IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Pharmaceutical Research and Manufacturers of America, Plaintiff, v. Ronda Chakolis, James Bialke, Amy Paradis, Rabih Nahas, Michael Haag, Ben Maisenbach, John M. Zwier, Barbara Droher Kline, and Kendra Metz, in their official capacities as members of the Minnesota Board of Pharmacy, Defendants.	Case No. 20-cv-1497 (DSD/DTS) **AMENDED 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" or "Defendants") and states as follows:

INTRODUCTION

1. On July 1, 2020, the Alec Smith Insulin Affordability Act (the "Act") went into effect in Minnesota. The Act sought to address a matter of public concern in an unconstitutional way.

2. The public concern was the high out-of-pocket costs that some patients had to pay for insulin, often because these individuals lacked health insurance coverage for prescription medications, or because their insurance required

significant out-of-pocket payments for their medications. But the Act sought to address that concern in a manner that violated the Takings Clause of the Fifth Amendment of the U.S. Constitution; it ordered 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. 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 these programs to respond to patients' new financial challenges.

4. PhRMA filed this lawsuit on July 1, 2020 because the Act *compelled* manufacturers to give their insulin away for free, and because manufacturers that

failed to comply with that unconstitutional demand were subject to substantial and increasing fines. The Act made no provision to compensate manufacturers for this compulsory appropriation of their property for public use. Nor did 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.

5. PhRMA filed this lawsuit because 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.

6. 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).

7. Because the Act effected a repeated and continuous series of unconstitutional *per se* takings, included no mechanism to compensate manufacturers for those takings, and, by its very design and purpose, foreclosed any compensation, the Complaint asked for a declaratory judgment that the Act violated the Takings Clause and an injunction against its enforcement.

8. The District Court granted Defendants' motion to dismiss the complaint for lack of standing. PhRMA appealed, and the Eight Circuit reversed. It held that PhRMA has standing to seek declaratory and injunctive relief to redress the repetitive series of allegedly unconstitutional takings of insulin compelled by the Act. *See Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932 (8th Cir. 2023).

9. On remand, the District Court struck defendants' affirmative defenses, leaving defendants with no viable legal defense to PhRMA's claim that the Act effects a series of unconstitutional takings of the manufacturers' insulin. Soon thereafter, the Minnesota legislature amended the Act by adding several provisions enacted as article 56 of 2024 Minn. Laws, ch. 127 ("Article 56"). These amendments do not solve the Act's constitutional defects. The amended Act continues to take insulin from the manufacturers without payment of just compensation.

10. In particular, Article 56 leaves undisturbed the Act's confiscatory requirements that insulin manufacturers must give insulin at no charge to eligible Minnesota residents. And while Article 56 provides a mechanism for insulin

manufacturers to request no more than $35 for each 30-day supply of insulin they are forced to give away after December 1, 2024, it also requires insulin manufacturers to pay a new so-called "registration fee" of $100,000 per year.

11. The $100,000 annual fee far exceeds the payment any of PhRMA's members could have obtained in 2020, 2021, 2022, or 2023 if Article 56 had been in effect since the Act was enacted in 2020. And the $100,000 annual fee will offset (and almost certainly will far exceed) the payment manufacturers can receive after Article 56 takes effect in December of 2024.

12. Accordingly, even after Article 56 takes effect, the Act will continue to repeatedly take insulin from PhRMA's members without payment of just compensation, and PhRMA is entitled to declaratory and injunctive relief to redress that repetitive and ongoing violation of the Takings Clause.

PARTIES

Plaintiff

13. 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.

14. 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.

15. 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]

16. 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.

[1] A full list of PhRMA's members is available at http://www.phrma.org/about (last visited Aug. 6, 2024) (click "Members").

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

Defendants

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

19. Defendant Ronda Chakolis is President of the Board of Pharmacy.

20. Defendant Kendra Metz is Vice-President of the Board of Pharmacy.

21. Defendant Ben Maisenbach is a member of the Board of Pharmacy.

22. Defendant Michael Hagg is a member of the Board of Pharmacy.

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

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

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

26. Defendant John Zwier is a member of the Board of Pharmacy.

27. Defendant Barbara Droher Kline is a member of the Board of Pharmacy.

JURISDICTION AND VENUE

28. 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.

29. 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.

30. 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

31. More than 30 million Americans, including approximately 390,000 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.

32. 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.

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

[2] Minnesota Dept. of Health, *Diabetes in Minnesota*, https://bit.ly/2WnlQBO (last visited Aug. 6, 2024).

34. 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.

35. 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.

36. 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.

37. 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 branded insulin products) are: Lilly (Basaglar®, Humalog®, Humulin®, Lyumjev®, and Rezvoglar®); Novo Nordisk (Tresiba®, Levemir®, Fiasp®, NovoLog Mix 70/30®, NovoLog®, and Novolin®); and Sanofi (Admelog®, Apidra®, Lantus®, and Toujeo®).

38. 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.

39. 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.

40. 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 (2019),

https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2019_ChartPack_Final.pdf.

41. 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

42. 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.

43. 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 that pay much of the cost of acquiring the medication.

44. Commercial health insurance companies typically retain Pharmacy Benefit Managers ("PBMs") to manage their commercial prescription drug programs and negotiate the price of the medications that covered by their insurance plans. 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), assuming they do not avail themselves of any patient affordability program. 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.

45. 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 connection with placement of the product on the plan's formulary in a preferred tier.

46. 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. Insulin manufacturers play no role in establishing these requirements of private plans.

47. Since January 1, 2020, Minnesota law has required 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, subdivs. (2)(e), (3).

48. 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.

49. 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.

50. 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

51. 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.

52. Lilly has undertaken multiple programs to improve access to insulin for those living with diabetes, which can be accessed directly at https://www.insulinaffordability.lilly.com (last visited Aug. 6, 2024). 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. Since 2020, Lilly has had in place the Insulin Value Program, which allows commercially insured and uninsured consumers the option buy their monthly prescription of Lilly insulin for $35, regardless of the number of pens or vials they need. Additionally, Lilly has entered an agreement specifically with Minnesota, under which Minnesotans who are uninsured or don't pay for insulin using their insurance will have access to Lilly insulin for no more than $35 per month into 2029, regardless of the number of pens or vials they need per month.

53. 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.

54. 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. Under Novo Nordisk's MyInsulinRx™ program, eligible patients, including those who are uninsured, can pay $35 for a monthly supply of up to 3 vials or 2 packs of pens of any combination of Novo Nordisk insulin products. Further, through its Immediate Supply program, Novo Nordisk provides a free one-time, immediate supply of up to three vials or two packs of pens of Novo Nordisk insulin to eligible patients who are at risk of rationing their insulin. Additionally, Novo Nordisk offers coupons and copay savings offers to help defray high out-of-pocket costs for eligible commercially insured patients.

55. 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.

56. Sanofi also offers all commercially insured patients—again, regardless of income—co-payment assistance for its insulin products.

57. 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, in general terms, amendments to the Medicare statute in the Inflation Reduction Act limit the out-of-pocket costs Medicare beneficiaries pay for insulin products to $35 per month. Pub. Law No. 117-169, §§ 11406-07, 136 Stat. 1902-05 (Aug. 16, 2022).

The Act

58. 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."

59. 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 Id.*, 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 Id.*, subdiv. 4(c).

60. 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 Id.*, subdiv. 5(a).

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

62. 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." *Id.*, 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. *Id.*, subdiv. 5(b).

63. 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. *Id*.

64. 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." *Id.*, 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

[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 advised that federal and state law prohibit manufacturers from doing so. Minn. Bd. of Pharmacy, *Minnesota Insulin Safety Net Program Guidance* 4 (updated Jan. 12, 2024), https://mn.gov/boards/assets/ISNP_Guidance%2001.12.2024_tcm21-606579.pdf. "Consequently, a manufacturer can only send prescription insulin directly to patients if it uses a pharmacy licensed by the Board." *Id.*

supply" to cover "the pharmacy's costs for processing and dispensing" the insulin. *Id.*, subdiv. 6(e).

65. 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." *Id.*, subdiv. 6(f) (emphasis added).

66. 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. *Id.*, subdiv. 2(a)–(b).

67. 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. *Id.*, 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." *Id.*, subdiv. 3(d).

68. 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. *Id.*, 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.

69. 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.

70. If a manufacturer fails to comply with the requirements of either program, the Board of Pharmacy 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. *Id.*, 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. *Id.*, subdiv. 10(b).

71. 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." *Id.*, 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." *Id.*, subdiv. 1(d).

72. 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 each manufacturer has insulin products with a WAC that is greater than $8 per milliliter.

73. As a result, each of PhRMA's members that sell insulin in Minnesota complied with the Act by giving away insulin at no charge to Minnesota residents in 2020, 2021, 2022, and 2023, as documented in reports submitted by the manufacturers to the Board of Pharmacy as required by the Act, Minn. Stat. § 151.74, subdiv. 13.

74. The Board of Pharmacy reviewed the reports from the manufacturers and submitted annual reports to the Minnesota legislature stating that the manufacturers complied with the Act and gave away insulin at no charge to Minnesota residents under the Act in 2020, 2021, 2022, and 2023. The Board of Pharmacy's reports to the legislature are available at https://www.lrl.mn.gov/mndocs/mandates_detail?orderid=16211, and copies are attached to this Amended Complaint as Exhibits 1–4.

75. For example, the most recent Board of Pharmacy report to the legislature shows that in 2023, Eli Lilly gave insulin to 104 Minnesota residents under the Urgent Need Program and six Minnesota residents under the Continuing Need Program, and the total value of the insulin provided to those residents was $56,172.53, as measured by the wholesale acquisition cost. Ex. 4 at 4. Novo Nordisk gave insulin to 33 Minnesota residents under the Urgent Need Program and five Minnesota residents under the Continuing Need Program, and the total value of the insulin provided to those residents was $44,326.40, as measured by the wholesale acquisition cost. *Id.* Sanofi gave insulin to 106 Minnesota residents under the Urgent Need Program and 11 Minnesota residents under the Continuing Need Program, and the total value of the insulin provided to those residents was $50,943.08, as measured by the wholesale acquisition cost. *Id.* at 5.

76. As they did in 2020-2023, each of PhRMA's members that sell insulin in Minnesota has complied with the Act by giving away insulin at no charge to Minnesota residents in 2024.

2024 Amendments to the Act

77. In May, 2024, the Minnesota legislature enacted and the Governor approved Article 56, legislation that amended the Act. *See* 2024 Minn. Laws, ch. 127, art. 56.

78. Article 56 leaves intact the Urgent Need Program, so PhRMA's members are still required to give insulin at no charge to Minnesota residents who qualify for the program. Further, Article 56 removed the Act's sunset clause under which the Continuing Safety Net Program would have expired on December 31, 2024. 2024 Minn. Laws, ch. 127, art. 56, § 8 (repealing Minn. Stat. § 151.74, subdiv. 16). Thus, the Continuing Safety Net Program is now a permanent part of Minnesota law, mandating that PhRMA's members continue to give insulin at no charge to Minnesota residents who qualify for the program.

79. Article 56 directs the commissioner of administration to develop a claims process for insulin manufacturers to request and receive "an amount not to exceed $35 for each 30-day supply of insulin" provided under the Urgent Need Program and "an amount not to exceed $105 for each 90-day supply" of insulin provided under the Continuing Safety Net Program. *See* 2024 Minn. Laws, ch. 127,

art. 56, § 4 (adding a new subsection (h) to Minn. Stat. § 151.74, subdiv. 3); *id.* § 5 (adding a new subsection (h) to Minn. Stat. § 151.74, subdiv. 6).

80. The sections of Article 56 allowing insulin manufacturers to request and receive up to $35 from the commissioner of administration do not take effect until December 1, 2024.

81. Article 56 also imposes a new "registration fee" of $100,000 per year on insulin manufacturers. *See* 2024 Minn. Laws, ch. 127, art. 56, § 6 (adding Minn. Stat. § 151.741). The Board of Pharmacy "shall notify each manufacturer of this requirement beginning November 1, 2024, and each November 1 thereafter." *Id.* § 6 (adding Minn. Stat. § 151.741, subdiv. 2(a)). "Each manufacturer must pay the registration fee by March 1, 2025 and each March 1 thereafter." *Id.* (adding Minn. Stat. § 151.741, subdiv. 3(a)).

82. This new $100,000 annual registration fee is imposed only on manufacturers that are "engaged in the manufacturing of prescription insulin." 2024 Minn. Laws, ch. 127, art. 56, § 6 (adding Minn. Stat. § 151.741, subdiv. 1(c)). And this annual registration fee is in addition to the annual licensing fees manufacturers must pay to obtain a license to sell prescription medicines in Minnesota. *See* Minn. Stat. §§ 151.251, 151.065.

83. $100,000 is more than the payment any of PhRMA's members could have obtained in 2020, 2021, 2022, or 2023 if Article 56 had been in effect since the Act was enacted in 2020.

84. "A manufacturer may request an exemption from the annual registration fee," and the Board of Pharmacy shall grant the exemption if "the manufacturer can demonstrate to the board, in the form and manner specified by the board, that gross revenue from sales of prescription insulin produced by that manufacturer and sold or delivered within or into Minnesota was less than five percent of the total gross revenue from sales of prescription insulin produced by all manufacturers and sold or delivered within or into Minnesota in the previous calendar year." 2024 Minn. Laws, ch. 127, art. 56, § 6 (adding Minn. Stat. § 151.741, subdiv. 2(b)).

85. PhRMA's members—Eli Lilly, Novo Nordisk, and Sanofi—will not be able to request and obtain an exemption from the $100,000 annual registration fee. PhRMA is not aware of any publicly available source reporting the "total gross revenue from sales of prescription insulin produced by all manufacturers and sold or delivered within or into Minnesota in the previous calendar year." *Id.* Without such information, no insulin manufacturer could even apply for the exemption. And because Eli Lilly, Novo Nordisk and Sanofi are the three largest producers of insulin

in the country, there is no reason to believe that any of them would qualify for the exemption even if they had the information needed to apply.

86. Annual registration fees paid by insulin manufacturers "must be deposited in the insulin safety net program account"—a new account "established in the special revenue fund in the state treasury." 2024 Minn. Laws, ch. 127, art. 56, § 6 (adding Minn. Stat. § 151.741, subdivs. 3(b) & 4). "Money in the account is appropriated each fiscal year" to the MNSure board and Board of Pharmacy to cover their costs of carrying out their assigned duties under the Act. *Id.* § 6 (adding Minn. Stat. § 151.741, subdiv. 4).

FIRST CLAIM FOR RELIEF
Violation of the Takings Clause

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

88. 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.

89. 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.*, 576 U.S. 350 (2015). Until subdivision 6(h) of Minnesota statute section 151.74 takes effect on December 1, 2024, the Act makes no provision, and includes no mechanism, for manufacturers to receive any money for insulin products they are statutorily required to give away for free. 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.

90. 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*, 576 U.S. 350. Until subdivision 3(h) of Minnesota statute section 151.74 takes effect on December 1, 2024, the Act makes no provision for manufacturers to receive any money for insulin products they are statutorily required to give away for free. 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.

91. 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).

92. Article 56 does not and will not cure the violation of the Takings Clause. It permits manufacturers to request up to $35 for each month's supply of insulin they are forced to give to Minnesota residents at no charge under the Act, and it also requires them to pay a $100,000 annual "registration fee" that will offset (and likely will far exceed) the amount any $35 repayments they will receive.

93. At a minimum, Article 56 takes back through the annual registration fee the limited payments it authorizes the commission of administration to provide. In all likelihood, Article 56 will provide a financial benefit to the State, because the sum total of the $35 payments a manufacturer receives in a year will be less than the $100,000 fee the manufacturer must pay the State. Under either scenario, the Act will not provide just compensation for the insulin that the manufacturers are continually required to give away at no charge to Minnesota residents.

94. Thus, even after the payment provisions in Article 56 take effect, PhRMA's members would still need to bring a continuous series of state court

inverse condemnation actions to obtain just compensation for the insulin they are continually required to provide at no charge to Minnesota residents. But as the Eighth Circuit has already held, requiring insulin manufacturers to "litigate a multiplicity of suits to be compensated" is not "an adequate remedy for the repetitive series of alleged takings under the Act." *PhRMA*, 64 F.4th at 945 (cleaned up). Accordingly, PhRMA is entitled to an injunction to prevent the unconstitutional taking of the manufacturers' property without just compensation.

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);
- A permanent injunction against enforcement of Subdivisions 3(d), 6(c), 6(f), and 10 of Minn. Stat. § 151.74;
- A permanent injunction against enforcement of Minn. Stat. § 151.741, Subdivisions 2 and 3(a).
- Award of PhRMA's attorney fees and costs; and
- Such other relief as the Court may deem just and proper.

Dated: September 3, 2024 **GREENE ESPEL PLLP**

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