No. 24-1019

IN THE
UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Association for Accessible Medicines,

Plaintiff-Appellee,

vs.

Keith M. Ellison, in his official capacity as
Attorney General of the State of Minnesota,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of Minnesota
Honorable Patrick J. Schiltz, District Judge

APPELLANT'S ADDENDUM

GOODWIN PROCTER LLP
William M. Jay
Benjamin Hayes
Collin M. Grier
1900 N Street, N.W.
Washington, DC 20036
Telephone: (202) 346-4000
Facsimile: (202) 346-4444
wjay@goodwinlaw.com
bhayes@goodwinlaw.com
cgrier@goodwinlaw.com

ATTORNEYS FOR PLAINTIFF-APPELLEE
(continued on inside cover)

KEITH ELLISON
Attorney General
State of Minnesota

NICK PLADSON
Assistant Attorney General
Atty. Reg. No. 0388148

JASON PLEGGENKUHLE
Assistant Attorney General
Atty. Reg. No. 0391772

ATTORNEYS FOR DEFENDANT-APPELLANT
(continued on inside cover)

FELHABER LARSON
David L. Hashmall
200 South 6th Street, Suite 2200
Minneapolis, MN 55402
Telephone: (612) 339-6321
Facsimile: (612) 338-0535
dhashmall@felhaber.com

ATTORNEYS FOR PLAINTIFF-APPELLEE

NOAH LEWELLEN
Assistant Attorney General
Atty. Reg. No. 0397556

445 Minnesota Street, Suite 1400
St. Paul, MN 55101-2131
(651) 300-7083 (Voice)
(651) 296-7438 (Fax)
Nick.Pladson@ag.state.mn.us
Jason.Pleggenkuhle@ag.state.mn.us
Noah.Lewellen@ag.state.mn.us

ATTORNEYS FOR DEFENDANT-APPELLANT

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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, v. KEITH ELLISON, in his official capacity as Attorney General of the State of Minnesota, Defendant.	Case No. 23-CV-2024 (PJS/JFD) ORDER

William M. Jay and Benjamin T. Hayes, GOODWIN PROCTER LLP; David L. Hashmall and Brandon J. Wheeler, FELHABER LARSON, for plaintiff.

Nicholas J. Pladson, Noah Lewellen, and Jason T. Pleggenkuhle, MINNESOTA ATTORNEY GENERAL'S OFFICE, for defendant.

Plaintiff Association for Accessible Medicines ("AAM") is a trade association that represents manufacturers and distributors of generic and biosimilar medicines. AAM brings this action to challenge a new Minnesota law that regulates the price of generic and off-patent prescription drugs ("the Act"). *See* Laws of Minnesota 2023, ch. 57, art. 2 §§ 22–27, *to be codified at* Minn. Stat. §§ 62J.841–62J.846.

This matter is before the Court on AAM's motion for a preliminary injunction and the State's motion to dismiss AAM's complaint for failure to state a claim. For the

reasons that follow, AAM's motion is granted and the State's motion is granted in part and denied in part.

I. BACKGROUND

A. The Act

The Act, which took effect on July 1, 2023, *see* Minn. Stat. § 645.02, regulates the price of generic and off-patent prescription drugs.[1] Specifically, the Act provides as follows:

> No manufacturer shall impose, or cause to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state.

Minn. Stat. Ann. § 62J.842, subd. 1. An "excessive price increase" is defined mathematically as a certain dollar and percentage increase over various benchmarks. *See id.* subd. 2.

Notably, the provision applies only to manufacturers, not to anyone else in the supply chain. *See id.* subd. 1 (stating that "[n]o *manufacturer* shall impose" an excessive price increase (emphasis added)). Another provision states that "[i]t is not a violation of

[1]The record does not seem to reflect why the Minnesota Legislature targeted only generic and off-patent drugs, and not all drugs. One possible explanation is that the Federal Circuit has previously held that a similar price-control law directed at patented drugs was preempted by federal patent law. *See Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

this section for a wholesale distributor or pharmacy to increase the price of a generic or off-patent drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug." *Id.* subd. 3. Although this latter provision seems to imply that it *would* be "a violation of this section" for a distributor or pharmacy to increase the price of a generic drug when that increase was *not* "directly attributable" to an increase imposed by a manufacturer, the parties seem to agree that the Act does not regulate prices charged by anyone but manufacturers. In short, the focus of the Act is not on what Minnesota consumers *pay*, but on what manufacturers *charge*.

The state health commissioner is responsible for notifying the attorney general and the relevant manufacturer of any price increase that the commissioner believes is excessive under the Act. Minn. Stat. Ann. § 62J.844, subd. 1. Various other commissioners, agency officials, and state pharmacy-benefit contractors may also provide notice. *See id.* On receipt of such notice, the manufacturer must submit certain information relevant to costs and pricing to the attorney general, who may investigate whether a violation has occurred. *See id.* subd. 2. The Act provides for a civil penalty of up to $10,000 per day for each violation of § 62J.842. *See id.* subd. 3(a)(6). Finally, the Act imposes a $500,000 penalty on any manufacturer who withdraws a generic or off-

patent drug from sale or distribution within Minnesota for the purpose of avoiding the prohibition on excessive price increases in § 62J.842. *See* Minn. Stat. Ann. § 62J.845.

B. The Prescription Drug Market

Pharmaceutical manufacturers are the start of the drug-supply chain. Compl. ¶ 23. Manufacturers typically sell to large national wholesale distributors, who, in turn, resell to retail pharmacies, hospitals, and other healthcare facilities. Compl. ¶ 23. Generic and biosimilar manufacturers typically sell their products to wholesale distributors pursuant to pre-negotiated, long-term bulk contracts that cover a range of products for resale nationwide. Compl. ¶ 24. The vast majority of such sales occur outside of Minnesota. Compl. ¶ 26. None of AAM's generic or biosimilar manufacturer-members are located in Minnesota. Compl. ¶ 26. Similarly, the three largest wholesale distributors—who collectively control over 90% of the market—are all incorporated and headquartered outside of Minnesota. Compl. ¶ 26. In short, almost no one regulated by the Minnesota Act is actually present in Minnesota.

Manufacturers do not control the prices at which wholesalers or retailers sell their products, nor do they control where the products are ultimately resold. Compl. ¶ 24. Nevertheless, manufacturers have the most influence over prices because they establish a baseline price called the "wholesale acquisition cost" ("WAC"). Lewellen Ex. B at 3, 19. The prices at which wholesalers buy drugs from manufacturers—and the

prices at which wholesalers sell drugs to retailers—are based on the WAC. Lewellen Ex. A at 11, 23; *id.* Ex. B at 3, 19.

For a drug to be sold or otherwise distributed in Minnesota, the manufacturers and wholesalers at every step of the distribution chain must be licensed by the state. Minn. Stat. § 151.252, subd. 1(g); Minn. Stat. § 151.47, subd. 1a(f); Minn. R. 6800.1400, subp. 3. The annual licensure process for manufacturers appears to consist of filing a fairly basic form application and paying a relatively small fee. Minn. Stat. § 151.065; Howard Decl. ¶ 9 & Ex. B.

II. PRELIMINARY INJUNCTION

A. Standard of Review

In reviewing a motion for a preliminary injunction, a court must consider four factors: (1) the movant's likelihood of success on the merits; (2) the threat of irreparable harm to the movant if the injunction is not granted; (3) the balance between that harm and the harm that granting the injunction will inflict on the other parties; and (4) the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (en banc).

"Ordinarily, the movant must show only a 'fair chance' of success on the merits." *Eggers v. Evnen*, 48 F.4th 561, 565 (8th Cir. 2022) (citation omitted). But a party seeking to enjoin the implementation of a state statute must meet a higher standard by showing

that it is likely to succeed on the merits. *See Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 731–32 (8th Cir. 2008) (en banc). "A preliminary injunction is an extraordinary remedy, and the burden of establishing the propriety of an injunction is on the movant." *Watkins Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003) (citation omitted).

B. Likelihood of Success

In its first cause of action, AAM alleges that the Act is unconstitutional under the dormant Commerce Clause because it directly regulates transactions that take place wholly outside of Minnesota. The Court finds that AAM is likely to succeed on this claim.

The Commerce Clause grants Congress the power to regulate interstate commerce. U.S. Const. art. I, § 8, cl. 3. This grant of power to Congress also "contains a further, negative command, one effectively forbidding the enforcement of certain state economic regulations even when Congress has failed to legislate on the subject." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 368 (2023) (cleaned up). This negative command—known as the dormant Commerce Clause—limits state power in various ways. Among other limitations, the dormant Commerce Clause prohibits states from directly regulating out-of-state transactions. *See Edgar v. MITE Corp.*, 457 U.S. 624, 640–43 (1982) (plurality opinion); *see also Pork Producers*, 598 U.S. at 376 n.1 (noting that

Edgar "spoke to a law that *directly* regulated out-of-state transactions by those with *no* connection to the State").

Recently, in *Pork Producers*, the Supreme Court clarified that a state law does not necessarily violate the dormant Commerce Clause merely because its regulation of in-state activity has out-of-state *effects*. *Pork Producers*, 598 U.S. at 371–76. The State does not dispute, however, that *Pork Producers* did not change the rule that a state may not directly regulate transactions that take place wholly outside the state and have no connection to it. *See id.* at 376 n.1 (distinguishing *Edgar* because the law at issue in *Pork Producers* did not directly regulate out-of-state transactions); Hr'g Tr. 24–26 [ECF No. 39]. The State likewise concedes that the Act directly regulates extraterritorial sales of drugs. Hr'g Tr. 9. The only issue, then, is whether those transactions have a sufficient connection to Minnesota to give the Minnesota Legislature authority to regulate them.

As the Court noted at oral argument, the operative language in § 62J.842 is somewhat odd. It prohibits manufacturers from imposing (or causing to be imposed) "an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the *sale* of any generic or off-patent drug *sold, dispensed, or delivered* to any consumer in the state." (Emphasis added.) If § 62J.842 simply prohibited excessive price increases on the "sale" of any generic drug "sold" in

the state, one could plausibly read it as applying only to in-state sales. But the additional language referring to drugs "dispensed" or "delivered" within the state suggests that the initial "sale" that the Act regulates does not have to be the sale of a drug *in Minnesota*.

In response to the Court's queries, the State confirmed that this language subjects manufacturers to liability as a result of sales that take place wholly outside of Minnesota—say, the sale of a drug by a manufacturer in Colorado to a national distributor in New Jersey—so long as the drug in question is eventually "sold, dispensed, or delivered" by *anyone* to any consumer in Minnesota. Hr'g Tr. 3–5. The State further confirmed that this is true even if, say, the Colorado manufacturer has no control whatsoever over what is done with its drugs after they are sold to the New Jersey distributor. Hr'g Tr. 6. The State likewise confirmed that this is true even if the Colorado manufacturer does not *know* whether drugs its sells to the New Jersey distributor will ever make their way to Minnesota. Hr'g Tr. 6. Indeed, the State indicated that the Act imposes liability on manufacturers whose drugs wind up in Minnesota even if the manufacturer has done everything in its power to *prevent* its drugs from being resold in Minnesota. Hr'g Tr. 30–32.

The State contends that the Minnesota Legislature can impose liability on such manufacturers because the Act is not triggered unless and until a drug that the

manufacturer sells outside of Minnesota somehow makes its way to Minnesota. According to the State, that means that the manufacturer's initial sale outside of Minnesota (such as the Colorado manufacturer's sale to the New Jersey distributor)—even though it has no connection whatsoever to Minnesota at the time it occurs—will *acquire* a sufficient connection to Minnesota when someone else (even someone far down the supply chain, acting outside of the control or knowledge of the manufacturer or the distributor to whom the manufacturer sold the drug) sells, dispenses, or delivers the drug to any consumer in Minnesota.

The Court cannot find any support for the notion that the dormant Commerce Clause permits Minnesota to directly regulate a sale that occurs in another state simply because the product eventually makes its way into Minnesota. To the contrary, such an expansive notion of an individual state's power to regulate commerce occurring in other states was rejected by *Styczinski v. Arnold*, 46 F.4th 907 (8th Cir. 2022), in which the Eighth Circuit held that a Minnesota law regulating out-of-state bullion transactions violated the dormant Commerce Clause.

The statute at issue in *Styczinski* regulated "Minnesota transactions," which it defined as transactions:

> (1) by a dealer that is incorporated, registered, domiciled, or otherwise located in Minnesota;
>
> (2) by a dealer representative at a location in Minnesota;

> (3) between a dealer and a consumer who lives in Minnesota; or
>
> (4) between a dealer and a Minnesota consumer when the transaction involves:
>
> (i) delivering or shipping a bullion product to an address in Minnesota;
>
> (ii) delivering to or shipping from a precious metal depository on behalf of a Minnesota resident; or
>
> (iii) making payment to a consumer or receiving a payment from a consumer at an address in Minnesota, unless the transaction occurs when the consumer is at a business location outside of Minnesota.

Id. at 910 (quoting Minn. Stat. § 80G.01, subd. 5a). The Eighth Circuit found the statute invalid because "it applies Minnesota law to commerce wholly outside of Minnesota," such as, for example, a "transaction anywhere in the world between a bullion trader and a Minnesota resident." *Id.* at 913. Despite the fact that the statute regulated only transactions involving a Minnesota resident, the Eighth Circuit regarded the transactions as having an insufficient Minnesota connection to pass muster under the dormant Commerce Clause.

Here, the Minnesota connection is even weaker. Whereas the statute in *Styczinski* regulated only transactions that involved a dealer or resident who had a connection to

Minnesota, the Act in this case applies to out-of-state drug transactions between parties that have no connection whatsoever to Minnesota. The only requirement for such a transaction to be subject to the Act is that somehow, someday, in some way, someone who is *not* a party to the transaction must sell, dispense, or deliver the drug to any consumer in Minnesota. Under *Styczinski*, the Act's regulation of transactions with such an attenuated connection to Minnesota clearly violates the dormant Commerce Clause.

The State contends that, because manufacturers must be licensed in Minnesota in order for their drugs to be distributed here, manufacturers know that their drugs will eventually be distributed in Minnesota. But the one does not follow from the other. AAM offers evidence that its members sell most of their products in bulk via negotiated multi-drug contracts and do not control where the drugs are resold. Galownia Decl. ¶¶ 4–5; *see also* de Gavre Decl. ¶¶ 4–5. In other words, the evidence indicates that, while the manufacturers may know, in the abstract, that *some* of their drugs may wind up in Minnesota, they do not know *which* of their drugs will do so. Given that *Styczinski* found that out-of-state sales to actual Minnesota residents did not have a sufficient connection to Minnesota to be regulated by the Minnesota Legislature, the Court does not understand how a non-Minnesota manufacturer's knowledge that some of the drugs that it sells to a non-Minnesota distributor may someday find their way into

Minnesota could be sufficient to validate Minnesota's direct regulation of that out-of-state sale.

The State points to *Cotto Waxo Co. v. Williams*, 46 F.3d 790 (8th Cir. 1995), and *Swanson v. Integrity Advance, LLC*, 870 N.W.2d 90 (Minn. 2015), as examples of cases supporting a more expansive view of the connection between a state and an out-of-state transaction. Both of these cases are easily distinguishable, however, as both cases involved laws that directly regulated only *in-state* sales. *See Cotto Waxo*, 46 F.3d at 794 (explaining that the law at issue did not have an impermissible extraterritorial reach because it "is indifferent to sales occurring out-of-state" and "Cotto Waxo is able to sell to out-of-state purchasers regardless of Cotto Waxo's relationship to Minnesota"); *Integrity Advance*, 870 N.W.2d at 92 (explaining that the law at issue applied if the borrower was a Minnesota resident and completed the transaction while physically located in Minnesota). By contrast, while the Act at issue here is not triggered until there is a sale or distribution in Minnesota, the Act directly regulates—and, in fact, attaches potentially astronomical liability to—conduct that occurs wholly outside of Minnesota between parties with no connection to Minnesota.

Finally, the State compares the Act to the law upheld in *Pork Producers*. Again, however, *Pork Producers* is readily distinguishable. The California law at issue in *Pork Producers* prohibited business owners and operators from "knowingly engag[ing] in the

sale *within the state* of . . . [w]hole pork meat that the business owner or operator knows or should know is the meat of a covered animal who was confined in a cruel manner." Cal. Health & Safety Code § 25990(b)(2) (emphasis added); *Pork Producers*, 598 U.S. at 365–66, 376 n.1 (explaining that § 25990(b)(2) "regulates only products that companies choose to sell 'within' California").

Here, by contrast, the State admits that the Act directly regulates upstream sales that take place wholly outside of Minnesota and imposes liability on those engaged in those sales, even though neither the sales nor the contracting parties have any connection to Minnesota. The State contends that the laws are nevertheless comparable because the offending conduct in *Pork Producers*—animal cruelty—occurs outside of California. The crucial difference, however, is that the California law does not attempt to impose liability on out-of-state actors for engaging in out-of-state conduct; instead, it regulates in-state actors who engage in in-state conduct (specifically, in-state sales of meat that has been produced in a certain way).

Although the Minnesota Act is not comparable to the California law at issue in *Pork Producers*, the Act does closely resemble the Maryland law found invalid in *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018). True, the Maryland law could be triggered without an actual sale or distribution of a drug in Maryland, as long as the drug was "made available for sale" in Maryland. *Id.* at 671

(noting that the Maryland law's "plain language allows Maryland to enforce the Act against parties to a transaction that did not result in a single pill being shipped to Maryland"). In that sense, the Maryland law appears to have a slightly broader reach than the Act, which is not triggered until a drug is "sold, dispensed, or delivered to any consumer" in Minnesota.

As the Fourth Circuit went on to explain, however, "[e]ven if the Act did require a nexus to an actual sale in Maryland, it is nonetheless invalid because it still controls the price of transactions that occur wholly outside the state." *Id.* This is so, the Fourth Circuit said, because "[t]he Act, by its own terms, is not fixated on the price the Maryland consumer ultimately pays for the drug. Instead, the lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*"—sales which, the parties agreed, nearly always took place outside Maryland. *Id.*

That is exactly how the Act works here. Although the Act is not triggered until a sale or distribution occurs in Minnesota, "the lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*" and "the conduct the Act targets is the upstream pricing and sale of prescription drugs." *Id.* As a result, just as in *Frosh*, the Act "effectively seeks to compel manufacturers . . . to act in accordance with [Minnesota] law outside of [Minnesota]."

Id. at 672; *see also Pharm. Rsch. & Mfrs. of Am. v. Dist. of Columbia*, 406 F. Supp. 2d 56, 68–71 (D.D.C. 2005) (holding that a similar law violated the dormant Commerce Clause and rejecting the argument that the requirement of a downstream sale in the District was a sufficient connection), *aff'd sub nom. Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).

The Court also finds significant the fact that the Act imposes a $500,000 penalty on manufacturers who try to avoid the risk of incurring liability under the Act by prohibiting their drugs from being sold or distributed in Minnesota. *See* Minn. Stat. Ann. § 62J.845. This provision reinforces the impermissible extraterritorial nature of the Act, as it puts manufacturers between a rock and a hard place: As noted, a manufacturer could be subjected to liability for wholly out-of-state sales based on the decisions and actions of others over whom it has no control, yet it must incur a significant financial penalty if it chooses to avoid this state of affairs by (for example) selling only to distributors who promise not to distribute its drugs in Minnesota. (Apparently, the manufacturer will still be subject to liability for any distribution of its drugs in Minnesota that nevertheless occurs through no fault of the manufacturer.) The extraterritorial reach of the Act is therefore nearly unavoidable, as the only sure way for a manufacturer to avoid liability is to either stop selling drugs altogether or to sell *all* of

its drugs—including the vast majority that will never reach Minnesota—only at prices that comply with the Act.

Moreover, the fact that the Act penalizes manufacturers for choosing not to engage in commerce in Minnesota in order to avoid the Act is fundamentally at odds with dormant Commerce Clause jurisprudence, which often relies on the principle that anyone who wishes to avoid being subject to a state's economic regulation can simply avoid doing business in that state. *See Pork Producers*, 598 U.S. at 384 (plurality opinion) (noting that the plaintiffs had the choice to withdraw from the California market if they wished to avoid the challenged law); *id.* at 364 (noting that "[c]ompanies that *choose* to sell products in various States must normally comply with the laws of those various States" (emphasis added)). The Minnesota Legislature was unwilling to give manufacturers that freedom.

The Court therefore concludes that AAM is likely to prevail on its claim that the Act violates the dormant Commerce Clause insofar as it applies to out-of-state sales of drugs.

C. Threat of Irreparable Harm

Two of AAM's members offer evidence that, due to increased manufacturing costs, supply shortages, and other factors, they intended to raise prices on certain drugs in a manner that would violate the Act. Galownia Decl. ¶¶ 8–16; de Gavre Decl.

¶¶ 8–16. Due to the threat of incurring liability under the Act, the members have decided not to proceed with the intended price increases. Galownia Decl. ¶¶ 11, 16; de Gavre Decl. ¶ 16. There is no dispute that the financial injuries that the members will suffer as a result of forgoing the intended price increases are not recoverable from the State or anyone else. These members are therefore facing a threat of irreparable harm.[2] *See Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss, however, does qualify as irreparable harm.").

The State characterizes this threat as speculative and unsupported. In particular, the State contends that the members have offered no evidence that the factors they cite (such as increased costs) require price increases that would violate the Act. It is not clear to the Court why that matters, however. The fact remains that, according to the

[2]The State argues that one of these AAM members, Teva Pharmaceuticals USA, Inc. ("Teva"), is not currently licensed in Minnesota and therefore distribution of Teva's drugs in Minnesota would violate Minnesota law no matter the price. In response, however, Teva points out that (1) one of the drugs whose price it intended to increase is manufactured at a foreign facility, Galownia Decl. ¶ 8, and the licensing requirement therefore does not apply, *see* Howard Decl. ¶ 9, Ex. B at 1 (stating an exception to the licensing requirement "if the manufacturer is located outside of the United States or its territories"), and (2) the other drug whose price it intended to increase is manufactured at a facility operated by a Teva subsidiary that, at least according to AAM's briefing, is licensed in Minnesota, Galownia Decl. ¶ 13; Savage Decl. ¶¶ 1–2. (The Court notes that, although there does not appear to be record evidence of the subsidiary's licensure, the State does not seem to dispute that it is licensed. The Court likewise notes that, while the State points out that "manufacturing" includes packaging and labeling, ECF No. 36 at 4 n.4, the State does not contend that Teva performs those functions for the drugs at issue.)

evidence before the Court, the members are refraining from implementing planned price increases to avoid incurring liability under the Act. Whether or not such price increases are the result of increased costs, supply shortages, or other factors is simply irrelevant to the members' potential liability under the Act. Moreover, even if a lower price increase that complied with the Act would cover any increased manufacturing costs, such a course of action would still result in irreparable harm in the form of unrecoverable lost revenue.

The State also contends that the members cannot show a threat of irreparable harm absent a showing that enforcement is imminent. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 382 (1992) ("In suits such as this one, which the plaintiff intends as a 'first strike' to prevent a State from initiating a suit of its own, the prospect of state suit must be imminent, for it is the prospect of that suit which supplies the necessary irreparable injury."). The Supreme Court has recognized, however, that a plaintiff has standing to "bring a preenforcement suit when he has alleged an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 160 (2014) (citation and quotation marks omitted). And the Supreme Court has applied this principle in the context of granting injunctive relief pending final disposition of the case. *See, e.g., Roman Cath. Diocese of*

Brooklyn v. Cuomo, 141 S. Ct. 63, 68 (2020) (per curiam) (citing *Susan B. Anthony List*); *see also Rogers Grp., Inc. v. City of Fayetteville*, 629 F.3d 784, 785, 789–90 (8th Cir. 2010) (affirming preliminary injunction in preenforcement suit alleging that a municipality's ordinance was beyond its powers under state law and finding a sufficient threat of irreparable harm where the plaintiff "admit[ted] that the Quarry currently operated at a level the Ordinance permitted" but "testified that the Ordinance would prevent the Quarry from expanding").

D. The Balance of Harms and the Public Interest

The remaining *Dataphase* factors are essentially a wash. While AAM offers evidence that two of its members are facing a threat of irreparable harm, the magnitude of that threatened harm is unclear. At the same time, although the Court does not doubt that, as a general matter, Minnesota consumers face harm from excessive price increases on generic medication, the record on this issue is not well developed; in particular, it is far from clear how much of this harm the Act would prevent, given that it does not regulate price increases by anyone in the supply chain but manufacturers, and given that it does not regulate the price charged to Minnesota consumers.

With respect to the public interest: On the one hand, "it is always in the public interest to protect constitutional rights." *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020) (per curiam) (citation omitted). On the other hand, "governmental policies

implemented through legislation or regulations developed through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined lightly." *Planned Parenthood Minn., N.D., S.D.*, 530 F.3d at 732 (citation omitted).

In sum, AAM has established that it is highly likely to succeed on the merits, and likelihood of success on the merits is "[t]he most important of the *Dataphase* factors." *Shrink Mo. Gov't PAC v. Adams*, 151 F.3d 763, 764 (8th Cir. 1998); *see also Sleep No. Corp. v. Young*, 33 F.4th 1012, 1016 (8th Cir. 2022) ("the third factor—probability of success—is the most significant"). Because AAM is likely to prevail, and because AAM has established at least some threat of irreparable harm, the Court will grant AAM's motion for a preliminary injunction.

E. Security

Under Fed. R. Civ. P. 65(c), "[t]he court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." AAM asks that it not be required to post security, ECF No. 22, and the State has not objected to that request. Accordingly, the Court will not require AAM to post security. *See Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Eng'rs*, 826 F.3d 1030, 1043 (8th Cir. 2016) ("Courts in this circuit have

almost always required a bond before issuing a preliminary injunction, but exceptions have been made where the State has not objected to the failure to require a bond or where the damages resulting from a wrongful issuance of an injunction have not been shown." (citation omitted)).

III. MOTION TO DISMISS

A. Standard of Review

In reviewing a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a court must accept as true all of the factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *See Perez v. Does 1–10*, 931 F.3d 641, 646 (8th Cir. 2019). Although the factual allegations need not be detailed, they must be sufficient to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must "state a claim to relief that is plausible on its face." *Id.* at 570.

B. Analysis

As the Court has found that AAM is likely to succeed on the merits of its first cause of action, the Court will deny the State's motion to dismiss that claim. Likewise, the Court will deny the State's motion to dismiss AAM's fourth cause of action, which alleges that the Act runs afoul of the dormant Commerce Clause under the balancing test set forth in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).

The State argues that, under *Pork Producers*, a plaintiff must allege discrimination against interstate commerce to state a plausible *Pike* claim. The Court does not agree. The hopelessly fractured nature of the opinions in *Pork Producers* makes the holding of the case difficult to identify, but a majority of the Justices acknowledged that the "Court has left the courtroom door open to [*Pike*] challenges premised on even nondiscriminatory burdens." *Pork Producers*, 598 U.S. at 379 (cleaned up); *see also id.* at 392 (Sotomayor and Kagan, JJ., concurring in part) ("*Pike* claims that do not allege discrimination or a burden on an artery of commerce are further from *Pike*'s core. As THE CHIEF JUSTICE recognizes, however, the Court today does not shut the door on all such *Pike* claims."); *id.* at 395–96 (Roberts, Alito, Kavanaugh, and Jackson, JJ., concurring in part and dissenting in part) ("As a majority of the Court acknowledges, 'we generally leave the courtroom door open to plaintiffs invoking the rule in *Pike*, that even nondiscriminatory burdens on commerce may be struck down on a showing that those burdens clearly outweigh the benefits of a state or local practice.'" (citation omitted)).

The State contends that, under *Pork Producers*, the only nondiscrimination claims that remain viable are those challenging alleged burdens on the instrumentalities of interstate commerce (such as trains and trucks). If that were true, though, the Supreme Court could have issued a very brief opinion affirming the dismissal of the plaintiffs'

complaint in *Pork Producers*, as the plaintiffs expressly disavowed any claim of discrimination, *id.* at 370–71, and as the plaintiffs were not challenging any burden on the instrumentalities of interstate commerce. Instead, a majority of the Court agreed that the plaintiffs had failed to state a claim under *Pike*, but they disagreed as to why, with a plurality opining that the plaintiffs had failed to plausibly plead a substantial burden on interstate commerce, *id.* at 383–87, and with three justices opining that *Pike* does not allow courts to strike down laws that regulate only in-state sales of ordinary consumer goods, *id.* at 380–83. Ultimately, however, a majority agreed on the more abstract premise that the plaintiffs' claim failed because the *Pike* line of cases has never "prevent[ed] a State from regulating the sale of an ordinary consumer good within its own borders on nondiscriminatory terms." *Id.* at 391.

As discussed above, this case differs from *Pork Producers* in a crucial respect: Unlike the California law at issue in *Pork Producers*, the Minnesota Act at issue here directly regulates out-of-state transactions. Indeed, based on AAM's allegations, it appears that the vast majority of the transactions that the Act regulates occur outside of Minnesota. In the Court's view, these facts give rise to a plausible claim under *Pike*, and nothing in *Pork Producers* suggests otherwise. And because AAM has pleaded a plausible *Pike* claim, the Court will permit AAM's due-process claim to proceed, as that

claim appears similar to AAM's *Pike* claim, and the Court would prefer to assess both claims on a full record.

The Court will, however, dismiss AAM's third and fifth causes of action. In its third cause of action, AAM alleges that the Act violates the Constitution's horizontal separation of powers. But the Court is unaware of any case applying this concept as a standalone cause of action separate from other express constitutional provisions. The third cause of action is therefore dismissed. AAM's fifth cause of action is also dismissed, as it simply cites 42 U.S.C. §§ 1983 and 1988 and requests various forms of relief, and thus it duplicates other claims.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. Plaintiff's motion for a preliminary injunction [ECF No. 14] is GRANTED.

2. Defendant, and all of his officers, agents, servants, employees, and attorneys, and all persons in active concert or participation with him, are ENJOINED from enforcing, or taking any other action under, Laws of Minnesota 2023, ch. 57, art. 2 §§ 22–23, 25–26, *to be codified at* Minn. Stat. §§ 62J.841–62J.842, 62J.844–62J.845, against any of plaintiff's members, or

any of the members' agents, privies, or licensees, based on any member's sale of generic or off-patent drugs outside of Minnesota.

3. Defendant's motion to dismiss [ECF No. 23] is GRANTED IN PART and DENIED IN PART as follows:

   a. The motion is GRANTED as to plaintiff's third and fifth causes of action, and those claims are DISMISSED WITHOUT PREJUDICE.

   b. The motion is DENIED in all other respects.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: December 4, 2023

s/Patrick J. Schiltz
Patrick J. Schiltz, Chief Judge
United States District Court

UNITED STATES DISTRICT COURT
District of Minnesota

Association for Accessible Medicines

Plaintiff,

v.

Keith Ellison

Defendant.

JUDGMENT IN A CIVIL CASE

Case Number: 23-cv-02024-PJS-JFD

☐ **Jury Verdict**. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

☒ **Decision by Court**. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED THAT:

1. Plaintiff's motion for a preliminary injunction [ECF No. 14] is GRANTED.

2. Defendant, and all of his officers, agents, servants, employees, and attorneys, and all persons in active concert or participation with him, are ENJOINED from enforcing, or taking any other action under, Laws of Minnesota 2023, ch. 57, art. 2 §§ 22–23, 25–26, *to be codified at* Minn. Stat. §§ 62J.841–62J.842, 62J.844–62J.845, against any of plaintiff's members, or any of the members' agents, privies, or licensees, based on any member's sale of generic or off-patent drugs outside of Minnesota.

3. Defendant's motion to dismiss [ECF No. 23] is GRANTED IN PART and DENIED IN PART as follows:

   a. The motion is GRANTED as to plaintiff's third and fifth causes of

action, and those claims are DISMISSED WITHOUT PREJUDICE.

b. The motion is DENIED in all other respects.

Date: 12/4/2023 KATE M. FOGARTY, CLERK

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Warren E. Burger Federal Building and U.S. Courthouse
316 North Robert Street
Room 100
St. Paul, MN 55101

Diana E. Murphy U.S. Courthouse
300 South Fourth Street
Room 202
Minneapolis, MN 55415

Gerald W. Heaney Federal Building and U.S. Courthouse and Customhouse
515 West First Street
Duluth, MN 55802

Edward J. Devitt U.S. Courthouse and Federal Building
118 South Mill Street
Fergus Falls, MN 56537

CIVIL NOTICE

The appeal filing fee is $505.00. If you are indigent, you can apply for leave to proceed in forma pauperis, ("IFP").

The purpose of this notice is to summarize the time limits for filing with the District Court Clerk's Office a Notice of Appeal to the Eighth Circuit Court of Appeals or the Federal Circuit Court of Appeals (when applicable) from a final decision of the District Court in a civil case.

This is a summary only. For specific information on the time limits for filing a Notice of Appeal, review the applicable federal civil and appellate procedure rules and statutes.

Rule 4(a) of the Federal Rules of Appellate Procedure (Fed. R. App. P.) requires that a Notice of Appeal be filed within:

1. Thirty days (60 days if the United States is a party) after the date of "entry of the judgment or order appealed from;" or
2. Thirty days (60 days if the United States is a party) after the date of entry of an order denying a timely motion for a new trial under Fed. R. Civ. P. 59; or
3. Thirty days (60 days if the United States is a party) after the date of entry of an order granting or denying a timely motion for judgment under Fed. R. Civ. P. 50(b), to amend or make additional findings of fact under Fed. R. Civ. P. 52(b), and/or to alter or amend the judgment under Fed. R. Civ. P. 59; or
4. Fourteen days after the date on which a previously timely Notice of Appeal was filed.

If a Notice of Appeal is not timely filed, a party in a civil case can move the District Court pursuant to Fed. R. App. P. 4(a)(5) to extend the time for filing a Notice of Appeal. This motion must be filed no later than 30 days after the period for filing a Notice of Appeal expires. If the motion is filed after the period for filing a Notice of Appeal expires, the party bringing the motion must give the opposing parties notice of it. The District Court may grant the motion, but only if excusable neglect or good cause is shown for failing to file a timely Notice of Appeal.

(8) if the proposal applies to a qualified health plan as defined in section 62A.011, subdivision 7, the cost to the state to defray the cost of the mandated health benefit proposal using commercial market reimbursement rates in accordance with Code of Federal Regulations, title 45, section ~~155.70~~ 155.170.

(c) The commissioner shall consider actuarial analysis done by health plan companies and any other proponent or opponent of the mandated health benefit proposal in determining the cost of the proposal.

(d) The commissioner must summarize the nature and quality of available information on these issues, and, if possible, must provide preliminary information to the public. The commissioner may conduct research on these issues or may determine that existing research is sufficient to meet the informational needs of the legislature. The commissioner may seek the assistance and advice of researchers, community leaders, or other persons or organizations with relevant expertise. The commissioner must provide the public with at least 45 days' notice when requesting information pursuant to this section. The commissioner must notify the chief authors of a bill when a request for information is issued.

(e) Information submitted to the commissioner pursuant to this section that meets the definition of trade secret information, as defined in section 13.37, subdivision 1, paragraph (b), is nonpublic data.

Sec. 22. **[62J.841] DEFINITIONS.**

Subdivision 1. **Scope.** For purposes of sections 62J.841 to 62J.845, the following definitions apply.

Subd. 2. **Consumer Price Index.** "Consumer Price Index" means the Consumer Price Index, Annual Average, for All Urban Consumers, CPI-U: U.S. City Average, All Items, reported by the United States Department of Labor, Bureau of Labor Statistics, or its successor or, if the index is discontinued, an equivalent index reported by a federal authority or, if no such index is reported, "Consumer Price Index" means a comparable index chosen by the Bureau of Labor Statistics.

Subd. 3. **Generic or off-patent drug.** "Generic or off-patent drug" means any prescription drug for which any exclusive marketing rights granted under the Federal Food, Drug, and Cosmetic Act, section 351 of the federal Public Health Service Act, and federal patent law have expired, including any drug-device combination product for the delivery of a generic drug.

Subd. 4. **Manufacturer.** "Manufacturer" has the meaning given in section 151.01, subdivision 14a, but does not include an entity that must be licensed solely because the entity repackages or relabels drugs.

Subd. 5. **Prescription drug.** "Prescription drug" means a drug for human use subject to United States Code, title 21, section 353(b)(1).

Subd. 6. **Wholesale acquisition cost.** "Wholesale acquisition cost" has the meaning provided in United States Code, title 42, section 1395w-3a.

Subd. 7. **Wholesale distributor.** "Wholesale distributor" has the meaning provided in section 151.441, subdivision 14.

Sec. 23. **[62J.842] EXCESSIVE PRICE INCREASES PROHIBITED.**

Subdivision 1. **Prohibition.** No manufacturer shall impose, or cause to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state.

Subd. 2. **Excessive price increase.** A price increase is excessive for purposes of this section when:

(1) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds:

(i) 15 percent of the wholesale acquisition cost over the immediately preceding calendar year; or

(ii) 40 percent of the wholesale acquisition cost over the immediately preceding three calendar years; and

(2) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds $30 for:

(i) a 30-day supply of the drug; or

(ii) a course of treatment lasting less than 30 days.

Subd. 3. **Exemption.** It is not a violation of this section for a wholesale distributor or pharmacy to increase the price of a generic or off-patent drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug.

Sec. 24. **[62J.843] REGISTERED AGENT AND OFFICE WITHIN THE STATE.**

Any manufacturer that sells, distributes, delivers, or offers for sale any generic or off-patent drug in the state must maintain a registered agent and office within the state.

Sec. 25. **[62J.844] ENFORCEMENT.**

Subdivision 1. **Notification.** (a) The commissioner of health shall notify the manufacturer of a generic or off-patent drug and the attorney general of any price increase that the commissioner believes may violate section 62J.842.

(b) The commissioner of management and budget and any other state agency that provides or purchases a pharmacy benefit except the Department of Human Services, and any entity under contract with a state agency to provide a pharmacy benefit other than an entity under contract with the Department of Human Services, may notify the manufacturer of a generic or off-patent drug and the attorney general of any price increase that the commissioner or entity believes may violate section 62J.842.

Subd. 2. **Submission of drug cost statement and other information by manufacturer; investigation by attorney general.** (a) Within 45 days of receiving a notice under subdivision 1, the manufacturer of the generic or off-patent drug shall submit a drug cost statement to the attorney general. The statement must:

(1) itemize the cost components related to production of the drug;

(2) identify the circumstances and timing of any increase in materials or manufacturing costs that caused any increase during the preceding calendar year, or preceding three calendar years as applicable, in the price of the drug; and

(3) provide any other information that the manufacturer believes to be relevant to a determination of whether a violation of section 62J.842 has occurred.

(b) The attorney general may investigate whether a violation of section 62J.842 has occurred, in accordance with section 8.31, subdivision 2.

Subd. 3. **Petition to court.** (a) On petition of the attorney general, a court may issue an order:

(1) compelling the manufacturer of a generic or off-patent drug to:

(i) provide the drug cost statement required under subdivision 2, paragraph (a); and

(ii) answer interrogatories, produce records or documents, or be examined under oath, as required by the attorney general under subdivision 2, paragraph (b);

(2) restraining or enjoining a violation of sections 62J.841 to 62J.845, including issuing an order requiring that drug prices be restored to levels that comply with section 62J.842;

(3) requiring the manufacturer to provide an accounting to the attorney general of all revenues resulting from a violation of section 62J.842;

(4) requiring the manufacturer to repay to all Minnesota consumers, including any third-party payers, any money acquired as a result of a price increase that violates section 62J.842;

(5) notwithstanding section 16A.151, requiring that all revenues generated from a violation of section 62J.842 be remitted to the state and deposited into a special fund, to be used for initiatives to reduce the cost to consumers of acquiring prescription drugs, if a manufacturer is unable to determine the individual transactions necessary to provide the repayments described in clause (4);

(6) imposing a civil penalty of up to $10,000 per day for each violation of section 62J.842;

(7) providing for the attorney general's recovery of costs and disbursements incurred in bringing an action against a manufacturer found in violation of section 62J.842, including the costs of investigation and reasonable attorney's fees; and

(8) providing any other appropriate relief, including any other equitable relief as determined by the court.

(b) For purposes of paragraph (a), clause (6), every individual transaction in violation of section 62J.842 is considered a separate violation.

Subd. 4. **Private right of action.** Any action brought pursuant to section 8.31, subdivision 3a, by a person injured by a violation of section 62J.842 is for the benefit of the public.

Sec. 26. **[62J.845] PROHIBITION ON WITHDRAWAL OF GENERIC OR OFF-PATENT DRUGS FOR SALE.**

Subdivision 1. **Prohibition.** A manufacturer of a generic or off-patent drug is prohibited from withdrawing that drug from sale or distribution within this state for the purpose of avoiding the prohibition on excessive price increases under section 62J.842.

Subd. 2. **Notice to board and attorney general.** Any manufacturer that intends to withdraw a generic or off-patent drug from sale or distribution within the state shall provide a written notice of withdrawal to the attorney general at least 90 days prior to the withdrawal.

Subd. 3. **Financial penalty.** The attorney general shall assess a penalty of $500,000 on any manufacturer of a generic or off-patent drug that the attorney general determines has failed to comply with the requirements of this section.

Sec. 27. **[62J.846] SEVERABILITY.**

If any provision of sections 62J.841 to 62J.845 or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions

or any other application of sections 62J.841 to 62J.845 that can be given effect without the invalid provision or application.

Sec. 28. **[62J.85] CITATION.**

Sections 62J.85 to 62J.95 may be cited as the "Prescription Drug Affordability Act."

Sec. 29. **[62J.86] DEFINITIONS.**

Subdivision 1. **Definitions.** For the purposes of sections 62J.85 to 62J.95, the following terms have the meanings given.

Subd. 2. **Advisory council.** "Advisory council" means the Prescription Drug Affordability Advisory Council established under section 62J.88.

Subd. 3. **Biologic.** "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under Code of Federal Regulations, title 42, section 447.502.

Subd. 4. **Biosimilar.** "Biosimilar" has the meaning provided in section 62J.84, subdivision 2, paragraph (b).

Subd. 5. **Board.** "Board" means the Prescription Drug Affordability Board established under section 62J.87.

Subd. 6. **Brand name drug.** "Brand name drug" means a drug that is produced or distributed pursuant to:

(1) a new drug application approved under United States Code, title 21, section 355(c), except for a generic drug as defined under Code of Federal Regulations, title 42, section 447.502; or

(2) a biologics license application approved under United States Code, title 45, section 262(a)(c).

Subd. 7. **Generic drug.** "Generic drug" has the meaning provided in section 62J.84, subdivision 2, paragraph (e).

Subd. 8. **Group purchaser.** "Group purchaser" has the meaning given in section 62J.03, subdivision 6, and includes pharmacy benefit managers, as defined in section 62W.02, subdivision 15.

Subd. 9. **Manufacturer.** "Manufacturer" means an entity that:

(1) engages in the manufacture of a prescription drug product or enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and

(2) sets or changes the wholesale acquisition cost of the prescription drug product it manufacturers or markets.

Subd. 10. **Prescription drug product.** "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

Subd. 11. **Wholesale acquisition cost or WAC.** "Wholesale acquisition cost" or "WAC" has the meaning given in United States Code, title 42, section 1395W-3a(c)(6)(B).

CERTIFICATE OF COMPLIANCE
WITH 8th Cir. R. 28A(h)(2)

The undersigned, on behalf of the party filing and serving this addendum, certifies that the addendum has been scanned for viruses and that the brief is virus-free.

/**s**/ Cole M. Werner__
COLE M. WERNER