® and Toujeo® at $99, though many patients pay far less. Across all of Sanofi's insulin products, the majority of patients receiving co-payment assistance in 2019 paid nothing or $10 per 30-day supply. There is no limit on eligible patients' receipt of co-payment assistance.

63. Certain of the manufacturers' programs do not currently provide discounts to Medicare Part D beneficiaries for prescription drugs because the Office of the Inspector General in the U.S. Department of Health and Human Services has issued guidance suggesting that manufacturers may violate the federal Anti-Kickback Statute by doing so. However, the Centers for Medicare & Medicaid Services has invited manufacturers to participate in a new Model Medicare Part D plan in 2021 in which Medicare beneficiaries would pay a maximum $35 co-payment for a 30-day supply of insulin in the deductible, initial coverage, and coverage gap phases of the

Part D benefit with qualifying plans. Lilly, Novo Nordisk, and Sanofi have each agreed to participate in that Model plan.

The Act

64. The Governor signed the Act into law on April 15, 2020. The Act establishes an "insulin safety net program" that requires manufacturers of "insulin that is self-administered on an outpatient basis," Minn. Stat. 151.74, subdiv. 1(b)(1), to provide insulin for free to Minnesota residents who meet the statutory criteria. That program has two parts: the "Continuing Safety Net Program" and the "Urgent Need Program."

65. Under the Act's Continuing Safety Net Program, a manufacturer "shall make a patient assistance program available" to provide free insulin products to "any individual" who meets the statutory eligibility criteria: Minnesota residents with valid identification and family income of 400% or less of the federal poverty level, who are not enrolled in Medicaid or MinnesotaCare, are not eligible for federally funded healthcare or Veterans Administration prescription drug benefits, and are not covered by an insurance plan under which they can obtain a 30-day supply of insulin for $75 or less out of pocket (including co-payments, deductibles, and coinsurance). *See* Minn. Stat. 151.74, subdiv. 4(a) & 4(b). The Act further provides that individuals with prescription drug coverage under Medicare Part D are eligible to receive free insulin under the Continuing Safety Net Program if they

have spent more than $1,000 on prescription drugs in the calendar year and meet the other eligibility criteria. *See* Minn. Stat. 151.74, subdiv. 4(c).

66. Upon receiving a Minnesota resident's application for free insulin under the Continuing Safety Net Program, the manufacturer must determine whether the individual meets the statutory eligibility criteria, and then notify the individual of that eligibility determination within 10 business days (unless additional information is needed, in which case brief extensions of time are permitted). *See* Minn. Stat. 151.74, subdiv. 5(a).

67. If the manufacturer denies the application, the resident may appeal to a review panel created by the Board of Pharmacy. Minn. Stat. 151.74, subdiv. 8. The panel may overrule the manufacturer, and its eligibility decision is binding. *Id*

68. For those eligible residents who have private health insurance, the Act allows the manufacturer to "determine that the individual's insulin needs are better addressed through the use of the manufacturer's co-payment assistance program, in which case, the manufacturer shall inform the individual and provide the individual with the necessary coupons to submit to a pharmacy." Minn. Stat. 151.74, subdiv. 5(c). Otherwise, the manufacturer must provide the individual with a "statement of eligibility" that is valid for 12 months and can be taken to a pharmacy with a prescription to obtain free insulin from the manufacturer under the Continuing Safety Net Program. Minn. Stat. 151.74, subdiv. 5(b).

69. Likewise, for those eligible residents who lack private insurance, the manufacturer must provide the individual with a "statement of eligibility" that the individual can then take to a pharmacy to obtain insulin under the Continuing Safety Net Program for up to one year. Minn. Stat. 151.74, subdiv. 5(b).

70. When the resident presents the eligibility statement to a pharmacy, the pharmacy orders the insulin from the manufacturer, and the manufacturer "shall send to the pharmacy a 90-day supply of insulin" "*at no charge* to the individual or pharmacy." Minn. Stat. 151.74, subdiv. 6(c) (emphasis added).[3] The pharmacy, in contrast, is allowed to charge the resident a co-payment "not to exceed $50 for each 90-day supply" to cover "the pharmacy's costs for processing and dispensing" the insulin. Minn. Stat. 151.74, subdiv. 6(e).

71. This process may be repeated as the individual orders more insulin throughout their full year of eligibility. "Upon receipt of a reorder from a pharmacy," the manufacturer must send "an additional 90-day supply of the product, unless a lesser amount is requested"—again "*at no charge* to the individual or pharmacy." Minn. Stat. 151.74, subdiv. 6(f) (emphasis added).

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[3] The text of the Act gives manufacturers the option of mailing the insulin directly to the individual. Minn. Stat. 151.74, subdiv. 6(g). But the Board of Pharmacy has since acknowledged that federal and state law may prohibit manufacturers from doing so. Minn. Bd. of Pharmacy, *Minnesota Insulin Safety Net Program Guidance* at 4 (May 20, 2020), https://mn.gov/boards/assets/ISNP-Guidance_tcm21-433509.pdf.

72. The Act also establishes an Urgent Need Program that requires manufacturers to provide a 30-day supply of free insulin for individuals who meet the statutory eligibility criteria: Minnesota residents who (1) are not enrolled in Medicaid or MinnesotaCare; (2) are not enrolled in a prescription drug coverage plan that would cover a 30-day supply of insulin for $75 or less out of pocket (including co-payments, deductibles, and coinsurance); (3) have not received insulin under the Urgent Need Program within the past 12 months; and (4) have readily available for use less than a seven-day supply of insulin and need insulin to avoid the likelihood of suffering significant health consequences. Minn. Stat. 151.74, subdiv. 2(a)-(b).

73. When an eligible resident submits an application along with a valid prescription for insulin, the pharmacy "shall dispense" a 30-day supply of the insulin. Minn. Stat. 151.74, subdiv. 3(c). The pharmacy then submits an electronic claim for payment to the manufacturer (or the manufacturer's vendor), who must then either "reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost" or else "send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed." Minn. Stat. 151.74, subdiv. 3(d).

74. Once again, the Act allows pharmacies to recoup their costs of providing the medication: the pharmacy may collect an insulin co-payment from the individual in an amount not to exceed $35 for the 30-day supply. Minn. Stat. 151.74,

subdiv. 3(e). But as with the Continuing Safety Net Program, none of that co-payment goes to the manufacturer that is required to provide the free insulin (or its monetary equivalent) to the pharmacy.

75. In addition to being forced to give away their insulin for free according to the state's terms, manufacturers will also incur significant expenses in developing and administering the Continuing Safety Net Program and Urgent Need Program.

76. If a manufacturer fails to comply with the requirements of either program, the Board of MNsure may assess administrative penalties that start at $200,000 per month of noncompliance and eventually increase to $600,000 per month if the manufacturer continues to be in noncompliance after one year. Minn. Stat. 151.74, subdiv. 10(a). A manufacturer is also subject to these penalties if it fails to provide a state-mandated telephone hotline (operated in accordance with the state's specific requirements), or if it fails to advertise the eligibility criteria for the Minnesota programs on its website. Minn. Stat. 151.74, subdiv. 10(b).

77. The Act requires all insulin manufacturers to fulfill these obligations under these two state-created programs, with two limited exceptions. First, a manufacturer is exempt from the law if it has "annual gross revenue of $2,000,000 or less from insulin sales in Minnesota." Minn. Stat. 151.74, subdiv. 1(c). Second, a manufacturer's insulin product is exempt if the product's WAC "is $8 or less per milliliter or applicable National Council for Prescription Drug Plan billing unit, for the entire

assessment time period, adjusted annually based on the consumer price index." Minn. Stat. 151.74, subdiv. 1(d).

78. Neither exemption applies to PhRMA's members that sell insulin in Minnesota. Each manufacturer has more than $2 million in annual gross revenue from the sale of insulin products in Minnesota, and the WAC for each of its insulin products is greater than $8 per milliliter.

79. MNsure estimates that 13,100 Minnesotans will participate in the Continuing Safety Net Program and another 16,600 Minnesotans will participate in the Urgent Need Program in the first year after the Act goes into effect. Minn. Health & Human Servs. Fin. Div., Consolidated Fiscal Note, HF 3100, 91st Leg. (Feb. 18, 2020), https://www.house.leg.state.mn.us/comm/docs/9b4c084f-4ef5-4ab7-af26-0c8ffb7abada.pdf. At those participation rates, PhRMA's members will be compelled to provide 173,800 monthly supplies of free insulin through these programs in just the first year of the Act's operation.

FIRST CLAIM FOR RELIEF
Violation of the Takings Clause

80. The prior paragraphs of the Complaint are incorporated by reference.

81. The Takings Clause of the Fifth Amendment provides that "private property [shall not] be taken for public use, without just compensation." U.S. Const., Amend. V. The Due Process Clause of the Fourteenth Amendment makes that prohibition applicable to the states.

82. The Act's Continuing Safety Net Program requires PhRMA's members to provide their insulin products free of charge to the public, *i.e.*, Minnesota residents. Until they are sold, those products are the private personal property of PhRMA's members that manufacture them. The requirement that PhRMA's members give away their personal property for free constitutes a *per se* taking of private property. *See Horne v. U.S. Dep't of Agric.*, 135 S. Ct. 2419 (2015). The Act makes no provision, and includes no mechanism, to compensate manufacturers for this taking. Accordingly, the Continuing Safety Net Program effects a series of *per se* takings of private property for public use without just compensation, in violation of the Takings Clause.

83. The Act's Urgent Need Program requires PhRMA's members to provide their insulin products free of charge to pharmacies that dispense their products to Minnesota residents. The requirement that PhRMA's members give away their personal property for free constitutes a *per se* taking of private property. *See Horne*, 135 S. Ct. 2419. The Act makes no provision, and includes no mechanism, to compensate manufacturers for this taking. Accordingly, the Urgent Need Program effects a series of *per se* takings of private property for public use without just compensation, in violation of the Takings Clause.

84. The Urgent Need Program's alternative of allowing a manufacturer to reimburse a pharmacy for the pharmacy's cost of acquiring the manufacturer's

product instead of providing a replacement unit does not avoid or ameliorate the unconstitutional taking. Even if reimbursing the pharmacy's acquisition cost is in some cases the less costly and/or more administrable option, it is a *per se* taking for Minnesota to require a manufacturer to pay for a particular dose of insulin that a particular pharmacist dispenses to a particular patient in order to avoid being required to replace, at no charge, the insulin the pharmacy dispensed to that patient. *See Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013).

85. Unless Defendants are enjoined from enforcing the Act, the law will continually effect unconstitutional takings of manufacturers' property without just compensation. The language and purpose of the Act make clear that Minnesota does not intend to, and will not, compensate PhRMA's members for the products they are required to provide to Minnesota residents for free. Accordingly, a continuous series of state court actions seeking to compel an inverse condemnation proceeding for each of the thousands of units of insulin that PhRMA's members must provide under the Act is not an appropriate or available remedy. Instead, the proper redress is an injunction against enforcement of the Act, which would also afford Minnesota the opportunity to repeal its law and reverse the unconstitutional taking. The Court has authority to grant such relief under *Ex Parte Young,* 209 U.S. 123 (1908).

SECOND CLAIM FOR RELIEF
Violation of the Commerce Clause

86. The prior paragraphs of the Complaint are incorporated by reference.

87. The Act provides an exemption for insulin products that have a WAC of "$8 or less per milliliter or applicable National Council for Prescription Drug Plan billing unit, for the entire assessment time period, adjusted annually based on the consumer price index." Minn. Stat. 151.74, subdiv. 1(d). PhRMA is not aware of any U.S. manufacturer that sells an insulin product for $8 per milliliter, and there is no explanation of the purpose of this exemption in the Act's legislative history. If this provision were interpreted to afford insulin manufacturers the "option" of avoiding the unconstitutional taking of their property by lowering the WAC of their products to $8 per milliliter, the exemption is independently unconstitutional under the Commerce Clause of the U.S. Constitution.

88. By granting Congress the power "[t]o regulate Commerce . . . among the several States," U.S. Const. art. I, § 8, cl. 3, the Commerce Clause operates, in its "dormant" aspect, to prohibit states from enacting laws that impose substantial burdens on interstate commerce. The Dormant Commerce Clause prohibits states from regulating commerce beyond their boundaries.

89. To the extent that Subdivision 1(d) of Minn. Stat. 151.74 conditions the ability of insulin manufacturers to escape the unlawful taking of their property on

a requirement that they charge a WAC of no more than $8 per milliliter, that provision violates the Dormant Commerce Clause because it would directly regulate the price of transactions that occur entirely outside Minnesota between out-of-state insulin manufacturers and out-of-state wholesalers. Indeed, the WAC is a national list price that manufacturers charge their wholesale customers for their products and thus cannot be changed in one state alone. Such regulation of extra-territorial commerce is impermissible under the Dormant Commerce Clause.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests judgment against Defendants as follows:

- A declaration that Subdivisions 3(d) and 6(f) of Minn. Stat. 151.74 violate the Takings Clause of the Fifth Amendment (applicable to the states under the Fourteenth Amendment), and that, if Subdivision 1(d) were interpreted as a condition on the ability of manufacturers to escape the unlawful taking of their personal property, that condition would violate the Commerce Clause;
- A permanent injunction against enforcement of Subdivisions 3(d), 6(f), and 1(d) of Minn. Stat. 151.74;
- Award of PhRMA's attorney fees and costs; and
- Such other relief as the Court may deem just and proper.

Dated: June 30, 2020

GREENE ESPEL PLLP

s/ Kathryn N. Hibbard

John M. Baker, Reg. No. 0174403
Kathryn N. Hibbard, Reg. No. 0387155
222 S. Ninth Street, Suite 2200
Minneapolis, MN 55402
(612) 373-0830
jbaker@greeneespel.com
khibbard@greeneespel.com

-and-

Joseph R. Guerra *(Pro Hac Vice Motion Forthcoming)*
Benjamin M. Mundel (*Pro Hac Vice Motion Forthcoming)*
SIDLEY AUSTIN LLP
1501 K Street, N.W., #600
Washington, DC 20005
(202) 736-8000
jguerra@sidley.com
bmundel@sidley.com

Attorneys for Plaintiff Pharmaceutical Research and Manufacturers of America