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, Defendants.	Case No. 20-cv-1497-DSD-DTS **PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") filed this suit to challenge the constitutionality of Minnesota's Alec Smith Insulin Affordability Act ("Act"), an extraordinary law that requires pharmaceutical manufactures to give their insulin products away for free, without any compensation from the State. The suit is back before this Court on remand from the Eighth Circuit, which held that PhRMA has standing to seek injunctive and declaratory relief if it prevails on the merits of its takings claim. Resolution of the merits question is straightforward. The Supreme Court has repeatedly held that, regardless of its motivation, a state may not commandeer personal property for the use of third parties without paying for it. Undisputed evidence shows that this is precisely what the Act does. This Court should grant PhRMA's motion for summary judgment, declare the Act causes unconstitutional takings, and permanently enjoin its enforcement.

PhRMA previously moved for summary judgment but, without addressing the merits, this Court denied that motion on the ground that PhRMA lacked standing to pursue equitable relief. *See* Doc. 81. In so ruling, the Court adopted defendants' theory that the inverse condemnation procedure available to PhRMA's members under Minnesota law barred injunctive and declaratory relief, and thus rendered PhRMA's injury unredressable. *Id.* at 7-12. The Eighth Circuit reversed, holding that this procedure was not an adequate remedy "for the repetitive series of alleged takings under the Act." *Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932, 946 (8th Cir. 2023). The Eighth Circuit also rejected defendants' other threshold arguments, holding that PhRMA has

associational standing and that its claim is not barred by sovereign immunity. *Id.* at 947-50. These rulings clear the way for this Court to resolve of the merits of PhRMA's claim. And the proper resolution of that claim is clear.

The Act compels insulin manufacturers to give away their products to certain state residents at no charge to the recipients, and without compensation from the state. These material facts cannot be disputed. And they establish as a matter of law that the Act effects unconstitutional *per se* takings every time it compels insulin manufacturers to give away their products: In each instance, the manufacturers are deprived of the entire bundle of rights in their insulin—"the rights to possess, use and dispose of" it, *Horne v. Department of Agriculture*, 576 U.S. 350, 360 (2015) (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982))—without just compensation.

Defendants previously strained to defend the Act on the merits. As noted, this Court did not have occasion to address defendants' arguments in light of its ruling on standing. It should reject them now. Most fail at the starting gate because they ignore the critical distinction the Supreme Court has drawn between *per se* physical takings (which PhRMA has alleged) and regulatory takings (which PhRMA has not alleged). None has merit. As a matter of settled law, the Act is unconstitutional.

PhRMA and the three insulin manufacturers wholeheartedly agree with Minnesota that no one living with diabetes should be forced to go without insulin because they cannot afford it. Indeed, as defendants themselves have acknowledged, the manufacturers have patient assistance programs for insulin that "have similar eligibility requirements to the Act" and "target the same populations that the Act seeks to protect." Doc. 16 at 18-19.

Under the Takings Clause, however, the Minnesota legislature cannot convert these voluntary programs into mandatory legal obligations backed by penalties. A "strong public desire to improve the public condition" does not allow the government to achieve its goals "by a shorter cut than the constitutional way of paying for the change." *Pennsylvania Coal Co. v. Mahon,* 260 U.S. 393, 416 (1922). Because Minnesota's law contravenes this principle, it should be declared unconstitutional and permanently enjoined.

BACKGROUND

Diabetes is a chronic disease caused by insufficient insulin production or the development of resistance to insulin. *See* Minn. Dep't of Health, *About Diabetes*, https://www.health.state.mn.us/diseases/diabetes/about/diabetes.html (last visited July 10, 2023). Insulin is a hormone that signals the body's cells to absorb glucose from the blood for energy. *Id.* Diabetes is often treated with injectable insulin. Since insulin was discovered, manufacturers have developed (and continue to develop) improved insulin products that help people with diabetes better manage their condition and live longer and healthier lives. Doc. 1, ¶¶ 39-44.

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).

Insulin manufacturers must accept applications from Minnesota residents, determine whether the individuals are eligible, and provide notice of those eligibility determinations. *Id.*, subdiv. 5(a). Applicants can appeal adverse eligibility decisions to a state review panel, which may overrule the manufacturer. *Id.*, subdiv. 8.

If a resident is deemed eligible, the manufacturer must provide a "statement of eligibility" that can be presented at a pharmacy to obtain free insulin from the manufacturer for up to one year. *Id.*, subdivs. 5(b), 6(a). Alternatively, for eligible residents with 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 presented with an eligibility statement, the pharmacy orders insulin from the manufacturer, which must send a 90-day supply to the individual or pharmacy "at no charge." *Id.*, subdivs. 6(c), 6(g). This process must be repeated if an individual orders more insulin throughout the full year of eligibility and, in any subsequent years of the program for which there is "a redetermination of eligibility." *Id.*, subdiv. 5(b).[1] "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." *Id.*, subdiv. 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.[2]

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

[1] The Continuing Safety Net program is set to expire on December 31, 2024, but the legislature will review the program and determine whether it should continue beyond that date. Minn. Stat. § 151.74, subdiv. 16.

[2] The Urgent Need program has no expiration date.

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).

3. Enforcement of the Act

If a manufacturer does not comply with the Act's requirements, it is subject to a penalty of $200,000 per month. *Id.*, subdiv. 10(a)-(b). This penalty increases to $600,000 per month if a manufacturer remains noncompliant after one year. *Id.*, subdiv. 10(a).

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).

B. Prior Proceedings in this Court

PhRMA filed this lawsuit on behalf of itself and three of its members—Eli Lilly and Company, Novo Nordisk Inc., and Sanofi—that are subject to the Act. Doc. 1, ¶ 13. PhRMA alleged that, by forcing manufacturers to give their products away for free, the Act causes a series of *per se* physical takings of private property. *See id.* ¶¶ 82-83. And

because the Act does not provide just compensation for that property, these takings are unconstitutional. *Id.* PhRMA also alleged that the Urgent Need Program's alternative of allowing a manufacturer to reimburse a pharmacy for the cost of acquiring the manufacturer's product instead of replacing it does not avoid the unconstitutional taking. *Id.* ¶ 84.[3] 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. Doc. 1, ¶¶ 15-32, 34, Prayer for Relief.[4]

Defendants moved to dismiss. Because PhRMA sued the day before the Act took effect, defendants argued that (1) PhRMA's claims were not ripe; (2) PhRMA lacked associational standing because its members had suffered no actual or threatened injury-in-fact; and (3) defendants were immune from suit, as there was no ongoing constitutional violation justifying equitable relief. *See* Doc. 16 at 11, 16-18, 21-26. Defendants also argued that, because property owners can seek just compensation through an inverse condemnation action in Minnesota state court, equitable relief is not available. *Id.* at 12-13, 20, 26-32. Finally, defendants claimed that PhRMA had failed to

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[3] PhRMA also alleged that, if the Act's WAC-based exemption was intended to give manufacturers the "option" of avoiding the unconstitutional taking by lowering their products' WAC, that "option" is unconstitutional under the Commerce Clause. Doc. 1, ¶¶ 86-89. Defendants did not raise such a defense, however, and PhRMA later agreed that this claim was moot. *See* Doc. 72 at 3 n.1.

[4] PhRMA also named employees of MNsure as defendants, but later stipulated to their dismissal based on defendants' representations that those employees have no enforcement responsibilities under the Act. *See* Doc. 21.

plead a valid takings claim because (according to defendants) states can take property if they pay just compensation, and need not pay before a taking occurs. *Id.* at 11.

PhRMA opposed defendants' motion and cross-moved for summary judgment. In response to defendants' jurisdictional arguments, PhRMA submitted declarations establishing that, since the Act had gone into effect, each manufacturer had been compelled to provide insulin and reimburse pharmacies (or were then in the process of reimbursing pharmacies) for insulin as required under the Act. *See* Docs. 29-31.[5] PhRMA explained that the government violates the Takings Clause the moment it "takes private property without paying for it … *without regard to subsequent state court proceedings*." *Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2170 (2019) (emphasis added). PhRMA had thus pled a valid takings claim, since Minnesota does not pay for insulin when it is taken. Doc. 27 at 12-14. The undisputed facts made clear, moreover, that the Act's requirements caused *per se* physical takings. *Id.* at 36-41; Doc. 72 at 4-26.

PhRMA argued that, in the circumstances of this case, an inverse condemnation action was not a plain, adequate, and complete legal remedy that precludes injunctive relief. Because the Act mandates repetitive and never-ending takings, manufacturers would have to bring a multiplicity of suits for just compensation, rendering the inverse condemnation remedy inadequate. Doc. 27 at 23-33; Doc. 72 at 27-36. At a minimum, PhRMA argued, it was entitled to declaratory relief. Doc. 27 at 33-34; Doc. 72 at 36-38.

[5] PhRMA also filed a contingent motion to file a supplemental complaint, which alleged the same post-effective-date facts. Doc. 34.

Defendants opposed the cross-motion and argued that the law does not effect a *per se* taking. Doc. 66 at 22-36. They also made passing references to discovery that they allegedly needed to support certain defenses to the takings claim. *Id.* at 10, 36.

This Court granted defendants' motion to dismiss and denied PhRMA's motions to file a supplemental complaint and for summary judgment. Doc. 81. The Court concluded that PhRMA lacked standing because it could not satisfy Article III's redressability prong. *Id.* at 8-11. The Court adopted defendants' view that, under the Supreme Court's decision in *Knick*, "injunctive relief is foreclosed 'as long as just compensation remedies are available,'" and that "just compensation remedies are available in Minnesota through inverse condemnation actions in state court." *Id.* at 9-10 (quoting *Knick*, 139 S. Ct. at 2179). In so ruling, the Court did not reach the merits of PhRMA's takings claim.

C. The Eighth Circuit's Decision

The Eighth Circuit reversed. It held that inverse condemnation actions do not provide an adequate remedy "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). "Contrary to the [defendants'] argument," the Eighth Circuit explained, "the imminence of multiple suits is not hypothetical or speculative." *Id.* And an "inverse condemnation action to reimburse a manufacturer for each discrete alleged taking is incapable of compensating the manufacturer 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.* Accordingly, PhRMA has standing to seek injunctive and declaratory relief. *Id.* at 946.

The Eighth Circuit then addressed—and rejected—two other jurisdictional arguments that this Court had not reached, but that defendants had raised in support of affirmance. First, the Eighth Circuit rejected defendants' contention that PhRMA lacks associational standing "'because its claim stems from the manufacturers' property interests, and their participation is required to provide the factual context needed to resolve that claim.'" *Id.* at 947 (quoting defendants' brief on appeal, at 37). The Eighth Circuit stressed that, in making this argument, defendants ignored the critical distinction between a *per se* physical takings claim and a regulatory takings claim. It explained that "the cases that the Board members rely on in arguing that PhRMA lacks associational standing involve *regulatory* takings, which require individualized inquiries necessitating the participation of the individual members." *Id.* at 948. This case, by contrast, "involves an allegation of a *physical* taking of insulin, not a *regulatory* taking. Under [the Supreme Court's decision in] *Horne*, this type of taking is 'a *per se* taking' that does not require a court to analyze other factors." *Id.* at 947-48.

This same flaw infected defendants' argument that PhRMA lacks standing to seek equitable relief. The Eighth Circuit explained that "[a]n organization lacks standing to assert claims of injunctive relief on behalf of its members where the fact and extent of the injury that gives rise to the claims for injunctive relief would require individualized proof, or where the relief requested would require the participation of individual

members in the lawsuit." *Id.* at 948 (cleaned up). Here, however, "individualized proof is not needed to show that the Act requires the taking of the insulin." *Id.*

Second, the Eighth Circuit rejected defendants' arguments that they are immune from suit under the Eleventh Amendment. The Court explained that PhRMA's request for equitable relief is not an improper attempt to obtain a ruling that it could use to seek damages from the state for harms already caused. Instead, PhRMA had established that it has no adequate remedy at law, and that it seeks declaratory and equitable relief to redress ongoing takings. *PhRMA*, 64 F.4th at 950.

The Eighth Circuit denied defendants' petitions for rehearing *en banc* and rehearing by the panel, without opinion or dissent. *See Pharm. Rsch. & Mfrs. of Am. v. Williams*, No. 21-1731, 2023 WL 3313605, at *1 (8th Cir. May 9, 2023). The Eighth Circuit's mandate issued one week later. PhRMA now moves for summary judgment on its *per se* physical takings claim.

PhRMA IS ENTITLED TO SUMMARY JUDGMENT

The Act is plainly unconstitutional. The Supreme Court's decision in *Horne* makes clear that requiring manufacturers to provide free insulin is a *per se* physical taking of personal property. Because the state does not pay compensation for these takings, they are unconstitutional. Nothing defendants have argued or may argue can overcome this core constitutional defect.

STANDARD OF REVIEW

On a motion for summary judgment, the court views "the record in the light most favorable to the nonmoving party and draw[s] all reasonable inferences in that party's

favor." *Chambers v. Pennycook*, 641 F.3d 898, 904 (8th Cir. 2011). The court "shall grant summary judgment if 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" Fed. R. Civ. P. 56(a).

STATEMENT OF UNDISPUTED MATERIAL FACTS

PhRMA has associational standing to bring this suit. *PhRMA*, 64 F.4th at 947-48. Three PhRMA members—Lilly, Novo Nordisk, and Sanofi—are subject to the Act and have complied with it. *See* Minn. Bd. of Pharm., *Report to the Legislature on the Minnesota Insulin Safety Net Program. (In Compliance with Minnesota Statutes Section 151.74, Subd. 13)*, at 6 (Mar. 1, 2023) (advising the state legislature that the "insulin manufacturers complied with the provisions of [the Act]")."[6] It is undisputed that, in accordance with the Act, the manufacturers received no compensation from the state for the insulin that they gave away for free under the Act (or for which they reimbursed pharmacies for dispensing under the Act).

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[6] Available at https://www.lrl.mn.gov/docs/2023/mandated/230628.pdf.

ARGUMENT

I. THE ACT VIOLATES THE TAKINGS CLAUSE OF THE U.S. CONSTITUTION.

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

PhRMA is entitled to summary judgment because the Act's requirement that manufacturers give their insulin to Minnesota residents at no charge is a *per se* taking of private property without just compensation, in violation of the Takings Clause.

The Takings Clause provides that "private property [shall not] be taken for public use, without just compensation." U.S. Const. amend. V. The Clause protects both real and personal private property, "without any distinction" between the two. *Horne*, 576 U.S. at 358.

The Supreme Court has divided takings claims into two distinct categories, each subject to a different analysis. One category consists of "physical takings." In *Loretto*, 458 U.S. 419, the Court held that physical appropriations of real property are *per se* takings—*i.e.*, they always violate the Fifth Amendment if done without payment of just compensation. In *Horne*, the Court applied this *per se* principle to physical takings of personal property. 576 U.S. at 359-60.

The other category of takings consists of "regulatory takings." "Regulatory takings" arise when *restrictions on the use* of property go "too far." *Id.* at 360. Determining whether a regulation goes "too far" requires "an 'ad hoc' factual inquiry" into a number of factors. *Id.* (citing *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978)).

Here, the Act's requirement that manufacturers give their insulin "at no charge," Minn. Stat. § 151.74, subdiv. 6(c), is a clear *per se* physical taking. Indeed, this requirement is indistinguishable in all material respects from the federal marketing order at issue in *Horne*. That order required that raisin growers set aside a certain percentage of their crop "for the account of the Government, free of charge." 576 U.S. at 354. A government-run committee could then "sell [the raisins] in noncompetitive markets"; "donate[] them to charitable causes"; give them to other "growers who agree to reduce their raisin production"; or otherwise "dispose[] of them" to maintain market prices. *Id.* at 355. 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*, 458 U.S. at 435); *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* Minn. Stat. § 151.74, 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. The Act thus compels *per se* physical takings of private property—without prior or contemporaneous payment of just compensation.

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 avoid a taking 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). If the rule were otherwise, the government could "evade the limitations" of the Takings Clause by "simply giv[ing] the owner a choice of either surrendering [the property] or making a payment equal to the [property's] value." *Id.* (government violated the Takings Clause by conditioning the grant of a land-use permit on the relinquishment of a "conservation easement" on part of the land, and could not avoid that violation by giving the owner the option of paying money "'in lieu of'" surrendering the easement).

In short, every time a manufacturer gives away insulin under the Act without charge, there is a *per se* physical taking of private property that requires payment of just compensation. And, because no compensation is paid before or simultaneously with that physical taking, the Takings Clause is violated by each such appropriation. *See Knick*, 139 S. Ct. at 2170.

B. Defendants' Previous Defenses To PhRMA's *Per Se* Physical Takings Claim Lack Merit.

In prior briefing in this Court, defendants tried to try to show that the Act does not actually take the manufacturers' property or, if it does, that no compensation is due. Many of their arguments relied on inapposite authority involving regulatory, rather than *per se* physical, takings. None has merit.

1. Defendants' "Regulatory Takings" Defense.

Defendants argued that "*Horne* is not controlling," Doc. 66 at 22-23, because the Act does not physically appropriate insulin "for the government's own use." *Id.* at 31. Instead, defendants claimed, the Act merely "regulates the manufacturer's use of the insulin," *id.*, to promote the public health, not to regulate economic activity, as the regulation in *Horne* did, *id.* at 23. Relying on regulatory takings and due process cases, defendants argued that the Act is a permissible exercise of the police power that simply requires manufacturers to use their assets for the benefit of others. *Id.* at 24, 32. Every aspect of this argument is contrary to Supreme Court precedent.

First, *Horne* makes clear that the Act causes physical takings because it strips manufacturers of "the entire 'bundle' of property rights in [their insulin products]—'the rights to possess, use, and dispose of' them." 576 U.S. at 361-62 (quoting *Loretto*, 458 U.S. at 435). A regulation on the use of property, by contrast, does not deprive the owner of possession. *See Andrus v. Allard*, 444 U.S. 51, 65-66 (1979) (restriction on sale of eagle feathers did not compel a "physical invasion" or "surrender" of the artifacts, as the owners continued to have the "rights to possess and transport their property," "to donate

or devise" it, or to "exhibit" it for a fee). To describe a requirement that property be given away for free as "'a mere restriction on its use,' is to use words in a manner that deprives them of all their ordinary meaning." *Nollan v. California Coastal Comm'n*, 483 U.S. 825, 831 (1987) (citation omitted).

It is irrelevant, moreover, that Minnesota does not take insulin "for its own use." Doc. 66 at 31. A physical appropriation "authorized by state law is a taking without regard to whether the State, or instead a party authorized by the State, is" the recipient. *Loretto*, 458 U.S. at 432 n.9.[7] Nor does it matter *why* the insulin is taken. *Loretto* squarely held that a physical appropriation of real property by the government "is a taking *without regard to the public interests that it may serve*." *Id.* at 426 (emphasis added). And *Horne* emphasized this aspect of the decision when it applied *Loretto* to physical appropriations of personal property. *See* 576 U.S. at 360-61.

Horne also forecloses defendants' reliance on regulatory takings cases. *Horne* explained that it is "inappropriate to treat cases involving physical takings as controlling precedents for the evaluation of a claim that there has been a 'regulatory taking,' *and vice versa*." *Id.* at 361 (emphasis added) (internal quotation marks and citation omitted). This same principle applies to cases involving due process challenges to restrictions on

[7] Although *Loretto* involved real property, "[n]othing in the text or history of the Takings Clause, or our precedents, suggests that the rule is any different when it comes to appropriation of personal property." *Horne*, 576 U.S. at 358.

harmful uses of property, which were simply the precursors to modern regulatory takings cases.[8]

2. Defendants' "Public Nuisance" Defense.

Defendants also argued that the Act can be upheld under a "nuisance" exception to the *per se* physical takings rule. Doc. 66 at 24-28. But insulin itself is not a nuisance or inherently noxious substance; it is a life-saving medicine. And defendants cited no statute, regulation, judicial decision, or accepted legal principle to support the untenable idea that the *pricing* of an FDA-approved medicine can constitute a cognizable "nuisance" under Minnesota law.

Moreover, doctrinally, "'[h]armful or noxious use' analysis was … simply the progenitor of [the Court's] more contemporary statements that land-*use regulation* does not effect a taking if it substantially advance[s] legitimate state interests." *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1024 (1992) (emphasis added) (alterations omitted). But as PhRMA has just shown, the Act does not "regulate" the manufacturers' "use" of insulin; it confiscates their property in certain circumstances, thereby depriving them of all rights in that property. That is a *per se* physical taking and, in *Lucas* itself, the Court reiterated that when a law effects such a physical taking, compensation is due "no

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[8] The concept of a regulatory taking originated in *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393 (1922). Prior to that decision, the Court had rejected the idea that the Takings Clause applied to restrictions on the use of property, *see Mugler v. Kansas*, 123 U.S. 623, 668 (1887), and instead analyzed challenges to such laws under the Due Process Clause. *See id.* at 669-70; *see also Munn v. Illinois*, 94 U.S. 113 (1877) (analyzing limits on warehouse charges for grain storage under due process principles).

matter how minute the intrusion, and no matter how weighty the public purpose behind it." *Id.* at 1015 (citing *Loretto*).

3. Defendants' Licensing Defense.

Defendants also argued that manufacturers waived their property rights by agreeing to comply with state law, which now includes the requirements of the Act. Doc. 66 at 30 (citing Minn. Stat. § 151.252, subdiv. 1(a), 1(d)). Defendants analogized this case to *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), which held that there was no taking when the federal government disclosed certain health and safety data, including protected trade secrets, that pesticide manufacturers had submitted to the government in order to obtain permits to sell pesticide products. This analogy is groundless.

The law in *Monsanto* did not cause *per se* physical takings; the data "*retain[ed] usefulness for Monsanto* even after they [were] disclosed." *Id.* at 1012 (emphasis added). *Monsanto* thus involved a regulatory takings claim, where Monsanto's awareness of the regulatory disclosure requirements when it submitted its data was relevant to the company's "reasonable investment-backed expectations." *Id.* at 1005-07. In holding that the disclosure provisions did not effect a regulatory taking, the Court further noted that the pesticide law itself conferred upon Monsanto an enormously valuable right: the right to market a product, and "a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978." *Id.* at 994. Thus, Monsanto gave up only some property rights—the right to exclude others from its trade secrets, but not the right to use those secrets—in exchange for a regulatory approval that was necessary for Monsanto to have a marketable pesticide product.

There is no comparable "exchange" here. The federal government, not Minnesota, approves the manufacturers' insulin products for sale in the United States. The "benefit" Minnesota has conferred is simply the right to sell a *federally* approved and *federally* regulated product within the State's borders. That is not a "special governmental benefit that [Minnesota] may hold hostage, to be ransomed by the waiver of constitutional protection." *Horne*, 576 U.S. at 366. Indeed, in *Horne*, the Court refused to extend *Monsanto* to physical takings "by regarding basic and familiar uses of property as a 'Government benefit.'" *Id.* Selling products in interstate commerce, it explained, is "not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection." *Id.*

The decision in *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare*, 742 F.2d 442 (8th Cir. 1984)—which predated *Horne*—is not to the contrary. That case involved limits on the rates nursing homes could charge non-Medicaid residents in facilities that also served Medicaid patients. *Id.* at 445-46. The Court upheld those measures because they did "not involve a forced taking of property," but were instead conditions on "voluntary participation in [a state] program." *Id.* at 446. Here, Minnesota is not placing conditions on manufacturers' "voluntary" participation in a state program that subsidizes insulin purchases by eligible residents. The whole point of the Act is to force manufacturers to give their insulin away for free to persons who fall

outside the state's safety net programs so that Minnesota will not have to directly subsidize insulin purchases for them.[9]

4. Defendants' "No Net Loss" Defense.

Finally, defendants argued that, "[e]ven if a taking occurred," PhRMA "failed to prove the insulin manufacturers have suffered a pecuniary loss." Doc. 66 at 35. Defendants claimed that "a net loss has not been proven and should not be presumed given" (1) the "potential benefits" manufacturers receive under the Act and (2) the possibility that they "would have provided the insulin for free" under their patient assistance programs. *Id.* at 35-36. This claim is meritless.

Because PhRMA does not seek damages, defendants' "no net loss" argument is apparently an attempt to show that no "just compensation" is due for the insulin that the Act takes, and thus that Minnesota does not violate the Takings Clause by failing to pay for that property. But the Supreme Court "has repeatedly held that just compensation normally is to be measured by 'the market value of the property at the time of the taking.'" *Horne*, 576 U.S. at 368-69 (citation omitted). The insulin taken from the three

[9] Defendants also cited two out-of-circuit cases. *See* Doc. 66 at 32-33. But *Sierra Medical Services Alliance v. Kent*, 883 F.3d 1216 (9th Cir. 2018), held that a state law mandating free ambulance services was a regulatory taking, not a *per se* taking, because (unlike the Act here) it did "not directly appropriate the Plaintiffs' ambulances or other personal property"; instead, it temporarily restricted use of the ambulances. *Id.* at 1225. *Franklin Memorial Hospital v. Harvey*, 575 F.3d 121 (1st Cir. 2009), relied on an analogy to rent control in holding that a state law requiring hospitals to serve indigent patients does not physically appropriate the hospital's property because the hospital "may choose to stop using its property as a hospital." *Id.* at 126. That analogy is inapposite here because the manufacturers cannot choose "to stop using" insulin as a medication for treating diabetes; that is its FDA-approved use.

PhRMA members necessarily has a market value of more than zero. Indeed, the Act applies to these manufacturers because the wholesale acquisition cost of their insulin is at least $8 "per milliliter or applicable National Council for Prescription Drug Plan billing unit." Minn. Stat. § 151.74, subdiv. 1(d). Accordingly, unless defendants can show that some exception to the market-value rule applies here, the Takings Clause is violated every time the Act takes insulin without payment of just compensation. Defendants have identified no such exception.

They rely on *Brown v. Legal Foundation of Washington*, 538 U.S. 216 (2003), but that case is *sui generis*—and irrelevant here. In *Brown*, a state program took interest earned on pooled funds deposited in Interest on Lawyer Trust Accounts (IOLTA). The relevant rules, however, provided that client funds could be deposited in IOLTA accounts only if they would *not* earn net interest if deposited separately (*i.e.*, because administrative costs would exceed the interest). *Id.* at 224, 239-40. The plaintiffs thus suffered no net pecuniary loss, because the interest that was taken existed only because of the program that took it. *Id.* at 240.[10] Here, the manufacturers' insulin indisputably is property that exists independently of the Act. Thus, the logic in *Brown*—that there is no net loss when the state takes away what it has created—is inapplicable.

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[10] On the other hand, the Court explained, when client funds that could generate net interest were *improperly* deposited in IOLTA accounts, the clients could lose property, but that loss "was the consequence of … incorrect private decisions [by escrow agents] rather than any state action"; the remedy was a suit against the agents, not a takings claim. *Brown*, 538 U.S. at 239.

There is likewise no merit to defendants' claim that the Act confers "benefits" on manufacturers that might outweigh any financial loss they suffer when their insulin is taken. The Act compels manufacturers to give away their property without compensation; it does not confer any legally cognizable "benefits" on those manufacturers. But even if it did, *Horne* forecloses this argument too. There, the government argued that the "reserve requirement," which took a percentage of an owner's raisin crop, increased the market value of the raisins that the owner retained and that the Hornes were therefore not entitled to just compensation unless they showed an overall loss. *See* 576 U.S. at 368, 372. The Court squarely rejected this theory, holding that the Hornes were entitled to the market value of the raisins taken, without regard to other factors. *Id.* at 368-69.

Finally, defendants claim that manufacturers are suffering no pecuniary loss because they might give away the same insulin voluntarily under their patient assistance programs. But defendants do not—and cannot—explain how the manufacturers' voluntary charitable actions can strip them of their constitutional right to just compensation under the Takings Clause. When manufacturers are forced to give away insulin under the Act, they are no longer exercising *their* rights to possess, use, or dispose of that property as they see fit. They are instead acting under compulsion of a state law that deprives them of that entire bundle of rights. That is a *per se* physical taking and, under *Horne*, the manufacturers are entitled to just compensation measured by the market value of the insulin taken—compensation that Minnesota does not pay. Nothing in *Brown* or any other authority defendants have cited creates an exception to these principles when

a state converts a property owner's previously voluntary donations of property into mandatory legal obligations backed by penalties.

C. No Discovery Is Necessary To Resolve PhRMA's *Per Se* Physical Takings Claim.

Defendants opposed PhRMA's earlier summary judgment motion on the ground that they needed discovery. But no discovery is necessary to resolve PhRMA's *per se* physical takings claim.

Defendants claimed that facts concerning the ways in which PhRMA's members priced and patented their insulin products, and the amount of money they and PhRMA spent on lobbying efforts in Minnesota, were material to PhRMA's claim. Doc. 66 at 2-4. Accordingly, they argued that "[t]he factual background must be explored … because the Act is a legitimate use of police power to protect the health and safety of the public." *Id.* at 24. The facts defendants wish to explore, however, would be potentially relevant only to a regulatory takings claim. These facts have no bearing on PhRMA's physical takings claim. Indeed, as noted above, *Loretto* squarely held that a physical appropriation of real property by the government "is a taking *without regard to the public interests that it may serve*." 458 U.S. at 426 (emphasis added). And this same principle applies to physical takings of personal property. *See PhRMA*, 64 F.4th at 947 ("'[A] physical *appropriation* of property [gives] rise to a *per se* taking, without regard to other factors'") (quoting *Horne*, 576 U.S. at 360)).

Defendants also claimed they need discovery to determine whether the manufacturers suffered a "net loss." Doc. 66 at 36. As discussed above, however, no

showing of "net loss" is required or relevant here. Nor is discovery needed to determine whether PhRMA is entitled to a permanent injunction, as discussed next.

II. THE ACT SHOULD BE PERMANENTLY ENJOINED.

PhRMA is entitled to a permanent injunction. Application of the four-factor test for such relief—(1) success on the merits, (2) irreparable harm to the plaintiff, (3) the relative balance of harms, and (4) the public interest, *see e.g., Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 608 n.14 (8th Cir. 2022); *Laredo Ridge Wind, LLC v. Nebraska Public Power District*, 11 F.4th 645, 654 (8th Cir. 2021)—is straightforward here.

For the reasons discussed above, PhRMA should succeed on the merits: the Act causes an ongoing series of violations of the Takings Clause. Because a constitutional violation ordinarily cannot be fully remedied with the payment of damages, courts routinely hold that "no further showing of irreparable injury is necessary." 11A Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. § 2948.1 (3d ed. 2023); *see also Ng. v. Bd. of Regents of Univ. of Minn.*, 64 F.4th 992, 998 (8th Cir. 2023) ("the denial of a constitutional right is a cognizable injury and an irreparable harm.") (citation omitted); *Little Rock Fam. Planning Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1321-22 (E.D. Ark. 2019) ("[D]eprivation of constitutional rights 'unquestionably constitutes irreparable injury'"). Of course, when the constitutional violation is the failure to pay just compensation at the time that property is taken, an *adequate* post-deprivation compensation mechanism can remedy that violation. But the Eighth Circuit has already held that there is no adequate compensation remedy for the repetitive takings the Act causes, *see PhRMA*, 64 F.4th at 945-46, so the injury is irreparable.

Moreover, because the Act is unconstitutional and causes irreparable harm, the third and fourth factors also weigh in favor of a permanent injunction. "[T]he question of harm to the [defendants] and the matter of the public interest drop from the case," because the "public interest will perforce be served by enjoining the enforcement" of the unconstitutional state law. *Bank One, Utah, N.A. v. Guttau*, 190 F.3d 844, 847-48 (8th Cir. 1999); *see also Odebrecht Constr., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1290 (11th Cir. 2013) (harm to defendants is "ephemeral because the public has no interest in the enforcement of … an unconstitutional statute").

If Minnesota believes an injunction will harm people in need of insulin, it can prevent those harms in a number of ways—such as by regulating insurance practices concerning drug coverage, by expanding the scope of its own safety net programs, and/or by purchasing insulin and providing it to those who fall outside the manufacturers' programs. But if the possibility of harm to residents from enjoining an *unconstitutional* law is accepted as a basis for denying injunctive relief, Minnesota will be allowed to achieve its goals "by a shorter cut than the constitutional way of paying for the change." *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922).

CONCLUSION

For the foregoing reasons, PhRMA respectfully requests that its motion for summary judgment be granted and that the Act be declared unconstitutional and permanently enjoined.

Respectfully submitted,

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