UNITED STATES DISTRICT COURT
FOR THE 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 **COMPLAINT**

Plaintiff Association for Accessible Medicines ("AAM") brings this complaint for declaratory and injunctive relief against Keith Ellison, in his official capacity as Attorney General of the State of Minnesota. AAM brings this complaint on behalf of its members, based on personal knowledge as to all AAM facts, and on information and belief as to all other matters.

PRELIMINARY STATEMENT

1. This lawsuit challenges Minnesota's new price-control law, which threatens to impose massive penalties on manufacturers of generic and biosimilar medicines. Any manufacturer that changes the price of a generic drug anywhere in the country can be penalized, if Minnesota considers the price change an "excessive price increase" and if the price increase is later passed on to a consumer in Minnesota by a third party. *See* Minnesota Session Laws – 2023, Regular Session, ch. 57, art. 2 §§ 22-27 (the "Act").

2. The Act does not limit its prohibition to sales that occur in Minnesota. Instead, it prohibits manufacturers from imposing "excessive price increase[s]" on sales of generic and biosimilar medicines made either directly to Minnesota consumers or indirectly "through a wholesale distributor, pharmacy, or similar intermediary." Act § 23(1). Notably, the Act does not impose liability on those intermediaries who pass on their price increases to Minnesota consumers; the law targets manufacturers, and it provides an express safe harbor from liability for all other entities in the supply chain. *Id*. § 23(1), (3).

3. To enforce its prohibition on excessive price increases, the Act authorizes Minnesota courts to impose a civil penalty of up to $10,000 per day for every sale that violates the Act, along with the payment of restitution and other remedies—exposing manufacturers to potentially millions of dollars of liability for sales of a single product. Act § 25(3)(a)-(b). And manufacturers cannot escape liability simply by leaving the Minnesota market: the Act imposes a mandatory $500,000 penalty on manufacturers that withdraw their products from Minnesota to avoid the Act's price controls. *Id*. § 26(3).

4. The Act regulates transactions that occur wholly outside Minnesota, and, in doing so, violates multiple provisions of the U.S. Constitution, as well as the limits on state authority implicit in the constitutional structure and design.

5. First and foremost, the Act violates the restrictions on extraterritorial state legislation imposed by the U.S. Commerce Clause—as every court to consider the constitutionality of similar price-control legislation has concluded. "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); *see* U.S. Const. art. I, § 8, cl. 3 ("Congress shall have Power … To regulate Commerce … among the several States"). This prohibition is absolute: "any attempt 'directly' to assert extraterritorial jurisdiction over persons or property would … exceed the inherent limits of the State's power.'" *Edgar v. MITE Corp.*, 457 U.S. 624, 643 (1982) (plurality opinion) (quoting *Shaffer v. Heitner*, 433 U.S. 186, 197 (1977)); *accord Healy v. Beer Institute, Inc.*, 491 U.S. 324, 336 (1989) ("[T]he 'Commerce Clause … precludes the application of a state statute to commerce that takes place wholly outside of the State's borders'") (citation omitted); *accord Davis v. Farmers Co-operative Equity Co.*, 262 U.S. 312, 314-17 (1923) (holding that a Minnesota law authorizing the exercise of personal jurisdiction over a lawsuit involving a "transaction [that] was in no way connected with Minnesota" violated the Commerce Clause).

6. When the Supreme Court recently "refined [its] Commerce Clause framework," *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. ---, 2023 WL 4187749, at *18, slip op., at 11 (June 27, 2023) (Alito, J., concurring in part and concurring in the judgment), it kept intact the bedrock principle prohibiting state laws that directly regulate out-of-state conduct, *see generally Nat'l Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023). Indeed, *Ross* went out of its way to confirm the vitality of the holdings of *Healy* and its forebears—that state laws that "*directly* regulate[]" the price term of "out-of-state transactions," and thereby "'prevent[] out-of-state firms from undertaking competitive pricing' or 'deprive[] businesses and consumers in other States of whatever competitive advantages they may possess,'" are unconstitutional. *Id.* at 1155, 1157 n.1 (second alteration in original; alterations omitted) (quoting *Healy*, 491 U.S. at 338-39).

7. The Act violates the Commerce Clause's clear command by directly regulating prices charged nationwide. Take, for example, a drug manufacturer located in Pennsylvania that sells generic drugs to a wholesale distributor located in Ohio. Some of those drugs may eventually be resold to a Minnesota resident. If the price charged by the Pennsylvania company to the Ohio company constitutes an excessive price increase under the Act, and is ultimately passed on to a Minnesota consumer, then the initial sale would be prohibited—even though it occurred wholly outside of Minnesota and the Pennsylvania manufacturer has "*no* connection to the State." *Ross*, 143 S. Ct. at 1157 n.1. By directly regulating commercial activities entirely outside the boundaries of Minnesota, the Act violates the Commerce Clause of the U.S. Constitution.

8. The Act's regulation of prices charged in out-of-state transactions independently violates the limitations on state legislative power imposed by the Due Process Clause of the Fourteenth Amendment. That clause restricts states' authority to "regulate and control activities wholly beyond [their] boundaries," *Watson v. Emps. Liab. Assurance Corp.*, 348 U.S. 66, 70 (1954), in the absence of "some minimal contact[s]" between both the "regulated party and the state" and "the regulated subject matter and the state," *Gerling Global Reinsurance Corp. of Am. v. Gallagher*, 267 F.3d 1228, 1236 (11th Cir. 2001) (emphasis omitted). AAM's members are all located *outside* Minnesota and sell their drug products to wholesale distributors that are overwhelmingly located *outside* Minnesota—leaving Minnesota without the necessary "substantial … contact[s]" with the regulated entities and transactions to justify applying its law to purely out-of-state activity. *McCluney v. Joseph Schlitz Brewing Co.*, 649 F.2d 578, 581 (8th Cir. 1981), *aff'd* 454 U.S.

1071 (1981).

9. The Act's extraterritorial reach not only runs afoul of these specific constitutional provisions, but it also violates principles implicit in the very structure of our constitutional order. The principle that states may not "reach out and regulate conduct that has little if any connection with the State's legitimate interests" is "an obvious and necessary result" of the Constitution's design—one that "is not confined to any one clause or section." *Mallory*, 600 U.S. ---, 2023 WL 4187749, at *16, slip op., at 5-6 (Alito, J., concurring in part and concurring in the judgment) (collecting cases). Rather, that tenet is embedded "in the very nature of the federal system," in "numerous provisions that bear on States' interactions with one another," *id*., and in the "historical understandings of the Constitution's structure and the principles of 'sovereignty and comity' it embraces," *Ross*, 143 S. Ct. at 1156 (citation omitted). By regulating activities that occur wholly outside Minnesota's borders, the Act transgresses "the horizontal separation of powers" embedded in the constitutional design. *Id*. at 1157 n.1.

10. Finally, separate and apart from the Act's impermissible extraterritorial reach, the law is also unconstitutional under the Commerce Clause because it imposes a "substantial burden" on interstate commerce that outweighs any local benefits. *See R&M Oil & Supply, Inc. v. Saunders*, 307 F.3d 731, 735-36 (8th Cir. 2002). To avoid violating the Act's price control, generic and biosimilar manufacturers would either have to try to keep their products out of the Minnesota market—which may well be impossible given the nature of the nationwide wholesale market—or else treat Minnesota's regulation as the national standard. A decision permitting state regulation like Minnesota's would allow all

50 states to adopt their own views of what price increases are "excessive," making compliance prohibitive if not impossible and disrupting patients' access to affordable generic and biosimilar products throughout the country. Those "cumulative effects" on "all" relevant market actors constitute a substantial burden on interstate commerce, *id.*, which far outweighs any interest Minnesota may have in regulating the upstream prices charged for drugs that are later resold to Minnesota consumers by third parties.

11. AAM's members, who manufacture, offer, and sell generic and biosimilar products, are suffering immediate and irreparable injury as the subjects of unconstitutional state action. Under the new price-control law, AAM's members will be exposed to massive civil penalties and other monetary liability for selling their products at prices deemed by the Act to be unacceptable, even if charged wholly outside Minnesota. AAM's members also will face significant economic harm as a result of the Act's price controls no matter what course of action they take—forced to choose between (a) forgoing price increases on generic and biosimilar products that are necessary for those products to remain profitable, (b) withdrawing those products from the Minnesota market and incurring the Act's mandatory $500,000 civil penalty for product withdrawal, or (c) raising prices on their products to maintain those products' thin profit margins, but, in doing so, triggering substantial civil penalties and other monetary liability.

12. The Act's draconian regulations come at a time when the generic industry is already undergoing "severe financial strain," Christina Jewett, *Drug Shortages Near an*

All-Time High, Leading to Rationing, N.Y. Times, May 17, 2023,[1] and where many generic and biosimilar manufacturers are "struggling to stay in business," Ike Swetlitz, *Teva Plans to Cut Back Generic Drug Production Even As Shortages Intensify*, Bloomberg, May 18, 2023.[2] These conditions have in turn led to significant drug shortages in the United States that are "approaching record levels," leaving "[t]housands of patients … facing delays in getting treatments for cancer and other life-threatening diseases." Jewett, *Drug Shortages*, *supra*. By imposing additional financial costs on generic and biosimilar manufacturers, the Act targets those entities *most* responsible for making affordable medicines available to U.S. patients and will only increase the likelihood that manufacturers will be forced to withdraw products from the market—exacerbating the already-severe drug-supply shortage and driving up prices for those products that remain.

13. For these reasons, and as explained below, AAM seeks an injunction against the enforcement of the Act, a declaration that the Act is unconstitutional and unenforceable, and any other relief this Court deems appropriate.

PARTIES

14. AAM is a nonprofit, voluntary association representing the leading manufacturers and distributors of generic and biosimilar medicines, as well as manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. A

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

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

complete list of AAM's membership for calendar year 2023 is publicly available on its website, and is attached as Exhibit A to this Complaint.

15. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medications. To that end, AAM's members provide American consumers with generic and biosimilar medicines that are just as safe and effective as their brand-name counterparts, but substantially less expensive. AAM is authorized by its Board of Directors to bring this suit on its members' behalf.

16. Keith Ellison is the Attorney General of Minnesota. In that capacity, he is authorized to investigate and bring enforcement actions in Minnesota court to assert violations of the Act.

JURISDICTION AND VENUE

17. AAM's causes of action arise under 42 U.S.C. § 1983 and the U.S. Constitution. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3).

18. Venue is appropriate in this district under 28 U.S.C. § 1391(b).

19. There is a justiciable case or controversy. AAM's claims do not require the participation of AAM's individual members. AAM fulfills its purposes in part through litigation against governmental authorities to defend its members from damaging and unconstitutional laws, and has previously brought successful lawsuits in defense of its members against similarly unconstitutional state price-control measures. The Act is already injuring AAM's members who sell generic and biosimilar products by subjecting those members to unconstitutional regulation, and will certainly and imminently injure

them by subjecting them to unrecoverable economic injury. Their injuries will be redressed by a favorable decision in this litigation.

FACTUAL BACKGROUND

I. Generic and Biosimilar Products and the Pharmaceutical Market

20. Generic and biosimilar medicines play a crucial role in reducing healthcare costs for Americans. *See* U.S. Dep't of Health & Hum. Servs., *ASPE Issue Brief: Understanding Recent Trends in Generic Drug Prices* 1 (Jan. 27, 2016).[3] Through vigorous competition, generic and biosimilar medicines have "drive[n] prices for generic drugs to be a fraction of that of the corresponding brand name drug." *Id*. As a result, generic and biosimilar medicines account for 91% of all prescriptions dispensed in the United States, but amount to only 18.2% of the money spent on prescriptions. *See* Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 9 (Sept. 2022).[4] These medicines have produced nearly $2.6 trillion in savings to the U.S. healthcare system over the past decade, with $373 billion in savings in 2021. *Id*. at 7. Minnesota realized $5.3 billion in healthcare savings that same year. *Id*. at 14.

21. However, generic and biosimilar manufacturers also face significant barriers to bringing their drugs to market and keeping them there, including "intense price competition, uncertain revenue streams, and high investment requirements, all of which

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

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

limit potential returns." FDA, *Drug Shortages: Root Causes and Potential Solutions* 22 (Feb. 21, 2020).[5] As a result, generic manufacturers often operate on "low profit margins" and are unable to "afford to support redundant capacity." *Id*. at 23, 41. Those challenges have only increased in recent years—"[m]ost generic drug manufacturers rely on other companies to produce" the raw ingredients "for the drugs they produce," Mariana P. Socal, et al., *Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients*, 42 Health Affairs 407, 407 (Mar. 2023),[6] and the "raw material prices for essential drugs" has risen sharply, by as much as 140% in the post-COVID era, *see Active Pharmaceutical Ingredients Market Size*, Precedence Research (Jan. 2023).[7]

22. The high cost of manufacturing generic products, combined with "a complex array of [other] factors," FDA, *Drug Shortages*, *supra*, at 7—such as "manufacturing problems …, shortage of raw materials, and just in time inventory," Sundus Shukar, et al., *Drug Shortage: Causes, Impact, and Mitigation Strategies*, 12 Frontiers in Pharmacology 1, 6 (July 9, 2021)[8]—can lead manufacturers to leave the market entirely or otherwise create a shortage in the supply of life-saving and cost-effective treatments to patients. Surges in demand, as occur with treatments for seasonal illnesses, for example, may also lead to shortages. *See* Jewett, *Drug Shortages*, *supra*. Such supply shortages in critical

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

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

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

[8] https://www.frontiersin.org/articles/10.3389/fphar.2021.693426/full.

medicines have increased substantially in recent years. "Between 2021 and 2022, drug shortages increased by approximately 30 percent," which has produced "devastating consequences for patients and health care providers." Comm. on Homeland Sec. & Governmental Affairs, U.S. Senate, *Short Supply: The Health and National Security Risks of Drug Shortages* 5 (Mar. 2023).[9]

23. Generic and biosimilar manufacturers, including many of AAM's members, are at the start of the drug-supply chain. Typically, these manufacturers do not sell their medicines directly to consumers. Instead, they sell their products to large national wholesale distributors, who then resell those products to retail pharmacies, hospitals, or other healthcare facilities. *See* Andrew W. Mulcahy & Vishnupriva Kareddy, RAND Corp., *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships* 4-5 (2021)[10]; Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 1-2 (Mar. 2005).[11]

24. Generic and biosimilar manufacturers, including AAM's members, do not make drug-pricing or drug-distribution decisions on a drug-by-drug or state-by-state basis. Instead, they sell their products to wholesale distributors in pre-negotiated bulk (and typically long-term) contracts that cover a range of products for resale nationwide.

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

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

[11] https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

Manufacturers do not control the prices at which wholesale distributors resell their medicines or where those products are ultimately resold.

25. A number of national and regional stakeholders, including wholesale distributors, pharmacy benefit managers, retail pharmacy chains, health insurers, Medicaid and Medicare contractors, hospital networks, and others, play a role in determining the ultimate prices that are paid for generic and biosimilar medications.

26. The vast majority of sales between generic and biosimilar manufacturers and wholesale distributors occur outside Minnesota, and wholesale distributors take title to those products outside Minnesota. None of AAM's members who are generic or biosimilar manufacturers is located in Minnesota. Similarly, none of the three largest wholesale distributors who control over 90% of the market—AmerisourceBergen, Cardinal Health, and McKesson—is incorporated or headquartered in Minnesota.[12]

II. Minnesota's New Drug Price-Control Law

27. Governor Tim Walz signed S.F. 2744 into law on May 24, 2023, and the relevant sections took effect on July 1, 2023. *See* Minn. Stat. Ann. § 645.02.

28. Sections 22 through 27 of the Act amend Chapter 62J of the Minnesota

[12] 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; *see* 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), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000927653/9bd04510-205f-479d-836a-06029dc4acc2.pdf.

Statutes to add sections regulating the prices charged for generic and biosimilar products that are eventually sold to consumers in Minnesota.[13]

29. Specifically, the Act prohibits any drug "manufacturer" from "impos[ing], or caus[ing] to be imposed, an excessive price increase" on the sale of a generic or biosimilar medicine to a Minnesota consumer. Act § 23(1).

30. The Act deems a price increase "excessive" if the increase, adjusted for inflation, is more than $30 for a 30-day supply of the drug or for a course of treatment lasting less than 30 days, and the price increase exceeds either a 15% increase over the wholesale acquisition cost[14] for the preceding calendar year, or a 40% increase over the wholesale acquisition cost for the preceding three calendar years. Act § 23(2).

31. A manufacturer can violate the Act based on sales made entirely outside Minnesota: the Act's prohibition applies if the excessive price increase is imposed either "directly *or* through a wholesale distributor, pharmacy, or similar intermediary," so long as the drug is eventually sold "to any consumer in [Minnesota]." Act § 23(1) (emphasis added). However, the wholesalers or other intermediaries do not themselves incur liability

[13] The Act applies to "[g]eneric or off-patent drug[s]," which encompasses "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 [42 U.S.C. § 262], and federal patent law have expired, including any drug-device combination product for the delivery of a generic drug." Act § 22(3).

[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).

for implementing an excessive price increase. The Act's prohibition targets "manufacturer[s]," and it expressly exempts price increases imposed by intermediaries that are "directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug." *Id*. § 23(3). The law does not provide a similar pass-through defense for manufactures who might be compelled to raise the prices of their generic or biosimilar products in response to changing market conditions outside their control, such as increased supply costs.

32. The Act creates a reporting mechanism to aid the Minnesota Attorney General in investigating and bringing enforcement actions to punish violations of the Act's price regulation. In particular, the law authorizes various state agencies and contractors to notify a generic or biosimilar manufacturer, as well as the Attorney General and the Board of Pharmacy, "of any price increase" that the entity "believes may violate" the prohibition on excessive price increases. Act § 25(1). Upon receiving this notice, the manufacturer must submit a "drug cost statement" to the Attorney General that provides information "relevant to a determination of whether a violation … has occurred." *Id*. § 25(2)(a). With that information in hand, the Attorney General may then "investigate" whether the manufacturer has violated the law. *Id*. § 25(2)(b). Thus, the Act's notice-and-reporting provisions are inextricably linked to its price regulation.

33. The law authorizes the Attorney General and private parties to bring suit in Minnesota court to remedy violations. Act § 25(3)(a). If a violation is found, the Act authorizes a court to impose a civil penalty up to $10,000 per day per violation, with each separate sale at an excessive price constituting a separate violation. *Id*. § 25(3)(a)(6). The

Minnesota court is also authorized to award restitution to Minnesota consumers and to enter injunctive relief, including requiring the manufacturer to "restore[]" its prices to "levels that comply" with the Act. *Id.* § 25(3)(a)(2).

34. The Act also prohibits manufacturers from withdrawing their products from the Minnesota market to avoid the law's price controls. Act § 26. If a manufacturer wishes to withdraw its product from Minnesota for permissible reasons, it must first provide the Minnesota Board of Pharmacy and the Attorney General 90 days' written notice. *Id.* § 26(2). The Attorney General is required to assess a $500,000 penalty against any manufacturer that violates either of these requirements. *Id.* § 26(3).

35. Finally, the Act requires every manufacturer that "sells, distributes, delivers, or offers for sale any generic or off-patent drug in [Minnesota]" to "maintain a registered agent and office within the state." Act § 24. The scope of this registration requirement is narrower than the reach of the Act's price-control provisions, which apply even to manufacturers who do not sell their products in Minnesota.

III. The Act Will Injure AAM's Members and Substantially Burden Interstate Commerce.

A. The Act Regulates AAM's Members' Anticipated Pricing Decisions.

36. Prior to the Act's taking effect, several of AAM's members who manufacture generic and biosimilar products intended to make competitively reasonable price adjustments to the wholesale acquisition cost for certain generic or biosimilar prescription medications during the second half of the 2023 calendar year. Specifically, these AAM members intended to raise the wholesale acquisition cost of their generic or biosimilar

medicines in a manner that qualifies as "excessive" under Section 23(2) of the Act (*i.e.*, price increases in excess of $30, adjusted for inflation, constituting more than a 15% increase over the wholesale acquisition cost for those medicines for the 2022 calendar year).

37. Many of AAM's members' planned price increases were necessitated by increased costs in the manufacture of their generic or biosimilar medicines that are outside the control of the member companies. These cost increases would render those products unprofitable without offsetting price increases.

38. Each of the products addressed in this section is a "generic or off-patent drug" within the meaning of the Act, because any exclusive federal marketing rights for the drugs have expired. Act § 22(3). The AAM members who manufacture those medicines are located outside Minnesota and sell those medicines overwhelmingly to large wholesale distributors also located outside Minnesota. Some of those medicines are eventually resold to consumers in Minnesota.

39. Thus, these AAM members intended to raise the prices of certain generic or biosimilar medicines in a manner that satisfies the Act's definition of "[e]xcessive price increase," *see* Act § 23(2), and which would trigger liability under the Act. However, these AAM members are refraining from raising their prices for these medicines, and are thus facing economic harm, due to the Act's draconian civil penalties and other monetary liability. Enjoining the Act would enable these AAM members to move forward with their previously planned price increases.

B. The Act Will Cause AAM's Members Significant and Immediate Harm and Substantially Burden the Interstate Market for Generic and Biosimilar Products.

40. The Act's regulations and penalties will cause AAM's members who manufacture generic and biosimilar products to suffer substantial and immediate economic injury and will burden the interstate market for generic and biosimilar medicines.

41. As a result of intense competition in the generic and biosimilar market, the profit margins for generic and biosimilar products are often thin. Increased costs for generic and biosimilar products, as well as other external factors outside manufactures' control, can erase manufacturers' thin profit margins for their products, thus making it unprofitable to continue producing those medicines at existing prices. In those circumstances, increasing prices may be the only way for manufacturers to profitably market a generic or biosimilar product.

42. The Act's price controls and penalties prevent AAM's members from making necessary price increases on certain of their generics or biosimilars in response to external market forces. The Act's restrictions place these manufacturers in a no-win dilemma that will cause significant economic losses no matter what course of action they take. Specifically, AAM's members will be forced to choose between: (a) forgoing price increases on their products, with the resulting loss of revenue and profitability; (b) withdrawing their products from the Minnesota market to avoid regulation, resulting in a loss of revenues from those products and triggering the Act's mandatory $500,000 penalty for product withdrawal; or (c) implementing the necessary price increases for their generic or biosimilar products and inviting liability under the Act. In all events, AAM's members

will suffer severe financial hardship as a result of the Act's regulations.

43. Further, by restricting the prices generic and biosimilar manufacturers may charge in out-of-state transactions for products eventually resold into Minnesota by third parties, the Act will substantially disrupt the contracting and distribution practices between manufacturers and wholesale distributors—entities that are located overwhelmingly outside Minnesota.

44. To avoid the Act's price control, AAM's members would have to prevent their products from being sold in Minnesota, or at least from being sold at a price Minnesota considers excessive. Segregating out and specially pricing products destined for Minnesota may well be impossible: at a minimum, manufacturers would have to contract with wholesale distributors to set drug prices on a state-by-state and product-by-product basis, to single out drug products that are ultimately to be resold to entities within Minnesota. Even if that were possible, it would not be sufficient, because drug products could still be resold to Minnesota patients by parties further down the supply chain with whom manufacturers have no direct contractual relationship.

45. Generic and biosimilar manufacturers, as well as wholesale distributors, will incur substantial costs in connection with efforts (like those described above, which may be impossible) to restructure their contracting and delivery processes, or to comply with the Minnesota law nationwide. Those increased costs will, in turn, place increased upward pressure on the cost of delivering prescription drugs to patients throughout the United States.

46. The substantial disruptions caused by a Minnesota-specific price regime—

potentially to be followed by 49 other states, as each adopts its own definition of what qualifies as an "excessive" price increase—will create enormous inefficiencies in the processing of generic and biosimilar products, resulting in significant delays and disruptions in the supply of life-saving medicines throughout the country on top of the existing drug supply shortages that are plaguing the U.S. pharmaceutical market and preventing patients from obtaining essential medications.

47. Accordingly, the Act's price controls will place significant burdens on the supply chains for generic and biosimilar medications, including manufacturers and wholesale distributors. Because AAM's members and the wholesale distributors they sell to are overwhelmingly located outside Minnesota, the substantial burdens the Act imposes will fall predominately on out-of-state entities and their interstate commercial activities.

LEGAL BACKGROUND

I. Limits on Extraterritorial State Regulation under the U.S. Constitution.

A. Commerce Clause

48. The Framers of the Constitution held "the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation." *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979). Thus, to "create an area of free trade among the several States," *McLeod v. J. E. Dilworth Co.*, 322 U.S. 327, 330 (1944), the Framers gave Congress the "Power ... [t]o regulate Commerce … among the several States," U.S. Const. art. I, § 8, cl. 3. This clause was meant to strike a balance between the "maintenance of a national economic union unfettered by state-imposed

limitations on interstate commerce and … the autonomy of the individual States within their respective spheres." *Healy*, 491 U.S. at 335-36. Consistent with that design, the Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007).

49. Although "[n]ot every exercise of state power with some impact on interstate commerce is invalid," the law is clear that "*direct* regulation is prohibited"—the Commerce Clause "precludes the application of a statute to commerce that takes place wholly outside the State's borders." *Edgar*, 457 U.S. at 640, 642 (plurality opinion) (emphasis added). If a state law "directly control[s] wholly out-of-state commerce," it "is invalid." *Styczinski*, 46 F.4th at 913 (citation and quotation marks omitted). This rule follows from the "inherent limits [on] the State's power"—"any attempt 'directly' to assert extraterritorial jurisdiction over persons or property would offend sister States" and therefore "must be held invalid." *Edgar*, 457 U.S. at 643 (plurality opinion) (citation omitted); *see Styczinski*, 46 F.4th at 913 (states may not "force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another") (citation omitted). Although the Supreme Court has recently limited the Commerce Clause's extraterritorial doctrine in other respects, it made clear that it was not disturbing the Commerce Clause's prohibition of state laws that "*directly* regulate[] out-of-state transactions." *Ross*, 143 S. Ct. at 1157 n.1.

B. Due Process Clause

50. Like the Commerce Clause, the Due Process Clause restricts states' authority "to exercise 'extra territorial jurisdiction,' that is, to regulate and control activities wholly

beyond its boundaries." *Watson*, 348 U.S. at 70; *see also Home Ins. Co. v. Dick*, 281 U.S. 397, 407-10 (1930) (holding that the application of a Texas law to activities lacking any meaningful connection with Texas violated the Due Process Clause); *Gerling Global Reinsurance Corp. of Am.*, 267 F.3d at 1236-37 (recognizing that the Due Process Clause places "constraints on a state legislature's ability to regulate subject matters and transactions beyond the state's boundaries").

51. Under the Due Process Clause, a state may not "apply its substantive law to factual and legal situations with which it has little or no contact." *McCluney*, 649 F.2d at 580. For a state to constitutionally impose its law on an out-of-state transaction, there must be "some minimal contact[s]" between both the "regulated party and the state" and "also the regulated subject matter and the state." *Gerling Global Reinsurance Corp. of Am.*, 267 F.3d at 1236 (emphases omitted); *accord McCluney*, 649 F.2d at 581 ("The basic rule is the state whose law is chosen to control a case must have a substantial factual contact with the parties or the transaction giving rise to the litigation."). "When a state's law is applied to a transaction with which the state has no significant contact, it infringes upon the legitimate interests that other states may have in the transaction." *McCluney*, 649 F.2d at 582. Importantly, the relevant contacts must be those of the regulated party—"the unilateral act of a third party is not sufficient to create the requisite contacts." *Am. Charities for Reasonable Fundraising Reg., Inc. v. Pinellas Cnty.*, 221 F.3d 1211, 1216 (2000) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985)).

C. The Constitution's Horizontal Separation of Powers

52. In addition to the specific restraints on extraterritorial legislation imposed by

the Commerce Clause and the Due Process Clause, the Constitution's structure and design "restricts a State's power to reach out and regulate conduct that has little if any connection with the State's legitimate interests." *Mallory*, 600 U.S. ---, 2023 WL 4187749, at *16, slip op., at 5 (Alito, J., concurring in part and concurring in the judgment). That bedrock principle of equal sovereignty among the states is inherent in the plan of the Convention, apparent in several of the Constitution's structural protections, and deeply rooted in our Nation's historical tradition. *See Ross*, 143 S. Ct. at 1157 n.1; *id.* at 1175-76 (Kavanaugh, J., concurring in part and dissenting in part); *Mallory*, 600 U.S. ---, 2023 WL 4187749, at *16, slip op., at 5-6 (Alito, J., concurring in part and concurring in the judgment) (deeming this principle an "'obvious[s]' and 'necessary result' of our constitutional order" that "is not confined to any one clause or section, but is expressed in the very nature of the federal system … and in numerous provisions that bear on States' interactions with one another").

53. The Supreme Court has emphasized the importance of looking to "original and historical understandings of the Constitution's structure and the principles of 'sovereignty and comity' it embraces" when it comes to cases "testing the territorial limits of state authority under the Constitution's horizontal separation of powers." *Ross*, 143 S. Ct. at 1156-57 & n.1 (citation omitted). Looking to those principles, it is plain that a state may not "*directly* regulate" pricing outside its borders. *Id*. at 1157 n.1.

54. At the outset, it is axiomatic that "the States in the Union are coequal sovereigns under the Constitution." *PPL Mont., LLC v. Montana*, 565 U.S. 576, 591 (2012). Indeed, "the constitutional equality of the states is essential to the harmonious operation of the scheme upon which the Republic was organized." *Coyle v. Smith*, 221

U.S. 559, 580 (1911). When a state reaches beyond its own borders to "directly regulate[] out-of-state transactions by those with no connection to the State," *Ross*, 143 S. Ct. at 1157 n.1 (emphasis omitted), it invades the sovereignty and impinges on the equality of other states. Accordingly, the plan of the Convention necessarily restricts one state from directly regulating conduct that neither occurs nor is directed within its borders, as a union of several *equal* states subject to the overarching regulation of only one federal sovereign could not succeed if each state could trump the others' sovereign powers whenever and however it saw fit. *Cf. State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) ("A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction.").

55. Consistent with that understanding, several provisions of the Constitution—in addition to the Commerce Clause and the Due Process Clause discussed above—impose and/or presuppose limits on the ability of one state to override the regulatory powers of another. For instance, Article I, section 10 of the Constitution deprives states of several powers that one sovereign might ordinarily exercise against another, including the right to "lay any Imposts or Duties on Imports or Exports," and to "lay any Duty of Tonnage, keep Troops, or Ships of War in time of Peace, [or] enter into any Agreement or Compact with another State." U.S. Const., art. I, § 10, cl. 2-3.

56. Conversely, Article IV of the Constitution is devoted entirely to preserving the rights of each state vis-à-vis the others, requiring (among other things) that "Full Faith

and Credit shall be given in each State to the public Acts, Records, and judicial Proceedings of every other State," U.S. Const. art. IV, § 1; that "[t]he Citizens of each State shall be entitled to all Privileges and Immunities of Citizens in the several States," *id*., § 2, cl. 1; that "no new State shall be formed or erected within the Jurisdiction of any other State," *id*., § 3, cl. 1; and that "[t]he United States shall guarantee to every State in this Union a Republican Form of Government," *id*., § 4.

57. Finally, the Tenth Amendment provides that "powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States *respectively*, or to the people," U.S. Const. amend. X (emphasis added), making clear that each state retains its *own* "integrity, dignity, and residual sovereignty," *Bond v. United States*, 564 U.S. 211, 221 (2011). It is little surprise, then, that the Supreme Court just reiterated that "the territorial limits of state authority under the Constitution's horizontal separation of powers" are grounded not just in any one provision, but in the "original and historical understandings of the Constitution's structure and the principles of 'sovereignty and comity' it embraces." *Ross*, 143 S. Ct. at 1156-57 & n.1 (citation omitted); *see also, e.g.*, *id.* at 1173, 1175-76 (Kavanaugh, J., concurring in part and dissenting in part); *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2100-01 (2018) (Gorsuch, J., concurring); *Mallory*, 600 U.S. ---, 2023 WL 4187749, at *16, slip op., at 5-6 (Alito, J., concurring in part and concurring in the judgment). And those understandings distill into the basic principle that a state cannot directly regulate conduct that occurs entirely outside its borders.

II. Limits on State Laws that Substantially Burden Interstate Commerce

58. Separate from its prohibition on state laws that "*directly* regulate[] out-of-state transactions," *Ross*, 143 S. Ct. at 1157 n.1, the Commerce Clause restricts states from enacting laws that impose undue burdens on interstate commerce. Under the Commerce Clause, a state law that "regulates evenhandedly to effectuate a legitimate local public interest" may still be unconstitutional under the Commerce Clause if "the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *United Waste Sys. of Iowa, Inc. v. Wilson*, 189 F.3d 762, 767-68 (8th Cir. 1999) (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)); *see IESI AR Corp. v. Nw. Ark. Reg'l Solid Waste Mgmt. Dist.*, 433 F.3d 600, 604 (8th Cir. 2006) (same).

59. In assessing whether a state law's burden is "clearly excessive in relation to the putative local benefits," *United Waste Sys. of Iowa, Inc.*, 189 F.3d at 767-68 (citation omitted), courts are "not limited" to assessing "the burdens suffered by the particular parties" in a case, but "must adopt an aggregate analysis" and "consider the interstate effect … if several jurisdictions were to adopt similar ordinances." *U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1069 (8th Cir. 2000); *see also R&M Oil & Supply, Inc.*, 307 F.3d at 736 ("In comparing the putative local benefit of the statute to the burden imposed on commerce…, we are not constrained (indeed, we are not allowed) to look only at the burden on [the plaintiff]," but "must look at the cumulative effects of the [Minnesota] statute on all [regulated entities]."). "Requiring a foreign corporation … to defend itself with reference to all transactions, including those in which it did not have [constitutionally adequate] minimum contacts [with the State], is a significant burden." *Bendix Autolite*

Corp. v. Midwesco Enters., 486 U.S. 888, 893 (1988); *see Mallory*, 600 U.S. ---, 2023 WL 4187749, at *19, slip op., at 13 (Alito, J., concurring in part and concurring in the judgment). Further, "[w]hen a law that burdens interstate commerce serves some legitimate local purpose, the availability of a less burdensome alternative is relevant to the inquiry." *U & I Sanitation*, 205 F.3d at 1070; *R&M Oil & Supply, Inc.*, 307 F.3d at 735.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Commerce Clause's Prohibition on State Laws That Regulate Extraterritorially)

60. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

61. A price-control statute that "directly control[s] wholly out-of-state commerce is invalid" under the Commerce Clause. *Styczinski*, 46 F.4th at 913 (citation and quotation marks omitted); *see Ross*, 143 S. Ct. at 1155-57 & n.1.

62. The Act directly regulates out-of-state commerce because it applies Minnesota law to prices charged in transactions wholly outside Minnesota.

63. The Act therefore violates the Commerce Clause and "must be held invalid." *Edgar*, 457 U.S. at 643 (plurality opinion).

SECOND CAUSE OF ACTION
(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Due Process Clause of the Fourteenth Amendment)

64. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

65. The Due Process Clause prohibits a state from regulating activities that occur

wholly outside the state's borders in the absence of "significant contact[s]," *McCluney*, 649 F.2d at 582, between both the "regulated party and the state" and "the regulated subject matter and the state," *Gerling Global Reinsurance Corp. of Am.*, 267 F.3d at 1236 (emphases omitted).

66. All of AAM's members that are generic and biosimilar manufacturers are located outside Minnesota, and they sell their products to wholesale distributors that are almost exclusively located outside Minnesota.

67. Minnesota lacks any significant contacts with AAM's members or the out-of-state prices they charge to wholesale distributors located outside Minnesota.

68. Accordingly, the application of the Act to AAM's members violates the Due Process Clause's limitations on state extraterritorial legislation.

THIRD CAUSE OF ACTION
(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the U.S. Constitution's Horizontal Separation of Powers)

69. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

70. The "Constitution's horizontal separation of powers," *Ross*, 143 S. Ct. at 1157 n.1—reflected in the fundamental principle of coequal sovereignty among the states, the Constitution's specific provisions restricting states' ability to control conduct outside their territorial bounds, the "historical understandings of the Constitution's structure," and "the principles of 'sovereignty and comity' it embraces," *id*. at 1156, 1157 n.1 (citation omitted)—prohibits states from directly regulating transactions that occur wholly outside their borders.

71. The Act directly regulates prices charged wholly outside Minnesota and therefore violates the Constitution's "horizontal separation of powers." *Ross*, 143 S. Ct. at 1157 n.1.

FOURTH CAUSE OF ACTION
(Declaratory/Injunctive Relief – Unduly Burdening Interstate Commerce)

72. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

73. A state law violates the Commerce Clause if it imposes a substantial burden on interstate commerce that is "clearly excessive in relation to [any] putative local benefits." *United Waste Sys. Of Iowa, Inc.*, 189 F.3d at 767-68 (citation omitted).

74. The Act's price and other regulations impose a substantial burden on interstate commerce, requiring that each manufacturer either make every sale nationwide comply with Minnesota's rules; or attempt to somehow restructure pricing and supply processes to segregate drug products for sale in Minnesota, resulting in significant compliance costs and disruptions to the drug-supply chain; or else "'defend itself'" in Minnesota "'with reference to all transactions,' including those with no forum connection," *Mallory*, 600 U.S., ---, 2023 WL 4187749, at *19, slip op., at 13 (Alito, J., concurring in part and concurring in the judgment) (quoting *Bendix Autolite Corp.*, 486 U.S. at 893).

75. Those burdens will fall overwhelmingly on interstate commerce, as drug manufacturers and the wholesale distributors they sell to are overwhelmingly located outside Minnesota. Those burdens are particularly substantial when "consider[ing] the interstate effect … if several jurisdictions were to adopt similar ordinances." *U & I*

Sanitation, 205 F.3d at 1069.

76. Those cumulative effects on interstate commerce far outweigh any interest Minnesota may have in regulating the upstream prices charged for drugs that are later resold to Minnesota consumers by third parties.

77. There are "less burdensome alternative[s]" available to Minnesota to regulate the prices of prescription drugs sold to Minnesota residents, *U & I Sanitation*, 205 F.3d at 1070, including providing generic and biosimilar manufacturers with the same pass-through defense the Act affords wholesale distributors and pharmacies, or limiting its regulation to in-state transactions.

78. The Act undermines Minnesota's interest in making life-saving medications available to Minnesota consumers by erasing generic and biosimilar manufacturers' thin profit margins for those products, potentially resulting in those manufacturers withdrawing those products from the market altogether.

79. Accordingly, the Act violates the Commerce Clause because it imposes a substantial burden on interstate commerce that is clearly excessive in relation to any putative local benefits.

FIFTH CAUSE OF ACTION
(42 U.S.C. § 1983 and 42 U.S.C. § 1988)

80. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

81. By seeking to implement and enforce the Act, Defendant, acting under color of state law, will violate and, unless enjoined by this Court, continue to violate the rights

of AAM's members to engage in activities free from unconstitutional state regulation in violation of the Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and/or the Constitution's horizontal separation of powers.

82. An actual "Case or Controversy" exists because the Act's unconstitutional provisions create a genuine, credible, and immediate threat that Defendant—acting in his official capacities under color of state law—will violate AAM's members' constitutionally protected rights.

83. AAM seeks a declaration that Defendant's enforcement of the Act against sales of generic and biosimilar products that occur outside Minnesota is unconstitutional under the Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and/or the Constitution's horizontal separation of powers.

84. AAM also seeks reasonable attorney's fees pursuant to 42 U.S.C. § 1988.

PRAYER FOR RELIEF

WHEREFORE, AAM prays:

A. For a declaration, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that the Act violates the Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and/or the Constitution's horizontal separation of powers, and is void and unenforceable;

B. For a preliminary injunction prohibiting Defendant from implementing or enforcing the Act against AAM's members in violation of the Constitution;

C. For a permanent injunction prohibiting Defendant from implementing or enforcing the Act against AAM's members in violation of the Constitution;

D. For such costs and reasonable attorney's fees to which it might be entitled by law; and

E. For any other relief that the Court deems just and proper.

Dated: July 5, 2023

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