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. 0:23-cv-02024-PJS-JFD

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

The Association for Accessible Medicines ("AAM") is dedicated to making medicine more affordable. AAM's members make generic and biosimilar medications, which lower prices by introducing competitive alternatives to brand-name drugs. Yet despite the generic industry's commitment to providing access to affordable medications, the State of Minnesota has targeted AAM's members—but *not* the brand-name drugmakers—with a new price-control statute. The new law threatens massive penalties for selling generics and biosimilars anywhere in the country at a price Minnesota thinks too high. By regulating transactions that occur entirely outside Minnesota, the new law violates the U.S. Constitution. Every court that has considered similar state price-control legislation has held it unconstitutional, including in AAM's challenge to a materially identical drug-pricing law, *see Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019). The Supreme Court's most recent Commerce Clause decision cited that decision with approval, *see Nat'l Pork Producers Council v. Ross*, 143 S. Ct. 1142, 1155 (2023); certainly nothing in *Ross* unsettles the ample precedent holding that one State may not directly regulate transactions in another. This Court should apply that precedent and enjoin this unconstitutional law.

The relevant provisions of S.F. 2744 prohibit manufacturers from imposing "excessive price increase[s]" on the sale of any generic or "off-patent" drug. *See* Minnesota Session Laws – 2023, Regular Session, ch. 57, art. 2, §§22-27 ("the Act").[1] The

[1] https://www.revisor.mn.gov/laws/2023/0/Session+Law/Chapter/57/.

Act's prohibition is not limited to sales in Minnesota; it applies to *all* sales of generics and biosimilars wherever they occur, if the product is *eventually* made available for sale—by anyone—to a Minnesota patient. "Excessiveness" is determined by a rigid formula that does not take manufacturers' costs into account. Any manufacturer that raises prices above the amount set by Minnesota can be penalized up to $10,000 every day for every sale at an excessive price *and* ordered to refund the supposedly excessive revenue. Act §25(3). And the Act leaves manufacturers no avenue of escape: any manufacturer who withdraws its product from Minnesota faces a mandatory $500,000 penalty. *Id*. §26.

The federal Constitution bars states from regulating transactions beyond their borders. "A statute directly controlling wholly out-of-state commerce 'is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature.'" *Styczinski v. Arnold*, 46 F.4th 907, 913 (8th Cir. 2022) (citation omitted). The Act violates this fundamental constitutional rule by regulating transactions between non-Minnesotans that take place entirely outside Minnesota. The generic and biosimilar companies that make up AAM's regular membership are based outside Minnesota, as are the large wholesalers they generally sell to. Yet the Act directly regulates the prices AAM's members charge in transactions outside Minnesota, with non-Minnesota wholesalers, anytime a product eventually finds its way to a Minnesota consumer. That is a clear violation of the Constitution.

The remaining preliminary-injunction factors support granting AAM's motion. A deprivation of constitutional rights is inherently irreparable, and on top of that harm, the Act would impose economic losses on AAM's members that they will never be able to

recoup. By contrast, Minnesota will not be injured if prohibited from enforcing an unconstitutional law. Enjoining the law also will serve the public interest: generic and biosimilar medications are enormously beneficial to the healthcare system—making lifesaving medicines available to more patients while saving hundreds of billions of dollars annually. Yet the law targets *only* generic and biosimilar manufacturers, while exempting brand-name drugs from liability despite costing exponentially more. The Act's draconian monetary liability will severely undermine generic and biosimilar manufacturers' ability to make their products while recouping their costs—especially given the thin profit margins for many generic products—and it will exacerbate the already severe drug-shortage problem plaguing the U.S. healthcare system.

The Court should enjoin enforcement of the Act against AAM's members based on their out-of-state transactions, pending litigation of this case on the merits.

STATEMENT OF FACTS

I. The Importance Of Generic Medicines

AAM is the leading trade association for generic and biosimilar medicines, which play a critical role in controlling healthcare costs. *See* U.S. Dep't of Health & Hum. Servs., *ASPE Issue Brief: Understanding Recent Trends in Generic Drug Prices* 1 (Jan. 27, 2016).[2] Through vigorous competition, generic products "offer[] relief from rising prescription drug costs" by "driv[ing] prices for generic drugs to be a fraction of that of the corresponding brand name drug." *Id*. As a result, generic medicines account for 91% of

[2] https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//141996/GenericsDrugpaperr.pdf.

all prescriptions dispensed in the United States, but only 18.2% of the money spent on prescriptions. Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 9 (Sept. 2022).[3] Over the last decade, generic drugs have produced nearly $2.6 trillion in savings for the U.S. healthcare system, with $373 billion in 2021 alone; they saved Minnesota $5.3 billion that year. *Id*. at 7, 14.

Drug manufacturers typically do not sell their medicines directly to patients. Rather, they generally sell to wholesale distributors, who resell to pharmacies, who in turn resell to patients. *See* Andrew W. Mulcahy & Vishnupriva Kareddy, RAND Corp., *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships* 4-5 (2021).[4] Three companies control over 90% of the wholesale distribution market.[5] These sales occur entirely outside Minnesota: None of AAM's regular members is based in Minnesota. *E.g.*, Declaration of Kevin Galownia ("Galownia Decl.") ¶¶2, 4; Declaration of Timothy de Gavre ("de Gavre Decl.") ¶¶2, 4.[6] Nor are any of the large wholesalers to which they sell.[7]

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[3] https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf.

[4] https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf.

[5] Adam J. Fein, PhD., *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, Drug Channels (Oct. 2, 2019), https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html.

[6] The Declaration of Kevin Galownia and the Declaration of Timothy de Gavre are being filed concurrently with this Memorandum of Law.

[7] AmerisourceBergen Corp., SEC Form 8-K (Mar. 9, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0001140859/3e7c2793-a349-4bdf-9991-0d274bf35277.pdf; Cardinal Health, Inc., SEC Form 8-K (Feb. 27, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000721371/b56d5c58-b963-47ba-a356-ba4feb0ce255.pdf; McKesson Corp., SEC Form 8-K (Feb. 13, 2023),

Manufacturers do not set prices for their drugs on a state-by-state or drug-by-drug basis, but typically sell to wholesale distributors in pre-negotiated bulk contracts covering a range of products for resale nationwide. Galownia Decl. ¶¶5-7; de Gavre Decl. ¶¶5-7. The ultimate prices charged at the wholesale level are determined by a multitude of market factors. Galownia Decl. ¶¶18, 20; de Gavre Decl. ¶¶18, 20. Manufacturers do not control the prices at which wholesalers or retailers resell their drugs, nor where those drugs are resold. Galownia Decl. ¶¶4, 18; de Gavre Decl. ¶¶4, 18.

Generic and biosimilar manufacturers face significant "barriers … to both enter and remain in the market." Comm. on Homeland Sec. & Governmental Affairs, U.S. Senate, *Short Supply: The Health and National Security Risks of Drug Shortages* 13 (Mar. 2023).[8] Manufacturers typically "face intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns." FDA, *Drug Shortages: Root Causes and Potential Solutions* 22 (Feb. 21, 2020)[9]; *see* Galownia Decl. ¶19; de Gavre Decl. ¶19. At the same time, the cost to manufacture generics and biosimilars has risen sharply. "Most generic drug manufacturers rely on other companies to produce" the ingredients "for the drugs they produce," Mariana P. Socal, et al., *Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical*

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https://d18rn0p25nwr6d.cloudfront.net/CIK-0000927653/9bd04510-205f-479d-836a-06029dc4acc2.pdf.

[8] https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.

[9] https://www.fda.gov/media/131130/download.

Ingredients, 42 Health Affairs 407, 407 (Mar. 2023),[10] and the "raw material prices for essential drugs" have continued to rise sharply, by as much as 140% in the post-COVID era, *Active Pharmaceutical Ingredients Market Size*, Precedence Research (Jan. 2023).[11] Combined, these factors have forced generic manufacturers out of the market and resulted in drug-supply shortages in the United States that are "approaching record levels" and depriving patients of access to lifesaving medicines. Christina Jewett, *Drug Shortages Near an All-Time High, Leading to Rationing*, N.Y. Times, May 17, 2023.[12]

II. Minnesota's New Price-Control Law

On May 24, 2023, Governor Walz signed omnibus legislation (S.F. 2744) including the Act, which took effect July 1, 2023. *See* Minn. Stat. Ann. §645.02.

The Act prohibits "manufacturer[s]" from "impos[ing], or caus[ing] to be imposed, an excessive price increase" on a "generic or off-patent drug." Act §23(1).[13] In deciding whether a price increase is "excessive," the Act completely ignores the manufacturer's costs—and even ignores whether the manufacturer makes any profit on the product. Rather, the Act follows a one-size-fits-all formula: it deems a price increase "excessive" if (adjusted for inflation) it is greater than $30 for a 30-day supply of the drug or a course

[10] https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01120.

[11] https://www.precedenceresearch.com/active-pharmaceutical-ingredient-market.

[12] https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html.

[13] "Generic or off-patent drug" is defined to include "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." Act §22(3).

of treatment lasting less than 30 days, and it exceeds either (1) a 15% increase in the wholesale acquisition cost ("WAC")[14] over the preceding calendar year, or (2) a 40% increase in the WAC over the preceding three calendar years. *Id*. §23(2).[15]

The Act's prohibition is not limited to prices charged in Minnesota. Instead, the law prohibits manufacturers from imposing "excessive price increase[s]" on drugs sold either "directly" to a "consumer in Minnesota" or *indirectly* "through a wholesale distributor, pharmacy, or similar intermediary," as long as the drug is eventually "sold, dispensed, or delivered to any consumer in [Minnesota]." Act §23(1). And the Act leaves manufacturers no way to escape: a manufacturer that "withdraw[s]" its drugs "from sale or distribution within [Minnesota] for the purpose of avoiding" the law's price regulation faces a mandatory $500,000 penalty. *Id*. §26(1), (3).

The Act empowers various state agencies and contractors to notify a manufacturer "of any price increase" that may violate the price control. Act §25(1). The manufacturer

[14] The term "wholesale acquisition cost" means, "with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available." 42 U.S.C. §1395w-3a(c)(6)(B); *see* Act §22(6) (incorporating federal definition).

[15] By contrast, the Act shields "wholesale distributor[s]" and "pharmac[ies]" from liability for imposing an excessive price increase if the price "is directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug." Act §23(3). Indeed, the Act does not expressly impose liability on retail pharmacies or wholesalers at all—the Act applies exclusively to "manufacturer[s]." *Id.* §23(1).

must then submit a "drug cost statement" to the Attorney General. *Id*. §25(2)(a)-(b).[16]

The Attorney General, and even private parties, may sue to enforce the Act. Act §25(3)-(4). Minnesota courts may order the manufacturer to relinquish "any money acquired as a result of a price increase" deemed unlawful; impose a "civil penalty of up to $10,000 per day for each violation," where "every individual transaction is … a separate violation"; and order "that drug prices be restored to levels that comply" with the Act's price controls. *Id*. §25(3)(a)(2)-(6), (b).

STANDING

But for the threat of enforcement under the Act, some AAM members would make competitively reasonable price adjustments, in transactions entirely outside Minnesota, for one or more products in amounts that would satisfy the Act's definition of "excessive price increase." *See, e.g.*, Galownia Decl. ¶¶8-24; de Gavre Decl. ¶¶8-24; *see* Complaint ¶¶19, 36-39. Those products would become subject to the Act as a result of being resold into Minnesota by third parties. *Id*. The Act therefore is causing AAM members injury-in-fact. *See Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 777-79 (8th Cir. 2019). This case is germane to AAM's mission, *e.g.*, *Frosh*, 887 F.3d at 667, and AAM has associational standing to seek equitable relief to redress that injury, *see, e.g.*, *Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932, 946-48 (8th Cir. 2023).

[16] "Any manufacturer that sells, distributes, delivers, or offers for sale any generic or off-patent drug in the state" must also "maintain a registered agent and office within the state." Act §24.

ARGUMENT

A party seeking a preliminary injunction against a state statute must establish that (1) it is "likely to prevail on the merits"; (2) it will suffer "irreparable harm"; (3) the "balance between this harm and the injury … [to] other parties" favors an injunction; and (4) "the public interest" favors an injunction. *Eggers v. Evnen*, 48 F.4th 561, 564-65 (8th Cir. 2022). The balance-of-harms and public-interest factors "merge" when the government is the non-moving party. *Id*.

All the relevant factors weigh decisively in favor of granting a preliminary injunction here.

I. AAM Is Likely To Succeed On Its Claims That The Act's Direct Regulation Of Out-of-State Transactions Is Unconstitutional.

AAM is likely to succeed on its claims that the Act violates the Constitution, including the Commerce Clause,[17] by directly regulating prices charged in transactions wholly outside of Minnesota—a clear violation of the rule against extraterritorial regulation. Courts addressing materially similar state legislation have repeatedly recognized that such laws are unconstitutional. This Court should follow suit.

A. The Commerce Clause Prohibits States From Directly Regulating Transactions That Occur Wholly Out Of State.

The U.S. Constitution provides that "Congress shall have [the] Power … [t]o

[17] The constitutional prohibition against direct state regulation of out-of-state transactions is not limited to the Commerce Clause, but is also inherent in the Constitution's structure and implicit in its other provisions. *See Ross*, 143 S. Ct. at 1157 n.1; *id*. at 1175-76 (Kavanaugh, J., concurring in part and dissenting in part); *Mallory v. Norfolk S. Ry. Co.*, 143 S. Ct. 2028, 2049 (2023) (Alito, J., concurring in part and concurring in the judgment); *see also* Complaint ¶¶52-57.

regulate Commerce … among the several States." U.S. Const. Art. I, §8, cl. 3. The Supreme Court has long interpreted "this language to contain a further, negative command, known as the dormant Commerce Clause," which prohibits States from legislating in ways that regulate or discriminate against interstate commerce. *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995).

Under this command, state laws may have an "incidental" effect on interstate commerce, but a state law that "directly control[s] wholly out-of-state commerce 'is invalid'" under the Commerce Clause. *Styczinski*, 46 F.4th at 913 (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 332 (1989)). In particular, States may not "force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another." *Id*. This constraint follows from the "inherent limits [on] the State's power" under the Constitution—"any attempt directly to assert extraterritorial jurisdiction over persons or property would offend sister States" and therefore "must be held invalid." *Edgar v. MITE Corp.*, 457 U.S. 624, 643 (1982) (plurality opinion) (quotation marks omitted); *see Styczinski*, 46 F.4th at 913; *accord Davis v. Farmers Coop. Equity Co.*, 262 U.S. 312, 314-17 (1923) (holding that Minnesota law requiring out-of-state companies to submit to suit involving a "transaction [that] was in no way connected with Minnesota" violated the Commerce Clause).

The Supreme Court has reiterated this principle in invalidating state price-affirmation laws. In *Brown-Forman Distiller Corp. v. New York State Liquor Authority*, 476 U.S. 573 (1986), the Court addressed the constitutionality of a state law that required out-of-state liquor distillers to affirm that the prices they charged in-state wholesalers were

no higher than those charged to out-of-state entities. *Id*. at 576. In doing so, the Court reiterated the principle that a state law is unconstitutional if it "*directly regulates* or discriminates against interstate commerce." *Id*. at 578 (emphasis added) (citing, *inter alia*, *Edgar*, 457 U.S. at 640-43 (plurality opinion)). Similarly, the Court in *Healy* reiterated the rule that "the 'Commerce Clause precludes the application of a state statute to commerce that takes place wholly outside of the State's borders." 491 U.S. at 336 (quoting *Edgar*, 457 U.S. at 642-43 (plurality opinion)) (alteration omitted); *accord Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935) (recognizing that one state "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [a product] acquired there"). And in *Edgar*, in which the Court invalidated an Illinois regulation of tender offers that would have "prevent[ed]" the defendant company from "concluding interstate transactions … with those living in other States and having no connection with Illinois," the plurality concluded that the Illinois statute "must be held invalid" because it "directly" regulated "commerce wholly outside the State." 457 U.S. at 642-43 (plurality opinion); *accord Ross*, 143 S. Ct. at 1157 n.1 (recognizing that *Edgar* "spoke to a law that *directly* regulated out-of-state transactions by those with *no* connection to the State"); *Healy*, 491 U.S. at 333 n.9 (characterizing the *Edgar* plurality opinion as "significantly illuminat[ing] the contours of the constitutional prohibition on extraterritorial legislation").

The Eighth Circuit reaffirmed the fundamental prohibition on direct regulation of wholly out-of-state transactions just last year in *Styczinski*. In that case, Minnesota sought to regulate the sale of bullion "'between a dealer and a consumer who lives in Minnesota.'"

46 F.4th at 913 (quoting Minn. Stat. Ann. §80G.01(5a)(3)). The law was not, however, limited to bullion transactions *within* Minnesota; it regulated "transaction[s] anywhere in the world between a bullion trader and a Minnesota resident," and thus subjected out-of-state traders to liability "without conducting a single transaction in Minnesota." *Id*. The court of appeals held this unconstitutional, because it would impermissibly "require 'an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another.'" *Id*. (citation omitted).

Courts have likewise applied the same constitutional rule to invalidate materially similar interstate restrictions on prescription-drug prices, including in AAM's successful challenge to a materially similar Maryland law. Much like the Minnesota law, the Maryland law prohibited any "unconscionable increase in the price of a prescription drug" for certain generic "essential medicines." *Frosh*, 887 F.3d at 666. The Fourth Circuit held the law unconstitutional because it regulated "conduct that occur[red] entirely outside Maryland's borders" and controlled the "prices … in transactions that [did] not take place in Maryland." *Id*. at 670-72. While the law applied only to drugs "made available for sale" in Maryland (by anyone), it did not "limit [its] application to sales that actually occur[red] within Maryland, nor [did] it restrict [its] operation to the context of a resale transaction with a Maryland consumer." *Id*. at 671.[18]

[18] Numerous other decisions have invalidated state laws that directly regulated out-of-state transactions. *See also, e.g.*, *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 612-16 (9th Cir. 2018); *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1321-24 (9th Cir. 2015) (en banc); *Vapors, LLC v. Cook*, 847 F.3d 825, 836 (7th Cir. 2017); *Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 662, 667-78 (7th Cir. 2010).

B. *Ross* Confirms That States May Not Directly Regulate Prices In Out-Of-State Transactions.

The Supreme Court's decision in *Ross* confirms the unconstitutionality of state laws that *directly* regulate wholly out-of-state transactions, leaving in place the settled precedent holding such laws invalid.

The California law at issue in *Ross* did not *directly* regulate any out-of-state conduct, but instead prohibited only "the *in-state* sale of whole pork meat" from any pig that had been housed under conditions deemed cruel. 143 S. Ct. at 1150 (emphasis added). Unsurprisingly, the plaintiffs did not attempt to premise their Commerce Clause claim on a "direct-regulation" theory, either: they argued that the law violated the Commerce Clause *per se*, because the law had "the '*practical effect* of controlling commerce outside [California].'" *Id*. at 1154 (emphasis added).

The Supreme Court rejected the plaintiffs' "practical effects" argument, but in doing so did not disturb the distinct prohibition under the Commerce Clause against state laws that *directly* regulate out-of-state commerce. Indeed, the Court expressly distinguished the California law from the Illinois tender-offer law invalidated in *Edgar*, reasoning that the Illinois law (unlike the California law) "*directly* regulated out-of-state transactions." 143 S. Ct. at 1157 n.1. Not only that, *Ross* approvingly cited the Fourth Circuit's decision in *Frosh*, which invalidated a law nearly identical to the Act because it directly regulated out-of-state drug prices. *Id*. at 1155-56. *Ross* thus confirms what settled precedent from the Supreme Court, the Eighth Circuit, and other courts of appeals made crystal clear: that under the Commerce Clause and the Constitution's "horizontal separation of powers," *id.*

at 1157 & n.1, laws that directly regulate wholly out-of-state transactions are invalid.

C. The Act Is Unconstitutional Because It Directly Regulates Prices Charged In Transactions Entirely Outside Minnesota.

1. The Act transgresses this fundamental constitutional rule against out-of-state price regulation. The Act prohibits *any* generic or biosimilar manufacturer from "impos[ing] … an excessive price increase" on "any generic or off-patent drug." Act §23(1). That prohibition applies wherever those sales occur—so long as the drug is eventually "dispensed" or "delivered" to a "consumer in [Minnesota]" by *someone*, which need not be the manufacturer. *Id*. Thus, the Act directly regulates prices charged "wholly outside of Minnesota" and therefore it "is invalid." *Styczinski*, 46 F.4th at 913.

The Act's extraterritorial reach is not merely theoretical. Given how the generic pharmaceutical industry operates, an overwhelming number of the Act's applications will involve wholly out-of-state transactions. AAM's regular members are based outside Minnesota, and they do not typically sell products to Minnesota consumers themselves; rather, they sell primarily to wholesale distributors. *See* p. 4, *supra*. The three dominant wholesalers also are based outside Minnesota. *See* p. 4, *supra*. Wholesalers, in turn, make their own independent decisions to resell those products to retailers. The manufacturer does not control whether its products end up being sold in Minnesota, *see* p. 5, *supra*, but the Act regulates the prices the manufacturer may charge the wholesaler anyway, in transactions with no Minnesota connection.

The Act's structure confirms that it targets out-of-state transactions. The Act applies to "manufacturer[s]," and it expressly exempts "wholesale distributor[s] and pharmac[ies]"

from liability "if the[ir] price increase[s] [are] directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer…." Act §23(1), (3). The Act does not, however, provide any similar defense for manufacturers who are compelled to raise the prices of their generic or biosimilar products in response to changing market conditions outside of their control. *See* pp. 6-7 & n.15, *supra*. Manufacturers—which are targeted—sell out-of-state; wholesalers and retailers—which are shielded—are more likely to sell within the State. That disparity "makes clear that the conduct the Act targets is the upstream pricing and sale of prescription drugs." *Frosh*, 887 F.3d at 671.

2. Minnesota is not the first state to try to regulate the prices charged in out-of-state transactions for prescription drugs. As discussed above, AAM won its challenge in the Fourth Circuit to a law that sought to regulate the prices charged for prescription drugs in out-of-state transactions. *Frosh*, 887 F.3d at 670-71. Consistent with *Frosh*, every other court that has considered such price-control laws has found them unconstitutional.

For instance, in *Pharmaceutical Research & Manufacturers of America v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005), the court enjoined a District of Columbia law prohibiting sales "that result[] in [a] prescription drug being sold in the District for an excessive price." *Id*. at 60. The court held that the District law impermissibly "regulate[d] transactions that occur[red] wholly out of state" because the "plaintiffs' members s[old] 'the overwhelming bulk' of their … drugs in out-of-state transactions to wholesalers or large retail chains." *Id*. at 68, 70. The fact that the law's penalties were triggered by the drug's eventual resale in the District made no constitutional difference, because "as soon

as that drug [wa]s sold in the District, the manufacturer's out-of-state sale bec[a]me[] the [law's] primary target." *Id*. at 69.

The same fate befell a Maine law prohibiting drug manufacturers (all "located outside the State of Maine") from "exacting or demanding an unconscionable price" or "exacting or demanding prices on terms that lead to any unjust or unreasonable profit." *Pharm. Rsch. & Mfrs. of Am. v. Comm'r, Maine Dep't of Hum. Servs.*, No. CIV. 00-157, 2000 WL 34290605, at *2 (D. Me. Oct. 26, 2000). The court found the law unconstitutional because it attempted to regulate prices in wholly out-of-state transactions. *Id*.

So too with a New York law that imposed an opioid-related fee on pharmaceutical manufacturers and others and prohibited them from "passing through" any portion of it to their customers. *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 246 (S.D.N.Y. 2018). The court held that the statute "violate[d] the Commerce Clause's prohibition on extraterritorial state legislation," because its bar on "pass through" charges was not limited to New York transactions. *Id*. at 261-62.[19]

The Act violates the Constitution for the same reasons as these other laws: by its terms, the Act "applies Minnesota law to commerce wholly outside of Minnesota." *Styczinski*, 46 F.4th at 913. Therefore, it "must be held invalid." *Edgar*, 457 U.S. at 643 (plurality opinion).

3. The Act's registration requirement cannot cure the constitutional violation.

[19] Although the Second Circuit reversed as to other issues that were appealed, it did not disturb the district court's Commerce Clause holding. *See Ass'n for Accessible Meds. v. James*, 974 F.3d 216, 218, 228 (2d Cir. 2020).

See Act §24. Minnesota raised a substantially similar argument in *Styczinski*, claiming the power to regulate out-of-state transactions involving Minnesota residents because, "by domiciling in Minnesota," those residents had "subject[ed] themselves to Minnesota regulation." 46 F.4th at 914. The Eighth Circuit rejected that argument: the mere fact that a business or person resides in Minnesota "does not give the State *carte blanche* to regulate all conduct of residents regardless of where it occurs" or to "pin its law onto its in-state dealers and their transactions wherever they travel." *Id*.

That conclusion should be the same here, where the law does not even regulate Minnesota residents, but seeks to bootstrap its way to regulatory authority over out-of-state businesses by demanding that they maintain an in-state registered office, which is well short of domicile. Registration does not displace the Commerce Clause's prohibition on direct regulation of out-of-state conduct. *See Davis*, 262 U.S. at 314-17.

Even if the constitutional rule were different, the Act's registration requirement does not apply to all manufacturers subject to the law's price regulation; rather, it is limited to manufacturers who *themselves* "sell[], distribute[], deliver[], or offer[] for sale" a generic product "in the state." Act §24. The price regulation, by contrast, applies to *all* manufacturers, including those who only transact business outside Minnesota and are not required to register. *Id*. §23(1). Thus, even if registration made a constitutional difference, the law's price control still would be impermissibly overbroad.

II. AAM's Members Will Suffer Irreparable Harm Absent An Injunction.

Without a preliminary injunction, AAM members will suffer irreparable harm while this case is litigated: first, the injury imposed by any unconstitutional regulation, and

second, unrecoverable monetary losses—a classic form of irreparable injury.

A. The Act Subjects AAM's Members To Unconstitutional Regulation.

The Act subjects AAM's members to unconstitutional regulation, which is an irreparable injury. *See, e.g.*, *Ng v. Bd. of Regents of Univ. of Minn.*, 64 F.4th 992, 998 (8th Cir. 2023) ("[T]he denial of a constitutional right is a cognizable injury and an irreparable harm").

That principle applies fully to the deprivation of rights under the Commerce Clause. This Court has recognized that it must "presume [a] Plaintiff[] will suffer irreparable harm" when it has shown likelihood of success on a Commerce Clause claim. *Paul's Indus. Garage, LLC v. City of Red Wing*, No. Civ. 06-4770, 2006 WL 3804243, at *8 (D. Minn. Dec. 22, 2006); *see Bergmann v. City of Lake Elmo*, No. Civ. 10-2074, 2010 WL 4123355, at *8 (D. Minn. Aug. 19, 2010) (same). And other courts agree. *ACLU v. Johnson*, 194 F.3d 1149, 1163 (10th Cir. 1999); *Ass'n for Accessible Meds. v. Bonta*, 562 F. Supp. 3d 973, 988 (E.D. Cal. 2021) (same), *as modified*, 2022 WL 463313 (E.D. Cal. Feb. 15, 2022).

B. The Act Will Cause Irreparable Economic Harm.

The Act will also cause AAM's members to suffer significant economic losses they will not be able to recoup if AAM prevails in this lawsuit. They face a no-win scenario: they must either comply with an unconstitutional law and lose substantial revenues, potentially rendering their products no longer economically viable, or violate the law and incur significant financial liability.

Financial or economic loss is irreparable when they are "unrecoverable" after successful litigation. *Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996). That is

the case here, where Minnesota's sovereign immunity will prevent any recovery. *See Entergy, Ark., Inc. v. Nebraska*, 210 F.3d 887, 899-900 (8th Cir. 2000) (holding that increased costs constituted irreparable harm where "[n]one of these additional costs would be recoverable in the event of Nebraska's successful assertion of sovereign immunity"); *Baker Elec. Coop., Inc. v. Chaske*, 28 F.3d 1466, 1473 (8th Cir. 1994) (similar).

Complying with the Act's unconstitutional price control will reduce AAM members' revenues, resulting in significant financial loss. Galownia Decl. ¶¶11, 16, 19-24; de Gavre Decl. ¶¶16, 19-24. Indeed, for some products, the inability to raise prices to account for increased costs will mean not just less profit, but no more profit at all. Galownia Decl. ¶22; de Gavre Decl. ¶22. That dilemma is particularly acute for generic and biosimilar manufacturers who frequently operate on thin profit margins and are often unable to both absorb increased costs and maintain existing prices while also remaining profitable. Galownia Decl. ¶¶21-22; de Gavre Decl. ¶¶21-22. AAM members will also incur separate costs in complying with the Act's mandatory notice-and-reporting regime—none of which will be recoverable. Galownia Decl. ¶¶19-24; de Gavre Decl. ¶¶19-24.

AAM's members would also suffer unrecoverable financial injury if they were to try to avoid these economic losses. A manufacturer that managed to withdraw a product from the Minnesota market not only would suffer the resulting loss of revenues from sales of that product, Galownia Decl. ¶¶23-24; de Gavre Decl. ¶¶23-24, but would also incur the mandatory $500,000 penalty for product withdrawal, Act §26(1)-(3). But if a manufacturer keeps its product on the market and raises prices to preserve product profitability (and, therefore, viability), any additional revenue would be subject to disgorgement, *and* the

company would expose itself to crippling civil penalties—up to $10,000 per day for every sale—plus the notice-and-reporting costs. Galownia Decl. ¶24; de Gavre Decl. ¶24; *see* p. 8, *supra*.

The Act thus makes unrecoverable economic loss a certainty: AAM's members must either comply with its unconstitutional command and lose revenue, or violate the Act and suffer massive, financial penalties. Such "unrecoverable economic loss" is quintessential irreparable harm. *Iowa Utils. Bd.*, 109 F.3d at 426. That harm is only exacerbated by the Act's nationwide reach, forcing AAM's members to make this choice on a national scale, as there is no way to comply with the Act without changing practices out of state. Galownia Decl. ¶¶5-6; de Gavre Decl. ¶¶5-6; *see also* p. 5, *supra*. This type of no-win scenario is the paradigm of irreparable harm. *See Am. Trucking Ass'ns, Inc. v. City of L.A.*, 559 F.3d 1046, 1058 (9th Cir. 2009) (finding irreparable harm from regulatory agreements because plaintiff could either "refuse to sign" and suffer "a loss of customer goodwill" or "sign[]" and be subject to "conditions which are likely unconstitutional" and "incur large costs"); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (finding irreparable injury where plaintiffs faced "choice" to either "continually violate the [challenged] law and expose themselves to potentially huge liability; or violate the law once as a test case and suffer the injury of obeying the law during the pendency of the proceedings and any further review").

III. The Balance Of Hardships And Public Interest Support An Injunction.

The remaining equitable factors—the balance of hardships and public interest—also favor an injunction.

The irreparable harm to AAM's members far outweighs any harm the Attorney General can claim from a preliminary injunction. A "State has no interest in enforcing laws that are unconstitutional … and an injunction preventing the State from enforcing the challenged statute does not irreparably harm the State." *Pavek v. Simon*, 467 F. Supp. 3d 718, 762 (D. Minn. 2020) (citation omitted); *see Leaders of a Beautiful Struggle v. Balt. Police Dep't*, 2 F.4th 330, 346 (4th Cir. 2021) ("a state is in no way harmed by issuance of a preliminary injunction which prevents the state from enforcing restrictions likely to be found unconstitutional" (citation omitted)). Put another way, "[i]t is always in the public interest to prevent the violation of a party's constitutional rights." *D.M. by Bao Xiong v. Minn. State High Sch. League*, 917 F.3d 994, 1004 (8th Cir. 2019) (citation omitted).

In addition, a preliminary injunction would serve the public interest by preventing the damaging consequences the Act will inflict on patients and the market for generics and biosimilars. *See* pp. 5-6, *supra*. The generic industry is currently undergoing "severe financial strain," Jewett, *Drug Shortages*, *supra*, with many generic and biosimilar manufacturers "struggling to stay in business," Ike Swetlitz, *Teva Plans to Cut Back Generic Drug Production Even As Shortages Intensify*, Bloomberg, May 18, 2023,[20] and some shutting down completely, *see* Jewett, *Drug Shortages*, *supra*. As a result, "drug shortages in the United States" have "approach[ed] record levels," *id*., producing "devastating consequences for patients and healthcare providers," *Short Supply*, *supra*, at

[20] https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages.

5, as "[t]housands of patients are facing delays in getting treatments for cancer and other life-threatening diseases," Jewett, *Drug Shortages*, *supra*.

The Act's draconian penalties—and refusal to consider a manufacturer's increased costs—will only exacerbate the drug-shortage problem. By forbidding price increases necessary to keep products profitable and threatening generic and biosimilar manufacturers with severe civil penalties for making necessary price adjustments to maintain product viability, the Act will place increasing pressure on generic and biosimilar manufacturers to withdraw their products from the market entirely. *See* Galownia Decl. ¶¶22-23; de Gavre Decl. ¶¶22-23. Thus, the Act's price control will not only reduce the supply of affordable generic alternatives, but also increase demand for those drugs that competed with the discontinued generics—driving prices for those drugs even higher. In the end, the Act will only make generics and biosimilars *less* available to patients in Minnesota, directly undermining the Act's goal of increasing access to affordable medications.

CONCLUSION

The Court should grant AAM's motion for a preliminary injunction.

July 19, 2023

Respectfully submitted,

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