UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Pharmaceutical Research and Manufacturers of America,

Plaintiff,

v.

Stuart Williams, et al.,

Defendants.

Case No. 0:20-cv-01497-DSD-DTS

DEFENDANTS' MEMORANDUM SUPPORTING DISMISSAL AND OPPOSING SUMMARY JUDGMENT

Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA), a lobbying organization, claims that certain provisions of the Alec Smith Insulin Affordability Act violate the Takings Clause of the Fifth Amendment. Rather than seek compensation for the alleged takings, however, PhRMA asks the Court to declare the provisions unconstitutional and permanently enjoin enforcement of those provisions. PhRMA also claims the Act's exemption of low-cost insulin violates the Commerce Clause, if the exemption is interpreted as a way for insulin manufactures to avoid the alleged taking. Defendants previously moved to dismiss the complaint and PhRMA now seeks summary judgment. [Docs. 12, 14.] Defendants submit this memorandum replying to PhRMA's arguments opposing dismissal and responding to PhRMA's motion for summary judgment.

As established in Defendants' principal memorandum, PhRMA's claims must be dismissed because Defendants are immune from suit, PhRMA lacks standing, and PhRMA's claims for equitable relief are foreclosed. PhRMA has not provided any

factual or legal bases to survive dismissal. The Court should therefore grant Defendants' motion to dismiss and deny PhRMA's summary judgment motion as moot. If, however, the Court addresses PhRMA's motion, it should be denied because the Act does not constitute a per se taking and PhRMA has failed to allege—or provide factual evidence to prove—a regulatory taking. Even if the Act could effect a taking, the Court should still deny PhRMA's motion because it failed to prove the manufacturers have suffered any pecuniary loss, an essential element of a Takings Clause violation; failed to demonstrate—or even discuss—that it meets the four-factor test necessary to obtain a permanent injunction; and failed to establish that it is entitled to declaratory relief.

FACTS

If the Court concludes that PhRMA's claims survive dismissal, the following facts, in addition to the facts PhRMA presented, are material to deciding this matter.[1]

Diabetes is a chronic disease caused by insufficient insulin production or resistance to insulin, a hormone that lets the body's cells absorb glucose from the blood for energy. (Compl. [Doc. 1] ¶ 36.) Supplemental insulin is critical to the management of diabetes. Without insulin, cells cannot absorb glucose, leaving too much blood sugar in the bloodstream and potentially causing serious health problems, including organ damage and death. (*Id.*; Krans Decl. Exs. 1 at 19-20, 2 at 22, 4 at 1.)[2]

[1] Defendants have not had an opportunity to verify PhRMA's stated facts through discovery and reserve the right to contest them should this matter proceed and in any other future matters. (*See* Krans Decl. ¶¶ 2, 3.)

[2] Page citations to the exhibits are to the articles' original pagination, not the exhibit page.

Insulin was discovered in 1921 by Canadian scientists who sold their U.S. patents to the University of Toronto for one dollar. (Compl. ¶ 39; Krans Decl. Ex. 1 at 5.) The university then allowed manufacturers to produce insulin royalty-free. (Krans Decl. Ex. 1 at 5.) Although manufacturers have continued to develop and refine insulin, the base formulation has remained generally the same. (*Id*.; Compl. ¶¶ 39-41). Despite this, the cost of insulin has risen exponentially over the past two decades and has increased by more than 1,200% since the 1990s. (Krans Decl. Exs. 2 at 22, 4 at 2.) The price of insulin has doubled since 2012, which follows a nearly 300% increase between 2002 and 2013. (*Id*. Exs. 1 at 6, 2 at 22, 4 at 2.) Although experts estimate that insulin could be profitably produced for $11 or less per patient per month (*Id*. Exs. 3 at 1, 9, 4 at 2), in the United States insulin retails for approximately $300 per vial (*Id*. Exs. 1 at 9). Patients regularly use two or more vials a month, resulting in monthly costs of more than $600. (*Id*.) These rising costs have led some individuals to ration their insulin, and in some cases—like that of Minnesotans Alec Smith and Jesimya David Scherer-Radcliff—to die. (*Id.* Exs. 1 at 6, 2 at 22, 4 at 2.)[3] In response to this public-health crisis, on April 15, 2020, Minnesota enacted the Alec Smith Insulin Affordability Act, Minn. Stat. § 151.74, which has been extensively discussed in the parties' opening briefs.

[3] Adrienne Broaddus, *Family Says 21-year-old Son Died Rationing Insulin*, KARE11 (July 12, 2019), https://www.kare11.com/article/news/family-says-21-year-old-son-died-rationing-insulin/89-d451a01b-9170-4341-9010-155cb87edccc; *Emergency Insulin Program Established, Minnesota Insulin Patient Assistance Program Established, Pharmacy and Insulin Manufacturer Participation Required, Reports Required, and Money Appropriated*: *Hearing on HF3100 Before the Commerce Comm.*, 2020 Leg., 91st Sess. (Minn. Feb. 11, 2020) (statement of Nicole Smith-Holt), https://www.house.leg.state.mn.us/hjvid/91/892535.

Three manufacturers (and PhRMA members), Eli Lily and Company, Novo Nordisk Inc., and Sanofi, collectively manufacture nearly all the insulin sold in the United States. (Compl. ¶ 13; Laganga Decl. ¶ 5; Krans Decl. Exs. 3 at 1, 4 at 2.) The manufacturers have taken advantage of their oligopoly of the market, and the nature of the product, to charge exorbitant prices. (Krans Decl. Exs. 1 at 11, 2 at 22-23, 4 at 1.) To protect their insulin prices, the manufacturers raise the prices of their competing insulins in lockstep, often called "shadow pricing." (*Id*. Exs. 1 at 11, 2 at 24); Fran Quigley, *Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry*, 53 U. Mich. J.L. Reform 755, 798 (2020). They also engage in "patent evergreening," the process of garnering repetitive patents on the same drugs for incremental changes to prolong the patent life and extend the monopoly on insulin products. 53 U. Mich. J.L. Reform at 799; (Krans Decl. Exs. 1 at 11-12, 2 at 23.) And, the manufacturers lobby heavily against changes to the current system. (Krans Decl. Ex. 2 at 24.) For example, in 2019, the year the Act was introduced, PhRMA and the manufacturers collectively spent more than $620,000 for lobbying in Minnesota, compared with $380,000 the previous year. (*Id*. ¶ 7.)

Under Minnesota law, no person may act as a drug manufacturer in Minnesota without first obtaining a license from the Minnesota Board of Pharmacy and paying the applicable free. Minn. Stat. § 151.252, subd. 1(a); Minn. R. 6800.1400; (Wiberg Decl. ¶¶ 2-3). An applicant for a drug-manufacturer license must agree to operate in accordance with federal and state law and the Minnesota Rules in order to obtain or renew a license. Minn. Stat. § 151.22, subd. 1(d); (Wiberg ¶ 4). The Board may take

action against a manufacturer's license, impose penalties upon a manufacturer, or reprimand the manufacturer for violations of any of the provisions of Minnesota Statutes Chapter 151, or violation of a federal, state, or local law relating to operation of the manufacturer. Minn. Stat. § 151.071, subds. 1, 2(8).

The three insulin manufacturers are licensed in Minnesota. (Wiberg Decl. ¶ 5-8.) And all have renewed their licenses since the enactment of the Act. (Id.)

ARGUMENT

A court should dismiss claims on the pleadings if the court lacks subject-matter jurisdiction or a party has failed to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(1), (6). The plaintiff bears the burden of proving subject-matter jurisdiction. *Buckler v. United States*, 919 F.3d 1038, 1044 (8th Cir. 2019). PhRMA has failed to meet its burden to prove jurisdiction and has failed to state a claim upon which this Court can grant relief. Accordingly, dismissal is proper, and PhRMA's motion is moot.

But if this Court considers PhRMA's motion for summary judgment, the Court must view all facts and draw all reasonable inferences in Defendants' favor. *See Odom v. Kaizer*, 864 F.3d 920, 921 (8th Cir. 2017). Summary judgment may only be granted if there are no disputes as to material facts and PhRMA is entitled judgment as a matter of law. Fed. R. Civ P. 56(a). As PhRMA has failed to establish it is entitled to judgment as a matter of law, summary judgment is inappropriate.

I. PHRMA'S CLAIMS MUST BE DISMISSED.

PhRMA's claims must be dismissed because Defendants are immune from suit, PhRMA lacks associational standing, equitable relief is an improper remedy for a taking, and PhRMA's dormant commerce clause claim fails as a matter of law.

A. Defendants Are Immune From Suit.

Defendants are immune from suit under the Eleventh Amendment because, at its core, PhRMA's action seeks to enjoin the state from exercising its sovereign right to take private property for public uses. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101-02 (1984) (holding the Eleventh Amendment bars a suit against state officials when "the state is the real, substantial party in interest."). PhRMA relies on the immunity exception stated in *Ex parte Young*, 209 U.S. 123 (1908), which allows state officials to be sued in their official capacities for prospective relief.[4] This immunity exception, however, cannot be properly reconciled with PhRMA's takings claim. The Takings Clause allows the government to take property for a public use. And when the government takes, the Takings Clause requires a specific remedy: payment of just compensation.

Contrary to PhRMA's claims, Defendants' immunity argument does not rest on the overruled *Williamson County Regional Planning Commission v. Hamilton Bank of Johnson City*, 473 U.S. 172 (1985). (Pl.'s Mem. [Doc. 27] 12.) Defendants' rely on the reasoning behind *Young* and the uniqueness of takings claims. *See Knick v. Twp. of*

[4] PhRMA dismissed the MNsure Defendants by stipulation. (Stipulation for Dismissal [Doc. 21].)

Scott, 139 S. Ct. 2162, 2181 (2019) (Kagan, J. dissenting) ("Takings Clause is unique among the Bill of Rights' guarantees."). The reasoning behind *Young's* so-called "legal fiction" is that an unconstitutional law is "void," so a state official lacks state authority to enforce it. *Ex parte Young*, 209 U.S. 123, 159 (1908). As such, "when a federal court commands a state official to do nothing more than refrain from violating federal law, he is not the State for sovereign-immunity purposes." *Church v. Missouri*, 913 F.3d 736, 747 (8th Cir. 2019). This exception is narrowly construed. *Pennhurst*, 465 U.S. at 114, n.25.

The power to take private property for public uses belongs to every independent government as an incident of sovereignty and requires no constitutional recognition. *United States v. Jones*, 109 U.S. 513, 518 (1883). The Fifth Amendment's assurance of just compensation for the property taken is merely a limitation upon the use of that power. *Id.*; *First Eng. Evangelical Lutheran Church of Glendale v. Los Angeles Cty.*, 482 U.S. 304, 314 (1987). It is the failure to compensate for the taking, not the taking itself, that gives rise to a takings claim.[5] *See Knick*, 139 S. Ct. at 2173, 2177; *First Eng.*, 482 U.S. at 315.

Under *Young* federal courts are limited to ordering public officials to adhere to the Constitution. But an order to adhere to the Takings Clause would be an order to pay just compensation, not an order to prevent a taking in the first instance. Regulations that authorize takings, but fail to provide contemporaneous compensation, may continue if the

[5] PhRMA does not challenge the alleged taking itself, only that it is done without compensation. (Compl. ¶¶ 82, 83.) PhRMA agrees that any taking under the Act is for a public use. (Id. ¶¶ 2-3.)

government has a mechanism for compensating post-taking. *Knick*, 139 S. Ct. at 2177. Minnesota has a mechanism for compensating takings, and litigating a federal takings claim that is based on state action in state court is not an injustice. *Foster v. State of Minnesota*, 888 F.3d 356, 359 (8th Cir. 2018).

Enjoining a public official from taking property where just compensation procedures are available would improperly prohibit the state from proceeding with a valid policy and interfere with the state's right as a sovereign to take private property for a public purpose. *See Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005) ("[T]he Takings Clause presupposes that the government has acted in pursuit of a valid public purpose."); *Idaho v. Coeur d'Alene Tribe of Idaho*, 521 U.S. 261, 281, 287 (1997) (holding *Young* exception was inapplicable where "special sovereignty interests" were implicated). Such an injunction would be against the state as the real party in interest, which is barred by the Eleventh Amendment. *See Pennhurst*, 465 U.S. at 100-02. The Court is therefore limited to ordering the public official to pay just compensation for a taking. But an order to pay just compensation is simply an order for traditional money damages, *Seven Up Pete Venture v. Schweitzer*, 523 F.3d 948, 956 (9th Cir. 2008), which is not permitted under the *Young* exception, *Treleven v. Univ. of Minn.*, 73 F.3d 816, 818 (8th Cir. 1996).[6] *See also Ladd v. Marchbanks*, 971 F.3d 574, 581 n.5 (6th Cir. 2020)

[6] Courts have allowed takings claims seeking prospective relief against public officials in their official capacities to proceed. *See Arnett v. Myers*, 281 F.3d 552, 567-68 (6th Cir. 2002) (applying *Ex parte Young* to takings claim seeking to enjoin officials from removing plaintiffs' duck blinds, without considering a sovereign's right to take or whether just compensation was available). Defendants, however, were unable to find a
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(holding *Ex parte Young* was unavailable for takings claim and recognizing injunctive relief is barred by *Knick*).

For the foregoing reasons, and because equitable relief is inappropriate for a takings claim, the *Ex parte Young* exception is inapplicable here and Defendants are immune from this suit under the Eleventh Amendment.

B. PhRMA Lacks Associational Standing.

PhRMA abandons its claim that it has standing in its own right to challenge the Act and focuses on its alleged associational standing to sue on behalf of the manufacturers. (*See* Compl. ¶ 13; Pl.'s Mem. 14-21.) PhRMA submits a declaration from each of the three major insulin manufacturers, reciting that each manufacturer has provided insulin under the terms of the Act. (*See* Boss, Siragusa, Asay Decls. [Docs. 29-31].) Defendants recognize, based on these declarations, that the injury requirement for standing is met. However, as the Supreme Court stated in *Hunt*, associational standing is improper when "the individual participation of each injured party [is] indispensable to proper resolution of the cause." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977) (quotation omitted). This requirement remains an obstacle to PhRMA's claim of associational standing.

PhRMA insists that its takings claim is a purely legal question, but this is rarely the case in takings law. And it is not the case here. Courts must examine the substance

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case addressing the specific arguments made here and PhRMA failed to cite any case that permitted a takings claim to proceed under *Ex parte Young*.

around the allegations to determine whether an alleged taking is, in fact, a per se taking. *See Mugler v. Kansas*, 123 U.S. 623, 661 (1887) (stating courts "are under a solemn duty, to look at the substance of things, whenever they enter upon the inquiry whether the legislature has transcended the limits of its authority."). Also, the proper remedy for a taking is just compensation, which requires inquiry into the value lost to the property owner. *See Wash. Legal Found. v. Legal Found. of Wash.*, 271 F.3d 835, 849-50 (9th Cir. 2001). These facts would necessarily have to come from the property owners themselves, which precludes associational standing. Accordingly, associational standing is not a good fit for takings claims. *Id.*; *Rent Stabilization Ass'n of N.Y.C., Inc. v. Dinkins*, 805 F. Supp. 159, 164 (S.D.N.Y. 1992); *see also Pennell v. City of San Jose*, 485 U.S. 1, 10 (1988). And PhRMA failed to provide authority stating otherwise.

For the Court to even determine whether the Act violates the Takings Clause, facts and participation from each manufacturer claiming a taking are necessary, making associational standing unavailable. Inquiry into the nature and scope of the manufacturers' insulin affordability programs is required to determine whether the manufacturers have suffered a net loss as a result of the Act, which is necessary to prove a takings violation. *See infra* Part II.B. Given the manufacturers' role in creating and contributing to the insulin affordability crisis, their participation would be required to determine whether the Act falls within the State's police power to regulate for the prevention of grievous harm. *See infra* Part II.A.1. And the participation of the manufacturers would also be required to establish all factors required for the granting of

injunctive relief, including irreparable harm and the balance of hardships. *See infra* Part II.C.

Further, a regulatory takings analysis under *Penn Central* requires consideration of "the economic impact of the regulation," whether it frustrates investment-backed expectations, and whether the interference "arises from some public program adjusting the benefits and burdens of economic life to promote the common good." *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978). PhRMA admits that such an analysis would require substantial participation of individual manufacturers, thus failing the third prong of *Hunt*. (Pl.'s Mem. 19-20.) If a *Penn Central* analysis applies, *see infra* Part II.A., PhRMA lacks associational standing.

From the merits of the claim, to the availability and appropriateness of the remedy PhRMA seeks, the manufacturers' participation is necessary. Their participation has already been employed to respond to Defendants' ripeness argument, and it is unlikely to end there. The Court should recognize at this early stage that the particular requirements of a takings claim renders it incompatible with associational standing, and that PhRMA's claim is no different.

C. The Equitable Relief PhRMA Seeks Cannot Be Granted as a Matter of Law.

The Supreme Court has repeatedly—and recently—held that equitable relief is not available to enjoin a taking of private property for public use when a suit for compensation can be brought against the government subsequent to the taking. *See e.g. Knick*, 139 S. Ct. at 2175-77, 2179; *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1016

(1984); *Hurley v. Kincaid*, 285 U.S. 95, 104 (1932). PhRMA does not dispute this, but asks this Court to make a new exception to the Supreme Court's general rule for "ongoing *per se* takings." (Pl.'s Mem. 23.) The Court should decline this invitation because the alleged taking of insulin is compensable and Minnesota's just compensation procedures are adequate and provide complete relief for takings.

1. Insulin manufacturers have an adequate and complete remedy at law for any taking under the Act.

PhRMA does not, and cannot, argue that insulin is not compensable. Rather, PhRMA first argues that Minnesota's inverse-condemnation procedure is incomplete because it fails to provide compensation for *future* takings, meaning takings that have not occurred. (*Id.* 23-26.) But a "future taking" is not a "taking" because no property has been taken. A takings claim does not even accrue until a government takes property without compensation. *Knick*, 139 S Ct. at 2177. And, the Fifth Amendment does not entitle property owners to be paid in advance of the taking. *Hurley*, 285 U.S. at 104. The possibility that property may be taken in the future is not compensable; the law does not provide compensation for future takings. *Banner v. United States*, 44 Fed. Cl. 568, 576 (1999), *aff'd*, 238 F.3d 1348 (Fed. Cir. 2001). As such, PhRMA's claim that a taking can be enjoined unless manufacturers are compensated in advance is untenable. That is especially true here, when it is impossible to know in advance if or when the manufacturers will provide insulin under the Act, the amount or type of insulin that they will provide, or the amount of the manufacturer's loss, if any. *See* Minn. Stat. § 151.74; (Defs' Mem. 19, 23-24).

Minnesota's procedures for seeking just compensation are adequate. *Am. Family Ins. v. City of Minneapolis*, 836 F.3d 918, 923-24 (8th Cir. 2016); *Koscielski v. City of Minneapolis*, 435 F.3d 898, 903 (8th Cir. 2006). A lack of advance compensation for potential "future takings" does not make the remedy inadequate or incomplete as PhRMA contends. For any property that is actually "taken," manufacturers would receive just compensation. Further, Minnesota law provides for interest from the date of taking (currently at 4%) and for attorney's fees, costs, and expenses. Minn. Stat. § 117.031, .045, .195; *DeCook v. Rochester Int'l Airport Joint Zoning Bd.*, 811 N.W.2d 610, 613 (Minn. 2012). Insulin manufacturers therefore would not suffer any loss by obtaining just compensation after a taking.

PhRMA's reliance on *McShane v. City of Faribault*, 292 N.W.2d 253 (Minn. 1980) to claim an injunction is an appropriate remedy is misplaced as *McShane* was abrogated by *DeCook*. Although the manufacturers may prefer payment in advance, the Fifth Amendment, "while guaranteeing that compensation be just, does not guarantee that it be meted out in a way more convenient to the landowner than to the sovereign." *United States v. 45.50 Acres of Land*, 634 F.2d 405, 407 n.2 (8th Cir. 1980) (quotation omitted)).

PhRMA challenges the proposition that potentially having to bring a series of inverse condemnations provides a complete compensatory remedy. (Pl.'s Mem. 27-28.) But it is PhRMA that seeks exceptions to *Knick*'s holding that injunctive relief is foreclosed in takings actions. It is PhRMA that must prove that Minnesota's procedures for seeking just compensation are inadequate. And PhRMA has failed to cite any binding

authority to support its position. Rather, PhRMA relies on the plurality decision in *Eastern Enterprises v. Apfel*, 524 U.S. 498 (1998) and on a First Circuit case, *Asociacion De Subscripcion Conjunta Del Seguro De Responsabilidad Obligatorio v. Galarza*, 484 F.3d 1 (1st Cir. 2007). Both cases are easily distinguishable as they involved direct transfers of funds and not physical property.

Apfel involved a takings and due process challenge to the Coal Act, which required coal operators to pay premiums into a health-care fund for mineworkers. 524 U.S. at 503. The plurality in *Apfel* believed that monetary relief was unavailable because Congress could not have contemplated that the Treasury would compensate coal operators a dollar for every dollar paid under the Coal Act. *Id*. at 521. The plurality determined that there is no presumption of Tucker Act availability and that equitable relief is permitted where a "challenged statute, rather than burdening real or physical property, requires a direct transfer of funds mandated by the Government," because, requiring plaintiffs to bring compensation claims dollar for dollar for what they were required to pay would be pointless. *Id*. (O'Connor, J., plurality opinion) (internal quotation omitted). The majority of justices decided the case on due process grounds. *Id*. at 539, 547, 556. The dissent questioned whether a law's invalidation is appropriate under the Takings Clause, rather than simply paying compensation. *Id*. at 556 (Breyer, J. dissenting).

Galarza involved an interlocutory appeal concerning immunity. 484 F.3d at 6. There, the challenged law and actions involved the transfers of funds between an underwriting association and the Puerto Rico Treasury Secretary. *Id.* at 6-10. The First

Circuit determined the matter was ripe for review under *Williamson County* because Puerto Rico had no process for the plaintiffs to seek compensation for an alleged unconstitutional taking of funds and because it involved a direct transfer of funds similar to *Apfel*. 484 F.3d at 19-20. The court did not decide the claims on their merits. *Id*. at 37.

The alleged taking in this case differs from those in *Apfel* and *Galarza*. Here, PhRMA alleges the taking of physical property—insulin. *Apfel* and *Galarza* were limited to statutes involving the direct transfer funds and *Apfel* specifically exempted statutes that burdened real or physically property from its holding. PhRMA argues that, to the extent manufacturers may choose to reimburse pharmacies for insulin dispensed under the Act's urgent-need program rather than replace the insulin, the takings claim directly mirrors the issue in *Apfel*. (Pl.'s Mem. 30.) But, even if the manufacturer chooses to reimburse the pharmacy rather than replace the insulin, it still is not a direct transfer of funds case because the item transferred for public use is insulin—physical property.

In *Apfel* it was clear Congress had not contemplated that a plaintiff would be required to sue to obtain dollar for dollar what they paid. *See Gordon v. Norton*, 322 F.3d 1213, 1218 (10th Cir. 2003) (distinguishing *Apfel*). Here, the Act does not involve dollar-for-dollar compensation. It involves insulin. The purpose of the Act is to provide insulin to those who need it and cannot afford it. Any just compensation the manufacturers may be entitled to under the Fifth Amendment may very well be less than what it would cost the state to purchase the insulin given the absurd mark-ups on insulin and the middlemen involved. As such, having the manufacturers seek compensation for any insulin provided or reimbursements made under the Act through inverse

condemnation is not an "utterly pointless set of activities" that the legislature could not have intended. Here, unlike the direct transfer of funds cases, the value of the manufacturers' loss, to the extent there is any, can only be determined through fact finding after the alleged taking occurs.

PhRMA's claim that the manufacturers would have to repeatedly bring mandamus actions is overstated. Even if the Act effects a taking and is not subsequently amended by the legislature, the manufacturers would not have to bring a multiplicity of suits to be fully and justly compensated. At most, they would have to bring an action once every six years. *See* Foster, 888 F.3d at 359 (stating Fifth Amendment takings claims are subject to a six-year statute of limitations). And, the Act's continuing safety net program expires December 31, 2024, unless the legislature affirmatively determines the need for its continuation. Minn. Stat. § 151.74, subd. 16. Even if manufacturers choose to bring a series of actions where they would have to "retain lawyers and present evidence" of their damages (Pl.'s Mem. 31), they would be fully compensated as Minnesota law provides for attorney's fees, costs, and interest from the date of taking. That the manufacturers would have to prove their damages is not a reason to allow injunctive relief for a takings claim.

Finally, PhRMA's attempts to distinguish *Rose Acre Farms, Inc. v. Madigan*, 956 F.2d 670 (7th Cir. 1992) and *National Fuel Gas Distribution Corp. v. N.Y. State Energy Research & Development Authority*, 265 F. Supp. 3d 286 (W.D.N.Y. 2017) are unavailing. (*See* Pl.'s Mem. 27-28.) Contrary to PhRMA's position, both involved allegations of continuous and ongoing takings.

Rose Acre involved federal regulations preventing egg producers whose eggs were suspected of having salmonella from selling the eggs as table eggs until the flock was certified as salmonella free. 956 F.2d at 671-72. Rose Acre sued the Agriculture Secretary "seeking an end to interference with its sale of whole eggs." *Id.* at 672. When the case was argued, the alleged taking had been occurring for over a year and it was impossible to predict how long it would continue or whether Rose Acre would be subject to the restrictions again. As such, the alleged takings were continuous and ongoing. Still, the court held that if the Constitution calls for compensation, setting aside the regulation is the wrong remedy. 956 F.2d at 673. Ultimately, Rose Acre was under the regulation's restrictions for twenty-five months, and did not suffer a compensable taking. *Rose Acre Farms, Inc. v. United States*, 559 F.3d 1260, 1264, 1283-84 (Fed. Cir. 2009).

In *National Fuel*, a natural gas distributor that had provided gas to a nuclear service site for decades sought an injunction so it could stop supplying gas to the site and abandon its pipeline. 265 F. Supp. 3d at 290. The distributor claimed the government took its right to terminate service. *Id*. at 293. Like PhRMA in the current case, National Fuel argued that monetary relief was unavailable because "the government's intrusion has been continuous and will continue into the future." *Id*. at 295 n.2. The court quickly rejected the argument because the "intrusion" alleged could be remedied by monetary damages. *Id*.

That compensation is an adequate remedy for a continuous taking is also supported by the *Regional Rail Reorganization Act Cases*. There, the Supreme Court reversed a judgment enjoining the enforcement of the Rail Act, which prevented railroads

from discontinuing services or abandoning any lines, unless authorized by the government, until a final bankruptcy reorganization plan became effective. *Blanchette v. Connecticut Gen. Ins. Corps.*, 419 U.S. 102, 107-08, 116-17 (1974). Railroad creditors and shareholders claimed that requiring the railroads to maintain service and keep lines would result in a taking as it would erode the estate beyond constitutional limits. *Id*. at 118. The taking was continuous because the government could not assure that the reorganization plan would be implemented within a reasonable time. *Id*. at 123. Still, the Supreme Court reversed the injunction, holding that the Tucker Act could provide just compensation for any "erosion taking" effected. *Id*. at 136. Because interest on a just compensation award runs from the date of taking, the Court also rejected arguments that a Tucker Act remedy comes too late. *Id.* at 148 n.35.

PhRMA's claim that it is entitled to an order enjoining enforcement of the Act because it results in continuous or ongoing takings is no different from the arguments made and rejected in *Blanchette*, *Rose Acre*, and *National Fuel*. The taking of insulin is compensable and Minnesota's inverse condemnation procedures are adequate and complete. If a manufacturer brings a mandamus action for inverse condemnation and the Act is determined to effect a taking, the legislature then would have to decide whether to amend the Act, withdraw the Act, or exercise eminent domain. *See First Eng.*, 482 U.S. at 321. But those options should be left with the state legislature. This Court should not decide on the legislature's behalf.

2. PhRMA's requested declaratory relief is not available for a takings claim.

PhRMA also requests a declaration that the Act's provisions "violate the Takings Clause of the Fifth Amendment." (Compl. 28.) But *Knick*'s prohibition on equitable relief in takings claims extends to a request for declaratory judgment. And because PhRMA seeks a declaration that the Act itself is unconstitutional, such a declaration would be functionally indistinguishable from an order enjoining the Act, which this Court cannot issue.

In arguing that *Knick* does not preclude declaratory relief, PhRMA disregards the language and reasoning in that opinion. As the Supreme Court stated in *Knick*, because "nearly all state governments provide just compensation remedies to property owners who have suffered a taking, *equitable relief* is generally unavailable." 139 S. Ct. at 2176 (emphasis added). The Court did not limit its language to injunctive relief only, and "equitable relief" is a category of remedies that includes declaratory judgments. *See, e.g.*, *Pub. Affairs Assoc., Inc. v. Rickover*, 369 U.S. 111, 112 (1962) (comparing a declaratory judgment to other forms of equitable relief); *Dakotas & W. Minn. Elec. Indus. Health & Welfare Fund v. First Agency, Inc.*, 865 F.3d 1098, 1103 (8th Cir. 2017) (holding declaratory judgment action was an equitable claim seeking remedies typically available in equity). Even in the short period since *Knick* was decided, several courts have applied it to dismiss takings claims seeking declaratory judgment.[7]

[7] *See, e.g.*, *Cty. of Butler v. Wolf*, No. 2:20-cv-677, 2020 WL 2769105, at *3-4 (W.D. Pa. May 28, 2020) (holding that declaratory relief "is not the appropriate avenue to pursue" a

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PhRMA relies upon *Duke Power Co. v. Carolina Environmental Study Group, Inc.*, where the Supreme Court stated in dicta that individuals threatened with a taking may resort to a declaratory judgment action "before potentially uncompensable damages are sustained." 438 U.S. 59, 71 n.15 (1978). But this statement is consistent with Defendants' reading of *Knick*. If there is a potential for uncompensable damages, then the procedure for obtaining just compensation either does not exist or is insufficient to compensate for the taking. In either case, there is no "adequate provision for obtaining just compensation," and the *Knick* prohibition on equitable relief does not apply. 139 S. Ct. at 2176. In this case, PhRMA has failed to demonstrate that the state inverse-condemnation procedure is not an adequate remedy at law. *See supra* Part I.C.1. As a result, it cannot seek declaratory relief.

Finally, the declaratory relief that PhRMA seeks is especially inappropriate because it would operate as a *de facto* injunction. PhRMA requests a declaration that the Act is unconstitutional, or a violation of the Takings Clause. (Compl. 28; *see also* Pl.'s Mem. 34.) Such a declaration would, in practice, have the same effect as an injunction, and thus is not an available remedy under *Knick*. *See Samuels v. Mackell*, 401 U.S. 66, 72 (1971) (stating declaratory relief has same practical impact as injunction); *Baptiste v. Kennealy*, --- F. Supp. 3d ---, 2020 WL 5751572, at *23 (D. Mass. Sept. 25, 2020) (holding that plaintiffs were not entitled to declaratory judgment on their takings claim

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takings claim); *HAPCO v. City of Philadelphia*, --- F. Supp. 3d ---, 2020 WL 5095496, at *12 n.112 (E.D. Pa., Aug. 28, 2020) (same); *Baptiste v. Kennealy*, --- F. Supp. 3d ---, 2020 WL 5751572, at 23 (D. Mass. Sept. 25, 2020) (same).

because it would be "the functional equivalent of an unwarranted injunction against the enforcement of the Act"); *Cty. of Butler v. Wolf*, No. 2:20-cv-677, 2020 WL 2769105, at *3-4 (W.D. Pa. May 28, 2020) (declining to issue a declaration that "the Governor's business shutdown orders effectuated an unconstitutional taking" because "*Knick* forecloses such relief," even though possible violation was continuing).

In *Knick*, the Court assured governments that they "need not fear that our holding will lead federal courts to invalidate their regulations as unconstitutional." 139. S. Ct. at 2179. If PhRMA can obtain a declaration that has the same effect, then this assurance is meaningless. Declaratory relief, especially of the type that PhRMA seeks, is not an available remedy for PhRMA's takings claim.

D. PhRMA's Dormant Commerce Clause Claim Should Be Dismissed.

PhRMA's Dormant Commerce Clause claim is premised on an argument that Defendants have not made. PhRMA asserts that, if interpreted as a saving provision for the takings claim, subdivision 1(d) of the Act, which exempts insulin products for which the wholesale acquisition cost does not exceed $8 per milliliter, violates the Dormant Commerce Clause. (Compl. 28.) But the Court should not seek an unconstitutional construction of subdivision 1(d) when a reasonable construction avoids constitutional doubt. *See, e.g.*, *Carhart v. Stenberg*, 192 F.3d 1142, 1150 (8th Cir. 1999) ("In interpreting the statute, it is our duty to give it a construction, if reasonably possible, that would avoid constitutional doubts."). Further, because the Dormant Commerce Clause claim relies on an underlying violation of the Takings Clause, the claims fall together.

(*See* Compl. ¶ 87.) Thus, if the Court dismisses the takings claim, the Dormant Commerce Clause claim must be dismissed also.

For the same reasons stated above, PhRMA has failed to establish that it is entitled to summary judgment on its Dormant Commerce Clause claim and, should the Court reach this question, it should deny the motion.

II. THIS COURT SHOULD DENY PHRMA'S SUMMARY JUDGMENT MOTION.

PhRMA's claims should be dismissed, making PhRMA's summary judgment motion moot. If addressed, however, this Court should deny PhRMA's motion. First, the Act does not effect a taking, but rather, involves a valid exercise of police power to abate the harm and nuisance caused by the insulin manufacturers, a voluntary exchange for a license, and a public program that adjusts economic benefits or burdens. Second, even if Act effects a per se taking, PhRMA has failed to prove the manufacturers have suffered any pecuniary loss, which is necessary to prove a takings violation. Third, PhRMA failed to prove—or even discuss—the four factors necessary to obtain injunctive relief. And finally, a declaratory judgment, even if permitted, would not be useful or appropriate.

A. The Act Does Not Effect a Per Se Taking.

PhRMA argues that the Act's provisions requiring manufacturers to provide insulin to certain eligible Minnesotans effectuate per se takings under *Horne v. Department of Agriculture*, 576 U.S. 350 (2015). (Pl.'s Mem. 38-41.) While at first blush their arguments may appear persuasive, this case is not straightforward as they contend. Takings cases "are among the most litigated and perplexing in current law." *Apfel*, 524 U.S. at 541 (Kennedy, J. concurring and dissenting in part). Likewise, this

case is complex with its own set of "particular facts" and *Horne* is not controlling. *See Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 474 (1987) (distinguishing takings cases involving similar regulations on their "particular facts").

Unlike the regulation addressed in *Horne*, the Alec Smith Insulin Affordability Act is a public health and safety law necessary to abate some of the harm caused by the insulin manufacturers. It is an exchange the manufacturers have agreed to make for the valuable government benefit of obtaining a drug-manufacturer license in Minnesota. And, it is a public program regulating the manufacturer's use of their insulin. In similar cases courts have held that no taking occurred, even though those cases appeared to implicate per se takings. A similar determination is warranted here.

1. The Act does not effect a taking because it is a proper exercise of the State's police power to protect the public health, safety, and welfare.

The Act protects the public health, safety, and welfare by providing life-sustaining insulin to those who cannot afford it and would die without it. This significantly differs from the Raisin Act at issue in *Horne*, the purpose of which was to maintain an orderly raisin market. *Horne*, 576 U.S. at 355. Under the Raisin Act, the Raisin Administrative Committee took growers' raisins and gave them away or sold them to exporters, foreign importers, and foreign governments at its discretion. *Id*. It was not enacted to protect the health, safety, or welfare of the citizens and it was "far from clear" that the government's conduct even met the public use requirement of the Fifth Amendment. *Id*. at 370-71 (Thomas, J., concurring). Accordingly, the *Horne* Court did not address the police power or nuisance cases.

PhRMA attempts to avoid any factual considerations by relying on *Horne* and declaring the Act a per se taking. The factual background must be explored, however, because the Act is a legitimate use of police power to protect the health and safety of the public—not a taking. *See Mugler*, 123 U.S. at 661.

In a society, an individual "necessarily parts with some rights or privileges" to allow laws for the common good. *Munn v. Illinois*, 94 U.S. 113, 124 (1876). If a person directs his property to a use in the public's interest, he "must submit to be controlled by the public for the common good, to the extent of the interest he has thus created. He may withdraw his grant by discontinuing the use; but, so long as he maintains the use, he must submit to the control." *Id*. at 126. Accordingly, "it cannot be said that the Taking Clause is violated whenever legislation requires one person to use his or her assets for the benefit of another." *Connolly v. Pension Ben. Guar. Corp.*, 475 U.S. 211, 223 (1986). And, if a business prejudicially affects community interests, "society has the power to protect itself, by legislation, against the injurious consequences of that business." *Mugler*, 123 U.S. at 660. Accordingly, "[i]f the state regulation appears genuinely designed to prevent harm to the public and is likely to achieve that goal and the harm suffered by the property owner does not appear to be one that should be borne by the entire community, we will not find a taking." *Zeman v. City of Minneapolis*, 552 N.W.2d 548, 554 (Minn. 1996) (reviewing a takings claim under both the United States and Minnesota Constitutions).

Although the insulin itself does not create a nuisance, the manufacturers—through their greedy, unethical, and potentially illegal acts—have caused a nuisance in the form

of the insulin affordability crisis. It is this nuisance, and the associated harm of people being forced to ration insulin and consequently dying or otherwise suffering, that the Act attempts to abate. The Court has refrained from finding constitutional violations in such "creation of the harm" or nuisance cases. *See e.g. Connolly*, 475 U.S. at 211; *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976); *Atchison, T. & S. F. Ry. Co. v. Pub. Utilities Comm'n of Cal.*, 346 U.S. 346 (1953); *Miller v. Schoene*, 276 U.S. 272 (1928). Further, persuasive case law has reasoned that the nuisance exception to takings applies for both regulatory and physical takings. *John R. Sand & Gravel Co. v. United States*, 60 Fed. Cl. 230, 236-39 (2004); *Hendler v. United States*, 36 Fed. Cl. 574, 586 (1996), *as amended on reconsideration* (Nov. 26, 1996), *aff'd*, 175 F.3d 1374 (Fed. Cir. 1999).

In *Usery*, the Court upheld against a due process challenge the Black Lung Benefits Act, which required coal mine operators to compensate former employees for any death or disability suffered due to black lung disease. 428 U.S. at 19-20. The Court found "that the imposition of liability for the effects of disabilities bred in the past is justified as a rational measure to spread the costs of the employees' disabilities to those who have profited from the fruits of their labor the operators and the coal consumers." *Id*. at 18. Similarly, in *Atchison*, the Court upheld against due process challenges orders allocating grade separation improvement costs on railroads. 346 U.S. at 354. In doing so, the Court found that the improvements were instituted for safety and convenience, and that, because the railroads' tracks necessitated the grade separation infrastructure, they could not complain that their share in the cost may exceed any special benefits received from the improvement. *Id*. at 352-53.

Although *Usery* and *Atchison* are due process and not takings cases, the creation of the harm idea is applicable to, and has been adopted in, takings cases. "The purpose of forbidding uncompensated takings of private property for public use is '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.'" *Connolly*, 475 U.S. at 227 (*quoting Armstrong v. United States*, 364 U.S. 40, 49 (1960)).

In *Connolly*, discussed further below, the Court held pension-law changes did not effect a taking even though the law completely deprived an employer of certain funds. *Id*. at 225, 228. The Court relied on *Usery*, stating that although it was a due process case, it would be surprising to discover now that Congress unconstitutionally had taken the coal mine operators' assets. *Id*. at 223. The Court was not persuaded that fairness and justice required the public, rather than the employers withdrawing from the pension plan, to shoulder the responsibility for rescuing plans that are in financial trouble. *Id*. at 227. As such, the Court saw no "constitutionally compelled reason to require the Treasury to assume the financial burden of attaining this goal." *Id*. at 228.

Further, in *Miller v. Schoene*, the Court upheld a law that required an owner to cut down a large number of red cedar trees to prevent cedar rust from infecting nearby apple orchards, even though the owner was not compensated for the trees or depreciation to his land. There, the Court determined that protecting a preponderant public interest over the interest of the individual, was one of the "distinguishing characteristics of every exercise of the police power which affects property." 276 U.S. at 279–80.

Here, the manufacturers' greed has caused the problem the Act aims to alleviate. The three insulin manufacturers have created and maintained an oligopoly on the industry allowing them to charge exorbitant prices for this life-sustaining drug. (Krans Decl. Exs. 1-4); 53 U. Mich. J.L. Reform 755 at 758-59, 798. And, consumers who will be dependent on the manufacturers' insulin products for their entire lives, have no choice to pay the price, regardless of the amount, because the alternative is death. The manufacturers have profited significantly at the consumer's and the public's expense and will continue to do so. (*See* Krans Decl. Ex. 4 at 3-4); 53 U. Mich. J.L. Reform at 798 (stating insulin sales yield $24 billion in annual revenue). There is no doubt a preponderant public concern in the preservation of lives, over the manufacturers' interest in their massive profits. Fairness and justice require that the manufacturers who caused the insulin crisis, not the public at large, should bear the responsibility of protecting people who cannot afford their insulin. *See* 53 U. Mich. J.L. Reform at 797-803 (arguing the nuisance exception exempts the government from having to pay just compensation to pharmaceutical corporations under takings law). As such, the Act does not effect a taking.

This does not mean states have unbridled power to control manufacturers' use of their insulin. "[W]hen particular individuals are singled out to bear the cost of advancing the public convenience, that imposition must bear some reasonable relation to the evils to be eradicated or the advantages to be secured." *Nashville, C. & St. L. Ry. v. Walters*, 294 U.S. 405, 429 (1935). This is similar to the requirement that land-use exactions must bear a sufficient nexus with and be roughly proportional to the specific interest the

government seeks to protect through the permitting process. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994); *Nollan v. California Coastal Comm'n*, 483 U.S. 825, 837 (1987). Here, the Act is designed to protect the people insulin manufacturers have harmed and profited from by charging exorbitant prices. It is reasonable and proportional as it only applies to manufacturers who profit significantly on insulin sales in Minnesota and is limited to only providing insulin to those most in need without the means to pay.

2. The Act's requirements are part of a voluntary exchange for licensure in Minnesota, not a taking.

Because drug manufacturers agree to abide by the Act as a condition to licensure in Minnesota, the Act's requirements are part of a knowing voluntary exchange for licensure, which under *Ruckelshaus* is not a taking. This case is more comparable to *Ruckelshaus* than *Horne*. In *Ruckelshaus*, the Court addressed an Environmental Protection Agency regulation that required chemical manufacturers to give up trade secrets, effectively destroying them, in exchange for a permit to sell pesticides. 467 U.S. at 990. After determining that the pesticide manufacturer, Monsanto, had a protectable property interest in its trade secrets, the Court held that no taking occurred for trade secrets provided after the regulation was amended because the trade secrets were given up as part of an exchange to market its pesticides in the United States. 467 U.S. at 1006-07. The Court found that such restrictions are simply burdens we all must bear in exchange for doing business in a civilized community. *Id*. at 1007. And, that it was particularly true for Monsanto because pesticide sale and use had long been the source of public concern and the subject of government regulation. *Id*.

While the Court could have determined the disclosure of Monsanto's trade secrets destroyed them, resulting in a per se taking, it instead applied *Penn Central* and held that Monsanto's lack of a reasonable, investment-backed expectation was dispositive. The Court determined that the regulation put Monsanto on notice that its trade secrets could be disclosed to the general public. *Id*. at 1006. Accordingly, if Monsanto still chose to submit trade secrets to receive a registration, knowing they could be disclosed, its investment-backed expectations would not be disturbed when the trade secrets were disclosed.[8] *Id*. at 1006-07. The Court also noted that Monsanto could decide to forego registration in the United States and sell a pesticide only in foreign markets. *Id*. at 1007, n.11.

By contrast, *Horne* did not involve a health and safety regulation or a permit to sell in a regulated market. The Court in *Horne* distinguished *Ruckelshaus* based on the nature of the product at issue, that the pesticide regulation involved health and safety concerns, and that *Ruckelshaus* involved a permit to sell in a regulated industry. 576 U.S. at 365-66. The Court determined that being able to sell raisins in interstate commerce is not a special governmental benefit in the way that a license to sell pesticides in commerce was a valuable government benefit. *Id.* The Court concluded by stating "[r]aisins are not dangerous pesticides; they are a healthy snack." *Id.* at 366.

[8] The Court also held that if the government considered or disclosed trade secrets that Monsanto submitted under the previous statutory scheme, it would constitute a taking in certain circumstances. 467 U.S. at 1010-14.

Just like raisins are not dangerous pesticides, pharmaceuticals are not raisins. Insulin is a highly-regulated lifesaving drug, not a "healthy snack." Like pesticide manufacturers, pharmaceutical manufacturers are highly regulated. Minnesota licenses drug manufacturers, including the three insulin manufacturers at issue here, who must agree as part of their licensure to operate in a manner prescribed by state law. Minn. Stat. § 151.252, subds. 1(a), (d); (Wiberg Aff. ¶¶ 2-8). Those laws include the Alec Smith Insulin Affordability Act. Minn. Stat. § 151.74. The Act—like the EPA regulation in Monsanto—was designed to protect the health and safety of Minnesotans by providing a safety net for people who need insulin, but could otherwise not afford it. A license to act as a drug manufacturer in Minnesota is on the same order as a permit to sell hazardous chemicals.

Further, like Monsanto, insulin manufacturers were on notice that if they sought a license in Minnesota, they were required to abide by the Act if they grossed more than $2,000,000 from insulin sales in Minnesota. Despite this notice, the manufacturers all chose to renew their licenses after the Act was enacted but before it was implemented. (*See* Wiberg Aff. ¶¶ 5-8.) Like Monsanto, the manufacturers here were willing to bear any burdens of the Act in exchange for a drug-manufacturer license. This is evidence by the fact that they renewed their licenses after having notice of the Act and sold more than $2,000,000 worth of insulin in Minnesota. *Ruckelshaus*, not *Horne*, applies here. And under *Ruckelshaus*, the Act does not effect a taking.

In a similar vein, shortly after *Ruckelshaus* was decided, the Eighth Circuit upheld a condition on Medicaid participation that limited the amount nursing homes can charge

non-Medicaid residents, determining it was not a taking. *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dept. of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). There, the court held that a nursing home's voluntary decision to participate in Medicaid foreclosed "the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." *Id*. And the condition was constitutional because the right to conduct a business may be conditioned. *Id*. at 447. Similarly, the drug manufacturers have voluntarily entered into Minnesota's insulin market and have agreed to abide by the Act as a condition of licensure.

3. The Act regulates the manufacturers' use of the insulin and does not appropriate it for the government's own use.

Further, the Act does not effect a taking because it does not allow the government to appropriate the insulin for its own use; but rather, regulates the manufacturer's use of the insulin as part of a public program. "A 'taking' may more readily be found when the interference with property can be characterized as a physical invasion by government, than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good." *Penn Cent.*, 438 U.S. at 124 (citation omitted). PhRMA contends the Act results in a clear physical appropriation of the manufacturer's property for the government's own use, similar to the raisin marketing order in *Horne*. Unlike the raisin marketing order, however, the Act does not allow the state to physically appropriate the manufacturers' insulin for its own use. Rather, the Act safeguards individuals with diabetes that may suffer serious illness or death because they

cannot afford the manufacturers' exorbitant insulin prices, by regulating how the manufacturers may use their property. The Act is a public program that adjusts the benefits and burdens of economic life to promote the common good, which, as the Supreme Court has held, does not constitute a taking.

The Supreme Court's pension plan takings cases illustrate this distinction. In two separate cases, the Court rejected takings challenges to amendments to pension plan laws after applying a *Penn Central* analysis. *See Concrete Pipe & Prod. of California, Inc. v. Constr. Laborers Pension Tr. for S. California*, 508 U.S. 602 (1993); *Connolly*, 475 U.S. at 228. That act required employers withdrawing from a multiemployer pension plan to pay a statutorily created debt to the pension plan. *Connolly*, 475 U.S. at 217. The Court held that, although the withdrawal liability permanently deprived the employer of those assets, the government "did not physically invade or permanently appropriate any of the employer's assets for its own use." *Id*. at 225; *Concrete Pipe*, 508 U.S. at 643 (quoting *Connolly*). Rather, the pension act safeguarded the participants in the pension plans by requiring a withdrawing employer to fund its share of the plan obligations. *Id*. The Court then applied the *Penn Central* regulatory taking considerations to hold there was no taking in both cases. *Concrete Pipe*, 508 U.S. at 643-47; *Connolly*, 475 U.S. at 224-28.

Likewise, courts have analyzed takings claims in the medical context as regulatory takings, not per se takings, even though hospitals or ambulance companies were required to provide services, medicines, and medical supplies to low income patients for free. The First Circuit held that Maine's laws requiring hospitals to provide free medical services to low-income patients did not effect a per se or regulatory taking. *Franklin Mem'l Hosp. v.*

Harvey, 575 F.3d 121 (1st Cir. 2009). Maine's act was unique in that its free-care mandate was not a license condition or linked to the state's certificate of need process, but was enforced through penalties. *Id*. at 124. The court rejected the hospital's argument that the law's requirement that the hospital freely provide medicines and medical supplies was a per se taking, holding that the laws did not directly appropriate the property but regulated how the hospital may use its property. *Id*. at 125-26. In applying the regulatory takings factors, the court determined that the free care laws adjusted the benefits and burdens of economic life by requiring hospitals to provide free care to low income persons, but otherwise allowed the hospital to set the terms on which it provided access to its facilities and services. *Id.* at 129.

The Ninth Circuit also found that a law requiring all ambulance companies to provide emergency services without first questioning the patient's ability to pay did not effectuate a per se or regulatory taking. *Sierra Med. Services All. v. Kent*, 883 F.3d 1216 (9th Cir. 2018). The law applied regardless of whether the provider was enrolled in California's Medicaid program.[9] *Id*. at 1224. The Court acknowledged *Horne* and the ambulance companies' property interest in their ambulances, equipment, and supplies. *Id*. at 1124-25. It then held that the law did not effect a per se taking because the government did not directly appropriate the personal property, but instead regulated how the ambulance companies could use their property. *Id.* at 1225.

[9] In its amicus brief, the Goldwater Institute incorrectly asserts that the mandate was voluntary because it applied only to ambulance companies participating in the Medicaid program. (Br. of Amicus Curiae Goldwater Inst. [Doc. 57] at 7.)

Like the cases above, the Act does not allow the state to physically invade or permanently appropriate property for its own use. It is a public program that adjusts the benefits and burdens of economic life to promote the common good and alleviate the burdens caused by the insulin manufacturers. In contrast, under the raisin marketing order in *Horne*, a percentage of a grower's crop was required to be physically set aside for the government, which acquired title to the raisins and decided how to dispose of them in its discretion. *Horne*, 576 U.S. at 354-55. Under the Act at issue here, manufacturers are not required to set aside any insulin for the state to take and use at its discretion. Rather, the Act regulates how manufacturers must use their insulin in specific, limited circumstances. Therefore, the *Penn Central* regulatory takings factors apply. Because PhRMA has failed to make a regulatory takings claim or provide evidence that would support a regulatory takings claim, its motion for summary judgment must be denied.

Whether viewed as a "creation of the harm" or nuisance matter, an exchange for a benefit, or a public program that adjusts economic benefits or burdens, or a combination of the three, the result is the same: PhRMA has failed to prove a taking. Fairness and justice require that the manufacturers who caused the insulin crisis, not the public at large, should bear the responsibility of protecting people who cannot afford their insulin. And, given the unique nature of the insulin market, people should not be concerned that a finding that no taking occurred here would impact other property rights. (*See* Krans Decl. Ex. 1 at 2 (stating the insulin market is nuanced even compared to the traditional drug market.))

B. PhRMA has Failed to Prove That the Manufacturers Have Suffered a Loss Due to the Act.

Even if a taking occurred, PhRMA's motion must be denied as it has failed to prove the insulin manufacturers have suffered a pecuniary loss from the alleged takings. Even if a per se taking occurs, there is no constitutional violation if the property owner's net pecuniary loss is zero.[10] *Brown v. Legal Found. of Wash.*, 538 U.S. 216, 240 (2003). Just compensation considers the property owner's net loss, not the government's gain. *Id*. at 235-37; *Bos. Chamber of Commerce v. Bos.*, 217 U.S. 189, 195 (1910). A property owner is entitled only to be put in the same financial position as if his property had not been taken; he is not entitled to more. *Olson v. United States*, 292 U.S. 246, 255 (1934). In determining whether the owner suffered a net loss, benefits conferred on the owner may be set off against the value of the property taken. *Bauman v. Ross*, 167 U.S. 548, 574 (1897); *see also Horne*, 576 U.S. at 372-376 (Breyer, J., concurring in part and dissenting in part) (summarizing cases).

PhRMA has failed to prove the manufacturers have suffered a net loss. (*See* Boss, Siragusa, Asay Decls.). And, as such, has failed to prove a violation of the Takings Clause and entitlement to judgment. Although the manufacturers state they have provided insulin under the Act, a net loss has not been proven and should not be presumed given the manufacturers' own assistance programs and potential benefits from

[10] This is consistent with the Court's holding in *Knick* that a Fifth Amendment violation occurs when the government takes property without just compensation. Because, if the property owner's net pecuniary loss is zero, the taking is not "without just compensation" and no violation has occurred.

the Act. All three manufacturers have programs—with eligibility requirements similar to the Act's—to provide free and reduced-cost insulin to individuals. (Pl.'s Mem. 1; Compl. ¶¶ 4, 56-63.) Also, a manufacturer is supposed to route eligible, insured individuals through the manufacturer's own co-payment assistance program, rather than the Act's program, if it better addresses the individual's needs. Minn. Stat. § 151.74, subd. 5(c). If the manufacturer would have provided the insulin for free to the individual or should have routed the individual through its own program, the manufacturer has not suffered a net loss and no violation of the Takings Clause has occurred even if the insulin was "taken."

If Defendants' motion to dismiss is denied, discovery is necessary to defend against any factual assertions by PhRMA that the manufacturers have suffered a net loss. The manufacturers possess information on the insulin or reimbursements they have provided under the Act, the applications received under the continuing program, and their own program requirements. Defendants do not possess that information and would have to get it from the manufacturers or others through discovery. *See* Fed. R. Civ. P. 56(d) (stating that a court may deny or stay a motion for summary judgment when the nonmovant shows that discovery is required on "facts essential to justify its opposition"); (Krans Decl. ¶¶ 2-5).

C. PhRMA Has Not Demonstrated that Injunctive Relief is Merited as a Matter of Law.

The Court should deny summary judgment on PhRMA's claim for injunctive relief because, in addition to the unavailability of this relief and the flaws of PhRMA's

merits argument, PhRMA has not put forth facts to satisfy the prerequisites of injunctive relief. Before a court may grant a permanent injunction, the party seeking the injunction must satisfy a four-factor test and demonstrate:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006); *see also Lowry ex rel. Crow v. Watson Chapel Sch. Dist.*, 540 F.3d 752, 762 (8th Cir. 2008) (stating four similar factors but including whether the movant proves actual success on the merits, rather than whether damages are inadequate). "An injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010).

PhRMA does not and cannot put forth facts sufficient to demonstrate it is entitled to injunctive relief. Its argument that monetary damages are inadequate is unconvincing for the reasons detailed above. *See supra* Part I.C. And PhRMA has made no attempt to argue, let alone established as a matter of law, that its members have suffered an irreparable injury, that the balance of hardships weighs in their favor, or that the public interest would be served by enjoining the Act. These factors must be established beyond any genuine dispute of fact for PhRMA to be entitled to an injunction, and PhRMA's lack of evidence or argument that they are met is further ground for denying their motion for summary judgment.

PhRMA cannot demonstrate that its members have suffered or will suffer an irreparable injury as a matter of law. Irreparable harm occurs "when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages." *Gen. Motors Corp. v. Harry Brown's, LLC*, 563 F.3d 312, 319 (8th Cir. 2009). But as Defendants discuss in detail in support of their motion to dismiss, *see supra* Part I.C.1., a party who has suffered a taking has a remedy at law in the form of just compensation. This remedy, specifically prescribed by the language of the Fifth Amendment, should be presumed to be an adequate remedy. *See Knick*, 139 S. Ct. at 2176. And because Minnesota, like "nearly all state governments," provides a just compensation remedy for property owners who have suffered a taking, there is no basis to conclude that any of PhRMA's members faces an irreparable injury. *Id.*; *see also Wis. Cent. Ltd. v. Pub. Serv. Comm'n of Wis.*, 95 F.3d 1359, 1369 (7th Cir. 1996) (holding that a plaintiff "would be hard pressed to demonstrate either irreparable harm or an inadequate remedy at law" when asserting a takings claim).

The injury PhRMA alleges is not irreparable. In fact, it is the opposite; the loss of saleable goods is among the most simple to remedy. If in fact the Act has caused manufacturers to lose the sales proceeds of the insulin products they provide to eligible participants, *see supra* Part II.B., any such losses may be remedied by monetary damages. *See, e.g.*, *DISH Network Serv. L.L.C. v. Laducer*, 725 F.3d 877, 882 (8th Cir. 2013) ("Economic loss, on its own, is not an irreparable injury so long as the losses can be recovered"); *Dexter 345 Inc. v. Cuomo*, 663 F.3d 59, 63 (2d Cir. 2011) (holding that possible loss of profit, loss of goodwill, or even threat to the existence of the plaintiff's

business did not constitute an irreparable injury in a takings claim). Threatened injuries inviting injunctive relief are a rare class, limited to catastrophic and irreversible events like loss of life. *City of Baton Rouge/Parish of East Baton Rouge v. Ourso*, No. 19-00457-DAJ-RLB, 2020 WL 3036546, at *2 (M.D. Louisiana, June 5, 2020) (loss of life). PhRMA claims no injury of this type, and PhRMA's failure to show irreparable harm is "an independently sufficient ground upon which to deny" an injunction. *Watkins Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003).

Further, PhRMA has not demonstrated that the balance of hardships weighs in favor of enjoining the Act. The declarations submitted from the manufacturers' representatives state that Eli Lilly, Novo Nordisk, and Sanofi have distributed insulin under the Act, but they do not quantify the Act's impact on the manufacturers' business. (*See* Boss, Siragusa, Asay Decls.) These declarations confirm that each manufacturer grosses more than $2,000,000 annually from selling their insulin products in Minnesota, but they do not state what percentage of their gross profits would be impacted by the requirements of the Act or how many 30-day or 90-day supplies of insulin the manufacturers have provided under the Act. *Id.* Thus PhRMA's evidence in support of its argument for summary judgment is completely devoid of information that would allow the Court to evaluate the actual burden or hardship imposed by the Act. *See, e.g.*, *Travelers Express Co., Inc. v. Transaction Tracking Techs., Inc.*, 305 F. Supp. 2d 1090, 1095 (D. Minn. 2003) (holding that the balance of hardships weighed against injunction because the violation impacted only a small proportion of the movant's business).

The Court cannot, and should not, assume that the balance of hardship lies with the manufacturers. The hardship to Defendants, should the Act be enjoined, is the immediate destruction of a statutory framework duly enacted by the Minnesota legislature for the public interest. "[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, J.) (staying an injunction of a state statute pending appeal). Enjoining the Act would deprive the State of its ability to govern, and to make determinations of how it should govern, during the crisis of insulin affordability in Minnesota. *See Hurley*, 285 U.S. at 104 n.3 (holding that an injunction was improper in a takings challenge to a national flood management plan, even if the "remedy at law is less clear and adequate," because an injunction "may seriously embarrass the accomplishment of important governmental ends"). To disable the action of the elected representatives of Minnesota works a hardship, and in the absence of any evidence of the degree of hardship to the manufacturers, the balance of hardships tilts against enjoining the Act.

Finally, PhRMA has not established as a matter of law that the public interest favors an injunction halting the provision of life-saving insulin under the Act. The public interest lies in protecting the lives of Minnesotans, and the Act serves that interest by providing a pathway to obtaining insulin for patients who cannot afford it. Without this pathway, these patients may be forced to ration their insulin and face serious health consequences, or death.

Courts have repeatedly noted the "robust public interest" in safeguarding access to healthcare for those who cannot afford it. *Planned Parenthood of Gulf Coast, Inc. v. Gee*, 862 F.3d 445, 471 (5th Cir. 2017) (internal quotation omitted); *accord Pashby v. Delia*, 709 F.3d 307, 330 (4th Cir. 2013); *M.R. v. Dreyfus*, 697 F.3d 732, 738 (9th Cir. 2012). For the same reason, there is a strong public interest in maintaining accessibility to products essential to public health. For example, in *Hybritech Inc. v. Abbott Laboratories*, a patent infringement case, the Federal Circuit reviewed a preliminary injunction enjoining Abbott from selling products that infringed on Hybritech's patent, but which excluded certain essential medical supplies from the list of enjoined products. 849 F.2d 1446, 1458 (Fed. Cir. 1988). The Federal Circuit upheld the district court's determination that patent-infringing cancer and hepatitis test kits should be excluded from the preliminary injunction, because "the public interest was served best by the availability of these kits." *Id.* The same logic applies here, where the Act allows for the continued availability of a lifesaving drug to those Minnesotans who would perish without it. It would disserve the public interest to enjoin the Act.

An injunction is extraordinary relief in any case, and PhRMA has failed to put forth any evidence or argument to show that its members face irreparable injury, that the balance of hardships favors injunction, or that an injunction would serve the public interest. This is another area where discovery would be required to adjudicate PhRMA's motion, and issuing a decision before any discovery would be premature. Fed. R. Civ. P. 56(d). The failure to establish any of these factors is an independent basis to deny the injunction that PhRMA seeks. *eBay*, 547 U.S. at 391.

D. Declaratory Judgment is Inappropriate in Light of the Available State Remedy.

Even absent *Knick*'s holding that declaratory relief is unavailable in takings cases, a declaratory judgment still would be inappropriate here. A request for declaratory judgment under 28 U.S.C. § 2201 is always a matter of judicial discretion. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995) ("[D]istrict courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites."). In fact, the district court "is afforded greater discretion in determining whether to exercise jurisdiction over a declaratory judgment action than in other circumstances." *Scottsdale Ins. Co. v. Detco Indus., Inc.*, 426 F.3d 994, 999 (8th Cir. 2005). Even if the Court rejects the above arguments and finds that PhRMA states a justiciable claim, the Court can and should decline to issue a declaratory judgment that the Act violates the Takings Clause of the Fifth Amendment.

When deciding whether to exercise jurisdiction over a declaratory judgment action, district courts consider, among other factors, whether the issues raised may be more efficiently resolved in state court, and whether the declaratory judgment sought "will serve a useful purpose in clarifying and settling the legal relations in issue." *Id.* at 998. Here, where repair to the state inverse-condemnation procedure is the proper remedy and the only way for the manufacturers to obtain just compensation for any taking that has occurred, there is no efficiency benefit to issuing a declaratory judgment in federal court. And a declaration that the Act effects a taking would serve no useful

purpose, because the remedy available to the manufacturers remains the same: just compensation, which cannot be obtained in federal court and must be sought through inverse condemnation. *See Treleven*, 73 F.3d at 818 (stating that suits against the state for monetary damages are barred by Eleventh Amendment immunity).

Given the limited degree of usefulness of a declaratory judgment on PhRMA's takings claim, the Court should decline to decide this complicated constitutional question. "A factor which is always to be considered in determining whether to grant declaratory relief in constitutional cases is the need for courts to be chary about adjudicating constitutional rights by means of declaratory judgment actions." *El Dia, Inc. v. Hernandez Colon*, 963 F.2d 488, 494 (1st Cir. 1992). Several courts have stated that declaratory judgment actions are at odds with the principle that "[u]ncertain questions of constitutional law should be addressed only when absolutely necessary." *Id.*; *see, e.g.*, *Fletes–Mora v. Brownell,* 231 F.2d 579, 581 (9th Cir. 1955) ("The adjudication of alleged constitutional rights in a declaratory judgment action is not to be encouraged for the reason that decisions in that field tend to be advisory unless based upon proof of definite and specific fact."). Here, the declaratory relief requested is barred by *Knick*. But to the extent it could be considered, the Court should exercise its discretion to decline deciding PhRMA's claim for a declaratory judgment.

CONCLUSION

For the reasons stated above and stated in their initial memorandum, Defendants respectfully request that the Court dismiss PhRMA's complaint in its entirety and deny PhRMA's pending motions as moot. Should the Court decide that dismissal is not

merited at this time, PhRMA's premature summary judgment motion still must be denied as PhRMA has failed to prove it is entitled to judgment as a matter of law.

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