

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
CIVIL NO. 20-1497 (DSD/DTS)

Pharmaceutical Research and
Manufacturers of America,

Plaintiff,

v.

ORDER

Stuart Williams, et al.,

Defendants.

Joseph R. Guerra, Esq. and Sidley Austin LLP, 1501 K. Street,
N.W., Washington, DC 20005, counsel for plaintiff.

Sarah L. Krans, Esq. and Minnesota Attorney General's Office,
445 Minnesota Street, Suite 1800, St. Paul, MN, counsel for
defendants.

This matter is before the court upon defendants' motion to
dismiss, plaintiff Pharmaceutical Research and Manufacturers of
America's (PhRMA) conditional motion for leave to file a
supplemental complaint, and PhRMA's motion for summary judgment.
Based on a review of the file, record, and proceedings herein, and
for the following reasons, defendants' motion to dismiss is
granted, PhRMA's motion for leave to file a supplemental complaint
is denied, and PhRMA's motion for summary judgment is denied.

BACKGROUND

This dispute arises out of the recently enacted Alec Smith Insulin Affordability Act (Act). Compl. ¶ 1. PhRMA is a nonprofit corporation that represents pharmaceutical companies and serves as the pharmaceutical industry's "principal public policy advocate." Id. ¶¶ 10, 12. Its member companies include Eli Lilly and Company (Lilly), Novo Nordisk Inc., and Sanofi, which collectively manufacture most of the insulin sold in Minnesota and the United States. Id. ¶ 13. Defendants are members of the Board of Pharmacy, named only in their official capacities, who enforce the Act.¹ Id. ¶¶ 15.

On April 15, 2020, the governor of Minnesota signed the Act into law to establish insulin safety net programs. Id. ¶ 64. The Act requires manufacturers to provide insulin for free to Minnesota residents who meet certain criteria. Id.; Minn. Stat. § 151.74, subdiv. 1(a). The Act has two programs: the Continuing Safety Net Program and the Urgent Need Program. Compl. ¶ 65.

The Continuing Safety Net Program mandates that manufacturers provide free insulin products to any individual who meets the

¹ Defendants Stuart Williams, Stacey Jassey, Mary Phipps, Andrew Behm, James Bialke, Amy Pardis, Rabih Nahas, Samantha Schirmer, and Kendra Metz are members of the Board of Pharmacy. Compl. ¶¶ 16-24. The parties stipulated to the dismissal of defendants Nate Clark, Peter Benner, Suyapa Miranda, David Fisher, Jodi Harpstead, Phil Norrgard, Stephanie Stoffel, and Andrew Whitman, who are members of the Board of MNSure. ECF No. 22. see also Compl. ¶¶ 25-32.

eligibility criteria.² Id. Under this program, manufacturers must review applications, determine whether the applicant meets the eligibility criteria, and notify applicants of their decision within ten business days. Id. ¶ 66; Minn. Stat. § 151.74, subdiv. 5(a). If denied, the applicant may appeal to a review panel created by the Board of Pharmacy, which may overrule manufacturers with binding decisions. Compl. ¶ 67; Minn. Stat. § 151.74, subdiv. 8.

If the manufacturer determines an applicant is eligible, it next determines whether to provide the individual with a statement of eligibility. An individual with a statement of eligibility may present it to a pharmacy to obtain free insulin for up to one year. Compl. ¶¶ 68-69; Minn. Stat. § 151.74, subdiv. 5(b). If an eligible applicant does not have private insurance, the manufacturer must provide the individual with a statement of eligibility. Compl. ¶ 69. If an eligible applicant does have

² To be eligible, an individual must: (1) be a Minnesota resident with valid identification; (2) have a family income of 400% or less of the federal poverty level; (3) not be enrolled in medical assistance or MinnesotaCare; (4) not be eligible for federal funded healthcare or Veterans Administration prescription drug benefits; and (5) not be covered by an insurance plan under which they can obtain a thirty day supply of insulin for \$75 or less out of pocket. Compl. ¶ 65; Minn. Stat. § 151.74, subdiv. 4(a)-(b). Additionally, if an individual meets some of the statutory criteria, has prescription drug coverage under Medicare Part D, and has spent more than \$1000 on prescription drugs in the calendar year, they are also eligible to receive free insulin. Compl. ¶ 65, Minn. Stat. § 151.74, subdiv. 4(c).

private insurance, the manufacturer may determine whether the individual's needs are better met through the manufacturer's co-payment assistance program. Id. ¶ 68. If it determines the manufacturer's assistance program better addresses the individual's needs, the manufacturer "shall inform the individual and provide the individual with the necessary coupons to submit to a pharmacy." Id.; Minn. Stat. § 151.74, subdiv. 5(c). Otherwise, it must provide the individual with a statement of eligibility. Compl. ¶ 68; Minn. Stat. § 151.74, subdiv. 5(b).

When presented an eligibility statement, pharmacies order insulin from the manufacturer, and the manufacturer must "send to the pharmacy a 90-day supply of insulin ... at no charge to the individual or pharmacy." Compl. ¶ 70; Minn. Stat. § 151.74, subdiv. 6(c). The pharmacy is allowed to charge the applicant a co-payment "not to exceed \$50 for each 90-day supply" to cover "the pharmacy's costs for processing and dispensing" the insulin. Compl. ¶ 70; Minn. Stat. § 151.74, subdiv. 6(e). The manufacturer does not receive any amount of the co-payment. This process may be repeated throughout a full year of eligibility, and the manufacturer must continue to send "an additional 90-day supply of the product ... at no charge to the individual or pharmacy." Compl. ¶ 71; Minn. Stat. § 151.74, subdiv. 6(f).

The second program is the Urgent Need Program. Compl. ¶ 72. The program requires manufacturers to provide a thirty-day supply

of free insulin to individuals who meet eligibility criteria.³ Id.; Minn. Stat. § 151.74, subdiv. 2(a)-(b). When an applicant submits an application with a valid prescription, the pharmacy must dispense a thirty-day supply of insulin to the individual. Compl. ¶ 73; Minn. Stat. § 151.74, subdiv. 3(c).

After dispensing insulin, the pharmacy submits a claim for payment to the manufacturer or the manufacturer's vendor. Compl. ¶ 73; Minn. Stat. § 151.74, subdiv. 3(d). The manufacturer must either "reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost" or else "send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed." Compl. ¶ 73; Minn. Stat. § 151.74, subdiv. 3(d). Pharmacies may collect an insulin co-payment form from the individual in an amount not to exceed thirty-five dollars for the thirty-day supply. Compl. ¶ 74; Minn. Stat. § 151.74, subdiv. 3(e). The manufacturer does not receive any of the co-payment amount. Compl. ¶ 74.

³ Eligible individuals must (1) be Minnesota residents who are not enrolled in Medicaid or MinnesotaCare; (2) not be enrolled in a prescription drug coverage plan that would cover thirty-day supply of insulin for \$75 or less out of pocket; (3) not have received insulin under the Urgent Need Program within the last twelve months; and (4) have less than a seven-day supply of insulin and need insulin to avoid the likelihood of suffering significant health consequences. Compl. ¶ 72; Minn. Stat. § 151.74, subdiv. 2(a)-(b).

PhRMA claims it will incur significant expenses by giving away free insulin and administering both programs. Id. ¶ 75. Moreover, if a manufacturer does not comply with the programs and other statutory requirements, the Board of MNSure may assess penalties. Id. ¶ 76; Minn. Stat. § 151.74, subdiv. 10(a)-(b).

The Act governs all insulin manufacturers unless one of two exceptions applies. Compl. ¶ 77. First, manufacturers with an “annual gross revenue of \$2,000,000 or less from insulin sales in Minnesota” are exempt under the Act. Id.; Minn. Stat. § 151.74, subdiv. 1(c). Second, if the wholesale acquisition cost (WAC) of a manufacturer’s insulin product “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,” then the product is exempt. Compl. ¶ 77; Minn. Stat. § 151.74, subdiv. 1(d). Neither exception applies to PhRMA’s members. Compl. ¶ 78.

On June 30, 2020, PhRMA filed this suit alleging that the Act’s programs violate the Takings Clause of the Fifth Amendment. Id. ¶¶ 80-85. PhRMA also asserts that one of the Act’s exemptions, if interpreted a certain way, violates the Commerce Clause. PhRMA seeks declaratory and injunctive relief. Defendants now move to dismiss for lack of subject matter jurisdiction and for failure to state a claim upon which relief can be granted. PhRMA moves for

summary judgment and conditional leave to file a supplemental complaint.

DISCUSSION

I. Defendants' Motion to Dismiss

A. Standard of Review

A court must dismiss an action over which it lacks subject-matter jurisdiction. Fed. R. Civ. P. 12(h)(3). In a facial challenge under Rule 12(b)(1), the court accepts the factual allegations in the pleadings as true and views the facts in the light most favorable to the nonmoving party. See Hastings v. Wilson, 516 F.3d 1055, 1058 (8th Cir. 2008); see also Osborn v. United States, 918 F.2d 724, 729 n.6 (8th Cir. 1990) ("[T]he nonmoving party receives the same protections [for facial attacks under Rule 12(b)(1)] as it would defending against a motion brought under Rule 12(b)(6).") (citation omitted).

B. Takings Claim

PhRMA alleges that the Act compels its members to give away insulin without compensation in violation of the Takings Clause. PhRMA seeks an injunction barring the Act's enforcement and a declaration that the Act is unconstitutional, but it does not seek compensation. Consequently, defendants argue that PhRMA's takings claim should be dismissed because the court lacks subject matter jurisdiction. The underlying basis for defendants' argument is

that the United States Supreme Court foreclosed prospective injunctive and declaratory relief for a takings claim under Knick v. Township of Scott, 139 S. Ct. 2162 (2019).⁴ PhRMA responds that Knick does not foreclose perspective equitable relief because state law remedies for providing just compensation are inadequate.

The court finds that PhRMA lacks standing to bring a takings claim. "The party invoking federal jurisdiction bears the burden of establishing [standing]." Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992). A plaintiff must allege (1) an injury, (2) "fairly traceable to the defendant's alleged conduct," that is (3) "likely to be redressed by the requested relief." Allen v. Wright, 468 U.S. 737, 751 (1984). The third prong of standing, redressability, requires plaintiff to show that "it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." Lujan, 504 U.S. at 561.

The Fifth Amendment's Takings Clause prohibits the government from taking "private property ... for public use, without just compensation." U.S. Const. amend. V. "The Fifth Amendment does not proscribe the taking of property; it proscribes taking without

⁴ Defendants argue that PhRMA's takings claim should be dismissed because defendants are immune from suit under the eleventh amendment, PhRMA lacks associational standing, the claim is not ripe, and PhRMA's claims fail as a matter of law. The court need not address these arguments because injunctive and equitable relief are unavailable for PhRMA's takings claim. See Va. Hosp. & Healthcare Ass'n v. Kimsey, No. 3:20CV587-HEH, 2020 WL 5947887, at *2 n.1 (E.D. Va. Oct. 7, 2020).

just compensation.” Williamson Cty. Reg’l Planning Comm’n v. Hamilton Bank of Johnson City, 473 U.S. 172, 194 (1985), overruled on other grounds by Knick, 139 S. Ct. 2162. A takings claim arises when the government takes private property for public use without compensation. Knick, 139 S. Ct. at 2170. The Supreme Court in Knick explained that the appropriate remedy for a government taking is compensation. 139 S. Ct. at 2175-77. Equitable relief is unavailable because “[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. The Court held that injunctive relief is foreclosed “as long as just compensation remedies are available – as they have been for nearly 150 years” Id. at 2179.

Here, just compensation remedies are available in Minnesota through inverse condemnation actions in state court.⁵ Am. Family Ins. v. City of Minneapolis, 836 F.3d 918, 923 (8th Cir. 2016) (citing Nolan & Nolan v. City of Eagan, 673 N.W.2d 487, 492 (Minn. Ct. App. 2003)). Despite the availability of compensation, PhRMA seeks injunctive and declaratory relief. PhRMA is foreclosed from seeking equitable relief because it may bring an action seeking

⁵ An inverse condemnation action may be brought through a mandamus action when the government takes property without formally invoking its eminent domain powers. Am. Family Ins. v. City of Minneapolis, 836 F.3d 918, 923 (8th Cir. 2016) (citation omitted).

just compensation. Consequently, PhRMA does not have standing under Count I because it does state a claim that can be redressed by a favorable decision. See Va. Hosp. & Healthcare Ass'n v. Kimsey, No. 3:20CV587-HEH, 2020 WL 5947887, at *3-4 (E.D. Va. Oct. 7, 2020) (dismissing a takings claim under Knick because plaintiffs did not meet the redressability requirement of standing).

PhRMA argues that equitable relief is not foreclosed because Minnesota inverse condemnation suits are inadequate for providing just compensation. PhRMA argues that inverse condemnation actions cannot compensate for "future takings" and continuous takings. The court disagrees. First, a "future taking" - or a taking that has not happened yet - does not give rise to a claim under the Takings Clause. Knick, 139 S. Ct. at 2171 ("[A] property owner has a constitutional claim for just compensation at the time of the taking.") (internal quotations and citation omitted). The government does not need to compensate for property it has not yet taken. Second, the court is not convinced that bringing multiple actions impairs the ability of Minnesota's inverse condemnation procedures to adequately compensate insulin manufacturers. The Supreme Court noted that where "nearly all state governments provide just compensations remedies," equitable relief is "generally unavailable." Id. at 2176. The court is unaware of any cases in which a court found a state's inverse condemnation

procedures to be inadequate.⁶ See Cormack v. Settle-Beshears, 474 F.3d 528, 531 (8th Cir. 2007) (“We have been unable to find a case in which this court has declared a state’s inverse condemnation procedures to be inadequate....”). Minnesota’s inverse condemnation actions allow state courts to determine whether a taking occurred and the monetary value of the harm. See Am. Family Ins., 836 F.3d at 923 (rejecting an argument that Minnesota’s inverse condemnation remedies are futile). The court finds Minnesota’s just compensation provisions to be adequate.

Alternatively, PhRMA argues that only injunctive relief is foreclosed, leaving declaratory relief as an available remedy under the Takings Clause. The court disagrees. A declaration that the Act is an unconstitutional taking would be the functional equivalent of an injunction barring enforcement. See Baptiste v. Kennealy, No. 1:20-CV-11335-MLW, 2020 WL 5751572, at *23 (D. Mass. Sept. 25, 2020) (holding that declaratory relief for a takings claim, without seeking just compensation, is the “functional equivalent of an unwarranted injunction” and is foreclosed under Knick). The Supreme Court assured governments that they “need not fear that [Knick] will lead federal courts to invalidate their regulations as unconstitutional.” Knick, 139 S. Ct. at 2179.

⁶ The court rejects PhRMA’s reliance on McShane v. City of Faribault, 292 N.W.2d 253 (Minn. 1980), which was abrogated by DeCook v. Rochester Int’l Airport Joint Zoning Bd., 811 N.W.2d 610, 612 (Minn. 2012).

Courts have routinely found that takings claims seeking declaratory relief are barred under Knick. See, e.g., Culinary Studios, Inc. v. Newsom, No. 1:20-CV-1340 AWI EPG, 2021 WL 427115, at *14 (E.D. Cal. Feb. 8, 2021) (dismissing a takings claim seeking declaratory or injunctive relief as inappropriate under Knick); Baptiste, 2020 WL 5751572, at *23 (finding that plaintiffs are not entitled to declaratory relief for a Takings Clause violation).

The court dismisses PhRMA's takings claim because PhRMA does not meet the redressability requirement of standing.

C. Dormant Commerce Clause Claim

PhRMA alleges that the exemption under subdivision 1(d) of the Act violates the dormant commerce clause. PhRMA asserts that the exemption could be interpreted "to afford insulin manufacturers the option of avoiding the unconstitutional taking of their property by lowering the WAC of their products" Compl. ¶ 87. Because the WAC is a national list price that manufacturers charge to all customers, including non-Minnesota wholesalers, PhRMA claims the exemption would directly regulate the price of out-of-state transactions. PhRMA seeks injunctive relief and a declaration that "if [the exemption] were interpreted as a condition on the ability of manufacturers to escape the unlawful taking of their personal property, that condition would violate the Commerce Clause." Id. at 28.

Defendants respond that PhRMA's dormant commerce claim should be dismissed as wholly derivative of its takings claim. Defendants argue that dormant commerce claim arises only if PhRMA's takings claim proceeds and the exemption is interpreted as a savings provision. PhRMA does not contest that its dormant commerce claim is derivative of its takings claim. Because the court dismissed PhRMA's takings claim as nonjusticiable, the court also dismisses the remaining dormant commerce claim.⁷

II. Motion for Leave to File a Supplemental Complaint

PhRMA conditionally moves to file a supplemental complaint to address subsequent events under Federal Rule of Civil Procedure 15(d), in the event the court dismisses the complaint on ripeness or injury-in-fact grounds.

The court denies PhRMA's motion. Rule 15(d) allows the court to "permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented." Fed. R. Civ. P. 15(d). If supplementing the pleadings would be futile, the court may deny the motion. See, e.g., Favors v. Mike, No. 20-cv-00365 (SRN/DTS),

⁷ The court also notes that it should "avoid deciding ... hypothetical questions of constitutional law." Boumediene v. Bush, 553 U.S. 723, 805 (2008). To the extent that PhRMA encourages an unconstitutional construction of the exemption, statutory interpretation instruct the court to give "a construction, if reasonably possible, that would avoid constitutional doubts." Carhart v. Stenberg, 192 F.3d 1142, 1150 (8th Cir. 1999), aff'd, 530 U.S. 914 (2000).

2021 WL 222935, at *5 (D. Minn. Jan. 22, 2021) (denying a motion to supplement the complaint as futile because it did not cure deficiencies in the complaint). As explained above, the court dismisses the complaint on separate grounds, and PhRMA's proposed amendments will not overcome the complaint's deficiencies. Therefore, the court denies PhRMA's motion as futile.

III. Motion for Summary Judgment

PhRMA also moves for summary judgment. Because the court grants defendants' motion to dismiss, the court must deny PhRMA's motion for summary judgment as moot.

CONCLUSION

Accordingly, based on the above, **IT IS HEREBY ORDERED** that:

1. The motion to dismiss [ECF No. 12] is granted;
2. The motion for leave to file a supplemental complaint [ECF No. 34] is denied;
3. The motion for summary judgment is denied as moot [ECF No. 14]; and
4. The case is dismissed without prejudice.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: March 15, 2021

s/David S. Doty

David S. Doty, Judge
United States District Court