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. 0:20-cv-01497 (DSD/DTS) **PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT**

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INTRODUCTION

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") filed this lawsuit over four years ago to challenge the constitutionality of Minnesota's Alec Smith Insulin Affordability Act ("Act"), an extraordinary law that required pharmaceutical manufacturers to give their insulin products away for free in violation of the Takings Clause of the Fifth Amendment. Although this Court originally dismissed the lawsuit because it thought it lacked the power to enjoin the Act, the Eighth Circuit reversed. It held that an injunction entered by this Court would be the only way to adequately remedy the injury to PhRMA's members, because "Minnesota's inverse condemnation procedures do not afford insulin manufacturers an adequate remedy for the repetitive series of alleged takings under the Act." *PhRMA. v. Williams*, 64 F.4th 932, 945 (8th Cir. 2023) (citations omitted).

Events on remand made it crystal clear that PhRMA would prevail. This Court affirmed the Magistrate Judge's decision striking Defendants' affirmative defenses, leaving them with no viable way to defend the Act. Indeed, Defendants now essentially concede that the Act as originally enacted effects a *per se* taking of property every time it compels insulin manufacturers to give away their products.

Soon thereafter, the Minnesota Legislature amended the Act, adding Article 56. *See* 2024 Minn. Laws, ch. 127, art. 56. But the amendments did not transform the Act into a constitutionally valid law. Article 56 retains the Act's requirement that insulin manufacturers give insulin away. And although Article 56 provides an administrative process for insulin manufacturers to obtain payment of up to $35 for each 30-day supply

of insulin they are forced to give away, that provision is a charade. Article 56 also requires manufacturers to pay a $100,000 "registration fee" to Minnesota annually to fund the state's administration of the Act. Indeed, using the last four years as a guide, this registration fee is almost certain to exceed the amount manufacturers could receive under the payment provisions by thousands of dollars. As a result, PhRMA's members will suffer greater injury under the amended Act than they have suffered so far. PhRMA thus filed an amended complaint to challenge the amended law.

Defendants' motion to dismiss that complaint is meritless. Its principal argument is that PhRMA lacks standing because it is "speculative" whether PhRMA's members will have to give away any insulin "in the future." MTD 14–15, ECF No. 155. That argument defies reason. PhRMA's members have been forced to give away insulin under the Act every year since it took effect. Just six months ago, the Minnesota Legislature reaffirmed the need for the Act by enacting Article 56. Article 56 not only prevents one of the Act's programs from expiring but also imposes the registration fee, which will be used to advertise the Act and to pay navigators to help Minnesotans access the Act's insulin. Defendants' argument is thus predicated on the nonsensical idea that the Legislature's amendments will have no effect. That argument should not be credited. Instead, the only plausible inference is that the Act will be used to take insulin from at least one of PhRMA's members in the future—as has been true every year since the Act's enactment.

Defendants' other arguments fare no better. The amended complaint plausibly alleges a violation of the Takings Clause. The amended Act does not provide just compensation for the insulin that manufacturers are forced to give away because any

compensation manufacturers will receive will be offset—and likely exceeded—by the new registration fees they must now pay to Minnesota.

The amended complaint also states a plausible claim for injunctive and declaratory relief. Defendants' argument to the contrary defies the Eighth Circuit's prior ruling in this case. PhRMA is entitled to equitable relief because, under the amended law, manufacturers will still have to bring a multiplicity of condemnation suits to obtain just compensation for the insulin they are required to give away under the Act.

Defendants' motion to dismiss should be denied.

BACKGROUND

A. The Act

The Alec Smith Insulin Affordability Act (the Act) requires manufacturers of "insulin that is self-administered on an outpatient basis" to provide insulin for free to certain Minnesota residents. Minn. Stat. § 151.74, subdiv. 1(b)(1). The Act has two parts.

1. The Continuing Safety Net Program

Under the Continuing Safety Net Program, a manufacturer "shall make a patient assistance program available" to provide free insulin to any Minnesota resident who (1) has family income of 400% or less of the federal poverty level; (2) is not enrolled in Medicaid or MinnesotaCare; (3) is not eligible for federally funded healthcare or Veterans Administration prescription drug benefits; and (4) is not enrolled in an insurance plan that covers a 30-day supply of insulin for $75 or less out of pocket (including co-payments, deductibles, and coinsurance). *See id.*, subdivs. 4(a), 4(b)(1)-(5). Individuals with prescription drug coverage under Medicare Part D can also receive free insulin if they have

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

Manufacturers must provide eligible residents with a "statement of eligibility" that can be presented at a pharmacy to obtain free insulin from the manufacturer, in 90-day increments, for up to one year. *Id.*, subdivs. 5(b), 6(a), 6(c).[1] The pharmacy may charge the resident a "co-payment" of up to $50, but none of the money goes to the manufacturer, which must send a 90-day supply to the individual or pharmacy "at no charge." *Id.*, subdivs. 6(c), 6(e), 6(g). This process must be repeated if an individual orders more insulin throughout the full year of eligibility and, in any subsequent years for which there is "a redetermination of eligibility." *Id.*, subdivs. 5(b), 6(f).

2. The Urgent Need Program

Under the Act's Urgent Need Program, manufacturers must provide a 30-day supply of free insulin to 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 (with some exceptions); (4) have readily available for use less than a seven-day supply of insulin; and (5) need insulin to avoid the likelihood of suffering significant health consequences. *See id.*, subdivs. 2(a)–(b), 9.

[1] Alternatively, if the resident has private health insurance, the manufacturer may "determine that the individual's insulin needs are better addressed through the use of the manufacturer's co-payment assistance program," and "provide the individual with the necessary coupons to submit to a pharmacy." *Id.*, subdiv. 5(c).

When an eligible resident applies under this program, the pharmacy "shall dispense" a 30-day supply of insulin to that person. *Id.*, subdiv. 3(c). The pharmacy then submits a claim for payment to the insulin manufacturer (or its vendor); the manufacturer must either "send to the pharmacy a replacement supply of the same insulin," or "reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost" for the dispensed insulin. *Id.*, subdiv. 3(d). The pharmacy may collect a co-payment of up to $35 for the 30-day supply. *Id.*, subdiv. 3(e). But none of that co-payment goes to the manufacturer that provides the free replacement insulin (or its monetary equivalent) to the pharmacy. *Id.*, subdiv. 3(d).

B. PhRMA's Members Are Forced To Give Away Insulin Under the Act

There are two exceptions to the Act's mandates. First, a manufacturer is exempt 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 from [the Act] if the wholesale acquisition cost ["WAC"] of the insulin 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).

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. Am. Compl. ¶ 72, ECF No. 150.

Thus, the manufacturers were required by the Act to give away insulin at no charge to Minnesota residents in 2020, 2021, 2022, 2023, and 2024. *Id.* ¶¶ 73, 76.[2] As further required by the Act, the manufacturers submitted reports to the Board of Pharmacy identifying the number of residents who received free insulin and the value of the insulin they received. *See id.* ¶ 73. The Board of Pharmacy submitted that information to the Minnesota Legislature in annual reports that are attached as Exhibits 1–4 of the Amended Complaint.[3]

C. The Legislature Amends the Act By Enacting Article 56

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.

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

[2] Had they not complied, the Board of Pharmacy could have imposed penalties of $200,000-$600,000 per month on each manufacturer. Minn. Stat. § 151.74, subdiv. 10(a)-(b).

[3] The reports address insulin that the manufacturers gave away under the Act in 2020-2023; insulin given away in 2024 will be addressed in reports manufacturers must file by February 15, 2025. *See* Minn. Stat. § 151.74, subdiv. 13.

Article 56 directs Minnesota's Department 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). These claims process provisions take effect on December 1, 2024. *Id.*

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). This registration fee is imposed only on insulin manufacturers—not on any other companies that do business in Minnesota. *Id.* (adding Minn. Stat. § 151.741, subdiv. 1(c)). And the fee is in addition to the annual licensing fees manufacturers must pay to obtain licenses to sell prescription medicines in the state. *See* Minn. Stat. §§ 151.251, 151.065. Manufacturers "must pay the registration fee by March 1, 2025 and by each March 1 thereafter." 2024 Minn. Laws, ch. 127, art. 56, § 6 (adding Minn. Stat. § 151.741, subdiv. 3(a)).

Article 56's annual registration fees "must be deposited in the insulin safety net program account"—a new account "established in the special revenue fund in the state treasury." *Id*. (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.* (adding Minn. Stat. § 151.741, subdiv. 4).

A manufacturer may request and obtain an exemption from the registration fee if it "can demonstrate to the [Board of Pharmacy], 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)). But PhRMA's members—Lilly, Novo Nordisk, and Sanofi—will not be able to request and obtain an exemption. Am. Compl. ¶ 85. 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 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. *Id.*

The $100,000 registration fee PhRMA's members are required to pay each year will offset, and will in all likelihood far exceed, the payments they are eligible to receive under Article 56 for the insulin they are forced to give away. Am. Compl. ¶ 11. Indeed, the $100,000 fee exceeds the amount any of the three insulin manufacturers would have

received for the insulin that the Act forced them to give away in 2020, 2021, 2022, or 2023 if Article 56 had been in effect during those years. *Id.* ¶ 85.

Using data from the Board of Pharmacy reports attached as Exhibits 1-4 of the Amended Complaint, the following charts show the amount each of PhRMA's members could have received if they could have requested $35 for each 30-day supply of insulin they were forced to give away in 2020, 2021, 2022, and 2023 under the Act.[4]

Lilly

	Amounts for Insulin Given Away Under Urgent Need Program	**Amounts for Insulin Given Away Under Continuing Safety Net Program**	**Total for both programs**
2020	$3,185 (for 91 recipients)	$5,040 (for 12 eligible participants)	**$8,225**
2021	$3,815 (for 109 recipients)	$6,300 (for 15 eligible participants)	**$10,115**
2022	$3,535 (for 101 recipients)	$7,140 (for 17 eligible participants)	**$10,675**
2023	$3,640 (for 104 recipients)	$2,520 (for 6 eligible participants)	**$6,160**

[4] The charts assume that each Urgent Need Program recipient received one 30-day supply, and each resident who was eligible to participate in the Continuing Safety Net Program placed an order every 90 days and thus received four 90-day supplies of insulin during the year.

Novo Nordisk

	Amounts for Insulin Given Away Under Urgent Need Program	**Amounts for Insulin Given Away Under Continuing Safety Net Program**	**Total for both programs**
2020	$2,135 (for 61 recipients)	$90,300 (for 215 eligible participants)	**$92,435**
2021	$3,815 (for 91 recipients)	$5,040 (for 12 eligible participants)	**$8,855**
2022	$1,750 (for 50 recipients)	$2,100 (for 5 eligible participants)	**$3,850**
2023	$1,155 (for 33 recipients)	$2,100 (for 5 eligible participants	**$3,255**

Sanofi

	Amounts for Insulin Given Away Under Urgent Need Program	**Amounts for Insulin Given Away Under Continuing Safety Net Program**	**Total for both programs**
2020	$ 4,970 (for 142 recipients)	$1,260 (for 3 eligible participants)	**$6,230**
2021	$7,280 (for 208 recipients	$3,360 (for 8 eligible participants)	**$10,640**
2022	$5,005 (for 143 recipients)	$12,600 (for 30 eligible participants)	**$17,605**
2023	$3,710 (for 106 recipients)	$4,620 (for 11 eligible participants)	**$8,330**

D. Procedural History

1. Initial Proceedings In This Court

PhRMA filed this lawsuit on behalf of itself and three of its members that are subject to the Act. Compl. ¶ 13, ECF No. 1. PhRMA alleged that the Act causes a series of *per se* physical takings of private property by forcing manufacturers to give their insulin products to Minnesota residents at no charge. *See id.* ¶¶ 82–83. And because the Act does not provide just compensation for those products, the takings violate the Takings Clause of the Fifth Amendment. *Id.* PhRMA sued the members of the Minnesota Board of Pharmacy in their official capacities under 42 U.S.C. § 1983 and *Ex Parte Young*, 209 U.S. 123 (1908), seeking declaratory and injunctive relief against the unconstitutional taking of their property. Compl. ¶¶ 15–32, 34, Request for Relief.

Defendants moved to dismiss; PhRMA opposed Defendants' motion and cross-moved for summary judgment. *See* ECF Nos. 12–14. This Court granted Defendants' motion and denied PhRMA's motion. Order, ECF No. 81. The Court held that PhRMA lacked Article III standing because the Court could not issue injunctive relief to redress the injury to PhRMA's members. *Id.* at 7–12. The Court concluded that, under the Supreme Court's decision in *Knick v. Township. of Scott*, 139 S. Ct. 2162 (2019), "injunctive relief is foreclosed 'as long as just compensation remedies are available,'" and "just compensation remedies are available in Minnesota through inverse condemnation actions in state court." Order at 9–10 (quoting *Knick*, 139 S. Ct. at 2179). The Court did not reach the merits of PhRMA's takings claim.

2. The Eighth Circuit Appeal

PhRMA appealed and the Eighth Circuit reversed. As relevant here, the Eighth Circuit held that PhRMA has standing to seek injunctive relief and that Minnesota's inverse condemnation remedy is an inadequate remedy for the taking of the manufacturers' insulin products "because PhRMA's members would be bound to litigate a multiplicity of suits to be compensated." *PhRMA*, 64 F.4th at 945 (internal quotation marks omitted). The Court explained that an "inverse condemnation action to reimburse a manufacturer for each discrete alleged taking is incapable of compensating the manufacturers for the repetitive, future takings that will occur under the Act's requirements. By contrast, equitable relief would protect manufacturer from those future harms." *Id.*

3. Proceedings on Remand

On remand, PhRMA filed another motion for summary judgment, arguing that the Act repeatedly takes the manufacturers' insulin products without just compensation and thus should be enjoined. ECF No. 93. Defendants opposed the motion under Rule 56(d), arguing that they needed time to take discovery. ECF No. 109. This Court agreed, and denied PhRMA's summary judgment motion without prejudice to PhRMA refiling the motion when discovery is complete. ECF No. 114.

Thereafter, Defendants made sweeping discovery requests, asserting that they needed "voluminous amounts of information and substantial third-party discovery" to support their public nuisance and licensing defenses to PhRMA's takings claim. ECF No. 126 at 1. But the Magistrate Judge held that these defenses were legally foreclosed by Supreme Court precedent. ECF No. 133. The Magistrate Judge thus struck those defenses

and ordered limited discovery, and this Court affirmed. ECF No. 141. Subsequently, as discussed above, the Minnesota Legislature amended the Act. *See supra* at 6–9.

PhRMA filed an amended complaint challenging the amended Act, which continues to violate the Takings Clause. ECF No. 150. Defendants' motion to dismiss the amended complaint is now before this Court. ECF No. 151. For the reasons explained below, it should be denied.

STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* This is "a context-specific task" that requires the court "to draw on its judicial experience and common sense," *id.* at 679, and to "grant[] all reasonable inferences to the non-moving party," *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 591 (8th Cir. 2009).

ARGUMENT

I. PhRMA Has Standing

As a threshold matter, PhRMA has associational standing, because one or more of its members has standing.[5] *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333,

[5] Under *Hunt*, PhRMA has associational standing to sue on behalf of its members if (1) any of its members would have standing to sue in its own right, (2) the interests PhRMA seeks to protect are germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *See Hunt*, 432 U.S. at 342–43. Here, Defendants challenge only the first element. In addition, Defendants'

343 (1977). Standing is generally self-evident where, as here, the challenge is brought by a regulated entity or an association representing regulated entities. *See, e.g.*, *Am. Petroleum Inst. v. Johnson*, 541 F. Supp. 2d 165, 176 (D.D.C. 2008) ("[S]tanding is usually self-evident when the plaintiff is a regulated party or an organization representing regulated parties."). That is because when an entity is an "object of" government action, there is "ordinarily little question that the action" will concretely affect the entity. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992); *see also, e.g.*, *St. Paul Area Chamber of Com. v. Gaertner*, 439 F.3d 481, 485 (8th Cir. 2006) ("When a statute is challenged by a party who is a target or object of the statute . . ., there is ordinarily little question that the statute has caused [the party] injury." (cleaned up)).

This case is no exception. Here, PhRMA has standing because its insulin-manufacturer members are the "objects of" a regulatory scheme that inflicts multiple injuries, any one of which is sufficient to support standing. *See Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 777 (8th Cir. 2019) (parties had standing because they "are the objects of the . . . Act and subject to future enforcement actions brought by the Commissioner"). First, the Act requires manufacturers to give away their insulin, *see* Am. Compl. ¶¶ 58–76, and loss of property is a straightforward injury in fact, *see generally* Wright & Miller, Federal Practice and Procedure, § 3531.4 at 830 (2005 Supp.) ("Standing is found readily, particularly when injury to some traditional form of property is asserted.").

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argument that PhRMA lacks standing because PhRMA is not *itself* injured is irrelevant. MTD 14. PhRMA does not seek to establish standing based on injury to itself as an organization.

Second, the manufacturers "will also incur significant" compliance costs in "administering the Continuing Safety Net Program and Urgent Need Program." Am. Compl. ¶ 69. These "compliance costs," too, are "a classic injury-in-fact." *City of Kennett v. EPA*, 887 F.3d 424, 431 (8th Cir. 2018).

Third, Article 56 requires PhRMA's members to pay a $100,000 registration fee. *See* 2024 Minn. Laws, ch. 127, art. 56, § 6 (adding Minn. Stat. § 151.741); *see also* Am. Compl. ¶¶ 81–85 (allegations that PhRMA's members are subject to the fee). This financial injury is a paradigmatic injury in fact that establishes standing. *See, e.g.*, *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017) ("For standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'"); *Nat'l Parks Conservation Ass'n v. EPA*, 759 F.3d 969, 975 (8th Cir. 2014) (holding that "[r]isk of direct financial harm" caused by regulatory scheme "stablishes injury in fact"). [6]

In contending that PhRMA "fails to allege a real and immediate threat of future harm" to its manufacturer-members, MTD 13 (cleaned up), Defendants confuse standing and the merits. It is a merits—not a standing—question whether the insulin manufacturers "would be justly compensated" for "provid[ing] insulin under the Act in the future." *Id.* at 14. Defendants' assertion (contested by PhRMA) that Defendants "ultimately will compensate [each manufacturer] for its property does nothing to erase [each manufacturer's] legally cognizable injury" for purposes of the threshold standing analysis.

[6] Defendants' argument that the registration fee cannot support standing to challenge the Act's provisions requiring the manufacturers to give away insulin fails because those provisions are part of the same scheme, for the reasons explained below. *Infra* 21–24.

B&J Oil & Gas v. FERC, 353 F.3d 71, 75 (D.C. Cir. 2004) (rejecting theory that regulatory scheme's provision of just compensation deprived plaintiff of standing to bring takings claim).

Defendants' next argument—that it is "speculative" that manufacturers will "continue to provide insulin under the Act in the future," MTD 16, 17—is equally flawed. The amended complaint "plausibly" establishes, *see Iqbal*, 556 U.S. at 679, a "substantial risk" that at least *one* manufacturer will give away at least *one* vial of insulin under the Act in the future, *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (holding that allegations of future injury suffice "there is a 'substantial risk' that the harm will occur"). That is all PhRMA needs to show. *See Sierra Club v. U.S. Army Corps of Eng'rs*, 645 F.3d 978, 988 (8th Cir. 2011) (explaining that "an identifiable trifle will suffice" to establish "imminent, concrete harm"). It has done so. Each manufacturer has given away insulin under the Act in 2020, 2021, 2022, 2023 and 2024. Am. Compl. ¶¶ 74–76 & Exs. 1–4. What is more, the enactment of Article 56 itself gives rise to a logical inference that there is continued demand for the program, and that it will be used by Minnesota residents. Article 56 repeals the sunset clause, making the Continuing Safety Net Program a permanent feature of Minnesota law, rather than a temporary program that ends on December 31, 2024.[7] If there were not still a need for the program, the Legislature would have allowed it to expire. The inference that Minnesota residents will continue to obtain insulin under the Act is buttressed by the new $100,000 registration fee, which Defendants

[7] *See* 2024 Minn. Laws, ch. 127, art. 56, § 8 (repealing Minn. Stat. § 151.74, subdiv. 16).

and MNSure will use to advertise the availability of free insulin under the Act and to train and pay insurance navigators to help people avail themselves of the Act's free insulin. *See* MTD 7 (citing statutory provisions); *see also* Am. Compl. ¶ 86.

Defendants maintain that "recent developments in the insulin-pricing landscape" between 2020 and 2024 somehow make it "speculative" that even a single Minnesotan will use the Act to obtain insulin in the future. MTD 16. But, as the complaint makes clear, there is every indication that Minnesotans will continue to use the Act's programs—regardless of the manufacturers' own, longstanding assistance programs and the settlements that two manufacturers entered regarding insulin pricing in Minnesota. MTD 16–17, 4. For one, insulin is cheaper under the Continuing Safety Net Program ("not to exceed $50" for a 90-day supply) than it is under some of the assistance programs Defendants reference ($35 for a 30-day supply, or $105 for 90 days' worth). *See* Am. Compl. ¶ 64. For another, a Minnesota resident can access insulin under the Urgent Need Program simply by walking into a pharmacy and filling out an application form, which is at least as simple as the mechanism for enrolling in any of the programs Defendants tout in their brief, MTD 17.[8] Indeed, consistent with the conclusion that the Act remains useful to Minnesota residents, Lilly gave away insulin to over 100 Minnesota residents under the Act in 2023, *see* Am. Compl. ¶ 75, even though Lilly has been capping patient out-of-

[8] *Compare* Minn. Insulin Safety Net Program, *Urgent Need Program*, https://tinyurl.com/492wpwbr (last visited Nov. 11, 2024) ("[P]lease ask your pharmacist for the 'urgent need insulin application.'"), *with, e.g.*, MTD 17 (describing settlement program), *and* Am. Compl. ¶¶ 52–55 (citing www.insulinaffordability.lilly.com; www.Novocare.com; www.sanofipatientconnection.com).

pocket costs for its insulin at $35 since 2020. *See* Am. Compl. ¶ 52 (discussing Lily's Insulin Value Program).

Defendants' contention that the Act is moribund, or even in disuse, thus defies logic and common sense. In light of the Legislature's recent reaffirmation of the Act and the continued investment of considerable resources in promoting the availability of free insulin under the Act, the only plausible inference is that at least one of PhRMA's members will have its insulin taken in the future.

II. PhRMA Has Stated A Takings Claim For Which Relief May Be Granted

A. The Act Causes *Per Se* Physical Takings of Private Property Without Payment of Just Compensation

The Takings Clause of the Fifth Amendment, applicable to the States through the Fourteenth Amendment, provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend. V. It protects both real and private property, "without any distinction" between the two. *Horne v. Department of Agriculture*, 576 U.S. 350, 358 (2015). The Supreme Court has made clear that any physical appropriation of property—real or personal—is a *per se* "taking." *Id.*; *see also, e.g.*, *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147–50 (2021) (discussing cases).

Defendants' motion to dismiss does not dispute that the Act takes the manufacturers' insulin. Nor could that be disputed, as the Act's requirement that manufacturers give insulin to Minnesota residents is a *per se* taking. It is indistinguishable in all material respects from the federal marketing order that the Court held to be a taking in *Horne*. That order required raisin growers to set aside a certain percentage of their crop

"for the account of the Government, free of charge." *Horne,* 576 U.S. at 354. A government-run committee could then dispose of the raisins as it wished. *Id.* at 361. The Court held this "reserve requirement" was "a clear physical taking," because the growers "lose the entire 'bundle' of property rights in the appropriated raisins—'the rights to possess, use and dispose of' them." *Id.* at 361-62 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982)); *see also id.* at 371 (Breyer, J., with whom Ginsburg, J., and Kagan, J., joined, concurring in part and dissenting in part) (agreeing that the marketing order effected a *per se* physical taking).

The Act's requirement that manufacturers provide insulin for free is likewise a "clear physical taking" of the manufacturers' property. Manufacturers must relinquish actual insulin under the Act's Continuing Safety Net Program. *See* Minn. Stat. § 151.74, subdivs. 6(c), 6(g). And they must send actual insulin to pharmacies to replace insulin dispensed under the Urgent Need Program (unless they elect to reimburse the pharmacies for the cost of the disbursed product instead). *See id.*, subdivs. 3(c), 3(d). Thus, like the raisin growers in *Horne*, manufacturers are deprived of the entire "bundle" of property rights in each dose of insulin they provide under the Act: they lose the ability to possess, use, or dispose of that property, and must instead give it away for free.[9] The Act thus compels *per se* physical takings of private property.

[9] It is irrelevant that, for the Urgent Need Program, manufacturers can reimburse pharmacies for the acquisition cost of the insulin dispensed instead of sending a replacement supply. The government cannot evade the limitations of the Takings Clause by giving a property owner the option "to spend money rather than give up" the property itself. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 611–12 (2013).

Instead, of challenging any of this, Defendants argue that PhRMA has not stated a takings claim because the "manufacturers will be justly compensated through the reimbursement mechanisms in the amended Act."[10] MTD 19. That argument fails as a matter of law.

The Minnesota legislature did not simply authorize payment (of up to $35 for each 30-day supply) for insulin that manufacturers are forced to give away under the Act.[11] It also required insulin manufacturers to pay a "registration fee" of $100,000 per year to fund the cost of administering the Act's taking of their insulin.[12] That $100,000 annual fee will offset—and almost certainly will exceed—the annual payment PhRMA's members could obtain for the insulin they are forced to give away under the Act. Am. Compl. ¶ 11.

Information from the Board of Pharmacy's reports to the Minnesota Legislature shows that if Article 56 had been in effect in 2023, each insulin manufacturer could have requested payment from Minnesota of less than $8,400 for the insulin they were forced to give away under the Act. *See supra* 9–10. In other words, no manufacturer would have received even *10%* of the $100,000 registration fee that each would have been required to pay to Minnesota. Indeed, the $100,000 annual registration fee exceeds the amount of

[10] Defendants also argue that the addition of the reimbursement mechanism renders "moot" PhRMA's "original challenge" to the Act before it was amended. MTD 10–11. But PhRMA's amended complaint does not challenge the original law; it challenges the amended law. Am. Compl. ¶¶ 9–12.

[11] *See* 2024 Minn. Laws, ch. 127, art. 56, § 4 (adding Minn. Stat. § 151.74, subdiv. 3(h)); *id.* § 5 (adding Minn. Stat. § 151.74, subdiv. 6(h)).

[12] *See* 2024 Minn. Laws, ch. 127, art. 56, § 6 (adding Minn. Stat. § 151.741).

payment any manufacturer could have obtained in any year if Article 56 had been part of the Act since 2020. *See* Am. Compl. ¶ 83; *see also supra* 9–10.

Thus, even assuming (as PhRMA does for purposes of this litigation) that payment of $35 would be just compensation for a 30-day supply of each insulin product taken by the Act, the amended Act still effects a taking of property without just compensation because the compensation it authorizes is more than offset by the $100,000 registration fee.

Defendants argue that the registration fee is a "separate financial obligation to the government" that "does not render just compensation provided for a taking inadequate." MTD 20. That argument can be easily rejected: Minnesota imposed the fee while amending the Act, and the provisions work together as a scheme. Notably, Defendants cite nothing to support their argument. And accepting it would provide a clear roadmap for any government to evade its obligations to pay just compensation for property it takes.

The scheme Minnesota has enacted for insulin here could be replicated for any number of consumer products, from baby formula to cell phones. The law could mandate that the property owners give their property away at no charge, provide compensation in an amount the legislature deems just, and then effectively take back some or all of that compensation by imposing special fees—even exceeding the amount of compensation provided—on the very owners whose property was taken. Such a scheme fails to provide the just compensation mandated by the Takings Clause. That it does so indirectly (by imposing the special fee) rather than directly (by refusing to pay just compensation in the first place) is irrelevant.

It is a well-established principle of constitutional law that the government "cannot do indirectly" what it "is barred from doing directly." *Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 190 (2024). Courts must assure that "constitutional guarantees, so carefully safeguarded against direct assault" are not "open to destruction" by an assault that is "indirect but no less effective." *Frost v. R.R. Comm'n*, 271 U.S. 583, 593 (1926). That principle applies to the rights protected by the Takings Clause just as it applies to other constitutional rights. *See, e.g., Koontz*, 570 U.S. at 612 (holding that the government may no more require property owners to pay "monetary exactions" than to convey an easement because it would otherwise "be very easy for land-use permitting officials to evade the limitations" of the Takings Clause by demanding money in lieu of the easement).

Over a century ago, courts held that similar schemes to take property, while shifting the costs to those whose property is taken, violate the Takings Clause. *Scott v. City of Toledo*, involved an ordinance that (1) directed the city attorney to commence eminent domain proceedings to acquire certain parcels of land to expand a street, and (2) imposed a special assessment on the landowners to cover the costs of building the road. 36 F. 385, 390 (N.D. Ohio 1888). The court held that the city could not exempt itself "from the duty and obligation of compensating" the landowners, and the ordinance was unconstitutional because the assessment effectively gave the landowners "the burden of compensating themselves or of returning to the city all they may be entitled to receive as compensation for their property." *Id.* at 396.

The same result was reached in *Baker v. Village of Norwood*, another case in which a local government took land by eminent domain and imposed a special assessment that

effectively required the landowner to "not only pay for her own property taken for the benefit of the village of the public without compensation, but also to pay the expense of so taking it." 74 F. 997, 999 (S.D. Ohio 1896), *aff'd* 172 U.S. 269 (1898). The court reasoned: "If such a proceeding is not a taking for public use without just compensation, I am at a loss to know what would constitute such a taking." *Id.* at 999–1000.

That reasoning is equally applicable here, where Article 56 effectively takes back through the $100,000 registration fee the payment it authorizes for the insulin that manufacturers are forced to give away.

Defendants may try to argue that Article 56 is different because the $100,000 registration fee is a fixed fee that doesn't vary with the amount of insulin a manufacturer is forced to give away, and the fee will be placed in different account than the account that will be will used to pay the manufacturers. *Cf.* MTD 20. Neither fact changes the analysis.

Defendants' premise is that the amended Act complies with the Takings Clause because payment of $35 is just compensation for each 30-day supply of insulin taken by the Act. But that premise falls apart when the $100,000 registration fee is considered. The registration fee effectively reduces the compensation a manufacturer can obtain. That is true regardless of whether the fee is larger or smaller than the payment the manufacturer could request, and regardless of what account the commissioner of administration uses to pay the manufacturer. Money is fungible, and the registration fees will reduce the financial burden on Minnesota by shifting it to the manufacturers, regardless of the account in which the fees extracted from the manufacturers are placed.

Finally, Defendants' characterization of the fee as "independent" of the Act is simply wrong. MTD 20. Article 56 requires that registration fees be deposited in a new "insulin safety net program account"[13]—an account that Defendants admit will be used by MNsure and the Board of Pharmacy "*to fulfill their duties under the Act*." MTD 7 (emphasis added). As Defendants explain, those duties include advertising the availability of insulin under the Act, training and paying insurance navigators to help people apply for insulin under the Act, and ensuring compliance with the Act. *Id.* In other words, through the enactment of Article 56, Minnesota is requiring PhRMA's members to pay the cost of administering the very programs that take their insulin.

Defendants have cited no case holding that Minnesota can enact a program to take private property and then shift the costs back on the owners whose property was taken.[14] By doing just that, the amended Act subverts the Taking Clause's "guarantee that private property shall not be taken for a public use without just compensation," a guarantee that "was designed to bar Government from 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).

[13] 2024 Minn. Laws, ch. 127, art. 56, § 6 (adding Minn. Stat. § 151.741, subdivs. 3(b), 4).

[14] Defendants argue only that taxes and user fees are not takings. MTD 20. But regardless of whether a fee itself normally survives takings scrutiny, that principle has no application to the $100,000 registration fee imposed by Article 56. That fee is *not* a general licensing fee on pharmaceutical manufacturers; it is an additional fee imposed only on insulin manufacturers. And its purpose and effect is *not* to fund some government service used by insulin manufacturers. As demonstrated above, its purpose and effect is to force insulin manufacturers to bear the costs of a government program that takes their insulin.

B. PhRMA Has Stated A Claim For Injunctive and Declaratory Relief

Finally, Defendants contend that *Knick* precludes injunctive relief here because PhRMA's members "ha[ve] some way to obtain compensation" for the insulin they give away under the Act. MTD 11–13 (emphasis omitted). But as discussed above, the Eighth Circuit already rejected that theory. As the Eighth Circuit earlier instructed, *Knick*'s bar on injunctive relief does not apply when "the state law remedies are inadequate." *PhRMA*, 64 F.4th at 940. And the state law remedy is inadequate here, for the very reason outlined by the Eighth Circuit: That remedy would require insulin manufacturers to bring a continuous series of state court inverse condemnation suits to obtain just compensation, and requiring the manufacturers to "litigate a multiplicity of suits to be compensated" for the insulin taken under the Act is not "an adequate remedy." *Id.* at 945 (cleaned up). "By contrast, equitable relief would protect manufacturers from those future harms." *Id.*; *see* Am. Compl. ¶ 94.

Defendants are wrong that the "appellate court's holding and reasoning" are now "inapposite" because the amended Act "includes compensation mechanisms." MTD 13. As discussed, the law permits manufacturers to request up to $35 for each month's supply of insulin they are forced to give to Minnesota residents under the Act, but it also requires them to pay the $100,000 fee that will offset, and likely far exceed, the amount any manufacturer receives in $35 reimbursement payments. *See* Am. Compl. ¶¶ 92–93; *supra* 9–10. Thus, the "compensation mechanisms" of the Act will not provide just compensation. Instead, the manufacturers would still need to bring a continuous series of inverse condemnation suits to obtain just compensation for the insulin that they are required to give

away under the Act.[15] *See id.* ¶ 94. As the Eighth Circuit has already held, such a "multiplicity of suits" is not "an adequate remedy for the repetitive series of alleged takings under the Act." *PhRMA*, 64 F.4th at 945 (cleaned up).

Defendants' last-ditch argument to prevent an injunction against the Act fails for similar reasons. In Defendants' mistaken view, "PhRMA alleges the amended Act remains unconstitutional only because of the registration fee" and so any violation of the Takings Clause could be remedied by enjoining the fee alone. MTD 21. But as repeatedly explained, the Act and the fee work together to effect a taking of the manufacturers' property. The Act and the fee must fall together, and PhRMA is entitled to a declaratory judgment stating that the scheme violates the Takings Clause[16] and an injunction against both the fee and the Act's requirement that insulin manufacturers give away their products for free.

CONCLUSION

For the foregoing reasons, PhRMA respectfully requests that Defendants' Motion to Dismiss Amended Complaint be denied. Alternatively, PhRMA requests leave to amend the complaint.

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[15] Without exposition, Defendants call these allegations "simply implausible," MTD 13, but the allegations are well supported. *See* Am. Compl. Exs. 1–4, *supra* 14–17.

[16] Even if the Court agrees with Defendants that any injunction against the fee would remedy the violation of the Takings Clause, PhRMA would still be entitled to a declaration stating that the Act effects a taking of insulin without just compensation. *See* Am. Compl., Request for Relief (requesting "[a] declaration that Subdivisions 3(d) and 6(f) of Minn. Stat. § 151.74 violate the Takings Clause of the Fifth Amendment"). The Declaratory Judgment Act provides an additional remedy, so federal courts may "declare the rights … of any interested party … whether or not further relief is or could be sought." 28 U.S.C. § 2201(a).

Respectfully submitted,

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