IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Pharmaceutical Research and Manufacturers of America, Plaintiff, v. Stuart Williams, Stacey Jassey, Mary Phipps, Andrew Behm, James Bialke, Amy Paradis, Rabih Nahas, Samantha Schirmer, and Kendra Metz, in their official capacities as members of the Minnesota Board of Pharmacy; and Nate Clark, Peter Benner, Suyapa Miranda, David Fisher, Jodi Harpstead, Phil Norrgard, Stephanie Stoffel, and Andrew Whitman, in their official capacities as members of the Board of MNsure, Defendants.	Case No. 20-cv-1497-DSD-DTS **PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) brought this action seeking a declaration that the Alec Smith Insulin Affordability Act (the Act) compels *per se* unconstitutional takings of insulin, and a permanent injunction barring the Act's enforcement. The Act seeks to address a matter of public concern—namely, the high out-of-pocket costs some patients must pay for insulin, often because they lack health insurance coverage for prescription medications, or because their insurance requires significant out-of-pocket payments for their medications. Compl. ¶ 2. But a "strong 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). The Act violates this principle. It compels the three PhRMA members that manufacture most of the insulin sold in the country to give away their products to specified state residents at no charge to the recipients, and it fails to compensate the manufacturers for that insulin.

PhRMA and the three manufacturers believe that no one living with diabetes should be forced to go without insulin because they cannot afford it. That is why all three manufacturers have programs that provide discounts and co-payment assistance to significantly reduce patients' out-of-pocket costs, and why they also provide free insulin (directly or through charitable organizations) to a great number of patients. Compl. ¶¶ 56-63. Defendants themselves acknowledge that these programs "have similar eligibility requirements to the Act" and "target the same populations that the Act seeks to protect." Defendants' Memorandum Supporting Motion to Dismiss (Defs. Mem.) at 18-19.

But the Minnesota legislature decided that the manufacturers have not been generous enough. It therefore required manufacturers to provide insulin at no charge to Minnesota residents under two new programs established by the Act. Pursuant to the Act's mandates, all three manufacturers have now provided free insulin to eligible residents—just as the legislature intended and expected. Thus, the *per se* takings that PhRMA alleged would begin to occur when the Act took effect have in fact occurred, and will continue in the future.

Defendants' efforts to dismiss PhRMA's challenge to this unconstitutional law are meritless. As state officials charged with enforcing an unconstitutional state law, defendants can be sued in federal court for declaratory and injunctive relief. *See Ex Parte Young*, 209 U.S. 123 (1908). Their contention that no unconstitutional taking occurs until the government denies compensation for the property it appropriated is foreclosed by controlling authority. *See Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2167-68 (2019).

Moreover, the timing of this suit has no bearing on the Court's authority to hear it: Because certain PhRMA members faced certainly impending injuries from the unconstitutional takings the Act was designed to compel, PhRMA had associational standing to challenge the law the day before it took effect. Since then, the law has caused the *per se* takings that PhRMA alleged would occur. These post-complaint facts, properly considered on a jurisdictional motion under Rule 12(b)(1), confirm PhRMA's standing.

Nor is it true that the PhRMA members who manufacture insulin must participate in this suit. Defendants' arguments to the contrary ignore the distinction between regulatory takings, which turn on individualized assessments of how a regulation affects

the economic value of a particular plaintiff's property, and *per se* takings, which do not require such plaintiff-specific assessments. PhRMA alleges only *per se* takings.

Finally, this Court can award the injunctive relief PhRMA seeks because Minnesota does not afford the manufacturers full compensation through "a plain, adequate, and complete remedy at law." *Knick*, 139 S. Ct. at 2175. Defendants argue that a state-law mandamus action could be brought to compel state officials to initiate condemnation proceedings. But a mandamus action cannot provide "complete" relief, because mandamus can only compel compensation for past takings, not future ones. And being forced continually to file after-the-fact mandamus suits to compel condemnation actions for insulin products after they are taken would be an unprecedented and inadequate "remedy" for an ongoing series of statutorily compelled takings. At a bare minimum, PhRMA is entitled to a declaration that the Act is unconstitutional.

Not only should defendants' motion to dismiss be denied, but the Court should grant PhRMA summary judgment on its constitutional claims. The undisputed material facts make clear that the Act compels an ongoing series of *per se* takings of personal property—insulin of the three PhRMA members—without just compensation. Accordingly, the Court should declare these takings unconstitutional and issue an injunction to prevent further takings. And if the Act's exemption for insulin products with a wholesale acquisition cost of $8 or less per milliliter is designed to coerce manufacturers to lower the national wholesale prices of their products to avoid these takings—a position defendants appear (wisely) to disclaim—PhRMA would also be entitled to a declaration that the exemption violates the Commerce Clause.

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 Sept. 30, 2020). Insulin is a hormone produced by the pancreas that signals the body's cells to absorb glucose from the blood for energy. *Id.* Without insulin, cells are unable to absorb glucose. *Id.* If not treated, diabetes can cause serious health problems. *Id.* Diabetes is often treated with injectable insulin.

A. The Act

Signed into law on April 15, 2020, 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, subd. 1(b)(1). The Act has two parts: the "Continuing Safety Net Program" and the "Urgent Need Program."

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 products 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.*, subd. 4(a), 4(b). Individuals with prescription drug coverage under Medicare Part D can also receive free

insulin under the Continuing Safety Net Program if they have spent more than $1,000 on prescription drugs in the calendar year and meet the other eligibility criteria. *Id.*, subd. 4(c).

Manufacturers must accept applications from Minnesota residents seeking insulin under the Continuing Safety Net Program, determine whether the individual is eligible, and provide notice of those eligibility determinations. *Id.*, subd. 5(a). Applicants can appeal an adverse eligibility decision to a state review panel. *Id.*, subd. 8. The review panel may overrule the manufacturer, and its eligibility decision is binding. *Id.*

If a resident is deemed eligible, the manufacturer must provide a "statement of eligibility" that the individual can present at a pharmacy to obtain free insulin from the manufacturer for up to one year. *Id.*, subd. 5(b), 6(a). For eligible residents with private health insurance, the manufacturer may instead "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.*, subd. 5(c).

When presented with an eligibility statement, the pharmacy orders the insulin from the manufacturer, and the manufacturer "shall send" a "90-day supply of insulin" to the individual or pharmacy "*at no charge* to the individual or pharmacy." *Id.*, subd. 6(c), 6(g) (emphasis added). The pharmacy, however, can charge a co-payment "not to exceed $50 for each 90-day supply" to cover "the pharmacy's costs for processing and dispensing" the insulin. *Id.*, subd. 6(e).

This process may be repeated as an individual orders more insulin throughout the full year of program eligibility. "Upon receipt of a reorder from a pharmacy," the manufacturer must send "an additional 90-day supply of the product, unless a lesser amount is requested"—again "at no charge to the individual or pharmacy." *Id.*, subd. 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); and (4) have readily available for use less than a seven-day supply of insulin, and need insulin to avoid the likelihood of suffering significant health consequences. *See id.*, subd. 2(a)-(b), 9.

When an eligible resident submits an application under the Urgent Need Program, the pharmacy "shall dispense" a 30-day supply of insulin to that person. *Id.*, subd. 3(c). The pharmacy then submits an electronic claim for payment to the manufacturer of the insulin that was dispensed (or to that manufacturer's vendor); the manufacturer must either "send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed," or "reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost" for the dispensed insulin. *Id.*, subd. 3(d). The pharmacy may collect a co-payment from the individual of up to $35 for the 30-day supply. *Id.*, subd. 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.*, subd. 3(d).

3. Enforcement of the Act

The Board of Pharmacy (Board) enforces the Act by assessing an administrative penalty of $200,000 per month on manufacturers that fail to comply with the requirements of the Continuing Safety Net Program or Urgent Need Program or that fail to advertise the program criteria or provide a mandatory telephone hotline. *Id.*, subd. 10(a), 10(b). This penalty increases to $600,000 per month for any manufacturer that remains noncompliant after one year. *Id.*, subd. 10(a).

There are two limited exceptions to the Act's mandates and penalties. First, a manufacturer is exempt from the Act if it has "annual gross revenue of $2,000,000 or less from insulin sales in Minnesota." *Id.*, subd. 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.*, subd. 1(d).

B. This Lawsuit

PhRMA filed this lawsuit on June 30, 2020, the day before the Act's mandates went into effect. PhRMA sued on behalf of itself and its members. Compl. ¶ 13. Its complaint explained that three of its members—Eli Lilly and Company (Lilly), Novo Nordisk Inc., and Sanofi—manufacture most of the insulin sold in the United States, including in Minnesota, and are subject to the Act. *Id.*

The complaint cited estimates from the Board of MNsure (a state health-insurance board) that thousands of Minnesota residents will request insulin under the Act in its first year of operation, and alleged that compelling PhRMA's members to give away insulin at no charge and without any compensation violates the federal Takings Clause. *Id.* ¶¶ 79-85. PhRMA further alleged that, if the Act's WAC-based exemption was intended to give manufacturers the "option" of avoiding the unconstitutional taking of insulin by lowering their the WAC of their products to $8 per milliliter or less—a price manufacturers necessarily would have to impose nationwide—then that option is independently unconstitutional under the Commerce Clause of the U.S. Constitution. *Id.* ¶¶ 86-89.

Just before the Act's mandates went into effect, MNsure began a social media campaign to raise awareness about the new state programs, *see* Decl. of Jennifer Sunga (Exhibit 1), and the Board of Pharmacy issued instructions advising residents and pharmacists how to obtain free insulin from PhRMA's members under the Act.[1] Since the programs went into effect on July 1, 2020, eligible residents have requested insulin under the Act. As a result, Lilly, Novo Nordisk and Sanofi have each provided insulin at no charge for Minnesota residents under the Continuing Safety Net Program, and have reimbursed (or are in the process of reimbursing) pharmacies under the Urgent Need

[1] *See* Minn. Bd. of Pharmacy, *Minnesota Insulin Safety Net Program (Program): Frequently Asked Questions for Pharmacists* (June 30, 2020); Minn. Bd. of Pharmacy, *Minnesota Insulin Safety Net Program: Information for Patients* (June 30, 2020). Both documents are available on the Board's website, *see* Minn. Bd. of Pharmacy, *Minnesota Insulin Safety Net Program*, https://mn.gov/boards/pharmacy/insulinsafetynetprogram/ (last visited Sept. 30, 2020).

Program, again at no charge. *See* Decl. of Carrie Siragusa ¶¶ 8-9 (Exhibit 2); Decl. of Derek L. Asay ¶¶ 9-10 (Exhibit 3); Decl. of Jeremy Boss ¶¶ 8-9 (Exhibit 4).

On August 27, 2020, defendants moved to dismiss this suit under Rules 12(b)(6) and 12(b)(1). Thereafter, PhRMA stipulated to the dismissal of the MNsure board members and employee, based on defendants' representation that these officials have no responsibility for enforcing the Act. Dkt. Entry 21. In this memorandum, PhRMA explains why the motion to dismiss should be denied as to the remaining defendants, and why PhRMA is entitled to summary judgment on its claims.

PhRMA'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Defendants' motion to dismiss should be denied.

Because PhRMA's claims squarely satisfy the requirements of *Ex Parte Young*, 209 U.S. 123, defendants are not immune from this suit. *See* Part I. PhRMA has pled valid claims for *per se* takings, which occur the moment the government takes private property without paying just compensation, and not—as defendants claim—only after the government denies a post-deprivation request for compensation. *See* Part II. PhRMA has standing to sue on behalf of its members, which faced certainly impending unconstitutional takings when the suit was filed, and have suffered such takings since. *See* Part III. Resolution of this suit does not require the participation of the manufacturers themselves, and PhRMA's claims are plainly ripe. *See id.* No Minnesota remedy for compensation forecloses PhRMA's right to injunctive or declaratory relief. *See* Part IV. Finally, PhRMA's Commerce Clause claim can be dismissed only if defendants disclaim

reliance on the Act's WAC-based exemption as a defense to PhRMA's Takings Clause claim. *See* Part V.

STANDARD OF REVIEW

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

Defendants have also moved to dismiss on jurisdictional grounds under Rule 12(b)(1). This Court can "consider matters outside the pleadings when subject matter jurisdiction is challenged under Rule 12(b)(1)." *Harris v. P.A.M. Transp., Inc.*, 339 F.3d 635, 637 n.4 (8th Cir. 2003).

I. DEFENDANTS ARE NOT IMMUNE FROM THIS SUIT.

As defendants acknowledge, Defs. Mem. 10, a state's Eleventh Amendment immunity from suit in federal court is subject to an important exception. Under *Ex Parte Young*, state officials responsible for enforcing a state law alleged to violate the federal Constitution can be sued in federal court for declaratory and injunctive relief to prevent further enforcement of that law. This suit fits squarely within that exception.

PhRMA has not sued the state or a state agency, but rather state officials in their official capacities, namely, the members of the Board of Pharmacy. Compl. ¶¶ 15-24.[2] PhRMA alleges that these officials have authority to enforce the Act, *id.* ¶ 15, an allegation defendants do not dispute. PhRMA further alleges that the Act violates the Fifth Amendment of the United States Constitution, made applicable to the states by the Fourteenth Amendment. *Id.* ¶¶ 8-9, 80-85. It likewise alleges that the Act's exemption would, if construed in a certain manner, violate the Commerce Clause of the U.S. Constitution. *Id.* ¶¶ 86-89. And PhRMA seeks only declaratory and injunctive relief, not damages. *Id.* at Prayer for Relief.

PhRMA has thus adequately pled a claim under *Ex Parte Young*. *See Verizon Md., Inc. v. Pub. Serv. Comm'n of Md.*, 535 U.S. 635, 645 (2002) (A "court need only conduct a 'straightforward inquiry into whether [the] complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective.'"). Defendants argue that PhRMA has not alleged an "*ongoing* violation" of federal law. Defs. Mem. 11 (emphasis added). This argument rests on two distinct claims: (1) that PhRMA has failed to allege a supposedly essential element of a takings claim—*i.e.*, that the government has refused to pay just compensation for the private property it took; and (2) the remarkable claim that it was unknown whether any private property (*i.e.*, insulin) would ever be taken under the Act. *Id.* PhRMA addresses the flaws in these arguments in Parts II and

[2] PhRMA sued members and an employee of MNsure. Based on defendants' representation that these individuals have no enforcement responsibilities, PhRMA stipulated to their dismissal. Dkt. Entry 21.

III, respectively, below. Finally, defendants argue that injunctive relief is not available in federal court because the manufacturers allegedly have a compensation remedy through state court mandamus actions. *Id.* at 11-12. PhRMA addresses the flaws in this argument in Part IV, below.

II. PhRMA HAS PLED A VALID TAKINGS CLAIM.

Defendants argue that PhRMA has failed to plead a valid claim under the Takings Clause. Specifically, defendants "dispute" that the Act can "result in a 'taking' of insulin," because the Takings Clause "permits the taking of private property, provided the government gives just compensation," and "the government does not need to provide compensation before a taking occurs." Defs. Mem. 11. This argument confuses two distinct concepts: (1) when an unconstitutional taking occurs, and (2) whether injunctive relief is an available remedy. Here, the Act does not compensate insulin manufacturers *when* their property is taken. That failure violates the Takings Clause, regardless of any post-deprivation compensation mechanism.

The Supreme Court has foreclosed defendants' contention that it is "constitutionally permissible" for the government to take property without simultaneously paying for it. Defs. Mem. 12. Defendants' contention rests on the Supreme Court's decision in *Williamson County Regional Planning Commission v. Hamilton Bank of Johnson City*, 473 U.S. 172 (1985). *Williamson County* reasoned that the Takings Clause does not prohibit the government from taking private property for public use, but instead requires the government to pay just compensation for such takings. Accordingly, *Williamson County* held that "if a State provides an adequate procedure for seeking just

compensation, the property owner cannot claim a violation of the [Takings] Clause until it has used the procedure and been denied just compensation." *Id.* at 195.

Last year, however, the Court overruled *Williamson County*. In *Knick v. Township of Scott*, the Court held that "[c]ontrary to *Williamson County*," a "property owner has a claim for a violation of the Takings Clause as soon as a government takes his property for public use without paying for it." 139 S. Ct. at 2170. Thus, when a government "takes private property without paying for it, that government *has violated the Fifth Amendment … without regard to subsequent state court proceedings*. And the property owner may sue the government at that time in federal court for the 'deprivation' of a right 'secured by the Constitution.'" *Id.* (quoting 42 U.S.C. § 1983) (emphasis added).

Defendants' position is directly contrary to *Knick*. Here, the Act mandates takings of private property, *see* Compl. ¶¶ 8-9, 80-85; *see also infra* at 38-41, and provides no compensation to manufacturers when those takings occur. Such takings are *not* "constitutionally permissible." Defs. Mem. 12. There is "a violation of the Takings Clause *as soon as*" the Act "takes [a manufacturer's insulin] for public use without paying for it," and the Act violates the Fifth Amendment at the moment of each such taking, "*without regard to subsequent state court proceedings*" for just compensation. *Knick*, 139 S. Ct. at 2170 (emphases added).

Nor is *Knick*'s holding limited to takings by local governments. Defs. Mem. 28 n.13. *Knick* construed the Takings Clause itself. *See* 139 S. Ct. at 2170 ("The Clause provides: '[N]or shall private property be taken for public use, without just compensation.' It does not say: 'Nor shall private property be taken for public use,

without an available procedure that will result in compensation.'" (alteration in original)). And *Knick* made clear that the "availability of any particular compensation remedy, such as an inverse condemnation claim under state law, cannot infringe or restrict the property owner's federal constitutional claim" that a taking occurred in violation of the Fifth Amendment. *Id.* at 2171.

In short, PhRMA has stated a valid takings claim. The availability of a compensation remedy bears only on whether an injunction is available to remedy such unconstitutional takings, *see infra* Part IV; it does not mean that no unconstitutional taking has occurred.

III. PhRMA HAS ASSOCIATIONAL STANDING, AND THE *PER SE* TAKINGS CLAIM IT ALLEGES IS RIPE.

Defendants' standing and ripeness challenges are equally groundless. PhRMA has associational standing because its complaint plausibly alleged that three of its members faced imminent, or clearly impending, threats of unconstitutional takings from the soon-to-be-operative Act. There was nothing speculative about that threat, as subsequent events—properly considered in response to defendants' jurisdictional challenge—confirm. And defendants' ripeness claims rest on their failure to recognize the critical distinction between regulatory takings (which are often found to be unripe) and per se takings (which are not).

A. PhRMA Has Associational Standing.

PhRMA has associational standing, because (a) one or more of its members "would otherwise have standing to sue in their own right; (b) the interests [PhRMA]

seeks to protect are germane to [its] purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). Defendants claim that PhRMA cannot satisfy the first or third prongs of *Hunt*. Defs. Mem. 16. They are wrong.

1. PhRMA Satisfies the First Prong of *Hunt*.

a. PhRMA adequately pled that three of its members faced imminent harm from the Act.

To satisfy *Hunt*'s first prong, PhRMA "must allege that its members, or any one of them, are suffering immediate *or threatened* injury as a result of the challenged action." *Hunt*, 432 U.S. at 342-43 (emphasis added). Here, PhRMA pled facts that were more than sufficient to establish a "plausible" claim, *Ashcroft*, 556 U.S. at 678, that three of its members faced an imminent, or certainly impending, threat of unconstitutional *per se* takings of their property from (at that time) the soon-to-be-operative Act. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 n.2 (1992) ("'imminence'" requirement is met when an injury "is '*certainly* impending'"); *see also Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2342 (2014) (future injury suffices for standing if "there is a 'substantial risk' that the harm will occur"). PhRMA alleged that the purpose of the Act was to compel manufacturers "to give their insulin away for free to *thousands* of Minnesota residents," Compl. ¶ 5 (emphasis added), and PhRMA cited the legislature's own estimates to support that allegation, *id.* ¶ 79.

Thus, PhRMA's standing does not rest on "rote recitations" and "speculation" that manufacturers will someday "be required to provide insulin under the Act." Defs. Mem.

17, 19. Because PhRMA members are the "objects of" an Act that requires them to give away their insulin products for free, they had standing to challenge the Act before any property was actually taken. *See Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 777 (8th Cir. 2019) (wineries had standing because they "are the objects of the Farm Wineries Act and subject to *future* enforcement actions brought by the Commissioner" (emphasis added)). Here, where "the plain text of [the] statute" allows Minnesota residents to obtain free insulin from manufacturers, it is more than "plausible" to conclude that manufacturers face a "certainly impending" threat that eligible persons will avail themselves of that opportunity. *Cf. id.* at 778.

This case is thus a far cry from those cited by defendants. Most of those cases involved plaintiffs who were *not* the objects of the laws or government actions they challenged.[3] While PhRMA's members were subject to a state law in *PhRMA v. Brown*, No. 2:17-cv-02573-MCE-KJN, 2018 WL 4144417 (E.D. Cal. Aug. 30, 2018), there the

[3] *See Clapper v. Amnesty Int'l USA,* 568 U.S. 398, 411 (2013) (plaintiff did not allege it would be target of surveillance under statute it challenged); *Summers v. Earth Island Inst.*, 555 U.S. 488, 493-94 (2009) (plaintiffs not the object of challenged regulations); *Lujan*, 504 U.S. at 561-62 (same); *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 233-35 (1990) (only one plaintiff subject to ordinance, and her claim was moot); *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) (plaintiff failed to show he would again be stopped by police who would illegally choke him); *Cty. of Mille Lacs v. Benjamin*, 361 F.3d 460, 464 (8th Cir. 2004) (plaintiffs' challenge was based on the "*assumed future intent* of the" tribe (emphasis added)); *Frost v. Sioux City*, 920 F.3d 1158, 1161 (8th Cir. 2019) (plaintiff who did not live in city or own pit bull lacked standing to challenge ban on pit bulls). Defendants cite two other cases where the plaintiffs did not challenge any law or policy, but instead lacked standing because they failed to show injury from the defendants' alleged violation of a law. *See Steger v. Franco, Inc.*, 228 F.3d 889, 892-93 (8th Cir. 2000); *Mendota Elec., Inc. v. Fair Contracting Found.*, 144 F. Supp. 3d 1053, 1057-58 (D. Minn. 2015).

court found no standing because it believed the complaint did not allege that members planned "to make a pricing change" that would trigger the law's requirements, or that "members will affirmatively refrain from increasing a drug price in order to avoid triggering the requirements." *Id.* at *5. Here, PhRMA's members do not need to take, or refrain from taking, any action to trigger the Act's requirements. And in *Young America Corp. v. Affiliated Computer Services (ACS)*, 424 F.3d 840, 844 (8th Cir. 2005), an organization that was the object of an audit statute lacked standing because there was no indication auditors had authority to enforce an audit request. Here, the manufacturers are subject to enforcement penalties for noncompliance.

Moreover, the Minnesota legislature's expectations that residents would obtain free insulin under the Act demonstrates that the manufacturers faced a "certainly impending" threat of harm the day before the Act's programs took effect. Defendants argue that the legislature's specific predictions were merely assumptions about an earlier version of the Act with different "procedures and eligibility requirements." Defs. Mem. 18 n.11. They miss the point. To establish Article III injury, PhRMA needed only to allege facts showing that one or more of its members was faced with an imminent threat of a *single* unconstitutional taking. *See Sierra Club v. U.S. Army Corps of Eng'rs*, 645 F.3d 978, 988 (8th Cir. 2011) ("an identifiable trifle will suffice" to establish "imminent, concrete harm"). Defendants do not (and cannot) explain why any differences in the enacted law would lead the legislature to anticipate that manufacturers would not have to provide free insulin to anyone, or that it would be such a distant possibility as to not constitute an imminent threat of harm.

Finally, defendants' own representations in their brief contradict their argument that actual takings under the Act are purely speculative. Defendants assert that the Act addresses a "public health crisis"; that the Act provides "lifesaving insulin to Minnesotans who are most at risk of being unable to access affordable insulin"; and that the relief PhRMA seeks in this suit will "crippl[e]" the Act and "depriv[e] Minnesotans who cannot otherwise afford their insulin of the lifesaving medicine." Defs. Mem. 2-5. Whatever the truth of those assertions, it is implausible and inconsistent with common sense to claim that the Act is a vital response to a public health crisis, but that the possibility that it will be used even once is speculative or even unlikely.

b. Subsequent events, properly considered on a motion under Rule 12(b)(1), confirm that the Act has resulted in takings.

Defendants' "speculative harm" argument is particularly untenable because the three PhRMA members have in fact each given away insulin under the Act since the two programs took effect. These facts are properly considered here, where defendants moved to dismiss under Rule l2(b)(1) as well as Rule l2(b)(6).

This Court can "consider matters outside the pleadings when urisdiction is challenged under Rule 12(b)(1)." *Harris*, 339 F.3d at 637 n.4; *Smith v. Geneva Props. LP*, No. 0:16-cv-02735-JRT-KMM, 2016 WL 7404744, at *2 (D. Minn. Nov. 29, 2016) ("Courts will consider affidavits, declarations, and other evidence outside the pleadings in ruling on a jurisdictional motion …."), *report and recommendation adopted*, No. 16-2735 (JRT/KMM), 2016 WL 7404692 (D. Minn. Dec. 21, 2016). Here, it is a matter of public record that Minnesota created a website (https://www.mninsulin.org) to encourage

people to obtain insulin under the Act. And the insulin manufacturers have provided free insulin for Minnesota residents under the Continuing Safety Net Program, and reimbursed (or are in the process of reimbursing) pharmacies for insulin dispensed to residents under the Urgent Need Program. *See infra* at 37-38. PhRMA's members have thus suffered the concrete injury necessary to meet *Hunt*'s first prong.[4]

2. PhRMA Satisfies the Third Prong of *Hunt*.

Defendants argue that PhRMA cannot satisfy the third prong of *Hunt* because PhRMA's takings claim "requires the participation of the individual members alleged to have suffered a taking." Defs. Mem. 19. This is so, defendants contend, because takings claims "involve 'essentially ad hoc, factual inquiries' into the nature, purpose, and value of the alleged taking." *Id.* This argument is mistaken.

Ad hoc factual inquiries are required in *regulatory* takings cases, where the critical question is whether a "regulation goes too far." *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922). Thus, in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978), "the Court clarified that the test for how far was 'too far' required an 'ad hoc' factual inquiry" into factors "such as the economic impact of the regulation" on the plaintiff, and "its interference with reasonable investment-backed expectations." *Horne v. Dep't of Agric.*, 135 S. Ct. 2419, 2427 (2015). Such ad hoc inquiries were required in the

[4] If the Court harbors any doubt about its jurisdiction, it should grant the conditional motion for leave to file a supplemental complaint that PhRMA is filing today. *See NCJC, Inc. v. Lawrence*, No. 17-cv-2385 (SRN/SER), 2018 WL 2122867, at *3-5 (D. Minn. May 8, 2018) (granting leave to supplement is preferable to "dismissing the case without prejudice only to have Plaintiffs initiate a new action").

various takings cases defendants cite—including those in which associations were found to flunk *Hunt*'s third prong—because these cases involved regulatory takings.[5]

No such inquiry, however, is required for *per se* takings. A physical appropriation of real property gives rise to a *per se* taking "*without regard to other factors*." 135 S. Ct. at 2427 (emphasis added). And *Horne* held that this rule applies to appropriations of personal property. *Id.* at 2427-28.

Accordingly, because PhRMA has alleged that the Act mandates *per se* takings of privately owned personal property, there is no need for ad hoc factual inquiries, and thus no need for PhRMA's members to participate as parties in this lawsuit. Instead, as explained *infra* at 38-41, the Act compels *per se* takings by depriving manufacturers of "the entire 'bundle' of property rights in the [insulin]—'the rights to possess, use and dispose of'" that property. *Horne*, 135 S. Ct. at 2428.

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[5] *See Pennell v. City of San Jose*, 485 U.S. 1, 10 (1988) (challenge to rent control ordinance would require "essentially ad hoc, factual inquir[y]" (alteration in original)); *Kaiser Aetna v. United States*, 444 U.S. 164, 178-80 (1979) (multifactor analysis to determine if government's assertion of navigational servitude resulted in taking); *Wash. Legal Found. v. Legal Found. of Wash.*, 271 F.3d 835, 841, 849-50, 856-57 (9th Cir. 2001) (en banc) (analyzing Interest on Lawyers' Trust Account program as regulatory taking), *aff'd sub nom. Brown v. Legal Found. of Wash.*, 538 U.S. 216 (2003); *Pharm. Care Mgmt. Ass'n v. Gerhart*, No. 4:14-cv-000345, 2015 WL 6164444, at *7-8 (S.D. Iowa Feb. 18, 2015) (analyzing state law regulating pharmacy benefit managers' reimbursement methodology as regulatory taking), *rev'd in part on other grounds*, 852 F.3d 722 (8th Cir. 2017); *Rent Stabilization Ass'n of N.Y.C., Inc. v. Dinkins*, 805 F. Supp. 159, 164 (S.D.N.Y. 1992) (as-applied regulatory taking challenge to rent control statute "a poor candidate for associational standing" "[g]iven the 'essentially ad hoc, factual inquiry' involved" (quoting *Pennell*, 485 U.S. at 10)), *aff'd*, 5 F.3d 591 (2d Cir. 1993). In addition, the court rejected associational standing in *Washington Legal Foundation* because the association sought injunctive relief, but its members were separately pursuing claims for just compensation. *See* 271 F.3d at 849-50. This factor is not present here.

For this same reason, PhRMA is not seeking injunctive and declaratory relief to "avoid the third *Hunt* requirement." Defs. Mem. 20. Its *per se* takings claim does not require any company-specific showings of impact or harm, and thus does not implicate *Hunt*'s third prong in the first place. *See also* Part IV, *infra* (addressing defendants' argument that injunctive relief is not available for any *per se* takings).

B. PhRMA's *Per Se* Takings Claim Is Ripe.

In determining whether a claim is ripe, courts examine "'the fitness of the issues for judicial decision and the hardship to the parties of withholding'" review. *Pub. Water Supply Dist. No. 10 v. City of Peculiar*, 345 F.3d 570, 572-73 (8th Cir. 2003). Defendants' ripeness arguments are simply variations of their arguments under the first and third *Hunt* prongs, and fail for the same reasons.

With respect to the hardship inquiry, a plaintiff "need not wait until the threatened injury occurs, but the injury must be certainly impending." *Id.* at 573 (quotation marks and citations omitted). *See also S.D. Mining Ass'n, Inc. v. Lawrence Cty.*, 155 F.3d 1005, 1009 (8th Cir. 1998) (plaintiff needs only to "demonstrate a realistic danger of sustaining a direct injury as a result of [a challenged] statute's operation or enforcement," and need not "await consummation of threatened injury" before suing).

As discussed above, PhRMA alleged facts that were more than sufficient to establish that its members faced a "clearly impending" and "realistic danger" of harm from the Act. The various cases defendants cite do not show otherwise. Most did not

involve challenges to a statute brought by the object of that statute.[6] In the few cases they cite that did involve that scenario, one held that the challenge was ripe, *281 Care Comm. v. Arneson*, 638 F.3d 621, 631 (8th Cir. 2011), and another did not reach the issue because subsequent events made clear that the alleged harm was concrete, *Blanchette v. Conn. Gen. Ins. Corps.*, 419 U.S. 102, 139-40 (1974), a circumstance present here as well. *See supra*, Part II.A.1.b. In the third case, *Arizonans for Official English v. Arizona*, 520 U.S. 43, 67-72 (1997), the Court concluded that the plaintiff's claim was moot—a circumstance obviously *not* present here—and thus did not discuss the ripeness doctrine.

Nor has PhRMA failed to present "a sufficiently concrete factual setting for the adjudication of [its] takings claim." Defs. Mem. 23 (quoting *Pennell*, 485 U.S. at 10). In *Pennell*, the Court deemed a regulatory takings claim premature because it was unclear how the "tenant hardship" provision of the rent control ordinance would operate, and thus unclear how it would affect the property rights of owners. 485 U.S. at 9-10. Here, PhRMA has not alleged a regulatory takings claim, nor any claim that mere enactment of the Act causes a taking. *Cf.* Defs. Mem. 24. PhRMA alleges instead that the Act affects a

[6] In two of defendants' cases, plaintiffs challenged only actions by third parties that might never harm the plaintiffs. *See Mo. Roundtable for Life v. Carnahan*, 676 F.3d 665, 668, 674 (8th Cir. 2012) (challenging state officials' summaries of proposed constitutional amendments plaintiffs submitted); *Pub. Water Supply Dist.*, 345 F.3d at 571 (alleging city was attempting to illegally dissolve water district). In another, a state agency sought a declaration concerning the legality of its own potential action that would require the court "to wade through a quagmire of what-ifs." *Missouri ex rel. Mo. Highway & Transp. Comm'n v. Cuffley*, 112 F.3d 1332, 1337-38 (8th Cir. 1997). In *Nebraska Public Power District v. MidAmerican Energy Co.*, 234 F.3d 1032 (8th Cir. 2000), the court found ripe a contract dispute that raised a "purely legal" question and threatened plaintiff with "definite, tangible and significant future harm." *Id.* at 1039.

series of *per se* takings of personal property. There is no uncertainty concerning the Act's requirements, and whether those requirements cause *per se* takings is a legal issue, fully ripe for resolution.

IV. PROSPECTIVE EQUITABLE RELIEF IN FEDERAL COURT IS NOT FORECLOSED BY STATE-LAW REMEDIES.

Under the rules governing injunctive relief in federal courts, a taking cannot be enjoined if the property owner has "a plain, adequate, and complete remedy at law" for just compensation. *Knick*, 139 S. Ct. at 2175. Defendants argue that Minnesota provides such remedies through a state court mandamus action to compel inverse condemnation. Defs. Mem. 29-32. That argument is mistaken. First, under Minnesota law, such an action cannot provide compensatory relief for future takings, and thus cannot provide "*complete*" compensatory relief for the series of ongoing *per se* takings the Act compels. Second, the alternative that defendants contemplate—a series of retrospective inverse condemnation lawsuits to compensate for takings that have occurred in the past—is a plainly "inadequate" compensatory remedy. Finally, and in all events, a mandamus action cannot foreclose PhRMA's request for declaratory relief.

A. A Mandamus Action To Compel Inverse Condemnation Is Not A Complete Compensation Remedy.

The state court mandamus action that defendants invoke is only a mechanism to obtain compensation for *past* takings. It allows a property owner to compel state officials to commence proceedings to condemn property that they have already taken and pay just compensation for that property. *See Thomsen v. State*, 170 N.W.2d 575, 580 (Minn. 1969). But a state court mandamus action cannot be used to obtain compensation for *future*

takings. Accordingly, a mandamus action to compel defendants to initiate condemnation proceedings cannot provide complete compensatory relief for the injuries that Act will cause. Instead, only an injunction can remedy the future (and inevitable) series of *per se* takings compelled by the Act.

In *McShane v. City of Faribault*, 292 N.W.2d 253, 259 (Minn. 1980), *abrogated in part by DeCook v. Rochester Int'l Airport Joint Zoning Bd.*, 811 N.W.2d 610 (Minn. 2012), the Minnesota Supreme Court held that mandamus does not lie where a governmental entity can avoid a taking. *McShane* involved a zoning ordinance that limited the use of plaintiffs' property in order to promote safety at a nearby municipal airport. *Id.* at 255-56. Because state law required the zoning ordinance, the city could not repeal it. *Id.* at 259. The trial court assumed that the city would not close the airport and that mandamus to compel eminent domain was therefore the only remedy. *Id.* The Minnesota Supreme Court reversed and denied mandamus relief. It held that the "decision to purchase property is a discretionary one," and that a court cannot use mandamus to require the government to purchase property, and thereby deprive it of the choice of forgoing such a purchase in order to save "potentially huge amounts of money on the necessary property rights." *Id.* On the facts before it, the Court concluded that the city had the option to close the airport and thus avoid a taking. The proper remedy, therefore, was an injunction, which would afford the city the option of deciding whether to go forward with the taking. *Id.*

Several years later, the United States Supreme Court agreed that the decision to exercise the power of eminent domain is discretionary, and that a court cannot, "at the

behest of a private person, … require the … Government to exercise the power of eminent domain." *First English Evangelical Lutheran Church v. Cty. of Los Angeles*, 482 U.S. 304, 321 (1987) (second omission in original). The Court held, however, that where an ordinance has already resulted in a compensable taking, "no subsequent action by the government can relieve it of the duty to provide compensation for the period during which the taking was effective." *Id.* The latter holding necessarily rejected the *McShane*'s court conclusion that the temporary taking occasioned by the airport zoning regulations in that case was "reversible," and thus that the city could avoid a taking that had already occurred. The Minnesota Supreme Court recognized as much in *DeCook v. Rochester International Airport Joint Zoning Board*, 811 N.W.2d 610 (Minn. 2012), and abrogated *McShane* insofar as it held that "mandamus to compel eminent domain proceedings was not the appropriate remedy for what could be only a temporary taking." *Id.* at 612.

But *DeCook* did not abrogate *McShane*'s recognition that mandamus to compel inverse condemnation is unavailable where a taking can be avoided. Here, the future takings that the Act mandates are "reversible," because the government retains the power to decide whether to go forward with those takings (and thus incur the obligation to pay just compensation) or to find another way to advance the government's public policy objectives. *See, e.g.*, *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 240 (1984) ("[T]he power of eminent domain is merely the means to the end…. Once the object is within the authority of [the legislature], the means by which it will be attained is also for [the legislature] to determine." (omission in original) (quoting *Berman v. Parker*, 348 U.S. 26,

33 (1954))). Indeed, *DeCook* relied on *First English*, which recognized that very principle. *See* 482 U.S. at 321 (citing *Midkiff*). And that principle clearly applies here.

A state court in a mandamus action could not compel the state to commence proceedings to "condemn" insulin products that the manufacturers will be required to give away in the future under the Act. Instead, an injunction is "the appropriate remedy," *McShane*, 292 N.W.2d at 259, because a mandamus order would improperly compel the state to exercise its power of eminent domain to purchase insulin that has not yet been dispensed under the Act. Such an order would thereby deprive the state of the option of complying with the Takings Clause by repealing the Act's confiscatory provisions and avoiding future takings.

Indeed, defendants acknowledge this very point. They note that, if a manufacturer prevailed in an inverse condemnation action, the "legislature would *then have options*"—including the option of "'withdraw[ing]'" the Act. Defs. Mem. 32 (emphasis added) (quoting *First English*, 482 U.S. at 321). Under *McShane*, the existence of that option forecloses a mandamus action to compel inverse condemnation for the future takings that PhRMA seeks to enjoin.

The inverse condemnation remedy thus does not provide a complete compensatory remedy for the ongoing unconstitutional takings that the Act compels. Accordingly, there is no basis for foreclosing injunctive relief for a taking in federal court.

B. Defendants Cite No Authority Holding That A Series Of Inverse Condemnation Actions Is A Complete Compensatory Remedy.

In an effort to avoid this fatal defect, defendants claim that "continuous" takings are common, thereby implying that a series of retrospective inverse condemnation suits is a "complete" compensation remedy that forecloses injunctive relief in federal court. This argument is mistaken.

Defendants claim that the law at issue in *Knick* caused "continuous" takings and yet the Supreme Court concluded that injunctive relief was unavailable. Defs. Mem. 32. This characterization of the taking in *Knick* is wrong. *Knick* involved a law that "allowed continuous public access over the plaintiff's property during daylight hours," *id.*, but each intrusion is not a distinct taking. Instead, a "permanent and continuous right to pass to and fro" is "a classic right-of-way easement," *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 831-32 & n.5 (1987), which is a property interest for which the government must pay just compensation, *id.* at 834. There is no new taking, and no new right to compensation, each time someone uses the easement.

Defendants' reliance on *National Fuel Gas Distribution Corp. v. N.Y. State Energy Research & Development Authority*, 265 F. Supp. 3d 286 (W.D.N.Y. 2017), is similarly misplaced. There, the plaintiff alleged that the government had physically taken its natural gas pipeline and argued (illogically) that because the physical taking was continuous, just compensation under the Tucker Act and state law was not available. But as the court explained, the very concept of a physical taking "presupposes continued government intrusion into private property." *Id.* at 295 n.2. A physical taking is complete

as soon as it occurs, and a single claim under the Tucker Act, or a single inverse condemnation proceeding under state law, would provide complete compensatory relief.

Finally, defendants argue that "[m]ost regulatory laws will be continuous," yet this "does not make equitable relief appropriate for takings claims." Defs. Mem. 31. But the continuous nature of a *law* does not mean that any *takings* it occasions are also continuous. Defendants cite *Rose Acre Farms, Inc. v. Madigan*, 956 F.2d 670 (7th Cir. 1992), a case where federal regulations allowed the Department of Agriculture to force below-market sales of chickens and eggs suspected of having salmonella until the flock was certified to be salmonella-free. *Id.* at 671-72. To the extent the regulations occasioned a taking requiring compensation—a question the court did not address, *see id.* at 673—that taking was not continuous and ongoing. It would cease when the chickens and facility were found to be disease-free. The fact that the regulations were on the books did not mean that the plaintiff would inevitably be subject to similar sales restrictions on a continuing basis in the future.

In short, none of the cases defendants cite addressed a law that compels the taking of new items of private property on an ongoing and regular basis. None of those cases holds, therefore, that the possibility of filing a continuous series of retrospective inverse condemnation actions is a "complete" compensation remedy that forecloses equitable relief for a taking in federal court.

C. In All Events, An Ongoing Series Of Mandamus Actions To Compel Inverse Condemnation Actions Is Not An Adequate Remedy.

Finally, even assuming that a series of inverse condemnation actions could constitute a "complete" compensation remedy—and it does not—such a remedy is plainly not an "adequate" one. Defendants cite no authority to support such a theory, and decisions in analogous circumstances confirm that any such theory is untenable.

In *Eastern Enterprises v. Apfel*, 524 U.S. 498 (1998), a plurality of the Supreme Court concluded that the Tucker Act did not foreclose claims for declaratory and injunctive relief to enjoin a succession of alleged takings mandated by the Coal Act. Under that statute, former employers in the coal industry were required to pay annual assessments to fund health care benefits for retired mineworkers. *Id.* at 514-15. The plurality explained that requiring these companies to submit repetitive claims for takings under the Tucker Act "would entail an utterly pointless set of activities," as every dollar the employer paid under the Coal Act to fund health care benefits would then entitle the employer to seek compensation from the federal government in the same amount. *Id.* at 521. The plurality reasoned that "Congress could not have contemplated" this kind of ongoing tit-for-tat compensation scheme—instead, Congress had wanted the employers to foot the bill. *Id.* For these reasons, the plurality concluded that "it cannot be said that monetary relief against the Government is an available remedy" and found that the district court had authority to issue declaratory and injunctive relief. *Id.* at 521-22.[7]

[7] The plurality went on to conclude that the Coal Act violated the Takings Clause. Justice Kennedy relied on substantive due process grounds to cast the deciding vote on the law's

The First Circuit relied on similar reasoning in *Asociación de Subscripción Conjunta del Seguro de Responsabilidad Obligatorio*, 484 F.3d 1 (1st Cir. 2007). There, private insurers had to fund reserves to reimburse motorists who paid duplicate insurance premiums under Puerto Rico's licensing requirements. *Id.* at 6-8. The reserves were transferred to Puerto Rico's Treasury Secretary, who was required to return unclaimed funds every five years. *Id.* at 9-10. The insurers alleged that the Secretary had taken their property by failing to return the unclaimed funds and by retaining interest earned on the funds, and they sought injunctive relief to prevent future takings. *Id.* at 10-12. The court concluded that the insurers did not have to comply with *Williamson*'s then-extant ripeness requirement because, among other reasons, requiring the insurers to continue to turn over reserves to the Secretary only to seek the return of unclaimed funds and interest through takings actions would "entail an utterly pointless set of activities" that the legislature could not have intended. *Id.* at 20 (quoting *E. Enters*, 524 U.S. at 521 (plurality opinion)).

Although these cases are not binding, their reasoning is compelling here. *See id.* (following the logic of *Eastern Enterprises* even though the case before it "differ[ed] … because, among other distinctions, it does not involve the federal government and the Tucker Act"). First of all, insofar as manufacturers reimburse pharmacies for insulin distributed under the Act's Urgent Need Program, their takings claims directly mirror those at issue in *Eastern Enterprises*. Here as there, the manufacturers must turn over

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unconstitutionality, and thus did not address the relevance of the Tucker Act remedy. *See* 524 U.S. at 547-48 (Kennedy, J., concurring in the judgment and dissenting in part).

funds to private parties and then (under defendants' logic) seek return of the same amount from the state in the form of a just-compensation award.

Second, forcing the manufacturers to bring a series of takings claims for insulin products they have given away under the Continuing Safety Net Program would also involve an "utterly pointless set of activities." The Minnesota legislature could have chosen to purchase insulin directly from the manufacturers and then authorized a state agency to distribute that medicine in accordance with the same criteria the Act establishes. But the legislature did not choose this method of "improv[ing] the public condition"—it instead chose the "short[] cut" of requiring the manufacturers to operate state-mandated programs under which they would to give away insulin for free, because the legislature obviously sought to spare taxpayers from "paying for the change." *Pennsylvania Coal*, 260 U.S. at 416. Now, defendants claim that the state stands ready to purchase the insulin after all, but that the "sales" must be effectuated through a repetitive series of mandamus actions in which manufacturers retain lawyers and present evidence of each insulin product they have given away since their last mandamus action to compel inverse condemnation of those products. As *Eastern Enterprises* and *Galarza* make clear, this is a highly burdensome, inefficient, and utterly pointless use of a judicial compensation mechanism.

Defendants effectively concede that such an outcome is untenable. They argue that, "as a practical matter, it is doubtful manufacturers would ever need to bring a series of state court actions," because if a manufacturer prevailed in a single inverse condemnation case, the legislature would have a "whole range of options," including

"'amendment of the regulation, withdrawal of the invalidated regulation, or exercise of eminent domain.'" Defs. Mem. 32 (quoting *First English*, 482 U.S. at 321). This response is unavailing for several reasons.

First, defendants do not—and indeed, cannot—provide any assurance that the legislature would in fact respond to a state court mandamus decision by repealing the confiscatory portions of the Act or by somehow exercising eminent domain with respect to the manufacturers' insulin on a prospective basis. It is entirely possible that the state would leave in place the burdensome and inadequate "remedy" of continuous takings claims.

Second, defendants cite no precedent nor any principle of equity jurisprudence for the extraordinary proposition that federal courts can or should deny equitable relief based on speculation about how a state legislature *might* respond to a *hypothetical outcome* in an alternative *hypothetical lawsuit* challenging the constitutionality of a state law. If anything, defendants' suggestion that this Court decline to exercise its equitable discretion on the basis of such speculation is really a disguised argument for exhaustion. A state law inverse condemnation suit, defendants claim, might "effectively provid[e] the declaratory judgment sought here," Defs. Mem. 32, and thus might result in the effective equivalent of an injunction, *i.e.*, state repeal of the law. Neither PhRMA nor the manufacturers, however, are required to exhaust state court remedies in order to challenge an unconstitutional state law in federal court, *Knick*, 139 S. Ct. at 2172-73, much less exhaust such remedies because they "might" result in comparable relief.

* * *

In sum, because Minnesota law does not provide a "'complete'" or "'adequate'" compensatory remedy for the continuous series of takings occasioned by the Act, *Knick*, 139 S. Ct. at 2175, injunctive relief is available in this Court to enjoin the Act's operation.

D. At A Bare Minimum, PhRMA Is Entitled To Declaratory Relief.

Even if a series of after-the-fact mandamus actions to compel inverse condemnation proceedings could constitute a "complete" and "adequate" compensation remedy—and it does not—such a "remedy" provides no basis for foreclosing the declaratory relief that PhRMA seeks.

In *Knick*, the Supreme Court explained that the availability of a complete and adequate compensation remedy would foreclose *injunctive* relief. But it did not state, much less hold, that such a remedy also forecloses *declaratory* relief. In addressing prior cases in which it had held that property owners were entitled to "reasonable, certain and adequate provision for obtaining compensation" after a taking, the Court stressed that these cases "concerned requests for *injunctive* relief, and the availability of subsequent compensation meant that *such* an equitable remedy was not available." 139 S. Ct. at 2175 (emphases added). And in discussing the import of its holding that property owners can sue for an unconstitutional taking as soon as the government takes property without paying, the *Knick* Court stressed that "[a]s long as an adequate provision for obtaining just compensation exists, there is no basis to *enjoin* the government's action effecting a taking." *Id.* at 2176 (emphasis added).

The clear import of the Supreme Court's statements is that declaratory relief remains available in federal court in takings cases. The Declaratory Judgment Act "expands the scope of available remedies" in federal court, and "allows individuals threatened with a taking to seek a declaration of the constitutionality of the disputed governmental action before potentially uncompensable damages are sustained." *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 71 n.15 (1978). Defendants argue that a state court inverse condemnation action would "effectively provid[e] the declaratory judgment sought here." Defs. Mem. 32. But *Knick* made clear that takings plaintiffs need not exhaust state remedies. 139 S. Ct. at 2172-73. And "a suit for prospective declaratory relief from" a state law that violates the federal constitution is not barred by the Eleventh Amendment. *In re SDDS, Inc.*, 97 F.3d 1030, 1035 (8th Cir. 1996). Accordingly, this Court can and should entertain PhRMA's request for a declaration that the Act compels unconstitutional *per se* takings of the manufacturers' personal property.

V. PhRMA'S COMMERCE CLAUSE CLAIM SHOULD NOT BE DISMISSED UNLESS DEFENDANTS DISAVOW RELIANCE ON THE ACT'S EXEMPTION TO DEFEND AGAINST PHRMA'S TAKINGS CLAIM.

Defendants argue that, because PhRMA's takings claim is not justiciable, the Commerce Clause claim should be dismissed because it is derivative of the takings claim. That argument fails because the takings claim *is* justiciable and should not be dismissed. But defendants further argue that, even if the takings claim is not dismissed, the Commerce Clause claim is still non-justiciable because it is "speculative" and "dependent on a particular interpretation of a provision of the Act" that PhRMA has not shown "that

the legislature intended" or that "is likely to be employed." Defs. Mem. 34. That is not PhRMA's burden.

It is up to *defendants* to defend the Act and to decide whether the potential interpretation of the exemption that PhRMA has identified "is likely to be employed" as part of that defense. If defendants disclaim that interpretation of the exemption, then the Court need not decide whether the exemption violates the dormant Commerce Clause.

But if defendants do attempt to argue that the Act does not compel any takings because manufacturers have the "option" of reducing the WAC of their products to $8/mL, then PhRMA's Commerce Clause challenge to that exemption would not be a "'hypothetical question[] of constitutional law.'" Defs. Mem. 33. It would be necessary to the resolution of defendants' own defense of the Act. And PhRMA did not need to allege that its members are suffering any distinct injury attributable to the exemption in order to challenge such a defense. *See id.* at 34. PhRMA's members faced "certainly impending" deprivations of their property the day the suit was filed, and have suffered concrete injuries since. Those injuries gave PhRMA standing to challenge the Act, and to contest any arguments advanced in defense of its constitutionality, including arguments that the WAC exemption somehow renders any property deprivations "voluntary."

PhRMA IS ENTITLED TO SUMMARY JUDGMENT

While unfounded, defendants' efforts to avoid the merits of PhRMA's claims is understandable. The Act is plainly unconstitutional. The Supreme Court's decision in *Horne* makes clear that the Act's requirement that manufacturers provide free insulin is a *per se* taking of personal property. And the option to reimburse pharmacies for insulin

dispensed under the Urgent Need Program, rather than send physical replacement insulin, does not avoid the taking. *See Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 612 (2013). Finally, if defendants claim the Act's WAC-based exemption affords manufacturers the "option" to avoid the appropriation of their property if they agree to reduce a national wholesale price, the exemption is invalid under the Commerce Clause.

STANDARD OF REVIEW

In ruling 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 "must 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 is a nonprofit corporation that represents the country's leading innovative pharmaceutical companies. Compl. ¶ 10; Decl. of Scott Laganga ¶ 2 (Exhibit 5). PhRMA serves as the pharmaceutical industry's principal public policy advocate, representing the interests of its members before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. Compl. ¶ 12; Ex. 5 ¶ 2. PhRMA's objectives include advocating for public policies that encourage investment in pharmaceutical innovation, address distortions in the market for medicines, and protect property rights that enhance pharmaceutical manufacturers' ability to develop and produce medicines for patients. Compl. ¶ 13; Ex. 5 ¶ 3.

Three of PhRMA's members—Lilly, Novo Nordisk, and Sanofi—manufacture most of the insulin sold in the United States. Ex. 5 ¶ 5. Each of these PhRMA members is subject to the Act because its annual gross revenue from the sale of its insulin products in Minnesota exceeded $2 million in 2019 and is expected to do so again in 2020. Ex. 2 ¶ 4; Ex. 3 ¶ 5; Ex. 4 ¶ 4.

These PhRMA members sell insulin products that are subject to the Act because the products are self-administered on an outpatient basis by individuals in Minnesota and have a wholesale acquisition cost of more than $8 per milliliter. Ex. 2 ¶ 5; Ex. 3 ¶ 4; Ex. 4 ¶ 5. The term "wholesale acquisition cost" (or "WAC") of a prescription drug is defined by Minnesota law and federal law as "the manufacturer's list price" to "wholesalers or direct purchasers in the United States," not including discounts or rebates. Minn. Stat. § 256B.0625, subd. 13e(a); *see also* 42 U.S.C. § 1395w-3a(c)(6)(B) (same). Accordingly, WAC is the national list price for sales of insulin products by PhRMA's members to wholesalers (or other direct purchasers). Ex. 2 ¶ 10; Ex. 3 ¶ 12; Ex. 4 ¶ 10.[8] The vast majority of these wholesale transactions occur outside of Minnesota. Ex. 2 ¶ 11; Ex. 3 ¶ 11; Ex. 4 ¶ 11.

Since the Act's mandates took effect on July 1, 2020, the manufacturers have provided insulin for residents under the Continuing Safety Net Program, and have

[8] Although not a material fact for purposes of this motion, the actual price wholesalers pay for the insulin products is lower than WAC because individual wholesalers negotiate contracts with manufacturers that give the wholesaler a discount for prompt payment and may include other discounts. Ex. 2 ¶ 10; Ex. 3 ¶ 12; Ex. 4 ¶ 10.

reimbursed (or are in the process of reimbursing) pharmacies for the acquisition costs of the insulin pharmacies dispensed under the Urgent Need Program. Ex. 2 ¶¶ 8-9; Ex. 3 ¶¶ 9-10; Ex. 4 ¶¶ 8-9.

I. The Act Violates The Takings Clause Of The U.S. Constitution.

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. "It protects 'private property' without any distinction" between "real property" and "personal property." *Horne*, 135 S. Ct. at 2425-26. Federal courts have thus applied the Takings Clause to all types of personal property, including personal possessions, *e.g.*, *Porter v. United States*, 473 F.2d 1329, 1331-32 (5th Cir. 1973), a patent for goods that were "desirable for government use," *e.g.*, *United States v. Palmer*, 128 U.S. 262, 271 (1888), and, as particularly relevant here, items produced by a business for sale, *e.g.*, *Horne*, 135 S. Ct. at 2424. Indeed, the Act's requirement that manufacturers give their insulin products to Minnesota residents and pharmacies "at no charge," Minn. Stat. § 151.74, subd. 6(c), is indistinguishable in all material respects from the federal marketing order requiring that raisin "growers set aside a certain percentage of their crop for the account of the Government, free of charge," *Horne*, 135 S. Ct. at 2424—a requirement that eight Justices held was a "per se taking" in violation of the Takings Clause, *see id.* at 2430; *id.*

at 2433 (Breyer, J., with whom Ginsburg, J., and Kagan, J., joined, concurring in part and dissenting in part).

The marketing order in *Horne* required raisin growers to relinquish a percentage of the raisins they produced to a government-run "Raisin Committee" that could "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 2424 (majority opinion). The Court held this "reserve requirement" was "a clear physical taking" because "[a]ctual raisins are transferred from the growers to the Government," and "[t]itle to the raisins passes to the Raisin Committee." *Id.* at 2428. As a result, the growers "lose the entire 'bundle' of property rights in the appropriated raisins—the rights to 'possess, use and dispose of' them." *Id.* (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982)).

The requirement that manufacturers provide insulin at no charge under the Act is likewise a "clear physical taking" of the manufacturers' property. Manufacturers must provide actual insulin for eligible Minnesota under the Act's Continuing Safety Net Program. *See* Minn. Stat. § 151.74, subd. 6(c), 6(g); *see also supra* at 37-38. And manufacturers must send actual insulin to pharmacies to replace the insulin the pharmacies dispensed to residents under the Urgent Need Program (unless the manufacturers elect to reimburse the pharmacies for the disbursed product instead). *See* Minn. Stat. § 151.74, subd. 3(c), 3(d); *see also supra* at 37-38. Thus, like the raisin growers in *Horne*, the manufacturers are deprived of the entire "bundle" of property

rights in their insulin products because they lose the ability to possess, use, or dispose of those products—which they are forced to give away at no charge under the Act. As in *Horne*, therefore, the Act compels a physical taking of private property.

It is of no moment that the growers in *Horne* were required to give their raisins to a government agency, while the manufacturers here are required to give their insulin to pharmacies and Minnesota residents who meet the Act's eligibility criteria. *See supra* at 4-7, 37-38. The Supreme Court has made clear that a law effects a taking when it compels property owners to give away their property, even if the recipient is a private entity. The Court has held, for example, that a law requiring owners of apartment buildings to "permit a cable television company to install its cable facilities upon [the landlords'] property" effected a *per se* physical taking of property. *Loretto*, 458 U.S. at 421. It is also "clearly establish[ed]" that a taking occurs where the government compels a landowner to allow another company to permanently occupy the landowner's property with "such installations as telegraph and telephone lines, rails, and underground pipes or wires." *Id.* at 430 (citing cases). Although those cases involved the compulsory transfer of an interest in 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*, 135 S. Ct. at 2426.

Nor does it matter that, for the Urgent Need Program, manufacturers have the option of reimbursing pharmacies for the acquisition cost of the insulin dispensed instead

of sending a replacement supply of the insulin itself.[9] The Supreme Court has rejected the argument that a government can avoid a taking by giving a property owner the option "to spend money rather than give up" the property itself. *Koontz*, 570 U.S. at 611-12. If the rule were otherwise, "it would be very easy" for the government to "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, here as in *Horne*, *Koontz*, and *Loretto*, the government seeks to improve the public condition "by a shorter cut than the constitutional way." *Horne*, 135 S. Ct. at 2428 (quoting *Pennsylvania Coal*, 260 U.S. at 416). And if Minnesota can take this short cut, then what is to stop the 49 other states from doing so? Just as the Takings Clause foreclosed that option in other cases, this Court should hold that it does so here as well.

II. The Act's Exemption Violates The Commerce Clause If It Is Construed As A Conditional Regulation Of The Wholesale Acquisition Cost Of Insulin.

As noted, the Act provides an exemption for insulin products that have a WAC of "$8 or less per milliliter." Minn. Stat. § 151.74, subd. 1(d). All of the insulin products of PhRMA's members that are covered by the Act have a WAC above that amount. *See*

[9] This option is only available under the Urgent Need Program, not under the Continuing Safety Net Program. *See* Minn. Stat. § 151.74, subd. 2.

supra at 37. While there is no explanation for this exemption in the Act's legislative history, Compl. ¶ 87, it is possible that the provision was included to enable defendants to argue that the Act does not compel the taking of insulin because manufacturers have the "option" to avoid the taking by lowering the WAC of their products to $8/mL. But if that is its purpose, then the exemption violates "well-established Commerce Clause principles [that] prohibit the state from controlling the prices set for sales occurring wholly outside its territory." *Healy v. Beer Inst.*, 491 U.S. 324, 328 (1989). *See* Compl. ¶¶ 87-89.

As a matter of federal law, WAC is the national list price for sales of insulin products to wholesalers (or other direct purchasers), excluding any discounts or rebates the wholesalers may negotiate. *See* 42 U.S.C. § 1395w-3a(c)(6)(B); Minn. Stat. § 256B.0625, subd. 13e(a); *supra* at 37. Unsurprisingly, since the manufacturers sell their insulin products throughout the United States, most sales of insulin products from manufacturers to wholesalers take place outside of Minnesota. *supra* at 37.

Because WAC is a national price, a regulation of WAC by a single state is "effectively a price control statute that instructs manufacturers … as to the prices they are permitted to charge in transactions that do not take place in [the state]." *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666, 672 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019). The Commerce Clause prohibits states from imposing such price controls. *Id.* at 666-68, 671-72 (striking down Maryland law restricting pharmaceutical price increases where "the lawfulness of a price increase is measured according to" changes in WAC). A "statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and

is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Healy*, 491 U.S. at 328; *see also, e.g.*, *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582-83 (1986) (a state "may not 'project its legislation into [other States] by regulating the price to be paid' … in those States" (alteration in original)).

Minnesota thus could not make the sale of insulin products in Minnesota conditional on the manufacturers' lowering the WAC to $8/mL or less. To do so would be to regulate the price of wholesale transactions in other states in violation of the Commerce Clause. Because Minnesota could not constitutionally impose an $8/mL WAC limit on insulin outright, it cannot rely on the Act's exemption to defend, or excuse, the Act's unconstitutional taking of the manufacturer's insulin. Simply put, Minnesota cannot require insulin manufacturers to either submit to unconstitutional deprivations of their property without compensation or to lower a national wholesale price that Minnesota lacks authority under the Constitution to regulate.

CONCLUSION

For the foregoing reasons, PhRMA respectfully submits that defendants' motion to dismiss should be denied and that PhRMA's cross-motion for summary judgment be granted.

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