UNITED STATES DISTRICT COURT
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. 0:20-cv-01497-DSD-DTS

DEFENDANTS' MEMORANDUM SUPPORTING MOTION TO DISMISS

Alec Smith died in 2017 at age 26. He had type 1 diabetes. After aging out of his parents' health insurance, Alec was forced to ration his insulin because he could not afford the $1,300-a-month refill. Shortly after losing his insurance, he died of diabetic ketoacidosis, an insulin deficiency that forces the body to break down fat and produces an overwhelming amount of harmful acid in the blood.[1]

[1] Jeremy Olson, *Son's Death Pushes Minnesota Mom Into Fight Against High, Rising Drug Prices*, MINNEAPOLIS STAR TRIBUNE (May 11, 2018), https://www.startribune.com/son-s-death-pushes-mom-into-drug-price-spotlight/482344871/.

Unfortunately, Alec's story is not unique. Americans are rationing their insulin and, in some instances, dying because they cannot afford the lifesaving medication.[2] In response to this public-health crisis, the Minnesota legislature enacted the Alec Smith Insulin Affordability Act. 2020 Minn. Laws ch. 73, § 4. The Act provides a safety net for individuals who are at risk of having to ration or go without insulin due to the cost, giving them access to insulin on urgent and continuing-need bases. *Id*. Relevant to this lawsuit, certain insulin manufacturers—based on their Minnesota insulin sales revenue and insulin prices—may be required to provide insulin to pharmacies to dispense to individuals in need. Or, for urgent needs, the manufacturers may be required to reimburse the dispensing pharmacy or replace the insulin dispensed.

Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) is a lobbying organization and not a manufacturer affected by the Act. Nonetheless, PhRMA sued the night before the Act became operational, alleging that requiring manufacturers to provide insulin to pharmacies is a taking without just compensation in violation of the U.S. Constitution and that exempting less expensive insulin violates the Commerce Clause. Rather than seek just compensation for the alleged taking, however, PhRMA seeks to enjoin enforcement of those provisions of the Act, effectively crippling the Act

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[2] Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes,* 179 JAMA INTERN MED. 112–114 (2019), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499; S. Vincent Rajkumar, MD, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 MAYO CLINIC PROC., 22, 22 (2020) https://www.mayoclinicproceedings.org/action/showPdf?pii=S0025-6196%2819%2931008-0.

and depriving Minnesotans who cannot otherwise afford their insulin of the lifesaving medicine. This Court should dismiss PhRMA's claims under Fed. R. Civ. P. 12(b)(1) and (6) because Defendants are immune from suit, PhRMA lacks standing, its claims are not ripe for adjudication, and its claims for equitable relief are foreclosed because just compensation remedies are available if the Act's requirements do effect a taking.

FACTS

The Insulin Crisis

More than 30 million Americans, including more than 330,000 Minnesotans, have diabetes. (Compl. ¶ 36.) Diabetes is a chronic disease caused by insufficient insulin production or resistance to insulin. (*Id.*) Insulin is a hormone that lets the body's cells absorb glucose from the blood for energy. (*Id.*) Without insulin, cells cannot absorb glucose, leaving too much blood sugar in the bloodstream and potentially causing serious health problems, including organ damage and death. (*Id.*) There are two types of diabetes. (*Id.* ¶ 37.) Type 1 diabetes occurs when a person's pancreas does not produce insulin. (*Id.*) There is no known way to prevent it, and no cure.[3] Type 2 diabetes is caused when the pancreas produces insulin, but the body develops a resistance to it. (*Id.)* Diabetes of either type can be treated with injectable insulin. (*Id.* ¶ 38.)

[3] Ctrs. for Disease Control & Prevention, *Type 1 Diabetes* (2020), https://www.cdc.gov/diabetes/basics/type1.html#:~:text=Currently%2C%20no%20one%20knows%20how,self%2Dmanagement%20education%20and%20support (last visited Aug. 20, 2020).

Over the past two decades, the cost of insulin has risen exponentially.[4] While a vial of analog insulin likely costs between $2 and $18 to manufacture,[5] it now retails in the $300 range.[6] These rising costs have led some individuals to ration their insulin, and in some cases—like that of Minnesotans Alec Smith and Jesimya David Scherer-Radcliff—to die.[7] The outrageous cost of insulin and the resulting crisis are widely reported on and have been the subject of congressional hearings. Three manufacturers, Eli Lily and Company, Novo Nordisk Inc., and Sanofi ("the manufacturers") collectively manufacture most of the insulin sold in the United States. (Compl. ¶¶ 4, 13.) The manufacturers' actions and pricing schemes are subjects of dispute and litigation. *See, e.g.*, *Minnesota by Ellison v. Sanofi-Aventis U.S. LLC*, No. 3:18-cv-14999-BRM-LHG, 2020 WL 2394155 (D.N.J. Mar. 31, 2020); *In re Insulin Pricing Litig.*, No. 3:17-CV-0699-BRM-LHG, 2019 WL 643709 (D.N.J. Feb. 15, 2019). Common reasons given for the rise in insulin costs are that the three biggest insulin manufacturers have an oligopoly

[4] Rajkumar, *supra* note 2, at 22 (stating price per vial of Humalog insulin increased more than 1,000%, from $21 in 1999 to $332 in 2019).

[5] Dzintars Gotham et al., *Production Costs and Potential Prices for Biosimilars of Human Insulin and Insulin Analogues*, BMJ GLOBAL HEALTH (Sept. 25, 2018) https://gh.bmj.com/content/bmjgh/3/5/e000850.full.pdf.

[6] Ritu Prasad, *The Human Cost of Insulin in America*, BBC NEWS (March 14, 2019), https://www.bbc.com/news/world-us-canada-47491964.

[7] Olson, *supra* note 1; Rajkumar, *supra* note 2, at 22; Adrienne Broaddus, *Family Says 21-year-old Son Died Rationing Insulin*, KARE11 (July 12, 2019), https://www.kare11.com/article/news/family-says-21-year-old-son-died-rationing-insulin/89-d451a01b-9170-4341-9010-155cb87edccc; *Emergency Insulin Program Established, Minnesota Insulin Patient Assistance Program Established, Pharmacy and Insulin Manufacturer Participation Required, Reports Required, and Money Appropriated*: *Hearing on HF3100 Before the Commerce Comm.*, 2020 Leg., 91st Sess. (Minn. Feb. 11, 2020) (statement of Nicole Smith-Holt), https://www.house.leg.state.mn.us/hjvid/91/892535.

on insulin and know that patients will spend whatever it takes to acquire it because the alternative is death; the manufacturers engage in patent evergreening to extend their oligopoly on insulin; and the complex pricing schemes encourage manufacturers to increase their list prices.[8] PhRMA downplays the role of manufacturers in the crisis and faults pharmacy benefit managers and health plans. (*See* Compl. ¶¶ 40-55.)

Acknowledging this public-health crisis, the manufacturers have implemented initiatives to provide insulin to those in need for free or at a reduced cost. (*Id.* ¶¶ 4, 56.) Under these programs, the manufacturers typically provide free insulin to eligible individuals whose income is at or below 400% of the federal poverty level and reduced-cost insulin in other need-based circumstances. (*Id.* ¶¶ 56-62.) Novo Nordisk also currently provides free insulin to individuals who have lost health insurance coverage because of a change in job status due to COVID-19 and to individuals at risk of rationing insulin. (*Id.* ¶ 59-60.)

The Alec Smith Insulin Affordability Act

In response to the insulin crisis and the deaths of Alec and Jesy, the Minnesota legislature enacted the Alec Smith Insulin Affordability Act. 2020 Minn. Laws ch. 73, § 4.[9] The Act, which required implementation by July 1, establishes urgent-need and continuing safety net programs that provide lifesaving insulin to Minnesotans who are most at risk of being unable to access affordable insulin. *See* Minn. Stat. § 151.74. Only

[8] Rajkumar, *supra* note 2, at 23-24.
[9] The Act will be codified as section 151.74 of the Minnesota Statutes. For convenience, Defendants cite the statute number going forward.

insulin manufacturers that annually gross $2,000,000 or more from insulin sales in Minnesota are subject to the Act. *Id*. subd. 1(c). The Act also exempts any insulin products that have a wholesale acquisition cost of $8 or less per milliliter (or other applicable billing unit). *Id*. subd. 1(d).

Under the Act's urgent-need program, Minnesota residents who need insulin and have less than a seven-day supply can apply for free insulin by attesting to their pharmacies that they are eligible under the Act.[10] *Id*. subds. 2, 3. The pharmacist then must dispense a 30-day supply of the prescribed insulin to any eligible individual. *Id*. subd. 3(c). The pharmacy may seek reimbursement from the manufacturer of the dispensed insulin, which then must reimburse the pharmacy's acquisition costs or replace the insulin dispensed. *Id*. subd. 3(c), (d).

Under the continuing safety net program, insulin manufacturers are required to have patient-assistance programs available for individuals needing access to an affordable insulin supply. *Id*. subds. 1, 4. Individuals in need of affordable insulin may apply directly to the manufacturer or through a health-care practitioner. *Id*. subd. 4(d). After confirming an individual's eligibility for the program, the manufacturer must provide the individual with an eligibility statement that is valid for 12 months and renewable if the individual remains eligible. *Id*. subd. 5(a), (b). But, if the eligible individual has prescription drug coverage through an individual or group health plan, the manufacturer

[10] Minnesota residents who are enrolled in medical assistance or MinnesotaCare, have insurance that limits out-of-pocket costs to $75 or less for a 30-day insulin supply, or have received urgent-need insulin under the Act within the previous 12 months (with some exceptions) are not eligible. Minn. Stat. § 151.74, subd. 2.

may use its own co-payment assistance program if it better addresses the individual's insulin needs. *Id*. subd. 5(c).

After receiving an eligibility statement, the individual submits it to a pharmacy, which orders the prescribed insulin from the manufacturer. *Id*. subd. 6(a), (b). The manufacturer then sends a 90-day insulin supply to the pharmacy at no charge to the individual or the pharmacy. *Id*. subd. 6(c). The pharmacy may continue to submit orders to the manufacturer while the individual's eligibility statement is active. *Id*. subd. 6(f). The pharmacy may not charge the individual or seek reimbursement from the manufacturer or a third-party payer. *Id.* subd. 6(d). The pharmacy may, however, collect a co-payment from the individual of $50 or less for each 90-day supply to cover its costs. *Id*. subd. 6(e).

The Act's eligibility requirements target Minnesotans most at risk of not having access to affordable insulin. Minnesota residents are eligible for the continuing safety net program if their family income is equal to or less than 400% of the federal poverty threshold; they are not enrolled in medical assistance or MinnesotaCare and are not eligible to receive health care through a federally-funded program or receive prescription drug benefits through the Department of Veterans Affairs; and they do not have insurance that limits out-of-pocket costs to $75 or less for a 30-day insulin supply. *Id*. subd. 4(b). Certain Minnesotans enrolled in Medicare Part D are also eligible. *Id*. subd. 4(c).

If a manufacturer fails to comply with the Act, the Minnesota Board of Pharmacy may assess administrative penalties, starting at $200,000 per month and increasing to a maximum of $600,000 per month after a year of continued noncompliance. *Id.* subd. 10.

Any penalty the board assesses must be deposited into an insulin-assistance account in the special revenue fund. *Id*.

PhRMA's Lawsuit

The day before the Act became operational, PhRMA commenced the current action on behalf of itself and its members, which include the three insulin manufacturers. (Compl. ¶¶ 10, 13.) PhRMA sued members of the Board of Pharmacy and the Board of MNsure in their official capacities only. (*Id*. ¶¶ 15-32.) The Board of Pharmacy and the Board of MNsure are Minnesota state boards. *See* Minn. Stat. §§ 62V.03-.04, 151.02-03. PhRMA alleges that requiring insulin manufacturers to provide free insulin to those who otherwise could not afford it constitutes a per se taking of private property for public use without just compensation in violation of the Takings Clause of the Fifth Amendment. (*Id*. ¶¶ 82, 83.) PhRMA also alleges that, if the Act's provision exempting less expensive insulin is interpreted as an option for manufacturers to avoid the alleged taking, it is impermissible under the dormant Commerce Clause. (*Id.* ¶¶ 87-89.) PhRMA asks the Court to declare those provisions of the Act unconstitutional and enjoin their enforcement.

ARGUMENT

A court should dismiss claims on the pleadings if the court lacks subject-matter jurisdiction or a party has failed to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(1), (6). The plaintiff bears the burden of proving subject-matter jurisdiction. *Buckler v. United States*, 919 F.3d 1038, 1044 (8th Cir. 2019). The court must "decide the jurisdictional issue, not simply rule that there is or is not enough

evidence to have a trial on the issue." *Id.* (quoting *Osborn v. United States*, 918 F.2d 724, 730 (8th Cir. 1990)).

In a motion to dismiss for failure to state a claim under 12(b)(6), the court must accept as true all factual allegations in the complaint, but it need not accept as true a plaintiff's conclusory allegations or legal conclusions drawn from the facts. *Glick v. W. Power Sports, Inc.*, 944 F.3d 714, 717 (8th Cir. 2019). Dismissal is appropriate when a complaint does not state "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Determining whether a complaint states a plausible claim for relief is context-specific, requiring the court to draw on its experience and common sense. *Id.* at 679. A plaintiff must provide more "than labels and conclusions" or a "formulaic recitation" of a cause of action's elements. *Twombly*, 550 U.S. at 555. Where well-pleaded facts only permit the court to infer the mere possibility of misconduct, the complaint has not shown "that the pleader is entitled to relief." *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

Defendants seek dismissal of PhRMA's claims under Fed. R. Civ. P. 12(b)(1) and (b)(6) because Defendants are immune from suit, PhRMA lacks standing, its claims are not ripe for adjudication, and the equitable relief requested is not an available remedy as a matter of law. Defendants also dispute that the Act effects a taking or violates the Commerce Clause. But such arguments would be premature because the Court lacks jurisdiction and the relief PhRMA seeks is foreclosed.

I. DEFENDANTS ARE IMMUNE FROM SUIT.

A state is immune from suit in federal court unless the state has consented to be sued or Congress has expressly abrogated the state's immunity. U.S. Const. amend. XI; *see also Kentucky v. Graham*, 473 U.S. 159, 169 (1985); *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 100 (1984). This jurisdictional bar applies regardless of the nature of the relief sought and extends to state officials if "the state is the real, substantial party in interest." *Pennhurst,* 465 U.S. at 100-01 (internal quotation marks omitted).

A state official, however, can be sued in his or her official capacity for prospective injunctive relief from continuing violations of federal law, so long as the official has "some connection with the enforcement of the act." *Ex parte Young*, 209 U.S. 123, 155-59 (1908); *see Church v. Missouri*, 913 F.3d 736, 747-48 (8th Cir. 2019). The reasoning behind this immunity exception is that an unconstitutional law is "void," so a state official's enforcement of that law is not authorized by, and does not affect, the state in its sovereign capacity. *Ex parte Young*, 209 U.S. at 159. In other words, if a federal court orders "a state official to do nothing more than refrain from violating federal law, he is not the State for sovereign-immunity purposes." *Church*, 913 F.3d at 747 (quoting *Virginia Off. for Prot. & Advoc. v. Stewart*, 563 U.S. 247, 255 (2011)). An enforcement connection is required because otherwise the officer "would be sued merely 'as a representative of the state' in an impermissible attempt to 'make the state a party.'" *Church*, 913 F.2d at 748 (quoting *Digit. Recognition Network, Inc. v. Hutchinson*, 803 F.3d 952, 960 (8th Cir. 2015)). To determine whether this exception to immunity

applies, "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.'" *Verizon Md., Inc. v. Pub. Serv. Comm'n of Md.*, 535 U.S. 635, 645 (2002) (citation omitted).

The *Ex parte Young* exception is inapplicable here because PhRMA fails to allege an ongoing violation of federal law and the prospective relief sought is foreclosed. PhRMA alleges that the Act "will continually effect unconstitutional takings of manufacturers' property without just compensation." (Compl. ¶ 85.) The complaint is devoid, however, of any factual allegations that any insulin has been "taken," that the alleged "takings" are imminent, or that just compensation remedies are unavailable for such takings. *See infra* Parts II, III. Even if the Act were to result in a "taking" of insulin as alleged—which Defendants dispute—the Act would not be void for unconstitutionality because the Takings Clause does not prohibit the taking of private property.

Under the Takings Clause, private property cannot be taken for public use without just compensation. U.S. Const. amend. V. The clause permits the taking of private property, provided the government gives just compensation. *See id.*; *First Eng. Evangelical Lutheran Church of Glendale v. Los Angeles Cty.*, 482 U.S. 304, 315 (1987). The clause is not designed to limit governmental interference with property rights, but to secure compensation if an interference amounts to a taking. *First Eng.*, 482 U.S. at 315. And, the government does not need to provide compensation before a taking occurs *Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2167-68 (2019). Minnesota provides just compensation remedies for takings through inverse condemnation actions, a fact which

PhRMA acknowledges. *See infra* Part III.B; Compl. ¶ 85. The injunction PhRMA requests goes beyond the *Ex parte Young* exception. It is not just enjoining Defendants from violating federal law; PhRMA is asking this Court to enjoin enforcement of a constitutionally permissible (alleged) taking. Because the taking of private property is permitted under the Constitution and just compensation remedies are available for any alleged takings, PhRMA has failed to allege ongoing violations of federal law.

Further, although PhRMA attempts to avoid Defendants' immunity by requesting injunctive and declaratory relief, such relief is typically foreclosed in takings claims because compensation is the remedy for a taking. *See Knick*, 139 S. Ct. at 2176, 2179; *Stop the Beach Renourishment, Inc. v. Fla. Dep't of Envtl. Prot.*, 560 U.S. 702, 740-41 (2010) (Kennedy, J., concurring) ("It makes perfect sense that the remedy for a Takings Clause violation is only damages."). When a property owner has some way to obtain just compensation after the fact, a taking should not be enjoined. *Knick*, 139 S. Ct. at 2179; *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1016 (1984) ("Equitable relief is not available to enjoin an alleged taking of private property for a public use . . . when a suit for compensation can be brought against the sovereign subsequent to the taking."). Just compensation is "on all fours with traditional monetary damages, which are the quintessential form of retrospective relief." *Seven Up Pete Venture v. Schweitzer*, 523 F.3d 948, 956 (9th Cir. 2008). As such, an injunction ordering state officers to adhere to the Takings Clause is an order to pay damages, to which *Ex parte Young* does not apply. *See id.* (holding that the Eleventh Amendment barred an inverse condemnation action against officials in their official capacities). Such a result also

would be completely inconsistent with an injunction's purpose, which is to provide relief only when damages are inadequate. *See Watkins Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003) (stating injunctions are not appropriate where there is an adequate remedy at law).

Because PhRMA failed to allege an ongoing violation of federal law and prospective relief is not available for a taking, the *Ex parte Young* exception is inapplicable. Defendants are immune from suit and PhRMA's takings claims must be dismissed. PhRMA also fails to allege an ongoing constitutional violation with its dormant commerce clause claim because it is dependent on, and secondary to, its takings claim. *See infra* Part IV.

Also, the *Ex parte Young* immunity exception is inapplicable to the MNsure board members because they have no connection with the enforcement of the Act. The law gives only the Board of Pharmacy authority to assess penalties for noncompliance with the Act. Minn. Stat. § 151.74, subd. 10. While MNsure has various duties under the Act, it has no enforcement powers. *See id.*, subds. 3(a), 7(c), (d). Additionally, Defendant Nate Clark, a MNsure staff member, has no conceivable enforcement connection to the Act. The MNsure defendants are immune from suit and must be dismissed.

II. PHRMA'S TAKINGS CLAIM SHOULD BE DISMISSED BECAUSE PHRMA LACKS STANDING AND THE CLAIM IS UNRIPE.

Federal courts have subject-matter jurisdiction only over "cases and controversies." U.S. Const. Art. III § 2. The requirement of a true "case or controversy" means that each party must have standing to bring their claims, and further that their

claims must be ripe for judicial review. PhRMA's claim under the Takings Clause of the Fifth Amendment fails to meet either of these requirements. PhRMA lacks standing to assert a takings claim, either by itself or as a representative of its members. Further, its claim is based on speculative events that may not occur and therefore, is not ripe for review.

A. PhRMA Lacks Standing.

PhRMA carries the burden to show that it has standing to bring a claim in federal court. *Young Am. Corp. v. Affiliated Comput. Servs., Inc.*, 424 F.3d 840, 843 (8th Cir. 2005). The "irreducible constitutional minimum" for standing is composed of three elements: (1) an injury in fact, (2) that is fairly traceable to the challenged conduct, and (3) that will likely be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). To meet the requirement for an injury in fact, PhRMA must show "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Id.* at 560 (citations omitted). These Article III standing requirements are also essential to any claim for a declaratory judgment. *See Cty. of Mille Lacs v. Benjamin*, 361 F.3d 460, 463 (8th Cir. 2004). And because PhRMA seeks injunctive relief, it must show that it faces "a real and immediate threat" of future injury that would be remedied by an injunction. *Frost v. Sioux City*, 920 F.3d 1158, 1161 (8th Cir. 2019); *see City of Los Angeles v. Lyons*, 461 U.S. 95, 101-02 (1983).

Standing is determined as of the commencement of a suit, and at the pleading stage courts accept as true all factual allegations in the complaint that may show standing.

Steger v. Franco, 228 F.3d 889, 892 (8th Cir. 2000). It is "long settled," however, that "standing cannot be inferred argumentatively from averments in the pleadings," and instead must "affirmatively appear in the record." *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (citations omitted).

PhRMA does not have standing to bring this suit. PhRMA states that it is "the pharmaceutical industry's principal public policy advocate." (Compl. ¶ 12.) But PhRMA does not allege that it has been, or will be, directly affected by the Act. PhRMA does not manufacture pharmaceutical drugs, but rather lobbies on behalf of the interests of its members. (*Id.* ¶ 12-13.) PhRMA can point to no provision of the Act that requires it to take any action or imposes any regulation or fine upon it. Thus, PhRMA fails to allege that it has suffered an injury in fact, much less one that is "concrete" and "actual or imminent." *Lujan*, 504 U.S. at 560; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009) (finding a lack of standing where the challenged regulations "neither require nor forbid any action" by the plaintiffs); *Mausolf v. Babbitt*, 85 F.3d 1295, 1301 (8th Cir. 1996) ("The Supreme Court has often emphasized that a lawsuit in federal court is not a forum for the airing of interested onlookers' concerns, nor an arena for public-policy debates."). PhRMA lacks standing to bring a takings claim on its own behalf.

B. PhRMA Fails to Adequately Plead a Factual Basis for Associational Standing.

PhRMA seeks to establish standing as a representative of its members, the three big insulin manufacturers. An organization may bring suit on behalf of its members only when: "(a) its members would otherwise have standing to sue in their own right; (b) the

interests it seeks to protect are germane to the organization's 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 Advertisement Comm'n,* 432 U.S. 333, 343 (1977). PhRMA's claim of associational standing fails on both the first and third prongs of the *Hunt* test.

PhRMA claims it can sue because its members manufacture insulin and are "subject to the Act." (Compl. ¶ 13.) To have associational standing under *Hunt*, PhRMA must show that the manufacturers themselves have standing to sue. 432 U.S. at 343. PhRMA has not met this burden. PhRMA pleads no injury to its members. As evidenced by its filing this lawsuit *before* the programs were implemented, its entire complaint is forward-looking. PhRMA does not allege a single instance in which one of its members has had to provide insulin under the provisions of the Act. This suit is similar to a previous unsuccessful lawsuit PhRMA filed to challenge a California law regulating price hikes in the pharmaceutical industry. *See PhRMA v. Brown*, No. 2:17-cv-02573, 2018 WL 4144417 (E.D. Cal. Aug. 30, 2018). The court in that case dismissed for a lack of jurisdiction, finding that PhRMA had not met its burden to show actual or impending harm to its members by alleging only that they "might be harmed at some point." *Id.* at *5; *accord Mendota Elec., Inc. v. Fair Contracting Found.*, 144 F.Supp.3d 1053, 1058 (D. Minn. 2015) (Doty, J.) (dismissing for lack of standing where plaintiff "fail[ed] to articulate any particular harm it has suffered"). Similarly, PhRMA's complaint here alleges only that PhRMA's members might be harmed at some point, which is insufficient to establish any actual injury.

In addition to this failure to plead any existing injury, PhRMA also fails to adequately plead a threat of future injury. To have standing to seek an injunction, a party must show a "real and imminent threat" of actual harm. *Lyons*, 461 U.S. at 102. Similarly, standing in a declaratory judgment action requires "immediate danger of sustaining threatened injury." *Cty. of Mille Lacs*, 361 F.3d at 464. "Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is certainly impending." *Lujan*, 504 U.S. at 564 n.2.

PhRMA's rote recitations of the likelihood of future harm are not sufficient to show that the manufacturers face a real and immediate threat of injury. PhRMA's allegations in this area are general, and PhRMA largely paraphrases the Act. *Cf. PhRMA v. Brown*, 2018 WL 4144417, at *5 (finding PhRMA had not established standing where it "describe[d] the operation of the statute in painstaking detail" but did not state factual allegations showing its members faced imminent harm); Compl. ¶¶ 64-77. PhRMA asserts that its members will be "forced to give away their insulin for free" and "will also incur significant expenses in developing and administering the Continuing Safety Net Program and Urgent Need Program," but its only specific factual allegation about the Act's potential impact is drawn from assumptions stated in a fiscal note that attempted to predict how many Minnesotans may participate under an earlier and different version of

the Act.[11] (Compl. ¶¶ 75, 79.) The complaint is devoid of any concrete factual allegations of whether, and when in time, eligible individuals will apply for insulin under the Act, causing the manufacturers to provide insulin.

At the same time, PhRMA highlights the affordability programs that the manufacturers already operate. (*See id.* ¶¶ 56-63.) These programs provide free insulin to charitable organizations and to certain high-risk or low-income patients, and provide low-cost insulin to patients who are uninsured or underinsured. (*Id.*) These programs have similar eligibility requirements to the Act; for example, household income below 400% of the federal poverty line is a requirement for the continuing safety net program, Minn. Stat. § 151.74, subd. 4(b), and for assistance through the Lilly Cares Foundation, (Compl. ¶ 58), Novo Nordisk's Patient Assistance Program (*id.* ¶ 59), and Sanofi's Patient Connection program, (*id.* ¶ 61). In addition to these programs, PhRMA alleges that the manufacturers "undertake other significant voluntary efforts" to provide access to affordable insulin products. (*Id.* ¶ 56.) The intended effect of these programs, PhRMA claims, is "to provide insulin to those in need, so that individuals living with diabetes are not forced to ration or forego life-saving insulin because they cannot afford it." (*Id.* ¶ 4.)

[11] The earlier version had different administrative procedures and eligibility requirements. *See* Minn. Health & Human Servs. Fin. Div., *Consolidated Fiscal Note, HF 3100 - 6A*, at 6-9 (Feb. 18, 2020), *available at* https://www.house.leg.state.mn.us/comm/docs/9b4c084f-4ef5-4ab7-af26-0c8ffb7abada.pdf. Additionally, the figure that PhRMA describes as an "estimate" is in fact an assumption and is consistently identified as such in the fiscal note. *Id.* at 9-11. Regardless, it is not sufficiently concrete to state a real and imminent threat.

The manufacturers' affordability programs actually undercut the alleged imminence of PhRMA's predicted injury, because they target the same populations that the Act seeks to protect. No taking claim can arise until some property has actually been taken from the manufacturers. *See Knick*, 139 S. Ct. at 2177. Given their existing affordability programs, it is not clear when the manufacturers will be required to provide insulin under the Act. The continuing safety net program, for instance, has the manufacturers redirect certain eligible applicants to the manufacturer's comparable affordability programs. Minn. Stat. § 151.74, subd. 5(c). Further, the Supreme Court has consistently been "reluctan[t] to endorse standing theories that rest on speculation about the decisions of independent actors." *Clapper v. Amnesty Int'l, USA*, 568 U.S. 398, 414 (2013). PhRMA's standing theory rests entirely on speculation that patients who are eligible for the Act's safety-net programs, and who are not covered by the manufacturers' existing affordability programs, will apply for and receive insulin through the Act's programs. PhRMA has not shown that there is a real and imminent risk that the conditions triggering manufacturers to provide insulin products will occur.

PhRMA also fails the third prong of the *Hunt* requirements for associational standing, because its takings claim necessitates the participation if its individual members. Takings claims involve "essentially ad hoc, factual inquiries" into the nature, purpose, and value of the alleged taking. *Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979). Thus a takings claim is generally a "poor candidate" for associational standing, because it requires the participation of the individual members alleged to have suffered a taking. *Rent Stabilization Ass'n of N.Y.C., Inc. v. Dinkins*, 805 F. Supp. 159,

164 (S.D.N.Y. 1992); *see also Wash. Legal Found. v. Legal Found. of Wash.*, 271 F.3d 835, 849-50 (9th Cir. 2001). As the Supreme Court has noted, "we have found it particularly important in takings cases to adhere to our admonition that 'the constitutionality of statutes ought not to be decided except in an actual factual setting.'" *Pennell v. City of San Jose*, 485 U.S. 1, 10 (1988) (quoting *Hodel v. Va. Surface Min. & Reclamation Ass'n, Inc.*, 452 U.S. 264, 294-95 (1981)). To evaluate the alleged taking in its "actual factual setting" would require substantial participation of the manufacturers actually subject to the Act. Because associational standing is fundamentally inconsistent with a takings claim, PhRMA lacks standing to sue on the manufacturers' behalf.

PhRMA does not avoid the third *Hunt* requirement by seeking injunctive and declaratory relief rather than damages. Because equitable relief is not a proper remedy here and the appropriate relief—just compensation—necessarily requires the manufacturers' participation, PhRMA does not have associational standing to pursue a takings claim. *See Wash. Legal Found.*, 271 F.3d at 849-50; *infra* Part III. Even if equitable relief were a viable remedy, PhRMA would still lack standing because it is not just the remedy but also "the nature of the claim" that determines whether associational standing exists. *Hunt*, 432 U.S. at 342. Even when injunctive and declaratory relief is sought for a takings claim, the third *Hunt* requirement may bar associational standing. *See Rent Stabilization Ass'n of N.Y.C. v. Dinkins*, 5 F.3d 591, 596-97 (2d Cir. 1993) (affirming dismissal of takings claim seeking equitable relief for lack of associational standing); *Cmty. Fin. Servs. Ass'n of Am., Ltd. v. Fed. Deposit Ins. Co.*, No. 14-cv-953, 2016 WL 7376847, at *6 (D.D.C. Dec. 19, 2016) ("The fact that all cases in which

associational standing has been found to exist involved a request for injunctive relief, does not mean that associational standing exists in all cases where an association seeks injunctive relief."); *Pharm. Care Mgmt. Ass'n v. Gerhart*, No. 4:14-cv-000345, 2015 WL 6164444, at *7-8 (S.D Iowa Feb. 18, 2015), *reversed on other grounds*, 852 F.3d 722 (8th Cir. 2017) (dismissing takings claim seeking only equitable relief for lack of associational standing because participation by individual members was required to determine whether a taking occurred). PhRMA may not avoid the incompatibility of associational standing and takings claims by seeking only equitable relief.

PhRMA has not met its burden to show that it has associational standing. To conclude that injury to PhRMA's members is "likely or immediate" would "take us into the area of speculation and conjecture." *Webb ex rel. K.S. v. Smith*, 936 F.3d 808, 815 (8th Cir. 2019) (internal quotation omitted). The risk PhRMA raises is speculative, especially in light of the manufacturers' existing affordability programs. Further, PhRMA's takings claim requires substantial participation of its individual members. In the absence of standing, PhRMA's takings claim must be dismissed for lack of jurisdiction.

C. PhRMA's Takings Claim Is Not Ripe.

PhRMA also carries the burden to show that its claims are ripe. *Pub. Water Supply Dist. No. 10 v. City of Peculiar*, 345 F.3d 570, 573 (8th Cir. 2003). The ripeness requirement flows both from Article III's "cases and controversies" requirement and from prudential limitations on jurisdiction. *Neb. Pub. Power Dist. v. MidAmerican Energy Co.*, 234 F.3d 1032, 1037 (8th Cir. 2000). For this reason, a ripeness analysis is

somewhat similar to a standing analysis, but also includes broader considerations of proper judicial restraint. *See Blanchette v. Conn. Gen. Ins. Corps.*, 419 U.S. 102, 138 (1974); *Mo. Roundtable for Life v. Carnahan*, 676 F.3d 665, 674 (8th Cir. 2012).

Ripeness is generally a two-pronged inquiry; the plaintiff must demonstrate both the "fitness of the issues for judicial decision" and some degree of "hardship to the parties of withholding court consideration." *Neb. Pub. Power Dist.*, 234 F.3d at 1038. A claim is not fit for review if the alleged injury "rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *281 Care Comm. v. Arneson*, 638 F.3d 621, 631 (8th Cir. 2011) (internal quotation omitted). Federal courts are especially careful of the ripeness requirement when asked to adjudicate the constitutionality of state laws. *Arizonans for Off. Eng. v. Arizona*, 520 U.S. 43, 79 (1997) ("Warnings against premature adjudication of constitutional questions bear heightened attention when a federal court is asked to invalidate a State's law."). Similarly, ripeness is often an obstacle in actions seeking a declaratory judgment. *See, e.g.*, *Pub. Water Supply Dist.*, 345 F.3d at 574; *State ex rel. Mo. Highway & Transp. Comm'n v. Cuffley*, 112 F.3d 1332, 1337-38 (8th Cir. 1997).

Ripeness must be established in a takings-based challenge to legislation. *Pennell*, 485 U.S. at 10. In *Pennell*, a landlord and a homeowners' association challenged a newly-enacted rent-control ordinance in San Jose. *Id.* at 4. Like the Act at issue here, the rent-control ordinance in *Pennell* included a provision to protect low-income residents from the dangers of a high-priced market; it required rent-control administrators to consider "hardship to a tenant" when deciding a landlord's request for a rent increase.

Id. at 5. The Supreme Court held that the takings challenge was premature. *Id.* at 9-10. The Court determined that the plaintiffs had not presented "a sufficiently concrete factual setting for the adjudication of the takings claim," because the challenged ordinance had not yet been applied in any rent-increase request. *Id.* at 10. The Court emphasized that, like most constitutional questions, a takings challenge is best decided "in an actual factual setting that makes such a decision necessary." *Id.*

PhRMA's takings claim, like the claim in *Pennell*, is premature because PhRMA has not alleged any actual impact from the Act, and PhRMA's anticipated injury is wholly contingent on future events. PhRMA's claim, to the extent that it states a potential takings injury, depends on a series of external factors "that may not occur as anticipated, and indeed may not occur at all." *281 Care Comm.*, 638 F.3d at 631. As illustrated by its title, the Act is designed as a safety net. Minn. Stat. § 151.74 ("Insulin safety net program"). It is intended to catch a small population of high-risk patients who, due to gaps in coverage, inaccessibility of insurance, and market forces, face life-threatening consequences from the high price of insulin. As a safety net, the Act is not sure to be utilized if the needs of Minnesota residents with diabetes are adequately met. In addition, eligible individuals with insurance can be directed through the manufacturers' own affordability programs if they better address the individual's insulin needs. *See* Minn. Stat. § 151.74, subd. 5(c). Thus, various conditions must be met before the safety net is triggered: people in need of insulin must apply through one of the programs, they must be determined to be eligible or win an appeal from a denial of eligibility, and they must not be diverted through the manufacturers' existing

affordability programs. Minn. Stat. § 151.74, subds. 2-5. PhRMA's alleged injury is contingent on a series of conditions and thus is unfit for judicial review.

Further, PhRMA has not shown that it will suffer hardship if the Court withholds consideration of its claim until it is ripe. *See Neb. Pub. Power Dist.*, 234 F.3d at 1038. Fulfilling the hardship prong requires more than the speculative possibility of sustaining an injury. *Pub. Water Supply Dist.*, 345 F.3d at 573. For the same reasons that PhRMA lacks standing to seek injunctive relief, it has not shown that hardship will result from withholding consideration. *See supra* Part II.B. PhRMA has failed to make the requisite showing that the injury it alleges is "direct, immediate, or certain to occur." *Pub. Water Supply Dist.*, 345 F.3d at 573. The claim of hardship is thus speculative and PhRMA's claim is not ripe.

The ripeness requirement applies also to facial challenges to legislation. Facial challenges are consistently disfavored in federal precedent. *See Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450 (2008). This is because "claims of facial invalidity often rest on speculation," and also run counter to the principle of judicial restraint by inviting courts to opine on constitutional questions that could be avoided. *Id.* "Refraining from 'premature' decisions on facial challenges is a proper exercise of judicial restraint." *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, 903 F.3d 750, 755 (8th Cir. 2018).

A facial takings challenge asserts that "the mere enactment of a statute constitutes a taking," while an as-applied challenge involves "a claim that the particular impact of a government action on a specific piece of property requires the payment of just

compensation." [12] *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 494 (1987). Facial challenges are generally ripe the moment the challenged statute is passed, although the proponent of a facial takings claim does face an "uphill battle" in proving their case. *See, e.g.*, *id.* at 495; *Suitum v. Tahoe Reg'l Plan. Agency*, 520 U.S. 725, 736 n.10 (1997). Because the basis of a facial takings challenge is that the statute's mere enactment has reduced the value of the property or has effected a transfer of a property interest, it is "a single harm measurable and compensable when the statute is passed." *Levald, Inc. v. City of Palm Desert*, 998 F.2d 680, 688 (9th Cir. 1993); *see also Hodel*, 452 U.S. at 295-96 (considering whether the "mere enactment" of a mining regulation constituted a taking by denying an owner "economically viable use of his land").

PhRMA's allegations do not constitute a facial challenge to the Act. PhRMA alleges that the Act's provisions requiring manufactures to provide insulin without compensation effects a series of takings; not a single taking measurable and compensable when the statute was passed. (Compl. ¶ 9, 82, 83, 85.) PhRMA does not allege that the "mere enactment" of the Act immediately deprived the manufacturers of their insulin. A takings injury does not occur until the actual property right has been affected. *Knick*, 139 S. Ct. at 2171. Whether the manufacturers will have to provide insulin under the Act

[12] The Court's decision in *Lingle v. Chevron,* 544 U.S. 528 (2005), which abrogated the "substantially advances" test announced in *Agins v. City of Tiburon*, 447 U.S. 255 (1980), arguably ended facial takings claims. *See Alto Eldorado P'ship v. Cty. of Santa Fe*, 634 F.3d 1170, 1175-1177 (10th Cir. 2011). Because PhRMA's allegations do not constitute a facial challenge even under the pre-*Lingle* standard, it is not necessary to delve further into the *Lingle* argument at this time.

depends on antecedent conditions, and thus PhRMA's takings claim is not a facial challenge and is not ripe.

PhRMA has not shown that its takings claim is fit for review or that hardship will result if this Court declines to adjudicate its unripe claim. Further, PhRMA's takings argument, based on an alleged potential future taking of personal property, is not a facial challenge that can be considered ripe upon filing. The Court should exercise its judicial restraint here and decline to address PhRMA's fundamentally unripe claim under the Takings Clause.

III. BECAUSE INSULIN MANUFACTURERS CAN SEEK LEGAL REMEDIES FOR THE ALLEGED TAKINGS, THE EQUITABLE RELIEF PHRMA SEEKS IS FORECLOSED AS A MATTER OF LAW.

PhRMA seeks a declaration from this Court that subdivisions 3(d) and 6(f) of the Act violate the Takings Clause of the Fifth Amendment and an order permanently enjoining enforcement of these subdivisions. These subdivisions require manufacturers subject to the Act to replace or reimburse pharmacies for insulin dispensed under the Act's urgent-need program and to provide insulin to pharmacies to dispense to eligible individuals under the continuing safety net program. PhRMA does not seek damages. As discussed above, Defendants are immune from suit and PhRMA lacks standing and ripeness to bring its takings claims. Even if PhRMA could overcome these jurisdictional deficiencies, however, its equitable claims necessarily fail because Minnesota provides just compensation remedies for takings through inverse condemnation.

A. Equitable Relief Is Unavailable for Takings Claims When Just Compensation Remedies Are Available.

An injunction or other equitable relief is inappropriate when there is an adequate remedy at law. *Taylor Corp. v. Four Seasons Greetings, LLC*, 403 F.3d 958, 967 (8th Cir. 2005); *see also eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (stating plaintiff seeking injunction must show legal remedies, such as damages, are inadequate). Inadequacy of legal remedies and irreparable harm have always been the basis for injunctive relief. *Watkins Inc.*, 346 F.3d at 844. Where injuries can be fully compensated through damages, there is no irreparable harm, and denial of an injunction is warranted. *See Gen. Motors Corp. v. Harry Brown's, LLC*, 563 F.3d 312, 319-20 (8th Cir. 2009). Accordingly, equitable relief is unavailable to property owners who have suffered a taking when a government provides just compensation remedies. *Knick*, 139 S. Ct. at 2176, 2179; *see also United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 127-128 (1985); *Ruckelshaus*, 467 U.S. at 1016.

In *Knick*, the Supreme Court recently held that injunctive relief on takings claims will be foreclosed if just compensation remedies are available 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." 139 S. Ct. at 2176. As such, the Court assured governments that federal courts will not invalidate their laws as unconstitutional against takings claims if the property owner has some way to obtain compensation after the fact. *Id*. at 2168, 2179. *Knick* involved a takings challenge to a township ordinance requiring all cemeteries—including those on private property—be kept open and accessible to the

public during the day, and allowing code-enforcement officers to enter any property to determine the existence and location of a cemetery. *Id*. at 2168. A property owner whose property allegedly contained a family cemetery brought a § 1983 claim seeking, among other things, declaratory and injunctive relief for her takings claim. *Knick v. Twp. of Scott*, 862 F.3d 310, 316 (3d Cir. 2017). The Third Circuit affirmed dismissal of Knick's takings claims for lack of ripeness under *Williamson County Regional Planning Commission v. Hamilton Bank of Johnson City*, 473 U.S. 172, (1985), which required property owners to seek just compensation under state law in state court before bringing a federal takings claim under § 1983. *Knick*, 139 S. Ct. at 2169. The Supreme Court overruled the state-litigation requirement of *Williamson County*, and held that a property owner may bring a takings claim against a local government in federal court upon the taking of his property without just compensation.[13] *Id*. at 2179.

In overruling *Williamson County*, the *Knick* Court recognized that for takings claims—given the availability of post-taking compensation and the fact that the federal and nearly all state governments provide just compensation remedies to property owners who have suffered a taking—equitable relief will ordinarily not be appropriate. *Id.* at 2176-77; *see also Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 71 n.15 (1978) (stating that declaratory judgment is permissible in takings actions only when

[13] *Knick* limited its holding to takings by local governments and did not address states' sovereign immunity.

"potentially *uncompensable* damages" may be sustained (emphasis added)).[14] The Court stressed that it was not exposing governments to new liability and that its holding will not lead federal courts to invalidate laws as unconstitutional so long as just compensation remedies are available. *Id*. at 2176, 2179.

B. Minnesota Provides Just Compensation Remedies for Takings.

Minnesota provides just compensation remedies to property owners whose property has been "taken" through inverse condemnation actions. *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)). In Minnesota, when a government has taken property without formally invoking its eminent-domain powers, an inverse condemnation action may be brought through a mandamus action. *Id.* In such an action, the court may determine whether a taking occurred and the compensation amount. *Id.* at 924.

PhRMA does not allege that Minnesota's procedures for seeking just compensation are inadequate. Nor have Minnesota's inverse condemnation procedures been determined to be inadequate. *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."). Accordingly, granting equitable relief to property owners who have suffered a compensable taking in Minnesota is inappropriate. *See Knick*, at 2176, 2179.

[14] In *Duke Power Co.* the Court declined to decide the takings issue because if a Tucker Act remedy would be available, the takings challenge would fail. 438 U.S. at 94 n.39.

C. PhRMA's Claims for Equitable Relief Fail Because Manufacturers May Seek Compensation Through Inverse Condemnation.

PhRMA's claims for declaratory and injunctive relief must be dismissed because the alleged takings would compensable through an inverse condemnation action in state court, if warranted. The Takings Clause does not prohibit the taking of private property for public use; it allows takings, but requires compensation for the property taken. Because manufacturers can be justly compensated for any insulin provided under the Act—if providing insulin constitutes a taking—PhRMA's claims for equitable relief fail as a matter of law.

PhRMA alleges that the state is "taking" insulin from manufacturers without compensation. PhRMA does not dispute that the alleged taking is for a public purpose as permitted under the Takings Clause. (*Id.* ¶¶ 2-3, 5.) Nor does PhRMA allege that manufacturers could not be compensated for any insulin they may provide under the Act. PhRMA alleges that the Act violates the Constitution because it fails to compensate manufacturers—so compensation would be the appropriate remedy to cure the alleged deficiency, not an injunction. If a taking occurs and compensation is constitutionally required, PhRMA's members could be justly compensated through damages. Regardless of the complex pricing schemes between manufacturers, pharmacy benefits managers, insurers, and pharmacies which impact the consumer's costs, insulin manufacturers know the cost of their insulin. (*See* Compl. ¶¶ 47, 49, 55.) Even if just compensation is difficult to ascertain, it is still the appropriate relief for takings claims. *See Carteret Sav. Bank, F.A. v. Office of Thrift Supervision,* 963 F.2d 567, 584 (3d Cir. 1992).

PhRMA alleges that equitable relief is appropriate because the Act effects repeated and continuous takings and forecloses the possibility of just compensation. (*Id.* ¶¶ 9, 85.) PhRMA claims that "a series of state court actions seeking to compel an inverse condemnation proceeding for each of the thousands of units of insulin that PhRMA's members must provide under the Act is not an appropriate or available remedy." (*Id.* ¶ 85.) The Court need not accept these flawed conclusions as true. The Act does not foreclose manufacturers from seeking compensation through an inverse condemnation action if a taking occurs. Although insulin manufacturers are not permitted to charge the individual receiving the insulin or the pharmacy dispensing the insulin, nothing in the Act forbids a manufacturer from bringing an inverse condemnation action. *See Ruckelshaus*, 467 U.S. 986 at 1017 (stating that a remedy for a taking arising from federal statute is available under Tucker Act unless statute has withdrawn the Tucker Act's grant of jurisdiction). The government does not need to provide compensation before a taking; if a property owner has some way to obtain compensation after the fact, the taking should not be enjoined. *Knick*, 139 S. Ct. at 2167-68.

Further, allegations that the takings are continuous do not preclude the availability of just compensation through monetary relief. Most regulatory laws will be continuous. That does not make equitable relief appropriate for takings claims. *See Nat'l Fuel Gas Distrib. Corp. v. N.Y. State Energy Rsch. & Dev. Auth.*, 265 F. Supp. 3d 286, 295 n.2 (W.D.N.Y. 2017) (rejecting argument that monetary relief is unavailable for continuous taking); *Rose Acre Farms, Inc. v. Madigan*, 956 F.2d 670, 673 (7th Cir. 1992) (holding that enjoining regulation barring certain egg sales was inappropriate because the Takings

Clause does not forbid takings, it requires compensation for them). In *Knick*, the challenged ordinance allowed continuous public access over the plaintiff's property during daylight hours. Irrespective of the continuous intrusion, the Court stressed that there is no basis to enjoin a government's action effecting a taking where just compensation remedies are available.

Further, as a practical matter, it is doubtful manufacturers would ever need to bring a series of state court actions as PhRMA alleges. A single inverse condemnation action would determine whether the Act effectuated a taking and, if so, the amount of compensation required for that taking, effectively providing the declaratory judgment sought here. The legislature would then have options: "Once a court determines that a taking has occurred, the government retains the whole range of options already available—amendment of the regulation, withdrawal of the invalidated regulation, or exercise of eminent domain." *First Eng.*, 482 U.S. at 321.

The Takings Clause does not proscribe the taking of property; it requires compensation for the taking. Here, if the Act effects a taking, the manufacturers can seek compensation through an inverse condemnation claim. Because adequate remedies at law are available, PhRMA's claims for equitable relief must fail. If the Constitution requires compensation, the proper remedy is to order payment, not to invalidate a law that provides life-saving medication to those who would otherwise be unable to obtain it. *See Rose Acre Farms,* 956 F.2d at 673 (reversing district court's invalidation of regulation because compensation was due).

IV. PHRMA'S DORMANT COMMERCE CLAUSE CLAIM SHOULD BE DISMISSED.

While focusing on its takings claim, PhRMA also asserts that, if interpreted a certain way, the Act is unconstitutional under the dormant Commerce Clause. (Compl. ¶¶ 87-89.) PhRMA alleges that, if subdivision 1(d)—the exemption for insulin products with low wholesale acquisition costs—"were interpreted to afford insulin manufacturers the 'option' of avoiding the unconstitutional taking of their property by lowering the WAC of their products to $8 per milliliter, the exemption is independently unconstitutional under the Commerce Clause." *Id.* ¶ 87. This auxiliary dormant commerce clause claim should also be dismissed, both because it is wholly dependent on the takings claim and because PhRMA lacks standing to assert it.

PhRMA's dormant commerce clause claim arises only if PhRMA's takings claim proceeds and subdivision 1(d) is interpreted as a saving provision. Thus, if PhRMA's takings claim is dismissed for any of the several independent reasons stated above, the Court should dismiss PhRMA's dormant commerce clause claim too. Without a justiciable takings claim, any decision on the remaining dormant commerce clause claim becomes little more than an advisory opinion. *See Boumediene v. Bush*, 553 U.S. 723, 805 (2008) ("Our precedents have long counseled us to avoid deciding such hypothetical questions of constitutional law.").

Further, PhRMA's dormant commerce clause claim suffers from the same justiciability defects as its takings claim. PhRMA lacks standing to assert its takings claim because the manufacturers' alleged injury is hypothetical and not certain to occur as anticipated. *See supra* Part II.B. Because PhRMA's dormant commerce clause claim

is wholly dependent on the existence of a Takings Clause violation, any allegation of injury giving rise to a claim under the Commerce Clause suffers from the same flaw. *See Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 777 (8th Cir. 2019) (stating, in dormant commerce clause case, that the plaintiff must state an injury that is "concrete, particularized, and either actual or imminent"). PhRMA makes no allegations that its members' decisions about the wholesale acquisition costs they set for their insulin products have changed as a result of subdivision 1(d) of the Act, nor that the Act will have an imminent impact on those decisions. *See FW/PBS, Inc.*, 493 U.S. at 231 ("[S]tanding cannot be inferred argumentatively from averments in the pleadings."); *PhRMA v. Brown*, 2018 WL 4144417, at *5 (holding that PhRMA lacked standing to challenge California law regulating price hikes because PhRMA "does not state that one of its members actually plans to make a pricing change"). Additionally, PhRMA's dormant commerce clause claim is dependent on a particular interpretation of a provision of the Act, and PhRMA states no facts showing that the legislature intended this interpretation or that it is likely to be employed. The dormant commerce clause claim is thus speculative and contingent in multiple ways, and PhRMA has not met its burden to show the claim is justiciable.

CONCLUSION

PhRMA's complaint seeks an unavailable remedy against parties who are immune from suit in federal court. Further, PhRMA lacks standing to bring its takings claim and the claim itself is premature. For these reasons, PhRMA's takings claim must be

dismissed, and its auxiliary dormant commerce clause claim dismissed with it. Accordingly, Defendants respectfully request that the Court dismiss PhRMA's complaint.

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