UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Pharmaceutical Research and Manufacturers of America,

Plaintiff,

v.

Ronda Chakolis, et al.,

Defendants.

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

DEFENDANTS' MEMORANDUM SUPPORTING MOTION TO DISMISS AMENDED COMPLAINT

The Court should dismiss PhRMA's amended complaint because it clings to a claim and an alleged harm that no longer exist. PhRMA started this case in 2020, alleging that the Alec Smith Insulin Affordability Act ("Act") violates the Takings Clause because its insulin-manufacturer members received no compensation for insulin provided under the Act. The legislature recently amended the Act, adding mechanisms to compensate manufacturers for any insulin they provide. Because the amendments addressed the infirmities PhRMA alleged, its claim is moot.

Rather than dismissing, PhRMA amended its complaint. Despite alleging an unconstitutional taking, PhRMA does not allege that the Act's compensation is inadequate for the insulin allegedly taken. It instead claims that the Act still effects a taking because a *different* law requires insulin manufacturers to pay an annual registration fee. PhRMA combines these laws to claim the fee "offsets" the compensation the manufacturers will receive, thereby invalidating the Act. PhRMA's "offset" theory fails. PhRMA further

lacks standing because it does not sufficiently allege a redressable harm or future injury. Accordingly, this Court should dismiss PhRMA's amended complaint.

FACTS

The Insulin Affordability Crisis

Without insulin, the more than 30 million Americans, including approximately 390,000 Minnesotans, who have diabetes will likely suffer organ damage and die. (Am. Compl. ¶ 31 [Doc. 150.]) PhRMA's members—Eli Lilly and Company, Novo Nordisk Inc., and Sanofi—manufacture most of the insulin sold in the United States. (*Id.* ¶ 16.) They have exploited their market control of this century-old-life-saving drug by increasing the cost of insulin by more than 1,200% over the past few decades.[1] The price increases were unrelated to any significant advances in the drugs' efficacy and dramatically exceeded rates of inflation.[2] Experts estimate that a vial of analog insulin can be profitably produced for between $2 and $18[3] and insulin treatment could cost as little $111 per year.[4] But some individual insulin vials retail for more than $300.[5] The rising insulin costs have caused

[1] Krans Decl., Exs. 1-4 [Docs. 68-1 to 68-4] (congressional report and articles on insulin pricing); Staff of S. Finance Comm., *Insulin*: *Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021) ("Senate Report"), https://perma.cc/HB4N-WNK4.
[2] *See,* Senate Report, *supra* note 1 at 5, 41.
[3] Doc. 68-3 at 5.
[4] Melissa J. Barber, et al., *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, JAMA NETWORK OPEN (March 27, 2024). https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2816824.
[5] Doc. 68-1 at 9.

roughly 25% of diabetes patients to ration their insulin.[6] And some patients—like Minnesotans Alec Smith and Jesimya David Scherer-Radcliff—died.[7]

During the four years since PhRMA commenced this lawsuit, the insulin pricing landscape has changed dramatically. Insulin pricing has been subject to numerous government investigations and lawsuits.[8] The Inflation Reduction Act limited the out-of-pocket costs that Medicare beneficiaries pay for insulin products to $35 per month. (Am. Compl. ¶ 57.) Also, the statutory cap on rebates drug manufactures pay to Medicaid was eliminated.[9] And, companies offering biosimilar insulins began entering the market.[10]

In response, the three big insulin manufactures have slashed insulin list prices by up to 78% and capped consumers' copays and out-of-pocket costs for insulin at $35 per month. (Am. Compl. ¶¶ 51-56; Second Krans Decl., Ex. 1 (manufacturers' press releases) [Doc. 111-1]; https://www.teamingupfordiabetes.com/sanofidiabetes-savings-program (last visited Oct. 23, 2024).) The manufacturers have also improved their own affordability programs by providing uninsured patients below certain income levels with free insulin.

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[6] Doc. 68-4 at 2.

[7] Doc. 68-1 at 6; 68-2 at 1; 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.

[8] *See, e.g.*, Senate Report, *supra* note 1; *In re Caremark Rx, LLC*, FTC Docket No. 9437 (2024); *In re Insulin Pricing Litig.*, No. 2:23-MD-03080 (D.N.J.); *Minn. by Ellison v. Sanofi-Aventis U.S. LLC*, No. 2:18-cv-14999-BRM-RLS (D.N.J.); *In re Insulin Pricing Litig.*, No. 2:17-cv-00699-BRM-RLS (D.N.J.).

[9] American Rescue Plan Act of 2021, Pub. Law No. 117-2, § 9816 (March 11, 2021).

[10] Mark C. Matli, et al., *The First Interchangeable Biosimilar Insulin: Insulin Glargine-yfgn*, 17(2) J DIABETES SCI TECH. 490-494 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10012380/pdf/10.1177_19322968211067511.pdf.

(Am. Compl. ¶¶ 53-55.) The manufacturers' income eligibility requirements for free insulin match the Act's requirements. *Id.*; Minn. Stat. § 151.74, subd. 4(b)(2). Novo Nordisk also provides a free, one-time, immediate supply of insulin to patients at risk of rationing their insulin. (*Id.*¶ 54.)

Further, Eli Lilly and Sanofi recently entered settlements regarding insulin pricing in Minnesota for the next five years. (*Id.*¶ 52; *Minn. by Ellison*, No. 2:18-cv-14999-BRM-RLS (Feb. 15, 2024 Order [Dkt 188, Eli Lilly]) (August 31, 2024 Order [Dkt 196, Sanofi] (D.N.J.)). Under the agreements, all Minnesotans—except those on a governmental health insurance program—may purchase a month's supply of Eli Lilly or Sanofi insulin products for just $35. Additionally, Eli Lilly will donate free insulin to certain clinics serving low-income Minnesotans and Sanofi will provide free insulin to Minnesotans with an annual household income of less than or equal to 400% of the federal poverty level.

The 2020 Alec Smith Insulin Affordability Act

In response to the insulin affordability crisis and the deaths of two young Minnesotans, Minnesota enacted the Alec Smith Insulin Affordability Act in 2020. 2020 Minn. Laws ch. 73, § 4, codified at Minn. Stat. § 151.74. The Act established 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. *Id.* Only insulin manufacturers that annually gross $2 million or more from insulin sales in Minnesota are subject to the Act. Minn. Stat. § 151.74, subd. 1(c). The Act also exempts insulin products with a wholesale acquisition cost ("WAC" or "list price") 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.[11] *Id.* subds. 2, 3. The pharmacist then dispenses a 30-day supply of the prescribed insulin. *Id.* subd. 3(c). The insulin's manufacturer must then either reimburse the pharmacy's acquisition costs for, or replace, the insulin dispensed. *Id.* subd. 3(d).

Under the continuing-safety-net program, insulin manufacturers must have patient-assistance programs to provide insulin to eligible Minnesotans.[12] *Id.* subd. 4. Eligibility is limited to Minnesotans who are both below certain income levels and otherwise lack affordable coverage through a private health plan or coverage through certain government programs. *Id.* subd. 4(b)-(c). Eligible individuals may apply directly to the manufacturer or through a health-care practitioner. *Id.* subd. 4(d). After confirming eligibility, the manufacturer gives the individual an eligibility statement, valid for 12 months,[13] that the individual submits to a pharmacy, which orders the prescribed insulin from the manufacturer. *Id.* subds. 5, 6(a)-(b). The manufacturer then sends the pharmacy a 90-day insulin supply, at no charge to the individual or the pharmacy. *Id*. subd. 6(c). The

[11] 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.

[12] Manufacturers may also have their own patient assistance programs separate from the program required by the Act.

[13] Manufacturers may also use their own co-payment assistance programs for privately insured individuals if the program better addresses the applicant's insulin needs. *Id.*, subd. 5(c).

pharmacy may continue submitting orders to the manufacturer while the individual's eligibility statement is active. *Id*. subd. 6(f). The pharmacy may collect a co-payment from the individual of $50 or less for each 90-day supply to cover its costs but may otherwise not charge for the insulin. *Id*. subd. 6(d), (e).

PhRMA's Original Lawsuit

In 2020, just before the Act became operational, PhRMA sued the Board of Pharmacy members, alleging that the Act created an unconstitutional taking by requiring insulin manufacturers to provide insulin without any compensation. (Compl. [Doc. 1], ¶¶ 82-83.) Rather than seek compensation, however, PhRMA sought declaratory and injunctive relief. (*Id.* at 28.)

This Court dismissed the complaint on jurisdictional grounds. (Doc. 81.) In April 2023, the Eighth Circuit reversed and remanded, holding that PhRMA stated a claim. *Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932, 950 (8th Cir. 2023) ("*PhRMA*"). Following disputes about the proper scope of discovery, the parties began the discovery phase in early 2024. (Doc. 133.)

Legislative Changes

In May 2024, the legislature amended the Act, adding provisions to reimburse manufacturers for any insulin they may provide under it. 2024 Minn. Laws ch. 127, art. 56, §§ 4-5, adding subds. 3(h) and 6(h) to Minn. Stat. § 151.74. Under the amendments, manufacturers may seek reimbursement from the Department of Administration, who must pay upon a proper request. *Id.* Reimbursements cannot exceed $35 for each 30-day supply—or $105 for each 90-day supply—of insulin the manufacturer provides under the

Act. *Id.* To give the Department time to develop a reimbursement process, manufacturers cannot submit requests until December 1. *Id.*; Grovall Decl. ¶ 3. But the Department will reimburse manufacturers for insulin provided during the entire fiscal year, which began July 1. (Gronvall Decl. ¶ 6.)

The legislature also established an insulin repayment account in the state treasury's special revenue fund. 2024 Minn. Laws ch. 127, art. 56, § 6, codified as Minn. Stat. § 151.741. Funds from the account are appropriated to the Department to reimburse manufacturers and cover the costs in providing the reimbursements. *Id.*, subd. 5. The account is funded from the health care access fund. *Id*.

Registration Fee

The legislature also recently enacted a law that, subject to some exemptions, requires insulin manufacturers to pay an annual registration fee of $100,000 beginning March 1, 2025. 2024 Minn. Laws ch. 127, art. 56, § 6 (Minn. Stat. § 151.741, subd. 2); Am. Compl. ¶¶ 81-82, 84. These fees will be exclusively deposited into a newly created insulin-safety-net-program account. 2024 Minn. Laws ch. 127, art. 56, § 6 (Minn. Stat. § 151.741, subds. 3(b), 4). Account funds will be appropriated to the MNsure and Pharmacy boards to fulfill their duties under the Act, which include educating people about the Act, training insurance navigators to assist individuals in accessing insulin programs, compiling a list of navigators, paying navigators for application assistance, conducting eligibility reviews, and ensuring compliance with the Act. *Id.* (Minn. Stat. § 151.741, subd. 4); Minn. Stat. § 151.74, subds. 7-8, 10, 13.

Amended Complaint

Although the Act now addresses the issue that was the impetus for PhRMA's complaint, PhRMA amended its complaint rather than dismiss it. PhRMA alleges that, at least until December 1, the Act still effects per se takings because manufacturers cannot request reimbursements until then. (Am. Compl. ¶¶ 89-90.) It further alleges that, despite the Act's new compensation mechanism, it still effects unconstitutional takings because the separate registration fee will "offset" any compensation received by the manufacturers. (*Id.* ¶¶ 92-93.) PhRMA does not allege that the Act's compensation of $35 per 30-day supply is insufficient or unjust. (*See generally* Am. Compl.) Nor does PhRMA allege that the registration fee is independently unlawful. (*Id*.)

Based on its single Takings Clause claim, PhRMA asks the Court to declare unconstitutional the Act's provisions requiring manufacturers to provide insulin and enjoin their enforcement. (*Id.* at 30.)Additionally, PhRMA seeks to enjoin the registration fee provisions in the new statute, Minn. Stat. § 151.741. (*Id.*)

ARGUMENT

A court should dismiss a complaint if it lacks subject-matter jurisdiction or if a party failed to state a claim for relief. Fed. R. Civ. P. 12(b)(1), (6). Both grounds apply here. PhRMA lacks standing because its claims are not redressable, and it fails to sufficiently allege an injury. PhRMA also fails to state a valid claim. By failing to allege that the Act does not provide just compensation, PhRMA failed to plead an essential element of its claim. And to the extent that PhRMA tries to invalidate the Act by bootstrapping in a

different law that imposes a financial obligation, its legal theory fails. The Court should dismiss the amended complaint.

I. PHRMA LACKS STANDING.

Federal courts have subject-matter jurisdiction only over "cases and controversies." U.S. Const. art. III, § 2. The plaintiff bears the burden of proving subject-matter jurisdiction. *Buckler v. United States*, 919 F.3d 1038, 1044 (8th Cir. 2019). When considering a factual attack on jurisdiction, courts may look outside the pleadings without converting the motion to summary judgment. *Moss v. United States*, 895 F.3d 1091, 1097 (8th Cir. 2018). The court must decide the jurisdictional issue, not simply rule whether sufficient evidence exists for a trial. *Buckler*, 919 F.3d at 1044.

To maintain a case or controversy, a plaintiff must have standing throughout the litigation. *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 601 (8th Cir. 2022). To have standing, a plaintiff must establish an injury in fact that is both fairly traceable to the defendant and redressable by the court. *Glow In One Mini Golf, LLC v. Walz*, 37 F.4th 1365, 1371 (8th Cir. 2022). The Court should dismiss PhRMA's amended complaint because PhRMA lacks standing for two independent reasons. First, PhRMA's claim is not redressable because its original assertion is moot and its equitable claims against the amended Act are foreclosed. Second, PhRMA does not sufficiently allege future harm.

A. PhRMA's Takings Claim Is Not Redressable.

Redressability focuses on whether the alleged injury is likely to be redressed through the litigation. *Sprint Comm'ns Co., L.P. v. APCC Services, Inc.*, 554 U.S. 269,

287 (2008). A plaintiff must show that it is likely, and not merely speculative, that its injury will be remedied by the relief it seeks. *Id.* at 273-74. PhRMA cannot do so here. PhRMA's original takings claim is moot and the equitable relief it seeks for the alleged takings under the amended Act is foreclosed. As such, this Court cannot redress PhRMA's alleged injury.

1. The Act's Amendment Renders PhRMA's Original Takings Claim Moot.

When a case no longer presents an actual, ongoing case or controversy, the case is moot, and the court must dismiss for lack of jurisdiction. *Glow In One*, 37 F.4th at 1371, *Hickman v. Missouri*, 144 F.3d 1141, 1142 (8th Cir. 1998). When a challenged law has been amended, actions seeking equitable relief for earlier versions are generally moot. *Teague v. Cooper*, 720 F.3d 973, 976 (8th Cir. 2013). This is true even though the legislature could reenact the law. *Id.* at 977.

PhRMA's original challenge to the Act is moot. PhRMA continues to allege a per se taking based on the Act's lack of a compensation mechanism for insulin provided under it until December 1. (Am. Compl. ¶¶ 89-90.) But the legislature has already amended the Act to provide exactly what PhRMA claimed it lacked: a compensation mechanism. *See* 2024 Minn. Laws, ch. 127, art. 56, §§ 4-5 (Minn. Stat. § 151.74, subds. 3(h), 6(h)). The December 1 effective date for submitting compensation requests does not affect mootness. A statutory change can moot a case even if the change is not yet effective. *See Moore v. Thurston*, 928 F.3d 753, 757 (8th Cir. 2019). And while reimbursement requests cannot be submitted until December 1, they will be processed to cover insulin provided dating

back to the beginning of the fiscal year, July 1. (Gronvall Decl. ¶ 6.) Because manufacturers will receive compensation for any insulin provided in the past approximately four months and for insulin provided moving forward, PhRMA's members face no threat of future or ongoing harm between now and December 1 or thereafter.

Declaring the Act invalid or enjoining its enforcement now based on PhRMA's original claim would be a purely advisory opinion; it would not benefit PhRMA's members or redress any injury. Accordingly, no case or controversy remains, and PhRMA's takings claim based on the Act not having a compensation mechanism must be dismissed.

2. Because the Act Provides Just Compensation, Injunctive Relief is Foreclosed.

PhRMA lacks standing because this Court cannot redress PhRMA's members' alleged injuries through the relief it requests. Under the Takings Clause, private property cannot be taken for public use without just compensation. U.S. Const. amend. V. The clause is not designed to limit governmental interference with property rights, but to secure compensation if an interference amounts to a taking. *See id.*; *First Eng. Evangelical Lutheran Church of Glendale v. Los Angeles Cty.*, 482 U.S. 304, 315 (1987). As such, when a property owner can obtain compensation, equitable relief to enjoin the taking is generally foreclosed. *See, e.g., Knick v. Twp. of Scott*, 588 U.S. 180, 185, 205 (2019). And the government need not compensate a taking in advance. *Id.* at 185 "So long as the property owner *has some way to obtain compensation after the fact*, governments need not fear that courts will enjoin their activities." *Id.* (emphasis added).

Because the Act now provides a mechanism for just compensation, *Knick* forecloses the equitable relief that PhRMA seeks. The Act provides manufacturers a plain, adequate, and complete remedy for any alleged "future takings" of their insulin. The Act's $35 per 30-day supply reimbursement is just, and PhRMA does not allege otherwise. To receive just compensation, manufacturers only must submit a proper request for reimbursement, and payment is made. 2024 Minn. Laws ch. 127, art. 56, §§ 4, 5 (Minn. Stat. § 151.74, subds. 3(h), 6(h)). Unlike the Act before its amendment, no inverse condemnation or other actions will be necessary for manufacturers to receive just compensation. Because the Act already provides manufacturers with the relief they would be entitled to under the Takings Clause—just compensation—this Court cannot redress PhRMA's members' alleged future injuries through the equitable relief it requests.

PhRMA is likely to argue that the Eighth Circuit's earlier decision leading to remand precludes dismissal. It does not. The court's decision was narrow and limited to the 2020 version of the Act. Based on the "specific context" of the allegations in PhRMA's 2020 complaint, the court applied a multiplicity-of-suits exception to *Knick*'s general rule. *PhRMA*, 64 F.4th at 945. The court held that PhRMA could pursue equitable relief because state law inverse-condemnation suits did not afford an adequate remedy "for the repetitive series of alleged takings under the Act." *Id.* at 945-46. On the face of the original complaint, the court concluded that the legal remedy provided by such suits was inadequate because PhRMA's members would be bound to litigate "a repetitive succession of inverse condemnation suits" to be compensated. *Id.* at 945.

The "specific context" on which the Eighth Circuit relied no longer exists. Over the past four years, this case's context has changed dramatically. Because the Act now includes compensation mechanisms, the appellate court's holding and reasoning regarding the *Knick* exception are inapposite. Now the manufactures will be justly compensated for any insulin provided under the Act upon request. As such, there will be no repetitive succession of inverse condemnation suits to obtain just compensation for insulin provided. PhRMA's allegations to the contrary are simply not plausible. (*See* Am. Compl. ¶ 94.)

B. PhRMA Fails to Allege a Real and Immediate Threat of Future Harm.

In addition to its claim lacking redressability, PhRMA fails to allege an injury in fact sufficient to confer standing. Because PhRMA seeks injunctive relief, it must show that it or its members face a real and immediate threat of ongoing or future harm to have standing. *See Frost v. Sioux City*, 920 F.3d 1158, 1161 (8th Cir. 2019); *Park v. Forest Serv. of U.S.*, 205 F.3d 1034, 1037 (8th Cir. 2000). Past exposure to alleged illegal conduct does not establish a present case or controversy for equitable relief if not accompanied by continuing effects. *O'Shea v. Littleton*, 414 U.S. 488, 495-96 (1974); *Frost*, 920 F.3d at 1161. Likewise, speculation and conjecture that a future injury may occur is insufficient to confer standing. *O'Shea*, 414 U.S. at 497. 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 lacks standing because it does not allege an injury that could confer it direct or associational standing. PhRMA is not a manufacturer subject to the Act, and it does not

sufficiently allege facts establishing that its members will provide any insulin under the Act in the future without just compensation.

As to direct standing, a plaintiff typically lacks standing when a law neither requires nor forbids any action by the plaintiff. *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009). PhRMA does not allege that the Act has, or will, directly affect it. It alleges only that it is "the pharmaceutical industry's principal public policy advocate." (Am. Compl. ¶ 15.) PhRMA is not an insulin manufacturer subject to the Act. (*See id.* ¶¶ 13-16.) No provision of the Act requires PhRMA to act or imposes any regulation or fine upon it. Thus, PhRMA lacks an injury in fact.

PhRMA next asserts standing as a representative of its members, the three big insulin manufacturers. (*Id.*¶ 16.) Relevant to this case, an organization may bring suit on behalf of its members only when "its members would otherwise have standing to sue in their own right." *Hunt v. Wash. State Apple Advertisement Comm'n,* 432 U.S. 333, 343 (1977). PhRMA's claim of associational standing fails this test because it does not plausibly allege that manufacturers will be subject to an uncompensated taking under the Act going forward. If a manufacturer was to provide insulin under the Act in the future, it would be justly compensated for it. Further, the future use of the Act is speculative given the recent changes with insulin's accessibility and affordability.

PhRMA broadly rests its associational standing on its members being "subject to the Act." (Am. Compl. ¶ 16.) But PhRMA must show that the manufacturers would have standing to sue, and it fails to allege any real and immediate threat of ongoing or future injury to its members. PhRMA alleges that its members provided insulin to Minnesota

residents under the Act beginning in 2020 without compensation. But it does not allege facts sufficient to show that the manufacturers will provide insulin under the Act in the *future* without just compensation, it merely makes conclusory statements. (*See id.* ¶¶ 9-12, 73-76.) That manufacturers provided insulin without compensation in the *past* is insufficient to establish standing for the equitable relief PhRMA seeks. *See O'Shea*, 414 U.S. at 495-96. And given the change in law and in the insulin landscape, the Court cannot infer from the amended complaint that the members will be subject to uncompensated takings under the Act in the immediate future. *See FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990).

PhRMA does not plausibly allege that the Act will fail to justly compensate manufacturers for any insulin they may provide under it going forward. The government violates the Takings Clause only if it fails to pay just compensation for the taking. *See First Eng.*, 482 U.S. at 315; *Knick*, 588 U.S. at 185. In an omission that speaks volumes, PhRMA does not allege that the Act's reimbursement amount is insufficient or unjust. (*See generally* Am. Comp.) Because the Act justly compensates manufacturers for any insulin provided, PhRMA fails to plausibly allege any future injury attributable to the Act.

Rather than challenge the adequacy of compensation the Act provides for the property allegedly taken, PhRMA claims an injury based on a different law requiring manufacturers to pay a registration fee beginning in March. *Id.* ¶¶ 10-11, 81-82, 92-93; 2024 Minn. Laws, ch. 127, art. 56, § 6 (Minn. Stat. § 151.741, subd. 2). As discussed below, PhRMA's claim necessarily fails. Regardless, any alleged injuries the manufacturers may suffer by paying the registration fee would be attributable to the

registration fee statute. It would not make the just compensation provided under the Act unjust. PhRMA fails to plausibly allege any future injury attributable to the Act.

Finally, recent developments in the insulin-pricing landscape further make the Act's future usage particularly speculative. The number of Minnesotans obtaining insulin under the Act declined each year. (Am. Compl. Exs. 1-4.) This decline has happened as manufacturers have improved their insulin pricing and programs. Since 2020, the insulin manufacturers have improved their affordability programs and recently capped copays and out-of-pocket costs for consumers at $35 a month, which is the same amount a patient may pay the pharmacy under the Act's urgent-need program. *Id.* ¶¶ 51-56; Doc. 111-1; Minn. Stat. § 151.74, subd. 3(b)(e). Minnesotans qualifying for the Act's programs now also qualify for free insulin through the manufacturer's programs. *Compare* Am. Compl. ¶¶ 52-56 *with* Minn. Stat. § 151.74, subds. 2, 4. Also, between May 2023 and January 2024, the insulin manufactures slashed insulin list prices, making some of their most prescribed insulin products exempt under the Act. *See* Doc. 111-1 (containing manufacturers' press releases on insulin pricing); Minn. Stat. § 151.74, subd. 1(d).

Further, beyond the broader national pricing changes, Eli Lilly and Sanofi both entered settlements this year that require them to provide all Minnesotans—except those on a governmental health insurance program—with their company's insulin products for just $35 per month's supply (or free if eligible) for the next five years, among other terms. *Minn. by Ellison*, No. 2:18-cv-14999-BRM-RLS (Feb. 15, 2024 Order), (Aug. 31, 2024 Order). The settlements have no income eligibility or urgent-need requirements. *Id.* Thus, Minnesotans either already can, or soon can, easily and cheaply obtain insulin under the

settlements. By answering just a few short questions, they can instantly download or electronically access a program card and use it to obtain a month's supply of insulin for $35. *Id.*; *see also* https://www.ag.state.mn.us/MNinsulin35/ (summarizing settlements) (last visited Oct. 21, 2024). This process is quicker and less cumbersome than qualifying under the Act. *Compare* Settlements *with* Minn. Stat. § 151.74, subds. 2-6.

The amended complaint is devoid of any non-conclusory, factual allegations of whether and when eligible individuals will apply for non-exempt insulin under the Act. Notably, it is also devoid of information on the amounts or types of insulin the manufacturers provided under the Act in 2024. PhRMA's standing theory rests entirely on speculation that eligible patients will apply for and receive insulin through the Act in the future rather than go through Minnesota's insulin settlements or the manufacturers' own programs. PhRMA simply has not shown a real and imminent risk that manufacturers will continue to provide insulin under the Act in the future.

II. PHRMA FAILS TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED.

A court must dismiss a complaint that fails to allege sufficient facts to state a plausible claim for relief; merely stating a "conceivable" claim is insufficient. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although a court must assume factual allegations are true, it need not accept a plaintiff's conclusory allegations or legal conclusions. *Id.* at 555*; Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). When considering a motion to dismiss, the court may consider materials that are part of the public record or do not contradict the complaint and materials that are necessarily embraced by the pleadings. *Glow in One*, 37 F.4th at 1370.

Despite alleging an unconstitutional taking, PhRMA does not dispute that the Act provides just compensation for the property allegedly taken. Rather, it attempts to invalidate the Act by pointing to the manufacturers' obligation to pay a registration fee under a different statute. It does not independently challenge the fee; instead, it attempts to "offset" the Act's compensation by the fee to argue the compensation is inadequate. Conflating two constitutional provisions does not render them both unconstitutional and subject to enjoinment. Further, even if the registration fee were invalid, it would not impact the Act's validity because the fee is severable under its enacting statute's terms. *See* 2024 Minn. Laws ch. 127, art. 56, § 6 (Minn. Stat. § 151.741, subd. 6). Because the Act provides just compensation for any insulin allegedly taken, PhRMA's takings claim fails as a matter of law.

A. PhRMA Fails to State a Takings Claim.

The government may take private property for public use if it provides just compensation. U.S. Const. amend. V; *First Eng.*, 482 U.S. at 315. Compensation need not be provided before a taking. *Knick*, 588 U.S. at 185. "As 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 201. A plaintiff who receives just compensation has no claim under the Takings Clause. *Id.* at 195.

PhRMA seeks only equitable relief in this action for the alleged future takings of the manufacturers' insulin products. (Am. Compl. at 27-30.) Given the Act's new compensation mechanisms, PhRMA's request for equitable relief under the Takings Clause necessarily fails.

Defendants dispute that the Act effects a taking requiring compensation. But even if the Act "takes" the manufacturers' insulin, PhRMA has no takings claim. The manufacturers will be justly compensated through the reimbursement mechanisms in the amended Act. 2024 Minn. Laws ch. 127, art. 56, §§ 4-5 (Minn. Stat. § 151.74, subds. 3(h), 6(h)). PhRMA does not allege that the Act's reimbursement amounts are inadequate. (*See generally* Am. Compl.) Because the Act contains adequate provisions for the manufacturers to obtain just compensation for any insulin provided under the it, PhRMA's takings claim fails as a matter of law.

B. The Registration Fee Does Not Render the Act's Compensation Inadequate.

PhRMA alleges that because a new law requires insulin manufacturers to pay an annual registration fee beginning in March 2025, they will be out money when combining that obligation with any compensation received under the Act. (*Id.* ¶¶ 92-93.) This "offset," PhRMA alleges, makes the Act's compensation inadequate. *Id.* PhRMA's offset theory lacks legal and factual support.

Having no legal basis to challenge either individually, PhRMA conflates the new annual registration fee with the amended Act's compensation provisions in attempt to invalidate both. Neither statute supports this interpretation. The Act's compensation and the registration fee are not substantively intertwined. Compensation to insulin manufactures under the Act is independent from, and not conditioned on, a manufacturer paying the registration fee. 2024 Minn. Laws ch. 127, art. 56, §§ 4-5 (Minn. Stat. § 151.74, subds. 3(h), 6(h)). Manufacturers will be reimbursed for any insulin provided on a rolling

basis as they seek it, beginning December 1, regardless of whether they pay the registration fee on March 1, 2025.[14] *Id.* Nor do the registration fees correlate to or fund the Act's reimbursements. The fee obligation is constant regardless of how much or how little insulin a manufacturer may provide under the Act. *Id.* § 6 (Minn. Stat. § 151.741, subd. 2.) The registration fees are deposited in a special account for the MNsure and Pharmacy boards to administer the Act; none of the registration fees are provided to the Administration Department to pay reimbursements. *Id.* (Minn. Stat. § 151.741, subds. 2-5). Additionally, if the registration fee is determined invalid, it does not affect the operation of—or reimbursements under—the Act. *Id.* (Minn. Stat. § 151.741, subd. 6). A person's separate financial obligation to the government does not render just compensation provided for a taking inadequate.

Further, the registration fee does not "take[] back" the just compensation provided by the Act. (*See* Am. Compl. ¶ 93.) The registration fee is an independent valid obligation, which PhRMA does not challenge as excessive or otherwise unconstitutional. Nor could PhRMA challenge the fee under the Takings Clause. *See e.g., E. Enters. v. Apfel*, 524 U.S. 498, 540 (1998) (Kennedy, J., concurring in part); *id*. at 554 (Breyer, J., dissenting) (holding no protected property interest exists in money under the Takings Clause); *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 615 (2013) (stating taxes and user fees are indisputably not takings). Insulin manufacturers' independent

[14] In fact, an insulin manufacturer subject to the Act may be exempt from paying the registration fee. *Compare* Minn. Stat. § 151.74, subd. 1(c), *with* 2024 Minn. Laws ch. 127, art. 56, § 6 (Minn. Stat. § 151.741, subd. 2(b)).

obligation to pay a valid fee does not reduce, offset, or invalidate the just compensation they will receive under the amended Act.

Even if the registration could be deemed invalid, it provides no basis to enjoin the Act. If invalid, the registration fee may be enjoined—not the Act— and the manufacturers' obligation to provide insulin under the Act would continue. PhRMA alleges the amended Act remains unconstitutional only because of the registration fee. But if the registration fee were to be enjoined as PhRMA requests, there would be no basis to enjoin the Act. Further, the legislature specifically severed the registration fee from the other provisions of Chapter 151. 2024 Minn. Laws ch. 127, art. 56, § 6 (Minn. Stat. § 151.741, subd. 6). By law, if the registration fee is held invalid, it does not affect other provisions of Chapter 151, including the Act.

PhRMA fails to state a takings claim upon which the relief requested could be granted. Accordingly, the amended complaint should be dismissed in its entirety.

CONCLUSION

Because the amended Act provides manufacturers with just compensation for any insulin provided under it, PhRMA lacks standing to bring its takings claim seeking equitable relief. Additionally, even if the Court reaches the merits, PhRMA's failure to plead that the Act's compensation is unjust is fatal to its takings claim. The manufacturers' separate obligation to pay a registration fee does not negate the Act's just compensation. The Court should dismiss the complaint in its entirety.

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