No. 25-2960

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff-Appellant,

v.

KWAME RAOUL,
in his official capacity as Attorney General for the State of Illinois,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of Illinois Case No. 1:24-cv-00544 (Kendall, C.J.)

SEPARATE APPENDIX OF PLAINTIFF-APPELLANT
VOLUME I OF II (A17 – A167)

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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois, *Defendant*.	Case No. 24-cv-_____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Association for Accessible Medicines ("AAM") brings this complaint for declaratory and injunctive relief against Kwame Raoul, in his official capacity as Attorney General of the State of Illinois. 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.

INTRODUCTION

1. This lawsuit challenges Illinois' new price-control law, which took effect on January 1, 2024. Public Act 103-167 ("the Act"), codified at 410 Ill. Comp. Stat. Ann. 725/1 *et seq*. The Act threatens to impose massive penalties on manufacturers of certain essential generic or other off-patent drugs or biosimilar medicines. Any manufacturer that increases the price of such a medicine can be penalized if the price change falls within the Act's extraordinarily vague definition of "price gouging" and the medicine is "ultimately sold in Illinois," even if the manufacturer "did not *directly* sell [the] product to a consumer residing in Illinois." Act §§ 5, 10,

410 Ill. Comp. Stat. Ann. 725/5, 725/10 (emphasis added). Thus, by its terms, the Act controls the prices charged for generic and biosimilar medicines *anywhere in the country*.

2. To enforce its price control, the Act authorizes Illinois 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 § 10(a), (c).

3. By regulating transactions that occur wholly outside Illinois, the Act violates multiple provisions of the U.S. Constitution, as well as the limits on state authority implicit in the constitutional structure and design.

4. First and foremost, the Act violates the restrictions on extraterritorial state legislation imposed by the Commerce Clause, U.S. Const. art. I, § 8, cl. 3—as every court to consider the constitutionality of similar price-control legislation has concluded. A state law that "directly regulates interstate commerce … 'is invalid,'" and that is so "'regardless of whether the statute's extraterritorial reach was intended by the legislature.'" *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 830 (7th Cir. 2017) (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)). "With almost two hundred years of [prior dormant Commerce Clause] precedents to consider," not "a single appellate case [has] permit[ted] any direct regulation of out-of-state" commerce. *Id.* at 831.

5. The Supreme Court recently "refined [its] Commerce Clause framework" in some respects, *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 160 (2023) (Alito, J., concurring in part and concurring in the judgment), in its decision in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). But the Court kept intact the bedrock principle prohibiting state laws that directly regulate out-of-state conduct. Indeed, *Ross* went out of its way to confirm the vitality of the rule 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. 598 U.S. at 374, 376 n.1 (quoting *Healy*, 491 U.S. at 338-39); *see Ass'n for Accessible Meds. v. Ellison*, No. 23-cv-2024, 2023 WL 8374586, at *3 (D. Minn. Dec. 4, 2023) (concluding that *Ross* "did not change the rule that a state may not directly regulate transactions that take place wholly outside the state").

6. The Act violates the Commerce Clause's clear command by directly regulating prices in transactions that take place entirely outside Illinois. Take, for example, a drug manufacturer located in Pennsylvania that sells generic drugs to a wholesale distributor located in Ohio. If the Act deems the price the Pennsylvania manufacturer charges the Ohio wholesaler in 2024 to be too much higher than the price charged in 2023, and if the drug "is ultimately sold in Illinois," Act § 10(a), then the Pennsylvania manufacturer's initial sale to the Ohio wholesaler would be prohibited—even though it occurred wholly outside of Illinois and the Pennsylvania manufacturer has "*no* connection to the State." *Ross*, 598 U.S. at 376 n.1. By directly regulating commercial activities entirely outside the boundaries of Illinois, the Act violates the Commerce Clause of the U.S. Constitution.

7. 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 Glob. Reinsurance Corp. of Am. v. Gallagher*, 267 F.3d 1228, 1236 (11th Cir. 2001) (emphasis omitted). AAM's members sell their

drug products to wholesale distributors that are located outside Illinois, and all but two of AAM's members are also located outside Illinois—leaving Illinois without the necessary "substantial … contact[s]" with AAM's out-of-state members and their 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).

8. The Act's extraterritorial reach not only runs afoul of these specific constitutional provisions, but 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. at 154 (Alito, J., concurring in part and concurring in the judgment) (alterations, citation, and quotation marks omitted) (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*, 598 U.S. at 376 (citation omitted). By regulating activities that occur wholly outside Illinois' borders, the Act transgresses the "horizontal separation of powers" embedded in the constitutional design. *Id*. at 376 n.1.

9. Separate from the Act's impermissible direct regulation of wholly out-of-state transactions, the law also violates the Commerce Clause because it imposes a burden on interstate commerce that "is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). To avoid violating the Act's price control, manufacturers of generic or other off-patent drugs or biosimilar medicines would either have to try to keep their medicines out of the Illinois market—which may well be impossible given the nature of the

nationwide wholesale market—or treat Illinois' regulation as the national standard. And because the lists of essential medicines to which the Act applies will be ever-changing—depending on shifting market dynamics and essential-medicine designations—manufacturers will be compelled to take these protective measures for all or a substantial portion of their generic and biosimilar products, not just those that currently qualify as an "essential off-patent or generic drug." A decision permitting state regulation like Illinois' would allow all 50 states to apply their own views of what price increases are permissible *nationwide*, 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 impose a substantial burden on interstate commerce, which far outweighs any interest Illinois may have in regulating the upstream prices charged for drugs that are later resold in Illinois by third parties.

10. Finally, the Illinois law violates the fundamental requirement of due process that a law be written with sufficient clarity to give regulated parties "'fair warning' as to what conduct will subject [them] to liability," and to "prevent … 'arbitrary and discriminatory' enforcement." *Karlin v. Foust*, 188 F.3d 446, 458-59 (7th Cir. 1999) (citation omitted). The Act fails these basic requirements: it authorizes massive civil penalties for price increases that are ultimately deemed "unconscionable" and "otherwise excessive and unduly burden[some]" by an Illinois court, Act § 5, but it does not define any of these operative terms. Nor does it offer regulated parties any guidance on what these nebulous statutory terms mean and how they differ from one another. Because the Act provides no meaningful guidance as to what price increases are prohibited, and thus simultaneously invites arbitrary enforcement by the Illinois Attorney General, the Act violates the Due Process Clause of the Fourteenth Amendment.

11. AAM's members, who manufacture, offer, and sell generic and biosimilar

products—including products currently on (and likely to remain on) the lists of essential medicines—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 the sales occur wholly outside Illinois. AAM's members also will face significant economic harm as a result of the Act's price control no matter what course of action they take—forced to choose between (a) forgoing reasonable price increases on their generic and biosimilar products, including price increases necessary to maintain profitability; (b) raising prices on those products, but in doing so, triggering substantial civil penalties and other monetary liability; or (c) withdrawing the regulated generic products from the Illinois market and losing all revenue from those sales.

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

[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.

manufacturers will withdraw products from the market—exacerbating the already-severe drug-supply shortage and driving up prices for those products that remain. And by applying its price control solely to medicines manufactured by *the fewest* number of manufacturers, the Act increases the likelihood that the rarest of essential medicines will be withdrawn from the market *entirely*.

13. For these reasons, and as explained below, AAM seeks an injunction prohibiting 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 complete list of AAM's current membership 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 patients 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. Kwame Raoul is the Attorney General of Illinois. In that capacity, he is authorized to investigate and bring enforcement actions in Illinois court to assert violations of the Act. *See* Act § 10(b)-(c).

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 proper in this district under 28 U.S.C. § 1391(b).

19. There is a justiciable case or controversy. AAM's claims and requested relief 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 members who manufacture and sell generic and biosimilar medicines by subjecting those members to unconstitutional regulation and, if not enjoined, will certainly and imminently injure them by subjecting them to unrecoverable economic injury. *See* ¶¶ 37-53, *infra*. 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 90% of all prescriptions dispensed in the United States but amount to only 17.5% of the money spent on prescriptions. *See* Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report*, 7, 10 (Sept. 2023).[4] These medicines have produced nearly $2.9 trillion in savings

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

[4] https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

to the U.S. healthcare system over the past decade, with $408 billion in savings in 2022 alone—a $35 billion increase over the prior year. *Id*. at 7-8. Illinois realized $15.3 billion in healthcare savings from generics and biosimilars in 2022. *Id*. at 16.

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 limit potential returns." U.S. Food & Drug Admin., *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. Moreover, a substantial share of generic products—up to 40%—are produced by only a single manufacturer, and many more are manufactured by only two companies. Ernst R. Berndt, et al., *The Landscape of US Generic Prescription Drug Markets, 2004-2016*, Nat'l Bureau of Econ. Rsch., 19-20 (July 2017)[6]; *see* Inmaculada Hernandez, et al., *Number of Manufactures and Generic Drug Pricing in 2005-2017*, Am. J. of Managed Care, 2 (July 2019).[7]

22. Numerous factors impact manufacturers' thin profit margins and put upward pressure on generic and biosimilar drug prices. For example, "[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),[8] and the "raw material prices for essential drugs" has risen sharply, by as much as 140% in the post-COVID era, *see Active*

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

[6] https://www.nber.org/system/files/working_papers/w23640/w23640.pdf.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6734551/pdf/nihms-1048940.pdf.

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

Pharmaceutical Ingredients Market Size, Precedence Research (Jan. 2023).[9] In addition, prices for biosimilar medicines and for drugs approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2),[10] face additional upward pressure due to the need to recover substantial costs arising from clinical and other studies needed to obtain FDA approval, as well as increased costs arising from marketing, patient-support services, and other non-production related costs.

23. The high cost of manufacturing generic and biosimilar products, combined with "a complex array of [other] factors," U.S. Food & Drug Amin., *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)[11]—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 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

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

[10] Section 505(b)(2) creates a pathway for approval of a new drug meant to build on FDA's previous approval of another drug—such as by creating a new dosage form for an existing drug. Because section 505(b)(2) drugs are not identical copies of the brand drug, they do not benefit from state laws that require or allow pharmacists to substitute a generic drug for a prescribed brand-name drug. Thus, manufacturers of section 505(b)(2) drugs must invest in marketing these products.

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

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).[12]

24. These harms may be especially acute when they impact the most essential medicines. The World Health Organization and the U.S. Department of Health and Human Services have published lists of "essential medicines" deemed necessary to meet the priority health care needs of a population, *see* World Health Organization, *The Selection and Use of Essential Medicines 2023: World Health Organization Model list of Essential Medicines – 23rd list* (2023),[13] and to protect society from outbreaks of infectious diseases and other threats, *see* U.S. Food & Drug Admin., Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs (May 23, 2022), respectively.[14] The World Health Organization's biannual list of essential medicines currently contains 502 medicines, *see* World Health Organization, *The Selection and Use of Essential Medicines 2023: Executive Summary of the Report of the 24th WHO Expert Committee on Selection and Use of Essential Medicines*, 1 (2023)[15]—a significant increase over the 479 medicines designated in the 2021 list. The FDA has similarly published a list of essential medicines, which designates 227 drug and biological products as essential medicines and medical countermeasures. *See* U.S. Food & Drug Admin., *FDA*

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

[13] https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02.

[14] https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs.

[15] https://iris.who.int/bitstream/handle/10665/371291/WHO-MHP-HPS-EML-2023.01-eng.pdf.

Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order (Oct. 30, 2020).[16]

25. 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 patients. 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, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp., 4-5 (2021)[17]; Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 1-2 (Mar. 2005).[18]

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

27. 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.

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[16] https://www.fda.gov/news-events/press-announcements/fda-publishes-list-essential-medicines-medical-countermeasures-critical-inputs-required-executive.

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

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

28. The vast majority of sales between AAM's members who are generic and biosimilar manufacturers and wholesale distributors occur outside Illinois, and wholesale distributors take title to those products outside Illinois. None of the three largest wholesale distributors (who collectively control over 90% of the wholesale market)—Cencora, Cardinal Health, and McKesson—is incorporated or headquartered in Illinois.[19] Only two of AAM's manufacturer members are located in Illinois.

II. Illinois' New Drug Price-Control Law

29. Governor J.B. Pritzker signed HB 3957 into law on July 28, 2023, and the law took effect on January 1, 2024. *See* Act § 99, 410 Ill. Comp. Stat. Ann. 725/99.

30. The Act regulates the prices charged for certain medicines that are eventually sold in Illinois. Specifically, the Act applies to prices charged for "[e]ssential off-patent or generic drug[s]," which the Act defines as "any prescription drug sold within the State": (1) for which any "exclusive marketing rights" under "the Federal Food, Drug, and Cosmetic Act, Section 351 of the federal Public Health Service Act [addressing biological products and biosimilars], and federal patent law have expired"; (2) "that appears on the model list of essential medicines most recently adopted by the World Health Organization or that has been designated by the United States Secretary of Health and Human Services as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an

[19] Adam J. Fein, Ph.D., *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* Cencora, Inc., SEC Form 8-K (Nov. 2, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0001140859/0514f5f3-1108-4cdc-aa9b-c13f0d8abd89.pdf; Cardinal Health, Inc., SEC Form 8-K (Nov. 3, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000721371/e13cff17-e82d-4bdc-9fb2-c43e86a48089.pdf; McKesson Corp., SEC Form 8-K (Nov. 7, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000927653/014f18c1-ddc5-4051-adbb-91353d9d73bd.pdf.

individual's ability to engage in activities of daily living"; and (3) "that is actively manufactured and marketed for sale in the United States by 3 or fewer manufacturers." Act § 5.

31. The Act prohibits any drug "manufacturer or wholesale drug distributor" from engaging in what the Act calls "price gouging in the sale" of any essential medicine "that is ultimately sold in Illinois." Act § 10(a).

32. The Act gives "price gouging" a complex, three-part definition. The term is defined as an "unconscionable increase in a prescription drug's price" that (1) would result in the drug's wholesale acquisition cost "exceeding $20" for a "30-day supply" of the drug; (2) would result in an increase in the wholesale acquisition cost of (a) "30% or more within the preceding year," (b) "50% or more within the preceding 3 years," or (c) "75% or more within the preceding 5 years"; and "is otherwise excessive and unduly burdens consumers because of the importance of the [drug] to their health and because of insufficient competition in the marketplace." Act § 5.

33. The Act excludes certain price increases from its definition of "price gouging." Specifically, price gouging "does not include a price increase" that can be "reasonably justified" by either (1) "an increase in the cost of producing the essential off-patent or generic drug"; or (2) "the cost of appropriate expansion of access to the [drug] to promote public health." Act § 5.[20]

34. A generic or biosimilar manufacturer can violate the Act based on sales made entirely outside Illinois. The Act prohibits price gouging "in the sale" of an essential medicine, even if the sale occurs outside Illinois, as long as the medicine is "*ultimately* sold in Illinois." Act § 10(a) (emphasis added). The law then drives the point home, providing that "a manufacturer or

[20] The Act also provides that "wholesale distributor[s]" do not violate the Act if a price increase "is directly attributable to an increase in the wholesale acquisition cost for the essential off-patent or generic drug imposed on the wholesale drug distributor by the manufacturer of the drug." Act § 10(a).

wholesale drug distributor … may not assert as a defense that the manufacturer or wholesale drug distributor did not *directly* sell a product to a consumer residing in Illinois." *Id*. § 10(c) (emphasis added).

35. The Act creates a reporting mechanism to aid the Illinois Attorney General in investigating and bringing enforcement actions to punish violations of the Act's price regulation. *See* Act § 10(a)-(b). In particular, the law authorizes the Director of Healthcare and Family Services to notify the Attorney General "of any increase in [] price … that amounts to price gouging" for an essential medicine made available through the Medication Assistance Program under Section V of the Illinois Public Aid Code. *Id*. § 10(a). Further, if the Attorney General otherwise has "reason to believe" a violation has occurred, he "may send a notice to the manufacturer or the wholesale drug distributor requesting a statement" providing information "relevant to a determination of whether a violation … has occurred." *Id*. § 10(b). With that information, the Attorney General may investigate whether a violation has occurred, including by issuing subpoenas or "examin[ing] under oath any person." *Id*.

36. The law authorizes the Attorney General to bring suit in Illinois court to remedy violations. Act § 10(c). If a violation is found, the Act authorizes a court to impose a civil penalty up to $10,000 per day for each prohibited sale. *Id*. § 10(c)(5). The court may also award restitution to Illinois consumers and enter injunctive relief. *Id*. § 10(c)(2), (3).

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

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

37. Several of AAM's members intend, or intended until the Act's adoption, to make competitively reasonable price adjustments to the wholesale acquisition cost for certain "essential off-patent or generic drugs" during the first half of the 2024 calendar year.

38. These AAM members intend, or intended until the Act's adoption, to raise the wholesale acquisition cost of certain generic or other off-patent drugs in a manner that meets the quantitative elements of "price gouging" under the Act—*e.g.*, constituting substantially more than a 30% increase of the wholesale acquisition cost for those medicines over one year. The increased wholesale acquisition cost for those medicines would exceed $20 for a 30-day supply. These AAM members include members that are located outside Illinois. Indeed, all but two of AAM's members are located outside Illinois.

39. Some of these AAM members' planned price increases are necessitated, at least in part, by economic or cost factors other than those excepted by the Act.

40. AAM members located outside Illinois sell their medicines overwhelmingly to large wholesale distributors, which are also located outside Illinois.

41. Each of the products addressed in this section is an "essential off-patent or generic drug" within the meaning of the Act, because any exclusive federal marketing rights for the medicines have expired, they appear on the World Health Organization's or the U.S. Department of Health and Human Services' most recent list of essential medicines, and they are manufactured and marketed for sale in the United States by three or fewer manufacturers. Although AAM members do not control where their products are resold, each of the products addressed in this section is eventually resold in Illinois.

42. Although the Act does not define a price increase that is "otherwise excessive" or "unduly burden[some]," there is, at a minimum, a substantial risk the Attorney General and an Illinois court would determine that the contemplated price increases by AAM's members of their essential off-patent or generic drugs meet those elements of the definition of "price gouging."

43. Thus, these AAM members intend, or intended until the Act's adoption, to raise the

prices of one or more "essential off-patent or generic drugs" in a manner that satisfies every ascertainable element of the Act's definition of "price gouging" and that would trigger liability under the Act. Some of these AAM members intend to proceed with their price adjustment notwithstanding the Act because the Act is unconstitutional. If the Act is not enjoined, they face severe economic harm from the potential enforcement of the Act, which threatens civil penalties and other monetary liability.

44. In addition, some AAM members are refraining from raising their prices for these medicines as a result of the Act, and are thus facing economic harm in the form of lost revenues they would otherwise realize but for the Act's prohibition on their planned price increases. Enjoining the Act would enable these AAM members to move forward with their previously planned price increases.

45. Enjoining the Act will enable AAM's members to sell their products as planned without the threat of the Act's civil penalties and other monetary liability.

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

46. The Act's regulations and penalties will cause AAM's members who manufacture essential generic and other off-patent drugs to suffer substantial and immediate economic injury and will burden the interstate market for generic and biosimilar medicines.

47. As a result of intense competition in the generic and biosimilar market, the profit margins for generic and biosimilar products are often thin. In addition to increased costs in the production of generic or biosimilar products, other external factors outside manufactures' control can reduce or outright 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. Moreover, pricing for biosimilars and drugs approved under section 505(b)(2) of the FDCA rely in part on manufacturers' needs to recoup upfront investment costs and to pay for marketing, patient-support, and other product-related services.

48. The Act's price controls and penalties either prevent AAM's members from making reasonable and necessary price increases on certain of their generic or other off-patent drugs, or punish those AAM members who do increase the prices of their products. The Act's restrictions therefore place these manufacturers in a no-win dilemma that will cause significant economic losses no matter their course of action. Specifically, AAM's members will be compelled to choose among: (1) forgoing reasonable price increases on their generic and biosimilar products, including price increases necessary to maintain product and overall profitability, and thereby losing the revenue they would otherwise realize; (2) raising prices on those products, but in doing so, triggering the threat of substantial civil penalties and other monetary liability; or (3) withdrawing the regulated generic and biosimilar products from the Illinois market and losing all revenue from the sale of those medicines. AAM's members will suffer severe financial injury as a result of the Act's price control no matter which option they choose.

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

50. To avoid the Act's price control, AAM's members would need to prevent their essential generic and biosimilar products from being resold in Illinois by a third party, such as a wholesale distributor or retail pharmacy. Segregating out and specially pricing products destined for Illinois 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 their essential generic or biosimilar products that are ultimately to be resold in Illinois. Moreover, because the Act defines the essential medicines it covers based on shifting market dynamics (*i.e.*, the number of companies that manufacture a product) and essential-medicine designations by the World Health Organization and the U.S. Department of Health and Human Services, manufacturers will have no reliable way to know whether or when a medicine not currently encompassed by the Act's definition of "essential off-patent or generic drug" may become regulated in the future, based on changed circumstances entirely beyond manufacturers' control. As a result, and in light of the long-term duration of manufacturers' contracts with wholesalers, if a manufacturer were to attempt to segregate products destined for Illinois, they would need to alter their distribution and contracting practices with wholesalers for a substantial portion of their medicines that are *not* currently regulated by the Act. However, even if these alterations to manufacturers' contracting practices were possible, it would not be sufficient, because their products could still be resold into Illinois by parties further down the supply chain with whom manufacturers have no direct contractual relationship.

51. 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 Illinois law nationwide. Those increased costs will, in turn, place increased upward pressure on the cost of delivering generic and biosimilar medications to patients throughout the United States.

52. The substantial disruptions caused by an Illinois-specific price regime—potentially to be followed by 49 other states, as each adopts its own definition of what qualifies as an unacceptable price increase—will create enormous inefficiencies in the processing of essential and

other 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.

53. Accordingly, the Act's price controls will place significant burdens on the supply chains for essential and other generic and biosimilar medications, including manufacturers and wholesale distributors. Because AAM's members and the wholesale distributors they sell to are overwhelmingly located outside Illinois, 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

54. 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).

55. 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 prohibits state "law[s] that *directly* regulate[] out-of-state transactions." *Ross*, 598 U.S. at 376 n.1; *see Edgar v. MITE Corp.*, 457 U.S. 624, 640, 642 ("precludes the application of a state statute to commerce that takes place wholly outside of the State's borders") (plurality opinion) (emphasis added). If a state law "directly regulates interstate commerce," it "is invalid." *Legato Vapors*, 847 F.3d at 830 (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 Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 665 (7th Cir. 2010) ("no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another" (citation omitted)); *Ellison*, 2023 WL 8374586, at *2 ("Among other limitations, the dormant Commerce Clause prohibits states from directly regulating out-of-state transactions."). In light of this rule, "the Supreme Court has never held that a state may impose truly direct and burdensome state regulation of commerce beyond the state's boundaries." *Legato Vapors*, 847 F.3d at 829, 831 ("With almost two hundred years of precedent to consider, our review of prior dormant Commerce Clause decisions has not revealed a single appellate case permitting any direct regulation of out-of-state [commerce]"); *accord Ellison*, 2023 WL 8374586, at *3 ("The Court cannot find any support for the notion that the dormant Commerce Clause permits [a state] to directly regulate a sale that occurs in another state simply because the product eventually makes its way into [that state]").

56. Although the Supreme Court recently clarified that the Commerce Clause does not impose any per se barrier to state laws that have indirect extraterritorial *effects*, the Court made

clear that it was not disturbing the Commerce Clause's prohibition of state laws that "*directly* regulate[] out-of-state transactions." *Ross*, 598 U.S. at 376 n.1; *see Ellison*, 2023 WL 8374586, at *3 ("[*Ross*] did not change the rule that a state may not directly regulate transactions that take place wholly outside the state and have no connection to it."); *Interlink Prods. Int'l, Inc. v. Crowfoot*, --- F. Supp. 3d ---, 2023 WL 4187496, at *4 (E.D. Cal. June 26, 2023) ("[I]n clarifying that … laws with extraterritorial effects are not prohibited by the dormant Commerce Clause, the Supreme Court [in *Ross*] distinguished them from those in which 'a law [] *directly* regulated out-of-state transactions by those with *no* connection to the State'" (quoting *Ross*, 598 U.S. at 376 n.1)).

B. Due Process Clause

57. The Due Process Clause of the Fourteenth Amendment provides that "[n]o State shall … deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. 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 Glob. 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"); *see also Midwest Title Loans, Inc. v. Ripley*, 616 F. Supp. 2d 897, 905 n.8 (S.D. Ind. 2009) ("The reach of a court's jurisdiction does not determine the territorial bounds of a state legislature's laws…. A state is generally prohibited from asserting legislative power over parties and activities wholly beyond its borders." (citing *Gerling Glob. Reinsurance Corp. of Am.*, 267 F.3d at 1233)), *aff'd sub nom. Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660 (7th Cir. 2010).

58. 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 Glob. 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 Regul., Inc. v. Pinellas Cnty.*, 221 F.3d 1211, 1216 (11th Cir. 2000) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985)).

C. The Constitution's Horizontal Separation of Powers

59. 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 "restrict[] 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. at 154 (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*, 598 U.S. at 376 n.1; *id.* at 408-10 (Kavanaugh, J., concurring in part and dissenting in part); *Mallory*, 600 U.S. at 154 (Alito, J., concurring in part and concurring in the judgment) (deeming this principle an "'obviou[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") (citation omitted).

60. 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*, 598 U.S. at 376 & n.1 (citation omitted). Under those principles, a state may not "*directly* regulate[]" pricing outside its borders. *Id*. at 376 n.1.

61. 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*, 598 U.S. at 376 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.").

62. 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.

63. 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.

64. 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*, 598 U.S. at 376 & n.1 (citation omitted); *see also, e.g.*, *id.* at 404, 408-10 (Kavanaugh, J., concurring in part and

dissenting in part); *South Dakota v. Wayfair, Inc.*, 585 U.S. ---, 138 S. Ct. 2080, 2100-01 (2018) (Gorsuch, J., concurring); *Mallory*, 600 U.S. at 154 (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

65. Separate from its prohibition on state laws that "*directly* regulate[] out-of-state transactions," *Ross*, 598 U.S. at 376 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 even-handedly 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." *Midwest Title Loans*, 593 F.3d at 665 (emphasis omitted) (quoting *Pike*, 397 U.S. at 142). Even state laws that do not discriminate against interstate commerce may be unconstitutional under *Pike*. *See Ellison*, 2023 WL 8374586, at *8 (recognizing that "a majority of the Justices [in *Ross*] acknowledged that the 'Court left the courtroom door open to [*Pike*] challenges premised on even nondiscriminatory burdens'" (first alteration added) (citation omitted)).

66. In assessing whether a state law's burden is "clearly excessive in relation to the putative local benefits," *Pike*, 397 U.S. at 142, courts are not limited to "considering the consequences of the statute itself," but must also "consider[] how the challenged statute may interact with the legitimate regulatory regimes of the other States and what effect would arise if not one, but many or every, jurisdiction adopted similar legislation," *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 406 (1994) (O'Connor, J., concurring in the judgment) (alterations and citation omitted); *see also U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1069 (8th Cir. 2000). "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., Inc.*, 486 U.S. 888, 893 (1988); *see Mallory*, 600 U.S. at 161 (Alito, J., concurring in part and concurring in the judgment). Further, the availability of a less burdensome alternative is relevant to whether the law's burdens on interstate commerce are clearly excessive. *See Pike*, 397 U.S. at 142 ("[T]he extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.").

III. Due Process Limits on Vague State Laws

67. Under the Due Process Clause, "laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). This basic requirement of clarity in legislation "is essential to the protections provided by the Due Process Clause," *id.*, since "[v]ague laws may trap the innocent by not providing fair warning," *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

68. There are "two means by which a statute can operate in an unconstitutionally vague manner." *Karlin*, 188 F.3d at 458-59. First, a "statute is void for vagueness if it fails to provide 'fair warning' as to what conduct will subject a person to liability." *Id*. at 458. A statute violates the Due Process Clause if it "forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application." *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926). Second, "a statute must contain an explicit and ascertainable standard to prevent those charged with enforcing the statute's provisions from engaging in 'arbitrary and discriminatory' enforcement." *Karlin*, 188 F.3d at 459. Thus, "'[t]he void-for-vagueness doctrine rests on the 'twin constitutional pillars of due process and separation of powers.'" *Planned Parenthood of Ind. & Ky., Inc. v. Marion Cnty. Prosecutor*, 7

F.4th 594, 598 (7th Cir. 2021) (citation omitted).

69. Although "[t]he Constitution tolerates a lesser degree of vagueness in enactments 'with criminal rather than civil penalties because the consequences of imprecision' are more severe,'" *Karlin*, 188 F.3d at 458 (citation omitted), "[w]hen a civil statute imposes penalties that, 'although civil in description, are penal in character,' the statute is … subjected to stricter vagueness review," *Advance Pharm., Inc. v. United States*, 391 F.3d 377, 396 (2d Cir. 2004) (citations omitted). Such "quasi-criminal" civil statutes are subject to the same vagueness standards as criminal exactions, and will be "deemed impermissibly vague if [they] fail[] to 'give the person of ordinary intelligence a reasonable opportunity to know what is prohibited," or to "provide explicit standards for those who apply them." *Id*. (citation omitted). Moreover, "[w]hen a law threatens to inhibit the exercise of constitutionally protected rights …, the Constitution demands that courts apply a more stringent vagueness test." *Karlin*, 188 F.3d at 458.

COUNT ONE

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

70. AAM re-alleges and incorporates herein by reference the allegations of all preceding paragraphs of this Complaint as if fully set forth in this paragraph.

71. A price-control statute that "directly regulates interstate commerce" that "takes place[] wholly outside of the State's borders" is "invalid." *Legato Vapors*, 847 F.3d at 830 (citation and quotation marks omitted); *see Ross*, 598 U.S. at 376 & n.1.

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

73. The application of the Act to these transactions therefore violates the Commerce Clause.

COUNT TWO

(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Due Process Clause's Prohibition on State Laws That Regulate Extraterritorially)

74. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

75. The Due Process Clause of the Fourteenth Amendment 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 Glob. Reinsurance Corp. of Am.*, 267 F.3d at 1236 (emphases omitted).

76. AAM's members sell their products primarily to wholesale distributors that are located outside Illinois. All but two of AAM's members that manufacture generic and biosimilar products are located outside Illinois.

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

78. Accordingly, the application of the Act to AAM's members located outside Illinois and their transactions outside Illinois violates the Due Process Clause's restrictions on state extraterritorial legislation.

COUNT THREE

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

79. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

80. The "Constitution's horizontal separation of powers," *Ross*, 598 U.S. at 376 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 376 & n.1 (citation omitted)—prohibits states from directly regulating transactions that occur wholly outside their borders.

81. The Act directly regulates prices charged wholly outside Illinois and therefore violates the Constitution's "horizontal separation of powers." *Ross*, 598 U.S. at 376 n.1.

COUNT FOUR

(Declaratory/Injunctive Relief – Unduly Burdening Interstate Commerce)

82. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

83. 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." *Pike*, 397 U.S. at 142.

84. The Act's price and other regulations impose a substantial burden on interstate commerce, requiring that each manufacturer either make every or a substantial portion of sales nationwide of generic or biosimilar medicines, whether or not presently encompassed by the Act's definition of essential medicines, comply with Illinois' rules; or attempt to somehow restructure pricing and supply processes to segregate drug products for sale in Illinois, resulting in significant compliance costs and disruptions to the drug-supply chain; or else "'defend itself'" in Illinois "'with reference to all transactions,' including those with no forum connection." *Mallory*, 600 U.S. at 161 (Alito, J., concurring in part and concurring in the judgment) (quoting *Bendix Autolite Corp.*, 486 U.S. at 893).

85. Those burdens will fall overwhelmingly on interstate commerce, as drug manufacturers and the wholesale distributors they sell to are overwhelmingly located outside

Illinois. Those burdens are particularly substantial when considering the effect if "not one, but many or every, jurisdiction adopted similar legislation." *C & A Carbone, Inc.*, 511 U.S. at 406 (O'Connor, J., concurring in the judgment) (alterations and citation omitted); *see also U & I Sanitation*, 205 F.3d at 1069.

86. Those cumulative effects on interstate commerce far outweigh any interest Illinois may have in regulating the prices charged outside Illinois for drugs that are later resold in Illinois by third parties.

87. There are alternatives to the Act's extraterritorial price regulation that will have "a lesser impact on interstate activities," *Pike*, 397 U.S. at 142, including limiting its regulation to in-state transactions.

88. The Act undermines Illinois' interest in making life-saving medications available to Illinois consumers by making it more difficult for generic and biosimilar manufacturers to preserve their thin profit margins for their products, potentially resulting in those manufacturers withdrawing those products from the market altogether.

89. 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.

COUNT FIVE

(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Due Process Clause's Prohibition on Vague State Laws)

90. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

91. A statute is unconstitutionally vague under the Due Process Clause if (1) "it fails to provide 'fair warning' as to what conduct will subject a person to liability"; or (2) it lacks "an

explicit and ascertainable standard to prevent … 'arbitrary and discriminatory' enforcement.'" *Karlin*, 188 F.3d at 458-59 (citations omitted).

92. The Act violates these twin requirements of due process. The Act defines "price gouging" not just as a price increase that meets specified quantitative increases in the generic drug's wholesale acquisition cost, but also as an "unconscionable" increase that is "otherwise excessive and unduly burdens consumers because of the importance of the … drug to their health and because of insufficient competition in the marketplace." Act § 5. The Act does not define what constitutes an "unconscionable," "excessive," or "unduly burden[some]" price increase, nor provide any guidance for discerning how these nebulous terms relate to one another.

93. Moreover, the Act provides no standard or guidance to determine when a price increase is "otherwise" excessive or unduly burdensome "*because of*" the "importance of the … drug" to consumer health and "insufficient competition in the marketplace." Act § 5 (emphasis added). By its terms, the Act applies exclusively to medicines that are both "essential" to public health and manufactured by three or fewer companies; thus, a price increase for such a product that is "excessive" or "unduly burden[some]" would necessarily be so, at least in part, because of the medicine's importance to consumer health and a lack of competition, but the Act gives manufacturers no guidance on how to discern when the excessiveness or burdensome nature of a price increase for these essential medicines is sufficiently attributable to those medicines' importance to consumer health or "insufficient competition in the marketplace" as to fall within the Act's definition of price gouging.

94. Thus, the Act fails to provide AAM's members with the fair notice necessary to determine whether the prices at which they sell their generic and biosimilar medicines will be deemed "price gouging," and simultaneously fails to provide any meaningful standards to cabin

the Attorney General's discretion in enforcing the law's prohibition.

95. Accordingly, the Act fails to provide the minimal fair notice to regulated parties that is required by due process and is therefore unconstitutional.

COUNT SIX

(42 U.S.C. § 1983 and 42 U.S.C. § 1988)

96. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

97. 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.

98. 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.

99. AAM seeks a declaration that Defendant's enforcement of the Act is unconstitutional under the Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and/or the Constitution's horizontal separation of powers.

100. 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, or any of their agents, privies, or licensees, in violation of the Commerce Clause of the U.S. Constitution, based on any AAM member's sale of a generic or other off-patent drug or biosimilar that occurs outside Illinois;

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

D. For such costs and reasonable attorney's fees to which it might be entitled by law, including 42 U.S.C. § 1988; and

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

Dated: January 22, 2024

Respectfully submitted,

s/ Andrianna D. Kastanek

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Counsel for Plaintiff

EXHIBIT A

AAM & Biosimilars Council Membership (as of 01/22/2024)

2024 AAM Regular Members

Accord Healthcare, Inc.

Ajanta Pharma USA, Inc.

American Regent

Amneal Pharmaceuticals LLC

Amphastar Pharmaceuticals, Inc.

Apotex Corp.

Aurobindo Pharma USA, Inc.

B. Braun Medical Inc.

Biocon Limited

Cipla USA

Dr. Reddy's Laboratories, Inc.

Fresenius Kabi USA

Glenmark Pharmaceuticals, Inc. USA

Hikma Pharmaceuticals USA

Jubilant Cadista Pharmaceuticals, Inc.

Lupin Inc.

Meitheal Pharmaceuticals

PAI Pharma

Sandoz Inc.

Somerset Therapeutics

Sun Pharmaceutical Industries, Inc.

Teva Pharmaceuticals USA, Inc.

Torrent Pharma Inc.

Zydus Pharmaceuticals USA, Inc.

2024 AAM Associate Members

ACIC Pharmaceuticals

Catholic Medical Mission Board, Inc. (CMMB)

ChemWerth Inc.

Direct Relief

Dispensary of Hope

Gedeon Richter USA

Husch Blackwell

Inmar

Lachman Consultant Services Inc.

Operation Smile

2024 Biosimilars Council Regular Members

(unless otherwise noted)

Amneal Biosciences

Axinn, Veltrop & Harkider (Associate)

Biocon

Dr. Reddy's Laboratories, Inc.

Fresenius Kabi USA

Lupin Inc.

Sandoz

Teva Pharmaceuticals

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois, *Defendant*.	Case No.

DECLARATION OF TIMOTHY DE GAVRE

I, Timothy de Gavre, declare as follows:

1. I am the Chief Commercial Officer for Sandoz Inc. ("Sandoz"). I joined Sandoz on February 1, 2010, and since June 1, 2021, I have overseen the wholesale distribution of Sandoz's generic and biosimilar prescription drugs in my role as CCO. I am knowledgeable about Sandoz's distribution system, including its sales arrangements with wholesalers and other customers.

2. Sandoz is a corporation organized and existing under the laws of Delaware with a principal place of business in Princeton, New Jersey.

3. Sandoz is a pharmaceutical company engaged in the manufacture, sale and distribution of, among other things, generic drugs and biosimilars.

4. In the vast majority of cases, Sandoz sells its products to large national wholesale distributors, which are located outside Illinois. The wholesale purchasers then re-sell Sandoz's products, including its generic and biosimilar products, to retail pharmacies, hospitals, or other

healthcare facilities, some of which are located in Illinois. Sandoz does not control the prices at which its drugs are resold by other entities in the supply chain, nor does it control where those drugs are resold. In rare circumstances, Sandoz sells its products to hospital systems, physicians, or specialty pharmacies with a physical presence in Illinois.

5. Sandoz's large wholesale-distributor purchasers typically purchase Sandoz's products in bulk via negotiated multi-drug contracts, rather than on a drug-by-drug basis.

6. Sandoz also sells its generic and biosimilar products directly to some retail pharmacy chains that maintain their own warehouse facilities, which are also located outside Illinois. Sandoz's large pharmacy-chain purchasers also typically purchase Sandoz's products in bulk via negotiated long-term, multi-drug contracts, rather than on a drug-by-drug basis.

7. Sandoz's sales to wholesale distributors and retail pharmacy chains take place outside Illinois.

8. Sandoz markets an [redacted], a generic prescription medication that [redacted]. Sandoz sells its [redacted] product in a [redacted] dosage. [redacted] is manufactured for Sandoz in [redacted], and Sandoz markets [redacted] for sale throughout the United States. Sandoz's sales of [redacted] to wholesale distributors and retail pharmacy chains take place outside Illinois. Sandoz does not sell [redacted] directly to consumers in Illinois.

9. The reference listed drug for [redacted] is [redacted]. There are [redacted] listed for [redacted] in the U.S. Food and Drug Administration's Orange Book.

10. [redacted] is on the World Health Organizations most recent model list of essential medicines. Sandoz is one of only three companies that markets [redacted] for the

United States, and Sandoz has struggled to [redacted] for its product. [redacted] is currently on the [redacted].

11. Sandoz sells [redacted] in [redacted]. An adult receiving a maintenance dose of [redacted] receives [redacted]. [redacted].

12. The process for producing [redacted] is [redacted] expensive, requiring the use of [redacted] and the implementation of [redacted], for example, requiring product-specific [redacted], specific [redacted], and even requiring [redacted]. Failure to maintain any of these costly processes could [redacted]. As a result, manufacturing [redacted] requires its own product-specific capital investment.

13. Over the past years, the cost of manufacturing Sandoz's [redacted] product has increased in multiple respects: production cost increases, product ingredient cost increases, increased costs associated with product validation (including inspection and testing), and changes to its active pharmaceutical ingredient that required additional expensive tests. Other costs that are not directly associated with production have also increased, such as regulatory approval costs and costs incurred due to product inventory loss. Additionally, as Sandoz recently [redacted] where [redacted] is manufactured, Sandoz expects that overhead costs related to [redacted] may continue to increase when compared to [redacted] And, should Sandoz decide to [redacted], it estimates that the [redacted] will cost upwards of $2,000,000. As a result, Sandoz has faced and expects in the future

to face significant new production hurdles requiring increased processes and investment at almost every stage of production.

14. For all of calendar year 2023, the wholesale acquisition cost of [redacted] was [redacted]. In the first quarter of 2024, Sandoz intends to increase the wholesale acquisition cost of [redacted] for certain customers by [redacted]. The wholesale acquisition cost for [redacted], both before and after the planned price increase goes into effect, will exceed $20 for a course of treatment lasting 30 days. Moreover, the planned increase of [redacted] in the wholesale acquisition cost for [redacted] constitutes a [redacted] increase over the calendar year 2023 wholesale acquisition cost for [redacted]. Even after Sandoz's planned price increase for its [redacted] product, the wholesale acquisition cost of its [redacted] will be [redacted] below the current wholesale acquisition cost for branded [redacted] and [redacted] below the current wholesale acquisition cost for the nearest competing generic [redacted].

15. A majority of the [redacted] increase in the wholesale acquisition cost of [redacted] is attributable to factors other than an increase in the cost of producing [redacted], or the cost of expanding access to [redacted] to promote public health. These factors include regulatory approval costs, costs incurred due to product inventory loss, and inflation. In addition, a portion of the price increase is attributable to Sandoz's assessment of current market dynamics for [redacted], including the pricing of competing generic products.

16. By implementing this price increase in the first quarter of 2024—after HB 3957 went into effect on January 1, 2024—Sandoz will be exposed to significant penalties and other monetary liability under HB 3957. Sandoz will have no way to recoup the revenue it may lose as a result of the enforcement of HB 3957 if the law is not enjoined.

17. At its current price, Sandoz's internal projections predict [redacted] will no longer be profitable given increased input costs. Withdrawing [redacted] from Illinois specifically would not be feasible. If it were, and if Sandoz were to withdraw [redacted] from Illinois to avoid HB 3957's price control, Sandoz would lose significant revenues.

18. Sandoz's anticipated pricing decisions constitute confidential and proprietary information. Sandoz does not publicly disclose the identities of any of the products for which it intends to make price changes, or the amount of any anticipated price change. Instead, Sandoz has internal safeguards and policies in place to ensure that its pricing plans do not become publicly known to its competitors or any third party.

19. Sandoz maintains the confidentiality of its internal pricing decisions to protect the integrity of its business operations, to maintain its competitive position in the market, as well as to ensure compliance with all applicable laws, including federal and state antitrust laws.

20. The public disclosure of Sandoz's confidential pricing decisions, including the identity of any product for which Sandoz intends to make a price change and the amount of that price change, would harm Sandoz and its competitive position. Sandoz's competitors would have the opportunity to make adjustments to their own pricing or other business strategies in response to Sandoz's non-public pricing plans. Even disclosing the identity of a product whose price Sandoz intends to increase (or intends not to increase), without disclosing the details of the increase, would harm Sandoz by providing its competitors for that product with otherwise confidential information regarding Sandoz's pricing plans they can use to compete with Sandoz.

21. Sandoz does not make drug pricing decisions on a state-by-state level. 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 national prices of the company's products. Sandoz has no ability to specify the price at which its products will be resold in Illinois specifically.

22. Cost is a significant factor in the pricing of Sandoz's generic and biosimilar medicines. The market for many generic medicines is highly competitive, with a dozen or more generic products competing for market share, including on price. Even where only one generic or biosimilar is available, the generic or biosimilar will generally be priced lower than the brand-name counterpart. As a result, Sandoz generally realizes significantly lower profit margins on each generic product than a brand company realizes on a brand product.

23. Under HB 3957, price increases on Sandoz's generic and biosimilar products could subject Sandoz to substantial liability. However, price increases for these products may be necessitated by numerous reasons unrelated to Sandoz. For example, prices are affected by the actions of market players that supply Sandoz with raw materials and other supplies and utilities used in the manufacturer of Sandoz's generic and biosimilar drugs. Moreover, end customer prices are affected by the actions of additional market players other than Sandoz, such as wholesale distributors, pharmacy benefit managers, retail pharmacy chains, health insurers, Medicaid and Medicare contractors, hospital networks, and others. Prices also are affected by market forces in states other than Illinois. Moreover, prices for biosimilar products may also be affected by increased costs of marketing, as well as a need to recoup the costs of clinical or other studies undertaken to obtain FDA approval.

24. Sandoz already faces significant economic risks associated with its manufacture of generic and biosimilar products. Even after overcoming the difficulties in obtaining FDA approval and avoiding or defeating claims of patent infringement, Sandoz faces significant risk and uncertainty after its generic and biosimilar products enter the market, particularly when there are

multiple other products for the same medicine. The threat of liability posed by HB 3957 exacerbates the financial and other risks that Sandoz already currently faces in producing and marketing generic and biosimilar products, which will make it even more difficult to bring and maintain affordable drugs to patients. In addition, Sandoz will face increased, unrecoverable costs due to being required to comply with HB 3957's mandatory notice-and-reporting regime.

25. A cost increase of any kind could make it unprofitable for Sandoz to manufacture its generic and biosimilar prescription products. If Sandoz faces increased costs of any kind but is unable to increase its prices due to HB 3957, then Sandoz's already thin profit margins could be erased or the product rendered unprofitable.

26. If Sandoz's thin profit margins disappear, there is a real risk that Sandoz will be forced to withdraw the relevant generic or biosimilar products it currently sells nationwide, as that is the only way for it to avoid the Act's price regulation. Product withdrawal would significantly harm Sandoz, resulting in a loss of revenues, which Sandoz could not regain in the event HB 3957 were invalidated.

27. Thus, under any scenario, Sandoz will be injured by HB 3957. Each time increased costs of production or other separate factors require Sandoz to consider a price increase like those described above for [redacted], Sandoz will have to either (1) forgo the price increase, thus sacrificing some or all of its already low profit margin; (2) raise prices to maintain profitability, but risk severe civil penalties and other monetary liability in Illinois court; or (3) if the product is no longer profitable without the covered price increase, potentially withdraw the product from the market, suffering a loss of revenue. Sandoz will never be able to recover any of these monetary damages.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 19, 2024.

DocuSigned by:

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Timothy de Gavre, CCO Sandoz Inc.

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois, *Defendant*.	)	No. 24 C 544 Judge Virginia M. Kendall

ORDER

This matter is before the Court on Plaintiff Association for Accessible Medicines' ("AAM") motion for preliminary injunction, (Dkt. 17), and Defendant Attorney General Kwame Raoul's motion to dismiss, (Dkt. 25). For the reasons below, AAM's motion [17] is denied and the Attorney General's motion [25] is granted.

BACKGROUND

The Association for Accessible Medicines is a nonprofit association representing manufacturers and distributors of generic and biosimilar medicines. (Dkt. 1 at ¶ 14). AAM is concerned about the constitutionality of House Bill 3957 ("the Act"), which took effect on January 1, 2024. (*Id*. at ¶ 29). The Act prohibits manufacturers and wholesale drug distributors from engaging in "price gouging" in the sale of certain drugs that are "ultimately sold into Illinois." (Dkt. 18-1 at 5). Price gouging is any price increase that meets certain metrics identified in the statute and is "otherwise excessive and unduly burdens consumers." (*Id*. at 4). It does not include price increases that can be "reasonably justified" by reasons identified in the Act. (*Id*. at 4–5). If the Attorney General has reason to believe that a manufacturer or wholesale drug distributor is engaged in price gouging, the Act authorizes him to "send a notice to [the company] requesting a statement" of information relevant to determining whether a violation of the Act occurred. (*Id*. at 5–6). Upon determining that a company engaged in price-gouging, the Attorney General may ask a circuit court to impose various penalties, such as a fine or injunction. (*Id*. at 7–8).

AAM brings this pre-enforcement action seeking declaration that the Act is unconstitutional and moves for a preliminary injunction prohibiting the Attorney General from enforcing the Act against AAM's members. (Dkt. 1 at ¶¶ 70–100; Dkt. 17). The Attorney General moves to dismiss. (Dkt. 25).

LEGAL STANDARD

In reviewing a Federal Rule of Civil Procedure 12(b)(1) motion to dismiss for lack of subject-matter jurisdiction, the plaintiff must carry its burden of establishing that jurisdiction is proper. *Ctr. for Dermatology & Skin Cancer, Ltd. v. Burwell*, 770 F.3d 586, 588–89 (7th Cir. 2014). "Facial challenges require only that the court look to the complaint and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction." *Apex Digital, Inc. v. Sears, Roebuck & Co*., 572 F.3d 440, 443 (7th Cir. 2009). A court lacking subject-matter jurisdiction must dismiss the action without proceeding to the merits. *See MAO-MSO Recovery II, LLC v. State Farm Mut. Auto. Ins. Co*., 935 F.3d 573, 581 (7th Cir. 2019).

DISCUSSION

The Attorney General argues that AAM's complaint should be dismissed for lack of subject-matter jurisdiction because AAM lacks standing to bring this action and the issues therein are not ripe for adjudication. He further argues that AAM's motion for preliminary injunction should be denied for the same reasons, adding that AAM fails to carry its burden of persuasion. The Court turns first, as it must, to the question of jurisdiction.

Article III of the Constitution "confines the federal judicial power to the resolution of 'Cases' and 'Controversies.'" *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021) (quoting U.S. Const. art. III., § 2). "For there to be a case or controversy under Article III, the plaintiff must have a 'personal stake' in the case—in other words, standing." *Id*. (citing *Raines v. Byrd*, 521 U.S. 811, 819 (1997)). While organizations do not have standing to assert claims based on their particular concept of the public interest, they may, through associational standing, assert the rights of their members. To show that it has associational standing, AAM must allege that (1) its members have standing to sue in their own right; (2) the members' interests are germane to the organization's purpose; and (3) neither the claim asserted nor the relief requested requires the individual participation of the organizations' members. *Milwaukee Police Ass'n v. Flynn*, 863 F.3d 636, 639 (7th Cir. 2017).

To establish that its members have standing to sue in their own right, AAM must allege that its members (1) suffered an injury in fact that is concrete, particularized, and actual or imminent; (2) the injury was likely caused by the defendant; and (3) the injury is likely to be redressed by judicial relief. *TransUnion*, 594 U.S. at 423. Where, as here, a party seeks pre-enforcement review of the constitutionality of a statute, a plaintiff may satisfy the injury-in-fact requirement by alleging "an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (citing *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)).

AAM insists that some of its members intend to raise the prices of certain drugs in a manner that satisfies "every ascertainable element of the Act's definition of 'price gouging'" such that their actions would "trigger liability under the Act." (Dkt. 1 at ¶ 43). Further, AAM alleges that some of its members, believing that the Act is unconstitutional, intend to proceed with their price

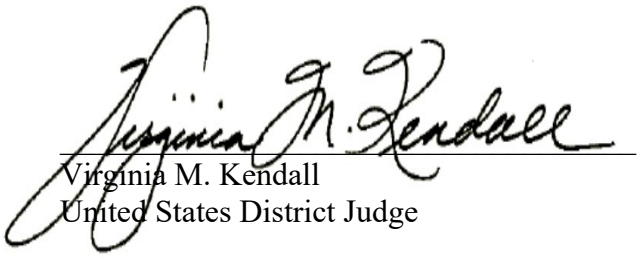
increases. This course of conduct, AAM maintains, could lead to "potential enforcement of the Act, which threatens civil penalties and other monetary liability." (*Id.* at ¶¶ 43–44).

Even interpreting the allegations favorably, as the Court must, AAM does not sufficiently allege an injury in fact for two reasons. First, AAM does not allege that its members intend to violate the Act in a manner that is proscribed by the Act. The Act's definition of price-gouging includes clearly delineated price increases, but those increases must also be "otherwise excessive and unduly burden[] consumers." (Dkt. 18-1 at 4). While AAM complains that these terms are "nebulous," it brings no allegations to support the conclusion that the intended price increases would in fact be excessive and unduly burden consumers. Indeed, as the Attorney General points out, AAM repeatedly describes the contemplated price increases as "reasonable" and "necessary," which suggests they would not violate the Act. Because AAM fails to allege that its members intend to do what the Act proscribes, AAM fails to satisfy the injury-in-fact requirement.

AAM also fails to allege that a credible threat of prosecution exists. As an initial matter, AAM does not allege that its members actions are guaranteed to violate the Act, so any threat of prosecution is based upon a purely hypothetical violation of the Act. Moreover, AAM does not allege that any of its members have received a notice of investigation, or have been subject to an investigation or enforcement action. The proposition that one of its members may at some point in the future implement a price increase that would satisfy the definition of price gouging does not give rise to a controversy of "sufficient immediacy and reality" to confer standing. *MedImmune, Inc. v. Genentech, Inc*., 549 U.S. 118, 127 (2007). AAM cannot successfully plead an injury in fact that is based on contingent future events which may not occur as anticipated or may not occur at all.

CONCLUSION

For the reasons set forth above, the Attorney General's motion to dismiss [25] is granted and AAM's motion for preliminary injunction [17] is denied as moot.



Virginia M. Kendall
United States District Judge

Date: June 18, 2024

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois, *Defendant*.	Case No. 1:24-cv-00544

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Association for Accessible Medicines ("AAM") brings this complaint for declaratory and injunctive relief against Kwame Raoul, in his official capacity as Attorney General of the State of Illinois. 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.

INTRODUCTION

1. This lawsuit challenges Illinois' new price-control law, which took effect on January 1, 2024. Public Act 103-167 ("the Act"), codified at 410 Ill. Comp. Stat. Ann. 725/1 *et seq.* The Act threatens to impose massive penalties on manufacturers of certain essential generic or other off-patent drugs or biosimilar medicines, which if left in place will result in interstate economic chaos. Any manufacturer that increases the price of such a medicine can be penalized if the price change falls within the Act's extraordinarily vague definition of "price gouging" and the medicine is "ultimately sold in Illinois," even if the manufacturer "did not *directly* sell [the]

product to a consumer residing in Illinois." Act §§ 5, 10, 410 Ill. Comp. Stat. Ann. 725/5, 725/10 (emphasis added). Thus, by its terms, the Act controls the prices charged for generic and biosimilar medicines *anywhere in the country*.

2. To enforce its price control, the Act authorizes Illinois 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 § 10(a), (c).

3. By regulating transactions that occur wholly outside Illinois, the Act violates multiple provisions of the U.S. Constitution, as well as the limits on state authority implicit in the constitutional structure and design.

4. First and foremost, the Act violates the restrictions on extraterritorial state legislation imposed by the Commerce Clause, U.S. Const. art. I, § 8, cl. 3—as every court to consider the constitutionality of similar price-control legislation has concluded. A state law that "directly regulates interstate commerce … 'is invalid,'" and that is so "'regardless of whether the statute's extraterritorial reach was intended by the legislature.'" *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 830 (7th Cir. 2017) (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)). "With almost two hundred years of [prior dormant Commerce Clause] precedents to consider," not "a single appellate case [has] permit[ted] any direct regulation of out-of-state" commerce. *Id.* at 831.

5. The Supreme Court recently "refined [its] Commerce Clause framework" in some respects, *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 160 (2023) (Alito, J., concurring in part and concurring in the judgment), in its decision in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). But the Court kept intact the bedrock principle prohibiting state laws that directly regulate out-of-state conduct. Indeed, *Ross* went out of its way to confirm the vitality of the rule

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. 598 U.S. at 374, 376 n.1 (quoting *Healy*, 491 U.S. at 338-39); *see Ass'n for Accessible Meds. v. Ellison*, No. 23-cv-2024, — F. Supp. 3d —, 2023 WL 8374586, at *3 (D. Minn. Dec. 4, 2023) (concluding that *Ross* "did not change the rule that a state may not directly regulate transactions that take place wholly outside the state").

6. The Act violates the Commerce Clause's clear command by directly regulating prices in transactions that take place entirely outside Illinois. Consider, for example, a drug manufacturer located in Pennsylvania that sells generic drugs to a wholesale distributor located in Ohio. If the Act deems the price the Pennsylvania manufacturer charges the Ohio wholesaler in 2024 to be too much higher than the price charged in 2023, and if the drug "is ultimately sold in Illinois," Act § 10(a), then the Pennsylvania manufacturer's initial sale to the Ohio wholesaler would be prohibited—even though it occurred wholly outside of Illinois and the Pennsylvania manufacturer has "*no* connection to the State." *Ross*, 598 U.S. at 376 n.1. By directly regulating commercial activities entirely outside the boundaries of Illinois, the Act violates the Commerce Clause of the U.S. Constitution.

7. 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 Glob. Reinsurance Corp. of Am. v.*

Gallagher, 267 F.3d 1228, 1236 (11th Cir. 2001) (emphasis omitted). AAM's members sell their drug products to wholesale distributors that are located outside Illinois, and all but two of AAM's members are also located outside Illinois—leaving Illinois without the necessary "substantial … contact[s]" with AAM's out-of-state members and their 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).

8. The Act's extraterritorial reach not only runs afoul of these specific constitutional provisions, but 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. at 154 (Alito, J., concurring in part and concurring in the judgment) (alterations, citation, and quotation marks omitted) (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*, 598 U.S. at 376 (citation omitted). By regulating activities that occur wholly outside Illinois' borders, the Act transgresses the "horizontal separation of powers" embedded in the constitutional design. *Id.* at 376 n.1.

9. Separate from the Act's impermissible direct regulation of wholly out-of-state transactions, the law also violates the Commerce Clause because it imposes a burden on interstate commerce that "is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). To avoid violating the Act's price control, manufacturers of generic or other off-patent drugs or biosimilar medicines would either have to try to keep their

medicines out of the Illinois market—which may well be impossible given the nature of the nationwide wholesale market—or treat Illinois' regulation as the national standard. And because the lists of essential medicines to which the Act applies will be ever-changing—depending on shifting market dynamics and essential-medicine designations—manufacturers will be compelled to take these protective measures for all or a substantial portion of their generic and biosimilar products, not just those that currently qualify as an "essential off-patent or generic drug." A decision permitting state regulation like Illinois' would allow all 50 states to apply their own views of what price increases are permissible *nationwide*, 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 impose a substantial burden on interstate commerce, which far outweighs any interest Illinois may have in regulating the upstream prices charged for drugs that are later resold in Illinois by third parties.

10. Finally, the Illinois law violates the fundamental requirement of due process that a law be written with sufficient clarity to give regulated parties "'fair warning' as to what conduct will subject [them] to liability," and to "prevent … 'arbitrary and discriminatory' enforcement." *Karlin v. Foust*, 188 F.3d 446, 458-59 (7th Cir. 1999) (citation omitted). The Act fails these basic requirements: it authorizes massive civil penalties for price increases that are ultimately deemed "unconscionable" and "otherwise excessive and unduly burden[some]" by an Illinois court, Act § 5, but it does not define any of these operative terms. Nor does it offer regulated parties any guidance on what these nebulous statutory terms mean and how they differ from one another. Because the Act provides no meaningful guidance as to what price increases are prohibited, and thus simultaneously invites arbitrary enforcement by the Illinois Attorney General, the Act violates the Due Process Clause of the Fourteenth Amendment.

11. AAM's members, who manufacture, offer, and sell generic and biosimilar products—including products currently on (and likely to remain on) the lists of essential medicines—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 the sales occur wholly outside Illinois. AAM's members also will face significant economic harm as a result of the Act's price control and the uncertainty created by its vague and ill-defined terms, no matter what course of action they take—forced to choose between (a) forgoing price increases on their generic and biosimilar products to steer clear of the Act's ill-defined price control; (b) raising prices on those products, but in doing so, triggering substantial civil penalties and other monetary liability; or (c) withdrawing the regulated generic products from the Illinois market and losing all revenue from those sales.

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

[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.

affordable medicines available to U.S. patients and will only increase the likelihood that manufacturers will withdraw products from the market—exacerbating the already-severe drug-supply shortage and driving up prices for those products that remain. And by applying its price control solely to medicines manufactured by *the fewest* number of manufacturers, the Act increases the likelihood that the rarest of essential medicines will be withdrawn from the market *entirely*.

13. For these reasons, and as explained below, AAM seeks an injunction prohibiting 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 complete list of AAM's membership at the time of the filing of the original Complaint to the present is attached as Exhibit A to this Amended 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 patients 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. Kwame Raoul is the Attorney General of Illinois. In that capacity, he is authorized to investigate and bring enforcement actions in Illinois court to assert violations of the Act. *See* Act § 10(b)-(c).

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 proper in this district under 28 U.S.C. § 1391(b).

19. There is a justiciable case or controversy. AAM's claims and requested relief 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 members who manufacture and sell generic and biosimilar medicines by subjecting those members to unconstitutional regulation and, if not enjoined, will certainly and imminently injure them by subjecting them to unrecoverable economic injury. *See* ¶¶ 38-54, *infra*. 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 90% of all prescriptions dispensed in the United States but amount to only 17.5% of the money spent on prescriptions. *See* Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines*

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

Savings Report, 7, 10 (Sept. 2023).[4] These medicines have produced nearly $2.9 trillion in savings to the U.S. healthcare system over the past decade, with $408 billion in savings in 2022 alone—a $35 billion increase over the prior year. *Id*. at 7-8. Illinois realized $15.3 billion in healthcare savings from generics and biosimilars in 2022. *Id*. at 16.

21. However, generic and biosimilar manufacturers also face significant and ever-growing 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 limit potential returns." U.S. Food & Drug Admin., *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. Moreover, a substantial share of generic products—up to 40%—are produced by only a single manufacturer, and many more are manufactured by only two companies. Ernst R. Berndt, et al., *The Landscape of US Generic Prescription Drug Markets, 2004-2016*, Nat'l Bureau of Econ. Rsch., 19-20 (July 2017)[6]; *see* Inmaculada Hernandez, et al., *Number of Manufactures and Generic Drug Pricing in 2005-2017*, Am. J. of Managed Care, 2 (July 2019).[7]

22. Numerous factors impact manufacturers' thin profit margins and put upward pressure on generic and biosimilar drug prices. For example, "[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*

[4] https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

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

[6] https://www.nber.org/system/files/working_papers/w23640/w23640.pdf.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6734551/pdf/nihms-1048940.pdf.

Pharmaceutical Ingredients, 42 Health Affairs 407, 407 (Mar. 2023),[8] 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).[9] In addition, prices for biosimilar medicines and for drugs approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2),[10] face additional upward pressure due to the need to recover substantial costs arising from clinical and other studies needed to obtain FDA approval, as well as increased costs arising from marketing, patient-support services, and other non-production related costs.

23. The high cost of manufacturing generic and biosimilar products, combined with "a complex array of [other] factors," U.S. Food & Drug Amin., *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)[11]—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 medicines have increased substantially in recent years. "Between 2021 and 2022, drug shortages increased by

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

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

[10] Section 505(b)(2) creates a pathway for approval of a new drug meant to build on FDA's previous approval of another drug—such as by creating a new dosage form for an existing drug. Because section 505(b)(2) drugs are not identical copies of the brand drug, they do not benefit from state laws that require or allow pharmacists to substitute a generic drug for a prescribed brand-name drug. Thus, manufacturers of section 505(b)(2) drugs must invest in marketing these products.

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

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).[12]

24. These harms may be especially acute when they impact the most essential medicines. The World Health Organization and the U.S. Department of Health and Human Services have published lists of "essential medicines" deemed necessary to meet the priority health care needs of a population, *see* World Health Organization, *The Selection and Use of Essential Medicines 2023: World Health Organization Model list of Essential Medicines – 23rd list* (2023),[13] and to protect society from outbreaks of infectious diseases and other threats, *see* U.S. Food & Drug Admin., Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs (May 23, 2022), respectively.[14] The World Health Organization's biannual list of essential medicines currently contains 502 medicines, *see* World Health Organization, *The Selection and Use of Essential Medicines 2023: Executive Summary of the Report of the 24th WHO Expert Committee on Selection and Use of Essential Medicines*, 1 (2023)[15]—a significant increase over the 479 medicines designated in the 2021 list. The FDA has similarly published a list of essential medicines, which designates 227 drug and biological products as essential medicines and medical countermeasures. *See* U.S. Food & Drug Admin., *FDA Publishes List of Essential*

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

[13] https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02.

[14] https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs.

[15] https://iris.who.int/bitstream/handle/10665/371291/WHO-MHP-HPS-EML-2023.01-eng.pdf.

Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order (Oct. 30, 2020).[16]

25. 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 patients. 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, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp., 4-5 (2021)[17]; Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 1-2 (Mar. 2005).[18]

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

27. 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.

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[16] https://www.fda.gov/news-events/press-announcements/fda-publishes-list-essential-medicines-medical-countermeasures-critical-inputs-required-executive.

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

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

28. The vast majority of sales between AAM's members who are generic and biosimilar manufacturers and wholesale distributors occur outside Illinois, and wholesale distributors take title to those products outside Illinois. None of the three largest wholesale distributors (who collectively control over 90% of the wholesale market)—Cencora, Cardinal Health, and McKesson—is incorporated or headquartered in Illinois.[19] Only two of AAM's manufacturer members are located in Illinois.

II. Illinois' New Drug Price-Control Law

29. Governor J.B. Pritzker signed HB 3957 into law on July 28, 2023, and the law took effect on January 1, 2024. *See* Act § 99, 410 Ill. Comp. Stat. Ann. 725/99.

30. The Act regulates the prices charged for certain medicines that are eventually sold in Illinois. Specifically, the Act applies to prices charged for "[e]ssential off-patent or generic drug[s]," which the Act defines as "any prescription drug sold within the State": (1) for which any "exclusive marketing rights" under "the Federal Food, Drug, and Cosmetic Act, Section 351 of the federal Public Health Service Act [addressing biological products and biosimilars], and federal patent law have expired"; (2) "that appears on the model list of essential medicines most recently adopted by the World Health Organization or that has been designated by the United States Secretary of Health and Human Services as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an

[19] Adam J. Fein, Ph.D., *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* Cencora, Inc., SEC Form 8-K (Nov. 2, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0001140859/0514f5f3-1108-4cdc-aa9b-c13f0d8abd89.pdf; Cardinal Health, Inc., SEC Form 8-K (Nov. 3, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000721371/e13cff17-e82d-4bdc-9fb2-c43e86a48089.pdf; McKesson Corp., SEC Form 8-K (Nov. 7, 2023), https://d18rn0p25nwr6d.cloudfront.net/CIK-0000927653/014f18c1-ddc5-4051-adbb-91353d9d73bd.pdf.

individual's ability to engage in activities of daily living"; and (3) "that is actively manufactured and marketed for sale in the United States by 3 or fewer manufacturers." Act § 5.

31. The Act prohibits any drug "manufacturer or wholesale drug distributor" from engaging in what the Act calls "price gouging in the sale" of any essential medicine "that is ultimately sold in Illinois." Act § 10(a).

32. The Act gives "price gouging" a complex, and ultimately incredibly vague, three-part definition. The term is defined as an "unconscionable increase in a prescription drug's price" that (1) would result in the drug's wholesale acquisition cost "exceeding $20" for a "30-day supply" of the drug; (2) would result in an increase in the wholesale acquisition cost of (a) "30% or more within the preceding year," (b) "50% or more within the preceding 3 years," or (c) "75% or more within the preceding 5 years"; and "is otherwise excessive and unduly burdens consumers because of the importance of the [drug] to their health and because of insufficient competition in the marketplace." Act § 5.

33. The Act excludes certain price increases from its definition of "price gouging." Specifically, price gouging "does not include a price increase" that can be "reasonably justified" by either (1) "an increase in the cost of producing the essential off-patent or generic drug"; or (2) "the cost of appropriate expansion of access to the [drug] to promote public health." Act § 5.[20]

34. A generic or biosimilar manufacturer can violate the Act based on sales made entirely outside Illinois. The Act prohibits price gouging "in the sale" of an essential medicine, even if the sale occurs outside Illinois, as long as the medicine is "*ultimately* sold in Illinois." Act

[20] The Act also provides that "wholesale distributor[s]" do not violate the Act if a price increase "is directly attributable to an increase in the wholesale acquisition cost for the essential off-patent or generic drug imposed on the wholesale drug distributor by the manufacturer of the drug." Act § 10(a).

§ 10(a) (emphasis added). The law then drives the point home, providing that "a manufacturer or wholesale drug distributor … may not assert as a defense that the manufacturer or wholesale drug distributor did not *directly* sell a product to a consumer residing in Illinois." *Id*. § 10(c) (emphasis added).

35. The Act creates a reporting mechanism to aid the Illinois Attorney General in identifying price increases that may violate the Act's price regulation. *See* Act § 10(a)-(b). In particular, the law authorizes the Director of Healthcare and Family Services to notify the Attorney General "of any increase in [] price … that amounts to price gouging" for an essential medicine made available through the Medication Assistance Program under Section V of the Illinois Public Aid Code. *Id*. § 10(a).

36. The Act also authorizes the Attorney General to independently investigate violations of the Act. First, if the Attorney General has "reason to believe" a violation has occurred, he "may," but is not required to, "send a notice to the manufacturer or the wholesale drug distributor requesting a statement" providing information "relevant to a determination of whether a violation … has occurred." Act § 10(b). Second, the Attorney General may investigate whether a violation has occurred by issuing subpoenas or "examin[ing] under oath any person." *Id*.

37. The law authorizes the Attorney General to bring suit in Illinois court to remedy violations. Act § 10(c). The Attorney General is not required to provide any form of notice or take any particular step before suing. If the court finds a violation, the Act authorizes the court to impose a civil penalty up to $10,000 per day for each prohibited sale. *Id*. § 10(c)(5). The court may also award restitution to Illinois consumers and enter injunctive relief. *Id*. § 10(c)(2), (3).

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

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

38. Several of AAM's members located outside Illinois intend, or intended until the Act's adoption, to increase the wholesale acquisition cost for certain "essential off-patent or generic drugs" after January 1, 2024. All of the allegations in this Amended Complaint relating to AAM members' pricing plans refer to plans that existed before the Complaint was filed and, if not yet consummated, continue through the present time.

39. These AAM members intend, or intended until the Act's adoption, to raise the wholesale acquisition cost of certain essential generic or other off-patent drugs covered by the Act, in a manner that meets the quantitative elements of "price gouging" under the Act. The increased wholesale acquisition cost for those medicines would exceed $20 for a 30-day supply of the medicines, and would constitute a 30% or more increase of the wholesale acquisition cost over a one-year period.

40. Each of the price increases referenced in this section is motivated, at least in part, by factors other than an increase in the cost of producing the essential medicine or increased costs associated with expanding public access to the medicine.

41. All but two of AAM's members are located outside Illinois. AAM members located outside Illinois sell their medicines overwhelmingly to large wholesale distributors, which are also located outside Illinois.

42. Each of the products addressed in this section is an "essential off-patent or generic drug" within the meaning of the Act, because any exclusive federal marketing rights for the medicines have expired, they appear on the World Health Organization's or the U.S. Department of Health and Human Services' most recent list of essential medicines, and they are manufactured

and marketed for sale in the United States by three or fewer manufacturers. Although AAM members do not control where their products are resold, each of the products addressed in this section is eventually resold in Illinois.

43. The Act does not define or provide any guidance regarding which price increases that exceed the Act's quantitative elements are "unconscionable," "otherwise excessive," or "unduly burden[some]," nor does the Act provide any standards to govern either the Attorney General's determination of when a price increase falls within these capacious terms or his discretion in deciding whether to initiate an investigation or bring an enforcement action. Moreover, the Attorney General has not identified any facts or factors that will guide his determination of whether a price increase qualifies as "unconscionable," "otherwise excessive," or "unduly burden[some]" or any facts that would shield a price increase in excess of the Act's quantitative threshold from liability.

44. There is, at a minimum, a substantial risk that the Attorney General will determine that one or more of the contemplated price increases by AAM's members of their essential off-patent or generic drugs meets the elements of the Act's definition of "price gouging," and bring an enforcement action against the relevant AAM member. The Attorney General has not disavowed bringing an enforcement action against an AAM member for any price increase that meets the Act's quantitative threshold.

45. Despite the Act's prohibition, some AAM members located outside Illinois intend to implement previously planned increases in the wholesale acquisition costs for their essential medicines in calendar year 2024 in an amount that substantially exceeds a 30% increase over the prior year's wholesale acquisition cost for the medicine (and will result in a wholesale acquisition cost that exceeds $20). Each of these medicines is manufactured for sale in the United States by

three or fewer manufacturers and is indicated for the treatment of a life-threatening or chronic health condition. These AAM members' price increases are motivated, at least in part, by factors other than increases in the cost of producing or expanding patient access to these "essential medicines," including these companies' goals of increasing profitability and shareholder value and offsetting price reductions on other products that have reduced these companies' overall profitability. These AAM members' price increases are possible, in part, because of the limited competition in the United States for these products.

46. For example, one AAM member located outside Illinois (Sandoz Inc.) markets an [redacted], a generic prescription medication that is indicated for [redacted], a condition that is both life-threatening and chronic, which Sandoz markets and sells in the United States in [redacted]. Sandoz's sales of [redacted] to wholesale distributors and retail pharmacy chains take place outside Illinois. All exclusive marketing rights for [redacted] and its reference listed drug have expired. [redacted] is on the World Health Organization's most recent list of essential medicines and is manufactured for sale in the United States by only three companies.

47. In calendar year 2024, Sandoz intends to increase the wholesale acquisition cost for a 10-day supply of [redacted], which constitutes a [redacted] increase over the product's price for calendar year 2023—substantially more than the Act's 30% threshold. A majority of the anticipated price increase for [redacted] is attributable to factors other than an increase in the cost of producing [redacted] or the cost of expanding patient access to [redacted] to promote public health. These factors include regulatory approval costs, costs incurred due to product inventory loss, and inflation. In addition, Sandoz's intended price increase for [redacted] is necessary to meet the company's long-term growth strategy, to increase or

sustain its overall profit margins, and to provide a greater return on investment for its shareholders. By increasing the price of [redacted], Sandoz will be able to offset price reductions on certain other Sandoz products that have reduced the company's overall profitability. As a publicly traded company, Sandoz must diligently manage its financial health so that it is able to carry out its ambition of expanding and maintaining access to a broad portfolio of products, which requires that Sandoz have flexibility to set prices for individual products based on market conditions, including those affecting other products in its portfolio. Sandoz's overall portfolio makes it a leader in reducing the cost of prescription drugs by bringing affordable off-patent medicines to market, which increases supply and lowers prices through increased competition.

48. Because of the reasons underlying this price increase, the Attorney General is likely to conclude that it is "unconscionable," "otherwise excessive," and would "unduly burden[]" patients because of the importance of [redacted] to patients' health (treating a life-threatening condition, including through long-term administration that make the effects of the price cumulate in a way not true of a medication patients take only once). Sandoz's intended price increase is possible, in part, because of the limited competition for [redacted] in the United States. The Attorney General has not disavowed bringing an enforcement action against Sandoz based on this price increase, including after reviewing the declaration AAM previously filed that details many of these facts.

49. Thus, these AAM members intend to raise the prices of one or more "essential off-patent or generic drugs" in a manner that satisfies every element of the Act's definition of "price gouging" and that would trigger liability under the Act. If the Act is not enjoined, those AAM members will face severe economic harm from the enforcement of the Act, which threatens civil penalties and other monetary liability.

50. As a result of the Act's prohibition and the threat of substantial civil penalties and other monetary liability, other AAM members located outside Illinois are refraining from implementing price increases previously planned for calendar year 2024 for certain of their essential medicines. These members' price increases for their essential medicines, if implemented, would have substantially exceeded a 30% increase over the prior year's wholesale acquisition cost for the medicines (and resulted in a wholesale acquisition cost exceeding $20). Moreover, each of these medicines is manufactured for sale in the United States by three or fewer manufacturers and is indicated for the treatment of a life-threatening or chronic health condition. These AAM members' previously intended price increases were motivated, at least in part, by factors other than increases in the cost of producing their essential medicines or expanding patient access to them, including these companies' goals of increasing profitability and shareholder value and offsetting price reductions on other products that have reduced these companies' overall profitability. These AAM members' price increases would have been possible, in part, because of limited competition in the United States for these essential medicines.

51. Some of these AAM members who are refraining from implementing their intended price increases are doing so because the Act's prohibition on price increases that are "unconscionable," "otherwise excessive," and "unduly burden[some]" provides no meaningful guidance regarding when a price increase that exceeds the Act's quantitative thresholds will be deemed by the Attorney General to violate the Act.

52. AAM's members who are refraining from raising their prices because of the Act are facing economic harm in the form of lost revenues that they would otherwise realize but for the Act's prohibition on their planned price increases and/or the chilling effect resulting from the Act's vague terms, which make it impossible for AAM's members to discern what price increases

are prohibited. Enjoining the Act would remove that uncertainty and enable these AAM members to move forward with their previously planned price increases.

53. The Act's vague terms, both standing alone and combined with the Attorney General's refusal to give definition to the Act's vague terms in a way that would enable companies to know which price increases are prohibited, independently harm AAM's members. Whether or not the Attorney General threatens or brings an enforcement action, the Act's vagueness is causing some AAM members to refrain from implementing previously planned price increases that satisfy the objective elements of the Act, because the possibility of massive penalties and disgorgement as a result of an enforcement action by the Attorney General make the risk of implementing those price increases too great.

54. Enjoining the Act will enable AAM's members to sell their products as planned without the threat of the Act's civil penalties and other monetary liability.

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

55. The Act's regulations and penalties will cause AAM's members who manufacture essential generic and other off-patent drugs to suffer substantial and immediate economic injury and will burden the interstate market for generic and biosimilar medicines.

56. The Act's price controls and penalties either prevent AAM's members from raising prices on certain of their generic or other off-patent drugs, or punish those AAM members who do increase the prices of their products. The Act's restrictions will cause significant economic losses no matter their course of action. Specifically, AAM's members that intended to implement price increases that would violate the Act, as well as those that intended price increases that (in light of the Act's vague terms) *could* violate the Act, will be compelled to choose among: (1) forgoing their intended price increases on their generic and biosimilar products, and thereby losing the

revenue they would otherwise realize; (2) raising prices as intended on those products, but in doing so, triggering the threat of substantial civil penalties and other monetary liability; or (3) withdrawing the regulated generic and biosimilar products from the Illinois market to avoid the Act's regulation and losing all revenue from the sale of those medicines. AAM's members will suffer severe financial injury as a result of the Act's price control no matter which option they choose.

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

58. To avoid the Act's price control, AAM's members would need to prevent their essential generic and biosimilar products from being resold in Illinois by a third party, such as a wholesale distributor or retail pharmacy. Segregating out and specially pricing products destined for Illinois 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 their essential generic or biosimilar products that are ultimately to be resold in Illinois. Moreover, because the Act defines the essential medicines it covers based on shifting market dynamics (*i.e.*, the number of companies that manufacture a product) and essential-medicine designations by the World Health Organization and the U.S. Department of Health and Human Services, manufacturers will have no reliable way to know whether or when a medicine not currently encompassed by the Act's definition of "essential off-patent or generic drug" may become regulated in the future, based on changed circumstances entirely beyond manufacturers' control. As a result, and in light of the long-term duration of manufacturers' contracts with

wholesalers, if a manufacturer were to attempt to segregate products destined for Illinois, they would need to alter their distribution and contracting practices with wholesalers for a substantial portion of their medicines that are *not* currently regulated by the Act. However, even if these alterations to manufacturers' contracting practices were possible, it would not be sufficient, because their products could still be resold into Illinois by parties further down the supply chain with whom manufacturers have no direct contractual relationship.

59. 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 Illinois law nationwide. Those increased costs will, in turn, place increased upward pressure on the cost of delivering generic and biosimilar medications to patients throughout the United States.

60. The substantial disruptions caused by an Illinois-specific price regime—potentially to be followed by 49 other states, as each adopts its own definition of what qualifies as an unacceptable price increase—will create enormous inefficiencies in the processing of essential and other 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.

61. Accordingly, the Act's price controls will place significant burdens on the supply chains for essential and other generic and biosimilar medications, including manufacturers and wholesale distributors. Because AAM's members and the wholesale distributors they sell to are overwhelmingly located outside Illinois, 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

62. 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).

63. 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 prohibits state "law[s] that *directly* regulate[] out-of-state transactions." *Ross*, 598 U.S. at 376 n.1; *see Edgar v. MITE Corp.*, 457 U.S. 624, 640, 642 ("precludes the application of a state statute to commerce that takes place wholly outside of the State's borders") (plurality opinion) (emphasis added). If a state law "directly regulates interstate commerce," it "is invalid." *Legato Vapors*, 847 F.3d at 830 (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 Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 665 (7th Cir. 2010) ("no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another" (citation omitted)); *Ellison*, 2023 WL 8374586, at *2 ("Among other limitations, the dormant Commerce Clause prohibits states from directly regulating out-of-state transactions."). In light of this rule, "the Supreme Court has never held that a state may impose truly direct and burdensome state regulation of commerce beyond the state's boundaries." *Legato Vapors*, 847 F.3d at 829, 831 ("With almost two hundred years of precedent to consider, our review of prior dormant Commerce Clause decisions has not revealed a single appellate case permitting any direct regulation of out-of-state [commerce]"); *accord Ellison*, 2023 WL 8374586, at *3 ("The Court cannot find any support for the notion that the dormant Commerce Clause permits [a state] to directly regulate a sale that occurs in another state simply because the product eventually makes its way into [that state]").

64. Although the Supreme Court recently clarified that the Commerce Clause does not impose any per se barrier to state laws that have indirect extraterritorial *effects*, the Court made clear that it was not disturbing the Commerce Clause's prohibition of state laws that "*directly* regulate[] out-of-state transactions." *Ross*, 598 U.S. at 376 n.1; *see Ellison*, 2023 WL 8374586, at *3 ("[*Ross*] did not change the rule that a state may not directly regulate transactions that take place wholly outside the state and have no connection to it."); *Interlink Prods. Int'l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. 2023) ("[I]n clarifying that … laws with extraterritorial effects are not prohibited by the dormant Commerce Clause, the Supreme Court [in *Ross*] distinguished them from those in which 'a law [] *directly* regulated out-of-state transactions by those with *no* connection to the State'" (quoting *Ross*, 598 U.S. at 376 n.1)).

B. Due Process Clause

65. The Due Process Clause of the Fourteenth Amendment provides that "[n]o State

shall … deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. 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 Glob. 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"); *see also Midwest Title Loans, Inc. v. Ripley*, 616 F. Supp. 2d 897, 905 n.8 (S.D. Ind. 2009) ("The reach of a court's jurisdiction does not determine the territorial bounds of a state legislature's laws…. A state is generally prohibited from asserting legislative power over parties and activities wholly beyond its borders." (citing *Gerling Glob. Reinsurance Corp. of Am.*, 267 F.3d at 1233)), *aff'd sub nom. Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660 (7th Cir. 2010).

66. 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 Glob. 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 Regul., Inc. v. Pinellas Cnty.*, 221 F.3d 1211, 1216 (11th Cir. 2000) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985)).

C. The Constitution's Horizontal Separation of Powers

67. 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 "restrict[] 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. at 154 (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*, 598 U.S. at 376 n.1; *id.* at 408-10 (Kavanaugh, J., concurring in part and dissenting in part); *Mallory*, 600 U.S. at 154 (Alito, J., concurring in part and concurring in the judgment) (deeming this principle an "'obviou[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") (citation omitted).

68. 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*, 598 U.S. at 376 & n.1 (citation omitted). Under those principles, a state may not "*directly* regulate[]" pricing outside its borders. *Id.* at 376 n.1.

69. 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*, 598 U.S. at 376 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.").

70. 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.

71. 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.

72. 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*, 598 U.S. at 376 & n.1 (citation omitted); *see also, e.g.*, *id.* at 404, 408-10 (Kavanaugh, J., concurring in part and dissenting in part); *South Dakota v. Wayfair, Inc.*, 585 U.S. ---, 138 S. Ct. 2080, 2100-01 (2018) (Gorsuch, J., concurring); *Mallory*, 600 U.S. at 154 (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

73. Separate from its prohibition on state laws that "*directly* regulate[] out-of-state transactions," *Ross*, 598 U.S. at 376 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 even-handedly 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." *Midwest Title Loans*, 593 F.3d at 665

(emphasis omitted) (quoting *Pike*, 397 U.S. at 142). Even state laws that do not discriminate against interstate commerce may be unconstitutional under *Pike*. *See Ellison*, 2023 WL 8374586, at *8 (recognizing that "a majority of the Justices [in *Ross*] acknowledged that the 'Court left the courtroom door open to [*Pike*] challenges premised on even nondiscriminatory burdens'" (first alteration added) (citation omitted)).

74. In assessing whether a state law's burden is "clearly excessive in relation to the putative local benefits," *Pike*, 397 U.S. at 142, courts are not limited to "considering the consequences of the statute itself," but must also "consider[] how the challenged statute may interact with the legitimate regulatory regimes of the other States and what effect would arise if not one, but many or every, jurisdiction adopted similar legislation," *C & A Carbone, Inc. v. Town of Clarkstown, N.Y.*, 511 U.S. 383, 406 (1994) (O'Connor, J., concurring in the judgment) (alterations and citation omitted); *see also U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1069 (8th Cir. 2000). "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., Inc.*, 486 U.S. 888, 893 (1988); *see Mallory*, 600 U.S. at 161 (Alito, J., concurring in part and concurring in the judgment). Further, the availability of a less burdensome alternative is relevant to whether the law's burdens on interstate commerce are clearly excessive. *See Pike*, 397 U.S. at 142 ("[T]he extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.").

III. Due Process Limits on Vague State Laws

75. Under the Due Process Clause, "laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567

U.S. 239, 253 (2012). This basic requirement of clarity in legislation "is essential to the protections provided by the Due Process Clause," *id.*, since "[v]ague laws may trap the innocent by not providing fair warning," *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

76. There are "two means by which a statute can operate in an unconstitutionally vague manner." *Karlin*, 188 F.3d at 458-59. First, a "statute is void for vagueness if it fails to provide 'fair warning' as to what conduct will subject a person to liability." *Id*. at 458. A statute violates the Due Process Clause if it "forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application." *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926). Second, "a statute must contain an explicit and ascertainable standard to prevent those charged with enforcing the statute's provisions from engaging in 'arbitrary and discriminatory' enforcement." *Karlin*, 188 F.3d at 459. Thus, "'[t]he void-for-vagueness doctrine rests on the 'twin constitutional pillars of due process and separation of powers.'" *Planned Parenthood of Ind. & Ky., Inc. v. Marion Cnty. Prosecutor*, 7 F.4th 594, 598 (7th Cir. 2021) (citation omitted).

77. Although "[t]he Constitution tolerates a lesser degree of vagueness in enactments 'with criminal rather than civil penalties because the consequences of imprecision' are more severe,'" *Karlin*, 188 F.3d at 458 (citation omitted), "[w]hen a civil statute imposes penalties that, 'although civil in description, are penal in character,' the statute is … subjected to stricter vagueness review," *Advance Pharm., Inc. v. United States*, 391 F.3d 377, 396 (2d Cir. 2004) (citations omitted). Such "quasi-criminal" civil statutes are subject to the same vagueness standards as criminal exactions, and will be "deemed impermissibly vague if [they] fail[] to 'give the person of ordinary intelligence a reasonable opportunity to know what is prohibited," or to "provide explicit standards for those who apply them." *Id*. (citation omitted). Moreover, "[w]hen

a law threatens to inhibit the exercise of constitutionally protected rights …, the Constitution demands that courts apply a more stringent vagueness test." *Karlin*, 188 F.3d at 458.

COUNT ONE

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

78. AAM re-alleges and incorporates herein by reference the allegations of all preceding paragraphs of this Complaint as if fully set forth in this paragraph.

79. A price-control statute that "directly regulates interstate commerce" that "takes place[] wholly outside of the State's borders" is "invalid." *Legato Vapors*, 847 F.3d at 830 (citation and quotation marks omitted); *see Ross*, 598 U.S. at 376 & n.1.

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

81. The application of the Act to these transactions therefore violates the Commerce Clause.

COUNT TWO

(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Due Process Clause's Prohibition on State Laws That Regulate Extraterritorially)

82. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

83. The Due Process Clause of the Fourteenth Amendment 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 Glob. Reinsurance Corp. of Am.*, 267 F.3d at 1236 (emphases omitted).

84. AAM's members sell their products primarily to wholesale distributors that are

located outside Illinois. All but two of AAM's members that manufacture generic and biosimilar products are located outside Illinois.

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

86. Accordingly, the application of the Act to AAM's members located outside Illinois and their transactions outside Illinois violates the Due Process Clause's restrictions on state extraterritorial legislation.

COUNT THREE

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

87. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

88. The "Constitution's horizontal separation of powers," *Ross,* 598 U.S. at 376 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 376 & n.1 (citation omitted)—prohibits states from directly regulating transactions that occur wholly outside their borders.

89. The Act directly regulates prices charged wholly outside Illinois and therefore violates the Constitution's "horizontal separation of powers." *Ross,* 598 U.S. at 376 n.1.

COUNT FOUR

(Declaratory/Injunctive Relief – Unduly Burdening Interstate Commerce)

90. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

91. 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." *Pike*, 397 U.S. at 142.

92. The Act's price and other regulations impose a substantial burden on interstate commerce, requiring that each manufacturer either make every or a substantial portion of sales nationwide of generic or biosimilar medicines, whether or not presently encompassed by the Act's definition of essential medicines, comply with Illinois' rules; or attempt to somehow restructure pricing and supply processes to segregate drug products for sale in Illinois, resulting in significant compliance costs and disruptions to the drug-supply chain; or else "'defend itself'" in Illinois "'with reference to all transactions,' including those with no forum connection." *Mallory*, 600 U.S. at 161 (Alito, J., concurring in part and concurring in the judgment) (quoting *Bendix Autolite Corp.*, 486 U.S. at 893).

93. Those burdens will fall overwhelmingly on interstate commerce, as drug manufacturers and the wholesale distributors they sell to are overwhelmingly located outside Illinois. Those burdens are particularly substantial when considering the effect if "not one, but many or every, jurisdiction adopted similar legislation." *C & A Carbone, Inc.*, 511 U.S. at 406 (O'Connor, J., concurring in the judgment) (alterations and citation omitted); *see also U & I Sanitation*, 205 F.3d at 1069.

94. Those cumulative effects on interstate commerce far outweigh any interest Illinois may have in regulating the prices charged outside Illinois for drugs that are later resold in Illinois by third parties.

95. There are alternatives to the Act's extraterritorial price regulation that will have "a lesser impact on interstate activities," *Pike*, 397 U.S. at 142, including limiting its regulation to in-state transactions.

96. The Act undermines Illinois' interest in making life-saving medications available to Illinois consumers, as it potentially will result in manufacturers withdrawing their products from the market altogether.

97. 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.

COUNT FIVE

(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Due Process Clause's Prohibition on Vague State Laws)

98. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

99. A statute is unconstitutionally vague under the Due Process Clause if (1) "it fails to provide 'fair warning' as to what conduct will subject a person to liability"; or (2) it lacks "an explicit and ascertainable standard to prevent … 'arbitrary and discriminatory' enforcement.'" *Karlin*, 188 F.3d at 458-59 (citations omitted).

100. The Act violates these twin requirements of due process. The Act defines "price gouging" not just as a price increase that meets specified quantitative increases in the generic drug's wholesale acquisition cost, but also as an "unconscionable" increase that is "otherwise excessive and unduly burdens consumers because of the importance of the … drug to their health and because of insufficient competition in the marketplace." Act § 5. The Act does not define what constitutes an "unconscionable," "excessive," or "unduly burden[some]" price increase, nor provide any guidance for discerning how these nebulous terms relate to one another. In addition, the Attorney General has not identified any factors he will use to determine whether a particular price increase falls within these vague terms.

101. Moreover, the Act provides no standard or guidance to determine when a price increase is "otherwise" excessive or unduly burdensome "*because of*" the "importance of the … drug" to consumer health and "insufficient competition in the marketplace." Act § 5 (emphasis added). By its terms, the Act applies exclusively to medicines that are both "essential" to public health and manufactured by three or fewer companies; thus, a price increase for such a product that is "excessive" or "unduly burden[some]" would necessarily be so, at least in part, because of the medicine's importance to consumer health and a lack of competition, but the Act gives manufacturers no guidance on how to discern when the excessiveness or burdensome nature of a price increase for these essential medicines is sufficiently attributable to those medicines' importance to consumer health or "insufficient competition in the marketplace" as to fall within the Act's definition of price gouging.

102. Thus, the Act fails to provide AAM's members with the fair notice necessary to determine whether the prices at which they sell their generic and biosimilar medicines will be deemed "price gouging." In addition, the Act fails to provide any meaningful standards to guide the Attorney General's determination of when a price increase meets the Act's definition of "price gouging," or to cabin his discretion in deciding whether to initiate an investigation or bring an enforcement action.

103. Accordingly, the Act fails to provide the minimal fair notice to regulated parties that is required by due process and is therefore unconstitutional.

COUNT SIX

(42 U.S.C. § 1983 and 42 U.S.C. § 1988)

104. AAM re-alleges and incorporates herein by reference the allegations of paragraphs 1-69 of this Complaint as if fully set forth in this paragraph.

105. 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.

106. 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.

107. AAM seeks a declaration that Defendant's enforcement of the Act is unconstitutional under the Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and/or the Constitution's horizontal separation of powers.

108. 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, or any of their agents, privies, or licensees, in violation of the Commerce Clause of the U.S. Constitution, based on any AAM member's sale of a generic or other off-patent drug or biosimilar that occurs outside Illinois;

C. For a permanent injunction prohibiting Defendant from implementing or enforcing the Act against AAM's members, or any of their agents, privies, or licensees, in violation of the

Constitution;

D. For such costs and reasonable attorney's fees to which it might be entitled by law, including 42 U.S.C. § 1988; and

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

Dated: July 9, 2024

Respectfully submitted,

s/ Andrianna D. Kastanek

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EXHIBIT A

AAM & Biosimilars Council Membership (as of 01/22/2024)

2024 AAM Regular Members

Accord Healthcare, Inc.

Ajanta Pharma USA, Inc.

American Regent

Amneal Pharmaceuticals LLC

Amphastar Pharmaceuticals, Inc.

Apotex Corp.

Aurobindo Pharma USA, Inc.

B. Braun Medical Inc.

Biocon Limited

Cipla USA

Dr. Reddy's Laboratories, Inc.

Fresenius Kabi USA

Glenmark Pharmaceuticals, Inc. USA

Hikma Pharmaceuticals USA

Jubilant Cadista Pharmaceuticals, Inc.

Lupin Inc.

Meitheal Pharmaceuticals

PAI Pharma

Sandoz Inc.

Somerset Therapeutics

Sun Pharmaceutical Industries, Inc.

Teva Pharmaceuticals USA, Inc.

Torrent Pharma Inc.

Zydus Pharmaceuticals USA, Inc.

2024 AAM Associate Members

ACIC Pharmaceuticals

Catholic Medical Mission Board, Inc. (CMMB)

ChemWerth Inc.

Direct Relief

Dispensary of Hope

Gedeon Richter USA

Husch Blackwell

Inmar

Lachman Consultant Services Inc.

Operation Smile

2024 Biosimilars Council Regular Members

(unless otherwise noted)

Amneal Biosciences

Axinn, Veltrop & Harkider (Associate)

Biocon

Dr. Reddy's Laboratories, Inc.

Fresenius Kabi USA

Lupin Inc.

Sandoz

Teva Pharmaceuticals

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois, *Defendant*.	)	No. 24 C 544 Judge Virginia M. Kendall

ORDER

This matter is before the Court on Defendant Attorney General Kwame Raoul's motion to dismiss Plaintiff Association for Accessible Medicines' ("AAM") First Amended Complaint. (Dkt. 38). For the reasons below, the Attorney General's motion [38] is denied.

BACKGROUND

The Association for Accessible Medicines is a nonprofit association representing manufacturers and distributors of generic and biosimilar medicines. (Dkt. 35 at ¶ 14). AAM is concerned about the constitutionality of House Bill 3957 ("the Act"), which took effect on January 1, 2024. (*Id*. at ¶ 29). The Act prohibits manufacturers and wholesale drug distributors from engaging in "price gouging" in the sale of certain drugs that are "ultimately sold into Illinois." (Dkt. 18-1 at 5). Price gouging is any price increase that meets certain metrics identified in the statute and is "otherwise excessive and unduly burdens consumers." (*Id*. at 4). It does not include price increases that can be "reasonably justified" by reasons identified in the Act. (*Id*. at 4–5). If the Attorney General has reason to believe that a manufacturer or wholesale drug distributor is engaged in price gouging, the Act authorizes him to "send a notice to [the company] requesting a statement" of information relevant to determining whether a violation of the Act occurred. (*Id*. at 5–6). Upon determining that a company engaged in price-gouging, the Attorney General may ask a circuit court to impose various penalties, such as a fine or injunction. (*Id*. at 7–8).

In January 2024, AAM brought this pre-enforcement action seeking declaration that the Act is unconstitutional and moved for a preliminary injunction prohibiting the Attorney General from enforcing the Act against AAM's members. (Dkt. 1 at ¶¶ 70–100; Dkt. 17). The Court granted the Attorney General's motion to dismiss, explaining that AAM failed to allege facts sufficient to confer standing and, even if they had, AAM failed to allege that a credible threat of prosecution existed. (Dkt. 32). AAM then filed an Amended Complaint, (Dkt. 35), seeking the same relief as before. (*See generally* Dkt. 35 at ¶¶ 78–108). The Attorney General again moves to dismiss. (Dkt. 38).

LEGAL STANDARD

In reviewing a Federal Rule of Civil Procedure 12(b)(1) motion to dismiss for lack of subject-matter jurisdiction, the plaintiff must carry its burden of establishing that jurisdiction is proper. *Ctr. for Dermatology & Skin Cancer, Ltd. v. Burwell*, 770 F.3d 586, 588–89 (7th Cir. 2014). "Facial challenges require only that the court look to the complaint and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction." *Apex Digital, Inc. v. Sears, Roebuck & Co*., 572 F.3d 440, 443 (7th Cir. 2009). A court lacking subject-matter jurisdiction must dismiss the action without proceeding to the merits. *See MAO-MSO Recovery II, LLC v. State Farm Mut. Auto. Ins. Co*., 935 F.3d 573, 581 (7th Cir. 2019).

DISCUSSION

The Attorney General argues that AAM's complaint should be dismissed for lack of subject-matter jurisdiction because AAM lacks standing to bring this action, and the issues therein are not ripe for adjudication. Alternatively, he argues that this case should be dismissed because AAM seeks premature adjudication of fact-intensive theories best reserved for as-applied challenges. The Court will consider each argument in turn.

I. AAM has standing to bring this action.

Article III of the Constitution "confines the federal judicial power to the resolution of 'Cases' and 'Controversies.'" *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021) (quoting U.S. Const. art. III., § 2). "For there to be a case or controversy under Article III, the plaintiff must have a 'personal stake' in the case—in other words, standing." *Id*. (citing *Raines v. Byrd*, 521 U.S. 811, 819 (1997)). While organizations do not have standing to assert claims based on their particular concept of the public interest, they may, through associational standing, assert the rights of their members. To show that it has associational standing, AAM must allege that (1) its members have standing to sue in their own right; (2) the members' interests are germane to the organization's purpose; and (3) neither the claim asserted nor the relief requested requires the individual participation of the organizations' members. *Milwaukee Police Ass'n v. Flynn*, 863 F.3d 636, 639 (7th Cir. 2017).

To establish that its members have standing to sue in their own right, AAM must allege that its members (1) suffered an injury in fact that is concrete, particularized, and actual or imminent; (2) the injury was likely caused by the defendant; and (3) the injury is likely to be redressed by judicial relief. *TransUnion*, 594 U.S. at 423. Where, as here, a party seeks pre-enforcement review of the constitutionality of a statute, a plaintiff may satisfy the injury-in-fact requirement by alleging "an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (citing *Babbitt v. United Farm Workers Nat. Union*, 442 U.S. 289, 298 (1979)).

A. AAM sufficiently alleges its members' intent to engage in a proscribed course of conduct.

In its Amended Complaint, AAM explains that one of its members, Sandoz, Inc. ("Sandoz"), produces [REDACTED], a generic medication for treating [REDACTED], which is a chronic and life-threatening condition. (Dkt. 35 ¶ 46). [REDACTED] is on the World Health Organization's most recent list of essential medicines and is manufactured in the United States by only three companies. (*Id.*). Sandoz intends to raise the wholesale acquisition cost of [REDACTED] by [REDACTED], which constitutes a [REDACTED] increase from the product's price in 2023. (*Id.* at 47). This price increase is driven by various financial goals, including increasing or sustaining the company's profit margins, "provid[ing] a greater return on investment" for company shareholders, and "offset[ting] price reductions on certain other Sandoz products that have reduced the company's overall profitability." (*Id.*). AAM alleges similar motivations for various other members' intended price increases on other medicines. (*Id.* ¶¶ 45, 50). Because the Act is explicitly concerned with the harm to the public's health caused by unconscionable price increases on medicines, AAM's allegations are sufficient to allege conduct that is "arguably affected" by the Act, which is all that is required at this stage. *Driehaus*, 573 U.S. at 159 (citing *Babbitt*, 442 U.S. at 298).

B. AAM sufficiently alleges a credible threat of prosecution.

To allege a credible threat of prosecution, a plaintiff must have a fear of prosecution that is not "imaginary or speculative." *Babbitt*, 442 U.S. at 298 (quoting *Younger v. Harris*, 401 U.S. 37, 42 (1971)). When plaintiffs "do not claim that they have ever been threatened with prosecution" or "that a prosecution is likely," they do not allege a dispute susceptible to resolution by a federal court. *Id.* These guidelines follow with the Supreme Court's repeated instruction that a "threatened injury must be certainly impending to constitute injury in fact" and that "allegations of possible future injury are not sufficient." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). There is no well-defined formula for evaluating whether a credible threat of enforcement exists. Accordingly, courts look at various factors, including: whether there is a law on the books at all; whether the law has been enforced against others; whether there has been a general showing of active enforcement intentions; whether there has been an express disclaimer of any intent to enforce the challenged law; and whether enforcement authority under the law is widely disbursed. *See Brown v. Kemp*, 86 F.4th 745, 768 (7th Cir. 2023) (collecting cases); *Am. C.L. Union of Illinois v. Alvarez*, 679 F.3d 583, 591 (7th Cir. 2012) (quoting *Bauer v. Shepard*, 620 F.3d 704, 708 (7th Cir.2010)).

Here, AAM does not claim that any of its members have been subject to an investigation or enforcement action, or that its members received notice from the Attorney General initiating an investigation into whether a violation occurred. Nor does AAM identify any instance in which the Act has been enforced against any manufacturer or distributor—AAM member or otherwise. Further, enforcement authority of the Act belongs exclusively to the Attorney General.

The Attorney General insists that a fulsome consideration of facts alleged necessitates a finding that AAM has not alleged a credible threat of prosecution. In rebuttal, AAM rests the weight of its case on the proposition that "[t]he very 'existence of a statute implies a threat to

prosecute.'" (Dkt. 40 at 16). Indeed, the Seventh Circuit has repeatedly reached this conclusion. *See Bell v. Keating*, 697 F.3d 445, 451 (7th Cir. 2012) ("[t]he existence of the statute constitutes the government's commitment to prosecute in accordance with it and, thus, a concrete prospect of future harm for one who would flout it"); *ACLU of Illinois v. Alvarez*, 679 F.3d 583, 591 (7th Cir. 2012) (same); *Ezell v. City of Chicago*, 651 F.3d 684, 696 (7th Cir. 2011) ("[t]he very 'existence of a statute implies a threat to prosecute'") (internal citations omitted); *Bauer v. Shepard*, 620 F.3d 704, 708 (7th Cir. 2010) (same); *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003) (a preenforcement plaintiff "need not show that the authorities have threatened to prosecute him" because "the threat is latent in the existence of the statute"). While these cases involve the exercise of fundamental constitutional liberties (such as those protected by the First and Second Amendments), the Seventh Circuit does not provide any limiting language to suggest that only the existence of a statue implicating "fundamental constitutional liberties" can imply a threat to prosecute. Nor does the Seventh Circuit suggest that the mere presence of a potentially unconstitutional law, without more, is necessarily insufficient to find a credible threat of prosecution. Accordingly, the Court finds that a credible threat of prosecution exists in the existence of the Act, especially because the Attorney General has not yet disclaimed his intent to prosecute AAM members' violations of the Act.

II. AAM's claims are ripe for adjudication.

"Much like standing, ripeness gives effect to Article III's Case or Controversy requirement by preventing the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements." *Sweeney v. Raoul*, 990 F.3d 555, 559 (7th Cir. 2021) (cleaned up). In evaluating ripeness, courts consider "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 560. In the context of a pre-enforcement challenge, like the present case, ripeness and standing often boil down to the same question.

When a plaintiff faces a realistic threat that a law will be enforced against him, "a party may advance a pre-enforcement challenge before suffering an injury—so long as the threatened enforcement is sufficiently imminent." *Sweeney*, 990 F.3d at 559 (internal quotation marks omitted) (quoting *Driehaus*, 573 U.S. at 159). The plaintiff need not suffer "an actual arrest, prosecution, or other enforcement action," nor does the plaintiff need "to confess that he will in fact violate the law." *Driehaus*, 573 U.S. at 163. Rather, a plaintiff may bring a pre-enforcement challenge where (1) he intends to perform conduct that is arguably constitutionally protected, (2) the conduct is prohibited by the rule or statute challenged, and (3) there is a credible threat of enforcement. *Id.* at 159.

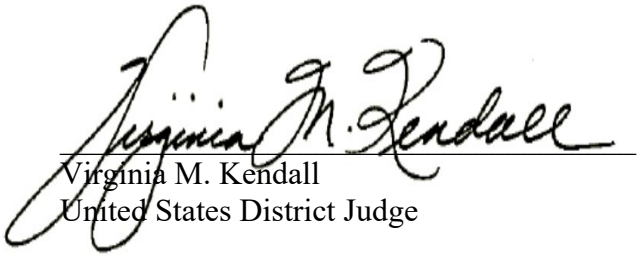
Having concluded that AAM sufficiently alleges its members' intent to engage in a proscribed course of conduct and that there is a credible threat of enforcement, the Court turns its attention to the constitutional liberty requirement. The Attorney General urges the Court to find that "AAM does not claim that the Act infringes on any fundamental constitutional liberty." (Dkt. 44 at 7). But AAM very clearly asserts that the Act violates the Due Process Clause and the Commerce Clause. (*See generally* Dkt. 35 ¶¶ 73–86). Nothing more is required of AAM at this stage.

III. AAM presents an as-applied challenge to the Act.

Finally, the Attorney General argues that this case should be dismissed because AAM seeks premature adjudication of fact-intensive theories best reserved for as-applied challenges. But the Attorney General's argument fails because AAM's claims are not "inherently fact-bound" and do not "depend on the specific circumstances" of a given sale. (Dkt. 39 at 18). AAM seeks adjudication of a purely legal issue: "whether the Constitution permits Illinois to regulate the prices charged in wholly out-of-state sales." (Dkt. 40 at 20).

CONCLUSION

For the reasons set forth above, the Attorney General's motion to dismiss [38] is denied.



Virginia M. Kendall
United States District Judge

Date: December 13, 2024

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois, *Defendant*.	Case No. 1:24-cv-00544

DECLARATION OF RODNEY EMERSON

I, Rodney Emerson, declare as follows:

1. I am the Vice President of Pricing and Contracts for Sandoz Inc. ("Sandoz"). I joined Sandoz on October 4, 2018. My responsibilities at Sandoz include the governance, pricing, and contracting of the U.S. injectables and generic portfolios of products. I am providing this declaration to update the information contained in the declaration previously provided by Timothy de Gavre, who is no longer employed at Sandoz.

2. I am knowledgeable about Sandoz's distribution system, including its sales arrangements with wholesalers and other customers, and its pricing decisions.

3. Sandoz is a corporation organized and existing under the laws of Delaware with a principal place of business in Princeton, New Jersey.

4. Sandoz is a pharmaceutical company engaged in the manufacture, sale, and distribution of, among other things, generic drugs and biosimilars.

5. In the vast majority of cases, Sandoz sells its products to large national wholesale distributors, which are located outside Illinois. The wholesale purchasers then re-sell Sandoz's products, including its generic and biosimilar products, to retail pharmacies, hospitals, or other healthcare facilities, some of which are located in Illinois. Sandoz does not control the prices at which its drugs are resold by other entities in the supply chain, nor does it control where those drugs are resold. In rare circumstances, Sandoz sells its products to hospital systems, physicians, or specialty pharmacies with a physical presence in Illinois.

6. Sandoz's large wholesale-distributor purchasers typically purchase Sandoz's products in bulk via negotiated multi-drug contracts, rather than on a drug-by-drug basis.

7. Sandoz also sells its generic and biosimilar products directly to some retail pharmacy chains that maintain their own warehouse facilities, which are also located outside Illinois. Sandoz's large pharmacy-chain purchasers also typically purchase Sandoz's products in bulk via negotiated long-term, multi-drug contracts, rather than on a drug-by-drug basis.

8. Sandoz's sales to wholesale distributors and retail pharmacy chains take place outside Illinois.

9. Sandoz markets an [redacted], a generic prescription medication that is indicated for the treatment of [redacted]. Sandoz sells its [redacted] product in a [redacted] dosage. [redacted] is manufactured for Sandoz in [redacted], and Sandoz markets [redacted] for sale throughout the United States. Sandoz's sales of [redacted] to wholesale distributors and retail pharmacy chains take place outside Illinois. Sandoz does not sell [redacted] directly to consumers in Illinois.

10. The reference listed drug for [redacted] is [redacted]. There are [redacted] listed for [redacted] in the U.S. Food and Drug Administration's Orange Book.

11. [redacted] is on the World Health Organization's most recent model list of essential medicines. Sandoz is [redacted] that markets [redacted] for the United States, and Sandoz has struggled to [redacted] for its product.

12. Sandoz sells [redacted] in [redacted]. An adult receiving a maintenance dose of [redacted] receives [redacted]. Therefore, [redacted].

13. The process for producing [redacted] is [redacted], requiring the use of [redacted] and the implementation of [redacted], for example, requiring product-specific [redacted], specific [redacted], and even requiring [redacted]. Failure to maintain any of these costly processes could [redacted]. As a result, manufacturing [redacted] requires its own product-specific capital investment.

14. Over the past years, the cost of manufacturing Sandoz's [redacted] product has increased in multiple respects: production cost increases, product ingredient cost increases, increased costs associated with product validation (including inspection and testing), and changes to its active pharmaceutical ingredient that required additional expensive tests. Other costs that are not directly associated with production have also increased, such as regulatory approval costs and costs incurred due to product inventory loss. Additionally, as Sandoz recently [redacted]

[redacted] where [redacted] is manufactured, Sandoz expects that overhead costs related to [redacted] may continue to increase when compared to [redacted] And, should Sandoz decide to [redacted], it estimates that the [redacted] will cost upwards of $2,000,000. As a result, Sandoz has faced and expects in the future to face significant new production hurdles requiring increased processes and investment at almost every stage of production.

15. For all of calendar year 2023, the wholesale acquisition cost of [redacted] was [redacted]. In calendar year 2024, Sandoz intended to increase the wholesale acquisition cost of [redacted] for certain customers by [redacted]. The wholesale acquisition cost for [redacted], both before and after that price increase, would exceed $20 for a course of treatment lasting 30 days. Moreover, the planned increase of [redacted] in the wholesale acquisition cost for [redacted] would constitute a [redacted] increase over the wholesale acquisition cost for [redacted] for calendar year 2023.

16. In the second half of calendar year 2024, Sandoz reevaluated its pricing plans for [redacted] and decided not to proceed with the previously planned price increase for that product until AAM members obtain relief in this litigation. Sandoz reevaluated its previously intended price increase because of the significant penalties and other monetary liability it is exposed to under HB 3957 and the increased threat of that monetary liability due to its participation in this litigation. Therefore, the wholesale acquisition cost of [redacted] remained [redacted] for all of calendar year 2024. But for the threat of significant penalties and other monetary liability under HB 3957, Sandoz would increase the wholesale acquisition cost for [redacted] for certain customers by [redacted] in calendar year 2025, which would constitute a [redacted]

increase over the wholesale acquisition cost of [redacted] for calendar year 2024. Sandoz plans to proceed with this price increase if HB 3957 is enjoined.

17. As a result of HB 3957, Sandoz will bring in less revenue this year and in future years from [redacted]. Sandoz has no way to recoup that revenue if the relevant provisions of HB 3957 are not enjoined.

18. A majority of the previously intended [redacted] increase in the wholesale acquisition cost of [redacted] is attributable to factors other than an increase in the cost of producing [redacted], or the cost of expanding access to [redacted] to promote public health. These factors include regulatory approval costs, costs incurred due to product inventory loss, and inflation. In addition, Sandoz's previously intended price increase for [redacted] is necessary to meet the company's long-term growth strategy, to increase or sustain its overall profit margins, and to provide a greater return on investment for its shareholders. By increasing the price of [redacted], Sandoz would be able to offset price reductions on certain other Sandoz products that have reduced the company's overall profitability. In addition, a portion of the previously intended price increase is attributable to Sandoz's assessment of current market dynamics for [redacted], including the pricing of competing generic products. The previously intended price increase for [redacted] would be possible, in part, because of the limited competition for [redacted] in the United States.

19. At its current price, Sandoz's internal projections indicate that [redacted] will no longer be profitable given increased input costs. Withdrawing [redacted] from Illinois specifically would not be feasible. If it were, and if Sandoz were to withdraw [redacted] from Illinois to avoid HB 3957's price control, Sandoz would lose significant revenues.

20. Sandoz's anticipated pricing decisions constitute confidential and proprietary information. Sandoz does not publicly disclose the identities of any of the products for which it intends to make price changes, or the amount of any anticipated price change. Instead, Sandoz has internal safeguards and policies in place to ensure that its pricing plans do not become publicly known to its competitors or any third party.

21. Sandoz maintains the confidentiality of its internal pricing decisions to protect the integrity of its business operations, to maintain its competitive position in the market, as well as to ensure compliance with all applicable laws, including federal and state antitrust laws.

22. The public disclosure of Sandoz's confidential pricing decisions, including the identity of any product for which Sandoz intends to make a price change and the amount of that price change, would harm Sandoz and its competitive position. Sandoz's competitors would have the opportunity to make adjustments to their own pricing or other business strategies in response to Sandoz's non-public pricing plans. Even disclosing the identity of a product whose price Sandoz intends to increase (or intends not to increase), without disclosing the details of the increase, would harm Sandoz by providing its competitors for that product with otherwise confidential information regarding Sandoz's pricing plans they can use to compete with Sandoz.

23. Sandoz does not make drug pricing decisions on a state-by-state level. 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 national prices of the company's products. Sandoz has no ability to specify the price at which its products will be resold in Illinois specifically.

24. Cost is a significant factor in the pricing of Sandoz's generic and biosimilar medicines. The market for many generic medicines is highly competitive, with a dozen or more

generic products competing for market share, including on price. Even where only one generic or biosimilar is available, the generic or biosimilar will generally be priced lower than the brand-name counterpart. As a result, Sandoz generally realizes significantly lower profit margins on each generic product than a brand company realizes on a brand product.

25. Under HB 3957, price increases on Sandoz's generic and biosimilar products could subject Sandoz to substantial liability. However, price increases for these products may be necessitated by numerous reasons unrelated to Sandoz. For example, prices are affected by the actions of market players that supply Sandoz with raw materials and other supplies and utilities used in the manufacturer of Sandoz's generic and biosimilar drugs. Moreover, end customer prices are affected by the actions of additional market players other than Sandoz, such as wholesale distributors, pharmacy benefit managers, retail pharmacy chains, health insurers, Medicaid and Medicare contractors, hospital networks, and others. Prices also are affected by market forces in states other than Illinois. Moreover, prices for biosimilar products may also be affected by increased costs of marketing, as well as a need to recoup the costs of clinical or other studies undertaken to obtain FDA approval.

26. Sandoz already faces significant economic risks associated with its manufacture of generic and biosimilar products. Even after overcoming the difficulties in obtaining FDA approval and avoiding or defeating claims of patent infringement, Sandoz faces significant risk and uncertainty after its generic and biosimilar products enter the market, particularly when there are multiple other products for the same medicine. The threat of liability posed by HB 3957 exacerbates the financial and other risks that Sandoz already currently faces in producing and marketing generic and biosimilar products, which will make it even more difficult to bring and

maintain affordable drugs to patients. In addition, Sandoz will face increased, unrecoverable costs due to being required to comply with HB 3957's mandatory notice-and-reporting regime.

27. A cost increase of any kind could make it unprofitable for Sandoz to manufacture its generic and biosimilar prescription products. If Sandoz faces increased costs of any kind but is unable to increase its prices due to HB 3957, then Sandoz's already thin profit margins could be erased or its products rendered unprofitable.

28. If Sandoz's thin profit margins disappear, then there is a real risk that Sandoz will be forced to withdraw the relevant generic or biosimilar products it currently sells nationwide, as that is the only way for it to avoid the Act's price regulation. Product withdrawal would significantly harm Sandoz, resulting in a loss of revenues, which Sandoz could not regain in the event HB 3957 were invalidated.

29. Thus, under any scenario, Sandoz will be injured by HB 3957. Each time increased costs of production or other separate factors require Sandoz to consider a price increase like that described above for [redacted], Sandoz will have to either (1) forgo the price increase, thus sacrificing some or all of its already low profit margin; (2) raise prices to maintain profitability, but risk severe civil penalties and other monetary liability in Illinois court; or (3) if the product is no longer profitable without the covered price increase, potentially withdraw the product from the market, suffering a loss of revenue. Sandoz will never be able to recover any of these monetary damages.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 1/3, 2025.

Rodney Emerson
Vice-President, Pricing & Contracts

CIRCUIT RULE 30(F) REQUIRED INDEX TO TRANSCRIPT OF PROCEEDINGS

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION FOR ACCESSIBLE MEDICINES,	)	Case No. 24 C 00544
Plaintiff,	)	
v.	)	
KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois,	)	
	)	Chicago, Illinois
	)	September 22, 2025
Defendant.	)	10:04 a.m.

TRANSCRIPT OF PROCEEDINGS - ORAL ARGUMENT
BEFORE THE HONORABLE VIRGINIA M. KENDALL

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PROCEEDINGS REPORTED BY STENOTYPE
TRANSCRIPT PRODUCED USING COMPUTER-AIDED TRANSCRIPTION

(Proceedings heard in open court:)

THE CLERK: 24 C 544, Association for Accessible Medicines versus Raoul.

Please present yourselves.

MR. DIERKES: Good morning, your Honor. Michael Dierkes for the defendant.

THE COURT: Good morning.

MR. JAY: Good morning, your Honor. William Jay for the plaintiff.

THE COURT: Good morning.

MS. KASTANEK: Good morning. Annie Kastanek also for the plaintiff.

THE COURT: Good morning.

And one more?

MS. MARIN: Good morning, your Honor. Isabel Marin for the plaintiff.

THE COURT: Good morning.

At least you know to introduce yourselves. See, I -- that's been happening since COVID, but that's a young prosecutor. Right? Doesn't even know to say "hello."

So we'll have to continue to teach them through fine examples.

All right. We're going to just do oral argument on this today so I can ask questions. And one side can sit down while -- did you talk about how you'll do it? Have a little

rebuttal argument at all?

MR. JAY: We haven't talked about the format but --

THE COURT: Is there a way that you want to do it? I mean --

MR. DIERKES: I think it's plaintiff's motion, so they can start first. My presentation is probably 15 or 20 minutes and --

THE COURT: That's fine.

MR. DIERKES: -- assuming a little rebuttal, I think we can fit it in.

THE COURT: That's fine, that's fine. And if I have any questions, doesn't really matter, either way I'll ask. Okay? All right. So we'll get started as soon as you're ready. Thank you.

MR. JAY: Thank you, your Honor.

May it please the Court, on behalf of AAM, we're asking for a preliminary injunction to enjoin the Illinois statute.

And the issues in this case really boil down to whether the settled law on the dormant Commerce Clause has changed because under the settled precedent of not just the Seventh Circuit, but every other circuit to have confronted one of these laws as well as decades of Supreme Court precedent, a state may not regulate transactions between people in other states. And the other side has hung its hat on either the

Supreme Court's decision in *Ross* or a Supreme Court decision from 1987 which predates a lot of the relevant precedent, and I'd like to go through in discussing the likelihood of success why neither of those things changes the outcome of the clear precedent on the extrater -- extraterritoriality doctrine, a word I'm going to stumble over.

THE COURT: And your injunction is based on the dormant clause issue as opposed to any of the other claims that are in there, right?

MR. JAY: That's correct. We've sought only a P.I. against the application of this law to transactions outside of Illinois.

THE COURT: Got it.

MR. JAY: The proposed order I think makes that pretty clear --

THE COURT: Okay.

MR. JAY: -- in the wording. I don't think the other side has taken issue with the wording we've proposed.

So, yes, it is based entirely, not just on the dormant Commerce Clause, but there -- I mean, there are multiple strands of the dormant Commerce Clause. We are focused on the extraterritoriality doctrine. And that is the basis of the injunction that my client won in Minnesota, affirmed by the Eighth Circuit. It's the basis of the injunction that we won in Maryland, affirmed from the Fourth Circuit. It's been the

basis of a lot of the other challenges to state price control legislation like this.

THE COURT: Okay. So let's -- maybe let's start with *Ross*. Do you want to talk to me about *Ross*?

MR. JAY: Sure. And I think --

THE COURT: I like that you call it *Ross* and not *National Pork Producers Council, et al.*, right?

MR. JAY: Right. The Blue Book would be angry with me for using the government party. But, yes, it's simpler to call it *Ross*.

THE COURT: Right.

MR. JAY: But -- so *Ross* -- the thing I most want you to look at in *Ross* is the part where they say, "We're saying nothing new," which is at page 374 --

THE COURT: Right.

MR. JAY: -- and Footnote 1.

And I think both of those things make clear that *Ross* was not a sea change, and it certainly was not overturning an aspect of the doctrine that was not before it.

So it's important to remember that the California law was a regulation of in-state conduct. It prohibited the in-state sale of pork meat that didn't comply with the California requirements for how the pig from which the pork came was treated. But the trigger was not --

THE COURT: I'm going to your Footnote 1, what your

focus is on that one.

MR. JAY: So our focus in Footnote 1 is on the -- the use of the plurality decision in *Edgar*. And the -- what the Court said is that *Edgar* -- so sort of halfway through the footnote, that decision spoke to a law that directly regulated out-of-state transactions by those with no connection to the state. And petitioners, meaning the pork producers, do not allege those conditions exist here.

So I think this footnote is a pretty good statement that the Supreme Court was not taking up a fact pattern that the case did not present, and it was not overturning a line of cases that the parties were not relying on in that case.

But that is the line of cases that we are relying on in this case because this law really does regulate a transaction between a manufacturer in, let's say, Pennsylvania, and a wholesaler in, let's say, Ohio. The -- if the manufacturer sells a product, a generic product, to the wholesaler, and that product then makes its way through the stream of commerce to Illinois, whether the manufacturer knows that's going to happen, whether the manufacturer has any control over whether that's happening, and no matter what price is actually charged in Illinois, Illinois regulates the price charged in the transaction between the manufacturer and the wholesaler in Pennsylvania or Ohio.

THE COURT: And in this setting, the manufacturer and

the wholesaler, they are always going to be not directly linked to the pharmacy, is that right? Or is the pharmacy linked to the wholesaler? How does that work?

MR. JAY: In most cases, manufacturers sell to the wholesalers.

THE COURT: Right.

MR. JAY: Wholesalers sell to retailers, which might be a neighborhood pharmacy, but it might also be a very large --

THE COURT: Okay.

MR. JAY: -- you know, company. It could be Walgreens. Right? And so sometimes the medication might move around even while in the possession of the retailer, so you might -- Walgreens might take delivery in one place and truck it to another place before it's actually dispensed, for example.

THE COURT: Okay.

MR. JAY: Now, we're not saying that no manufacturer would ever sell directly to a large customer like a hospital or something like that, but we've not sought to enjoin transactions like that. What we're seeking to enjoin is the application -- I should say we're not seeking to enjoin the application of the law to transactions like that. We are seeking to enjoin the application of the law to out-of-state transactions between manufacturer and wholesaler not in

Illinois, where neither is in Illinois.

THE COURT: Okay, okay.

MR. JAY: And I think that the -- to look at the two key Seventh Circuit decisions, *Midwest Title* and *Legato Vapors*, both of them I think have some instructive things to say about this fact pattern.

But I don't want to get off of *Ross* if your Honor has more questions about that.

THE COURT: Well, they're all kind of related in some ways. But if you want to finish up with *Ross* first, that's fine, and then we'll go to *Legato Vapors*. That's my next area of questioning.

MR. JAY: Sure.

I think the only other key thing that I want to emphasize about *Ross* is that -- remember that the case came from the Ninth Circuit. It actually -- so the Supreme Court affirmed the Ninth Circuit, which had affirm -- in turn, affirmed the dismissal of the pork producer's complaint.

In other words, the doctrine in the Ninth Circuit did not recognize the sort of effects -- extraterritorial effects claim that the pork producers were trying to rely on.

But the Ninth Circuit does have another robust body of case law typified by their en banc decision in *Sam Francis Foundation* that is just like the Seventh Circuit's case law. It is just like the Eighth Circuit's case law. It is just like

all of the things that our friends on the other side say have been overturned by *Ross*.

And so AAM is challenging a state law in California. We've cited you to a case called *AAM versus Bonta* from the Eastern District of California, which postdates *Ross*, and it says the same thing as these other -- these other decisions that we've cited to your Honor, which is *Ross* does not displace the Ninth Circuit's precedent in cases like *Sam Francis Foundation* about actually trying to regulate transactions that occur outside of California or outside of the relevant state.

So I think that helps to illustrate why *Ross* didn't change the law even in the circuit from which *Ross* came. I don't think it can be thought to change the law in this circuit, in the cases like *Midwest Title*.

The other thing about it is that our friends on the other side say that after *Ross*, the key is discrimination, that without discrimination, there can be no claim under the dormant Commerce Clause. I think *Ross* itself makes clear that that is not correct.

The things I would point you to are the statement at page 379 about leaving the courthouse -- leaving the courtroom door open to such claims without discrimination. And that's at the beginning of Part 5. Justice Sotomayor and Justice Kagan, who were the two votes without which there wouldn't have been a majority for that part, wrote a separate concurrence,

confirming that they were not seeking to overturn the previous *Pike* balancing case law that says that you can have a dormant commerce claim without discrimination. So if the -- if discrimination were required, not only would extraterritoriality, which the Supreme Court said in Footnote 1 it wasn't considering the out -- out the window, *Pike* would be out the window, and it wouldn't make sense that the Supreme Court would have this, like, very long discussion in I think Part 5 of its decision about the -- whether the *Pike* balancing claim that the pork producers had pleaded could state a claim. They would have just said there is no discrimination and, therefore, there is no dormant Commerce claim. And there were three votes I think to do that, but only three. And Justice Sotomayor's concurrence makes clear that her rationale, which is narrower, was that *Pike* continues to exist and it continues to be a valid theory even without discrimination.

And I think that's an easy segue, right, into *Midwest Title* --

THE COURT: Right.

MR. JAY: -- and *Legato* because those cases make clear that in this circuit, discrimination is not an element and neither is this sort of benefits and burdens balancing, when the claim is that a state is trying to regulate transactions that occur in another state between citizens of the other state and -- and maybe a third state. I mean, indeed, *Midwest Title*

involved Indiana trying to regulate Indianian -- or Hoosiers, I should say, leaving the state and engaging in certain kinds of transactions.

In this case, you don't even have that type of tie between the State of Illinois and the transaction that Illinois is trying to regulate because, as I said before, it could well be a manufacturer and a wholesaler, neither of which is located in Illinois or has any contact with Illinois. The contact comes later. And it's -- as the statute puts it, it's in the -- entirely in the passive voice. If the medicine is sold in Illinois later -- by anyone, for any reason, for any price -- then that medication is sort of regulated back up the chain by the Illinois statute.

Just a word about a couple of the other arguments that the State makes to distinguish *Midwest Title*, *Legato*, and the -- and the line of Supreme Court cases on which they rely.

CTS is one of the Supreme Court cases they cite. That's a corporate law decision about an anti-takeover statute. And most of that decision, including I think all of the parts that they cite, are a *Pike* claim. In other words, the lower court had invalidated the state statute on a *Pike* balancing theory, and the Supreme Court refers to that. So the balancing, you know, of benefits and burdens, that's not the kind of claim that we are presenting here. And I don't think that you can read *CTS* to stand for the proposition that

whenever the state has some local interest that it can say belongs on the scale that the -- that the law can survive even if it regulates into other states. There's only the briefest discussion in *CTS* of extraterritoriality. And the reason is that in corporate law, a state that creates the corporation has the right to regulate the, sort of, internal corporate governance of that corporation. It's called the Internal Affairs Doctrine. And every corporation is regulated by one and only one state. That's why it is not a problem under the Commerce Clause for the home state of a corporation, like the state that creates it, to specify what bylaws that it will have or how its board meetings operate and so on.

But this case and cases like it are a good illustration of why the dormant Commerce Clause's extraterritoriality principle exists, because there absolutely will be conflicting obligations that a nationwide company, shipping pharmaceuticals nationwide and selling them to nationwide wholesalers, will encounter. I think our declarant goes into this.

We can't really separate out medication for -- like, that will wind up in Illinois. There's no way to say, "Well, we want to be a non-Illinois company so that we don't have to meet the Illinois requirements."

And when you have -- if you had all 50 states passing their own requirements -- we've already seen that Minnesota's

formula looks different from Illinois's formula.

Just to give you another example, there have been other proposed laws, some of which say that they will regulate only medications that are in a declared shortage, and others that say they will regulate only medications that are not in a declared shortage.

So there would be pretty obvious conflict, you know, the -- a patchwork, to use the sort of well-worn metaphor, that manufacturers would have to deal with if every state could do this.

It really would be a race to the bottom, that you would have to comply with the -- on a nationwide basis with the strictest state law, the strictest formula, and what that would produce is just a complete inability to set prices.

THE COURT: I want to go back to what -- your beginning with the footnote, okay? Footnote Number 1 in the *Ross* case.

So it also says here that: "Some have questioned whether the state law at issue in *Edgar* posed a dormant Commerce Clause question as much as one testing the territorial limits of state authority under the Constitution's horizontal separation of powers."

So doesn't that discussion then in *Baldwin, Healy* cases and this comment here support the potential conclusion that there is no specific extraterritorial --

extraterritoriality principle left as part of the dormant Commerce Clause?

MR. JAY: I think that would be an awful lot to read out of the "Some have questioned" sentence.

And here is how I read that sentence.

I think that the authors of the -- the author of the majority opinion and the dissenters, Justice Kavanaugh's dissent in particular, agreed that we can't have a federal system where each state is sovereign in its own sphere, but in which they are -- each of them is one of our United States in a national market with a national government and the national government having authority over commerce. You can't have a structure set up in that way if each state can just regulate willy-nilly outside its borders where it has no connection to the transaction.

Some people have -- commentators have suggested that maybe the Import-Export Clause is the best way to get at that. Others have said maybe the Due Process Clause is the best way to get at that. And I think what this is alluding to is that debate about where in the Constitution it finds a home. But I take our friends on the other side to be saying it doesn't have any home in the Constitution, that there is nothing that the courts can do when a state seeks to regulate transactions far outside its borders.

So we think that the settled doctrine, certainly in

this circuit, is that that finds a home in the dormant Commerce Clause. And I -- the way that -- the way that I think about that is that when the transaction that is the sole target of the regulation occurs in another state, how can the state not be regulating interstate commerce? In other words, it is indeed regulating commerce that might -- that -- to that state might as well be foreign commerce because it is commerce that is occurring between Pennsylvania and Ohio or the like.

Now, sure, there's some tangential connection when the medication later down the stream of commerce winds up in Illinois, but that's no different than the vape liquid in *Legato Vapors*, ground up in Indiana, or the Hoosier with a car getting a title loan, in *Midwest Title*, would eventually go back to Indiana, with -- often with the car. But the Seventh Circuit said in both cases that that's not enough of a connection and it's not sort of -- we're not talking about minimum contacts that you would borrow from the personal jurisdiction context.

THE COURT: Right.

MR. JAY: There has to be an actual hook between the state that's passing the regulation and the transaction that it's trying to regulate.

THE COURT: Okay.

MR. JAY: I was going to spend just a minute --

THE COURT: Yes, go ahead --

MR. JAY: -- on irreparable harm --

THE COURT: -- anything you want.

MR. JAY: -- if that's -- unless -- but if the Court has any other questions about -- about the merits, I'd be happy to -- happy to involve those. Our submission really is on the merits that, like, the case law all lines up on our side. So if there's anything --

THE COURT: So you should just go home.

(Laughter.)

MR. JAY: I'm confident that our friend on the other side will not just go home and will have excellent points to make.

On irreparable harm, I think this Court recognized in its motion to dismiss decision that we're facing an impending injury from -- indeed, we are -- my client's members are being injured on an ongoing basis because this law is in force. And because of the threat of civil penalties and disgorgement, they can't set prices in the way that they had intended before this law was passed and that they would do but for this law. That's an ongoing injury. And it's an irreparable injury for two reasons. One, it's a constitutional harm, rises to the same level that this Court and many other district courts within this circuit have often recognized is -- is per se irreparable because it is a violation of a right protected by the Constitution. And our friends on the other side basically say

the dormant Commerce Clause is different. That's been rejected each time a court in this circuit has heard it. And I think that rationale doesn't really make sense. This is a protection against one state violating the liberties of citizens of other states. If you are from Illinois, you at least have the right to participate in the political process if you don't like the law that Illinois passes. Out-of-state companies don't have any such ability to participate. And it makes very good sense in light of -- this is referring back to the footnote that you read about the horizontal separation of powers. This is exactly the kind of structural protection for individual liberty that should be treated the same way for irreparable harm purposes.

But even if you didn't want to rest on that basis, our alternative is our economic harm for which we will get no compensation. The State is not going to waive its sovereign immunity. We can't get money damages from the state. And so every day that goes by where the threat of enforcement under this statute prevents our client's member companies from charging the prices that they want to charge, that's a financial injury that they're suffering and that they are never going to get redress for. The only redress is going to be an injunction. And this is exactly the kind of economic harm that warrants an injunction.

Our friends on the other side say basically it's not

serious enough or that we waited too long to sue. I don't think either of those is a substantial objection.

The sovereign immunity is the response to the seriousness point. We're not saying that we're going to go out of business, but we are saying that we will get no redress at the end of this case if you don't give us an injunction.

And we've sued promptly after the law took effect when we had a declarant able to provide a standing declaration.

THE COURT: Do you think there's such a distinction between the downstream sales or the upstream regulation? Do you find that to be so distinctive?

MR. JAY: I do. And I think that the Seventh Circuit likewise has found it to be a significant --

THE COURT: In the *Vapors* case.

MR. JAY: In the *Vapors* case, and then the same point has been made in each of the price control cases that AAM has brought. And I think it's a pretty commonplace understanding that where a product is going to move in commerce, regulating only the transaction that occurs out of state, that is the subject of the state law, and if the -- if the product then bounces around the nationwide market and ends up in the state, it's not as if the state is trying to invoke a public health interest in saying "We want that medication kept out of our state." It's not even regulated in the price that's charged at the cash register at the pharmacy. There's nothing in this

statute that regulates what prices are charged in Illinois to Illinois consumers. It's only regulating the prices that can be charged by a manufacturer or a wholesaler.

THE COURT: Well, wouldn't that automatically affect the price being charged to the consumers, or no?

MR. JAY: Maybe, maybe not. I mean, just to give a couple of examples, not every product is priced kind of on an ala carte basis. So often wholesalers and retailers or even direct customers will negotiate sort of package deals, so you might not be able to even disaggregate what price is being charged --

THE COURT: I see.

MR. JAY: -- at the register. But just kind of sharpening the focus, the statute says that if the wholesaler can establish that it's just passing on a price increase from the manufacturer, the wholesaler is off the hook under this statute, too.

THE COURT: Yes.

MR. JAY: So it really does just focus on the manufacturer. And these -- you know, these are manufacturers located out of Illinois that are selling to wholesalers out of Illinois -- outside of Illinois.

THE COURT: I find it complicated to figure out the logistics of it, but, you know, what -- who is determining the unconscionable increase for this amount of money and that

percentage, who is making that call?

MR. JAY: I -- it's a great question. And we obviously had a debate with the other side at the motion-to-dismiss stage about --

THE COURT: Yes.

MR. JAY: -- how anyone would tell, and we have a vagueness count in our complaint --

THE COURT: Yes.

MR. JAY: -- about exactly that point.

I think the answer is that the Attorney General would argue and the state court would decide. And based on what, we do not know, that -- we just know that it would be -- it is sort of subjectively excessive and meets the -- it meets this quantitative formula as well. And I think that really underscores the problem, that if every state adopts a different formula and if every state is as subjective in its definition as this one, it makes it well-nigh impossible for a nationwide manufacturer to understand what risks it's taking just by placing its pills in the stream of commerce. And for exactly that reason, and that kind of takes me right to the public interest prong that's also -- also the balance of the harms.

Our friends on the other side basically say that, "Well, it's got to be in the public interest for Illinois to regulate prices because high prices are not in the public interest." And I certainly understand the point, but this law

does not come without cost. And our declarant, I think, makes clear what that cost is. When you -- when you have costs go up, when you're one of just a few generics that manufactures an important product and you have costs go up -- and not just necessarily the cost of manufacture, but it can be regulatory cost, it can be inflation, which are things that this statute does not take account of -- if the statute does not allow you to recapture your costs by increasing your price in a way that the market will bear --

THE COURT: Doesn't it have that exception? I thought it did.

MR. JAY: Only for manufacturing costs.

THE COURT: "Reasonably justified price hikes stemming from increased production costs or costs incurred to expand access to a specific drug" --

MR. JAY: Right. Those are the only exceptions. I don't understand either of those to include things like regulatory costs or overhead costs or the -- or inflation.

THE COURT: Okay.

MR. JAY: And so if the inability to make a profit on a particular product is the necessary consequence of Illinois' attempt to regulate for the whole nationwide market, the consequence is just going to be products that are not profitable will get taken off the market. And that means fewer choices, fewer generics bringing costs down, and it is -- this

is a statute that only regulates generic medications.

THE COURT: Right.

MR. JAY: Generic medications are what bring costs down in this country. Generic alternatives introduce competition and lower prices. And so it is profoundly odd that this is the target of this statute. And it is not in the public interest to force more generics off the market, especially in the situation that this statute covers, which is where there's only a limited amount of generic competition to begin with.

Unless the Court has any further questions --

THE COURT: No, I think that's very helpful. Thank you. Appreciate you.

MR. JAY: Thank you very much.

THE COURT: Okay, please come on up.

Do you have anything to say? Because he said all the case law is in his favor.

(Laughter.)

MR. DIERKES: Yes, I'll have a few things to say about that.

So good morning, your Honor.

THE COURT: Good morning.

MR. DIERKES: Michael Dierkes for the defendant.

We obviously have a pretty interesting dormant Commerce Clause issue here.

THE COURT: I know, right?

MR. DIERKES: A complicated one.

THE COURT: You are probably the geeks who, you know, like talking dormant Commerce Clause, right?

Are you ladies also similarly geeky with the dormant Commerce Clause?

It's not the kind of thing you can have a beer with somebody and discuss. You really have to know what you're talking about.

MR. DIERKES: One of my first cases at the Attorney General's Office was a dormant Commerce --

THE COURT: Was it?

MR. DIERKES: -- Clause case.

THE COURT: What was it?

MR. DIERKES: It was a liquor case --

THE COURT: Okay.

MR. DIERKES: -- against Anheuser-Busch, and Judge Dow seemed particularly excited.

THE COURT: That is exactly the kind of person that would be excited about it.

MR. DIERKES: Yeah.

THE COURT: I will tell my good friend Bob that he's missing out, being in DC and not sitting here.

MR. DIERKES: I hope he's doing well.

THE COURT: He is, he is.

MR. DIERKES: Good.

So, yeah, before I get into the juicy dormant Commerce Clause stuff, I think I wanted to start with some comments about the irreparable harm and the balance --

THE COURT: Okay.

MR. DIERKES: -- of equities and so on.

THE COURT: Okay.

MR. DIERKES: And I think it's -- you know, probably start with the obvious, which is that the State of Illinois has a strong interest in preventing price gouging of prescription drugs. That's probably an understatement. It can be a matter of life or death, particularly for the most vulnerable populations like the elderly or the poor, and that's what the Illinois General Assembly is trying to address with this statute.

I think one of the important things about the statute is that it does try to strike a balance, and this goes to some of the points opposing counsel was mentioning near the end.

So, yes, it bars price gouging; but at the same time, the legislature recognizes that, you know, there are going to be some legitimate reasons for a price increase, and it tries to strike that balance.

THE COURT: With those exceptions --

MR. DIERKES: With those --

THE COURT: -- that I mentioned?

MR. DIERKES: Right, right, with those exceptions. And I think, you know, one of the issues here is that the contours of those exceptions are a little bit unclear. This has all been untested.

So in the statute, in the definition of "price gouging," they use the phrase like -- I think they say "unconscionable increase." So there's already a little bit of room right there, an unconscionable increase.

So in addition to these kind of quantitative tests about how much of an increase over what period of time, it also has to be otherwise excessive or unduly burden consumers.

And then on top of that, there's a carve-out for price increases that are due to the cost of increasing production and so on.

So when we keep in mind that there are these exceptions, I guess I ask, well, what -- what exactly is the irreparable harm that AAM is talking about other than just, well, we think you're violating the dormant Commerce Clause and that's a harm. What's the practical irreparable harm?

It's probably not too far off to say the harm is that we want to -- we're going to be harmed if we can't price gouge Illinois consumers. Maybe that's a little bit unfair. I think -- I think opposing counsel might provide a little bit more nuance. But I think what they're trying to get at -- and this is one of the declarations that they submitted -- is they

say, "Well, you know, we're planning this price increase and there are a bunch of reasons that go into it, but, basically, it's not clear that this is going to be allowed under the statute."

And so I think there's a lot of speculation going on about whether this planned price increase really is going to be considered price gouging under the statute. And that sort of speculation about a price increase that maybe isn't even barred by the statute isn't really enough for a clear showing of irreparable harm. And I think it's kind of particularly --

THE COURT: Do you have a definition for "price gouging"?

MR. DIERKES: Well, the statute has a definition for "price gouging."

And, you know, like I say, some of the things that are mentioned in the statute, like the cost of inventory loss and stuff --

THE COURT: Right.

MR. DIERKES: -- I mean -- well, those are mentioned in the affidavit.

Is it really going to be considered price gouging if there's a legitimate reason, just because it doesn't fall within this, you know, particular thing that's mentioned in the statute?

I think the statute gives enough wiggle room for some

judgment about what's a legitimate price increase and what isn't.

THE COURT: And there's the language in the second clause that says that: "It would unduly burden consumers because of the importance of the essential off-patent or generic drug to their health," like the way you started out, "and because of insufficient competition in the marketplace."

But isn't that exactly why drug manufacturers are manufacturing drugs, trying to get that drug out there that doesn't have the competition in the marketplace, but does it one up?

MR. DIERKES: Yeah, it could be, but I -- it could be, but I do think that the ledger -- legislature was trying to accommodate legitimate price increases and through some of this broad language about "unconscionable increases" --

THE COURT: Right.

MR. DIERKES: -- or "otherwise excessive" or "unduly burdensome."

THE COURT: Okay.

MR. DIERKES: I think it managed to accomplish that, or at least I think it's enough to say that whether this planned price increase that's talked about in the affidavit really would be price gouging.

And I think kind of on that point, it is telling, when you look at what is the injunctive relief that they're

requesting, it's not an injunction that says let us go forward with this one price increase. I mean, it's an injunction that would bar us from enforcing the statute, essentially, period. So I think, you know, there could be lots of instances that would be clearly price gouging under the statute that would be covered by the injunction. I think that weighs -- it weighs against it when you look at the balance of the equities.

I'll just briefly, the public interest point, you know, I think opposing counsel had referenced one of their declarations that talks about their kind of, you know, assessment of whether the statute is a good idea from a policy standpoint and while it may actually make things worse rather than better. I think on that point I would say that, you know, that's what they say, but the Illinois legislature doesn't think that. And I think the legislature's findings are entitled to some deference on that point. And the Supreme Court's decision in *CTS* talks about that and says that courts really don't like to second-guess the empirical judgments of the legislature.

So, you know, I understand they've got their policy take on it, but that's not the General Assembly's take, and I think it's the General Assembly's view that should take precedence here.

So those are the -- you know, I think the balance of equities weighs against an injunction.

But then kind of turning to the likelihood of success on the merits, I think that also weighs against an injunction in part just because this issue is actually quite novel. I think we're in uncharted territory here.

I do agree with opposing counsel that really the focus should be on this Footnote 1 in the *Ross* case.

So I guess just to step back for a second, the fundamental principle is that the dormant Commerce Clause, the core function of the dormant Commerce Clause is to bar discrimination, to bar economic protectionism. And what we're talking about here today is kind of a -- a more obscure strand of dormant Commerce Clause, clause jurisprudence, that has to do with this extraterritoriality principle.

And so *Ross* talked about that extraterritoriality principle, that plaintiffs in *Ross* had to rely on that because they weren't really alleging discrimination. And I think what's important is that the Supreme Court, it said, "Well, what's your source for that? Let's look at the actual case law." Because we have to keep in mind, we talk about the dormant Commerce Clause. There really is no dormant Commerce Clause. There's no such thing in the Constitution.

THE COURT: Right.

MR. DIERKES: This is a judge-made doctrine. So, you know, what it means is going to depend on what the cases say.

And so the Supreme Court says: Okay, you're citing

this trilogy of cases, *Brown* and *Healy*, and I think, you know, one other case. Yeah, maybe there's some broad language in those cases that talks about out-of-state effects, but that's just not enough. We have to look at the actual factual context of those cases, and those were discrimination cases.

So then we get to this question of, okay, well, the Supreme Court rejected the extraterritoriality argument that the plaintiffs were making in *Ross*.

So the question is, is there anything left of extraterritoriality? There are commentators that say no. There are Law Reviews that say extraterritoriality is dead after *Ross*.

But, you know, if you're going to find it, I think opposing counsel is right, you have to look at Footnote 1. So we should probably focus in on that footnote.

Kind of a -- a couple points. And so, first of all -- maybe -- I mean, so what the Supreme Court is basically saying is, "Yes, plaintiffs, you cite this *Edgar* case, but it's distinguishable, it doesn't apply here."

I don't consider that a ringing endorsement of *Edgar*. Just because they put it in a footnote and said it's distinguishable, I don't think that means that the Supreme Court is saying, you know, this is still a thing.

Maybe another point that I think is important is *Edgar* was just a plurality decision. It's not binding.

We did point out in our briefs that there's a subsequent Supreme Court case called *CTS*, which is a little bit different factually, but does call *Edgar* into question.

But I think even if we kind of take this on its own terms and you look at the language in the footnote, it says that *Edgar*, you know, was a dormant Commerce Clause claim where the plurality "declined to enforce an Illinois securities law that directly regulated transactions which took place ... wholly outside of the state and involved individuals having no connection to Illinois."

And I think "directly" is in italics and -- twice in that footnote, as is the phrase "no connection to the state."

And so, you know, even if we take this at face value and assume that this is still a thing, I don't think that *Edgar* gets them far enough.

And the question is, you know, are we directly regulating transactions that occur wholly outside of Illinois? And our view is that if the transaction is part of the stream of commerce that enters the state, then it's not wholly outside of the state.

And that's something we discuss in our brief, pages 18 and 19.

But another, I guess, source that's helpful for that point is the dissent in that Eighth Circuit case that plaintiffs are relying on, *Frosh*. The dissent is pretty

thorough. I understand it's just a dissent, but it's pretty thorough on this point. And I think its reasoning -- I think it's well reasoned.

What the Court says is that the modern definition of "commerce" -- I'm skipping a little bit -- is -- it says, "A state regulates commerce wholly outside of its borders if no transactions in that stream take place within the state's borders."

And then it goes on to discuss the Seventh Circuit case, *Brand Name Prescription Drugs*, and it says that is precisely the conclusion of the Seventh Circuit in this *Brand Name Prescription Drugs* case.

So, you know, our position is even under *Edgar*, we're not talking here about something that's occurring wholly outside of Illinois. I understand that one of the transactions could be outside of Illinois, but under the statute, the drug ultimately has to enter the state.

So maybe one kind of final comment, I guess if you look at *Edgar*, just look at *Edgar* on the facts, I don't think it gets plaintiffs where they need to go.

So the law at issue in *Edgar*, it was a Delaware corporation that was trying to take over an Illinois corporation, and there was an Illinois statute that might block that. And a plurality, it was just a plurality, said, "Well, this has sweeping extraterritoriality" --

extraterritoriality --

THE COURT: I know, I said --

MR. DIERKES: -- "and that it might be a problem under the dormant Commerce Clause."

But I think what was really important about *Edgar* is this plurality said, yes, we recognize that 27 percent of the shareholders were in Illinois, but the statute would apply even if none of the shareholders were in Illinois. And then the plurality goes on to say, "Insofar as the Illinois law burdens out-of-state transactions, there's nothing to be weighed in the balance to sustain the law."

So I think that that plurality was looking at the interests at stake, and it wasn't really finding state interests in *Edgar*.

Here, in contrast, there are obvious state interests in terms of preventing price gouging.

And so when we're asking what is the impact of *Edgar*, I'd refer back to what the Supreme Court said in the *Ross* case about what's the role of precedent in, you know, interpreting what the dormant Commerce Clause means. And it says our cases are not like statutes. They can't be read like you read a statute. You have to look at the actual factual circumstances of each case. And the factual circumstances of *Edgar* were very different than this case. The state interest here is much more clear.

So I just don't think *Edgar* gets them far enough.

And I would say that, you know, given the considerations about the balances of equities that I mentioned earlier and the fact that we have a complicated, kind of novel dormant Commerce Clause issue, there just isn't a clear showing that would entitle plaintiffs to injunctive relief.

THE COURT: All right. Thank you very much.

Would you like to do a rebuttal?

MR. JAY: Thank you, your Honor. And I'll make it a little rebuttal, and I won't -- I won't go too long.

Just to note on the merits, my friend didn't touch any of the Seventh Circuit case law that's on point, so no discussion of --

THE COURT: Meaning the *Vapors* case?

MR. JAY: *Legato* and *Midwest Title*, that's right.

So those cases find this principle in the Constitution. And even if we were looking only at Supreme Court precedent -- I just point to I think it's Footnote 9 of *Healy*, which says that: "The *Edgar* plurality significantly illuminates the contours of the constitutional prohibition on extraterritorial legislation."

So I don't think that you need to read *Edgar* as the source of this obligation, but I do think that it's a good illustration of the fact that even when there is some connection between the state and sort of the economic

interconnection of the transaction -- so remember that the transaction in that case involved an Illinois corporation headquartered in Illinois and that's why it was subject to the statute, so it didn't have to have any Illinois shareholders, that it was an Illinois company. But the transaction that's the right focus for the extraterritoriality question is between buyer and seller. Buyer, the Delaware corp; the seller, the willing shareholders who might live anywhere in the world. And in this case, it's the -- it's the manufacturer and the wholesaler who are both outside of Illinois.

So my friend said that this case involves some uncharted territory, and I respectfully submit that it's actually pretty well charted. It's been charted for decades. And what my friend needs to show is that the map was erased by *Ross*.

So, in other words, we don't have to find the source of the constitutional obligation in Footnote 1. We've shown where the dormant Commerce Clause's extraterritoriality prohibition comes from and that it has been followed by decades of cases. I think our friend on the other side needs to show where the Supreme Court tore that up. And I don't think Footnote 1 does that.

And to the colloquy that you and I had in the top side of the argument, it may have mused a little bit about where that -- where in the Constitution is the right place to put it,

but it certainly did not reflect the Court's suggestion that there is no such protection in the Constitution. And for now, the fact that the plaintiffs in *Ross* did not bring an extraterritorial regulation claim I think is the -- is the complete answer to that point. Remember, California wasn't regulating the hog lots in Iowa. It was regulating the sale of pork meat in California. But that's not what Illinois is doing here.

I think the only thing that I would say on the -- on the harm, our friend characterized this as, you know, that the only harm that we're alleging is the inability to engage in price gouging. But I think in the colloquy that he had with your Honor illustrates the harm is that we're not able to set prices knowing what prices will be lawful. And if we guess wrong, the consequences are not only disgorgement of anything above what Illinois thinks was fair, but also daily civil penalties that can mount up extremely quickly.

THE COURT: Right.

MR. JAY: So it's --

THE COURT: What was it, $10,000 a day or something?

MR. JAY: 10,000 a day, right. So the term "chilling effect" is thrown around in the law a lot. This is, I think, a pretty good demonstration of a chilling effect.

And the reason that the harm is irreparable is because the State of Illinois is not going to make us whole if your

Honor or the Seventh Circuit or the Supreme Court holds that this statute is unlawful, they're not going to say "Here's a check for the prices that you were unable to charge." That's why this is an irreparable harm, separate and apart from the individual liberty aspect of the dormant Commerce Clause that I mentioned in the top side. And I don't think our friend has responded to that.

And the last bit is just the public interest. Remember that the state claims to share the goal of increasing competition in this area. But if it's choking the revenue that a company can make in this area, why would another company enter the market for a product that already has very thin margins? That's a recipe for less competition and not more, higher prices and not lower.

THE COURT: That's interesting.

Do you want to say anything on that?

MR. DIERKES: I don't think so.

THE COURT: Okay, that's great. Thank you. That was really interesting. I appreciate you both.

I'll get you an order very quickly, okay?

Thank you.

MR. JAY: Thank you very much, your Honor.

THE COURT: Thanks. Have a good day.

(Concluded at 10:51 a.m.)

* * * * *

I certify that the foregoing is a correct transcript of the record of proceedings in the above-entitled matter.

/s/ GAYLE A. McGUIGAN *September 24, 2025*
GAYLE A. McGUIGAN, CSR, RMR, CRR
Official Court Reporter

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois, *Defendant*.	Case No. 1:24-cv-00544

PLAINTIFF'S NOTICE OF APPEAL

By this Notice, Plaintiff Association for Accessible Medicines ("AAM") appeals to the United States Court of Appeals for the Seventh Circuit from the district court's order denying AAM's motion for preliminary injunction, entered on September 26, 2025 [Dkt. 85].

Dated: October 16, 2025

Respectfully submitted,

s/ Andrianna D. Kastanek
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1:24cv544, Association For Accessible Medicines V. Raoul

US District Court Docket

United States District Court, Illinois Northern

(rev. 1.8.5 Chicago)

This case was retrieved on 01/22/2026

Header

Case Number: 1:24cv544
Date Filed: 01/22/2024
Assigned To: Honorable Virginia M. Kendall
Nature of Suit: Constitutionality (950)
Cause: Civil Rights Act
Lead Docket: None
Other Docket: None
Jurisdiction: Federal Question

Class Code: Open
Statute: 42:1983
Jury Demand: None
Demand Amount: $0
NOS Description: Constitutionality

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Proceedings

#	Date	Proceeding Text
1	01/22/2024	COMPLAINT for Declaratory and Injunctive Relief filed by Association for Accessible Medicines; Filing fee $ 405, receipt number AILNDC-21551650. (Attachments: # 1 Exhibit A)(Kastanek, Andrianna) (Entered: 01/22/2024)
2	01/22/2024	CIVIL Cover Sheet (Kastanek, Andrianna) (Entered: 01/22/2024)
3	01/22/2024	NOTIFICATION of Affiliates pursuant to Local Rule 3.2 by Association for Accessible Medicines (Kastanek, Andrianna) (Entered: 01/22/2024)
	01/22/2024	CASE ASSIGNED to the Honorable Virginia M. Kendall. Designated as Magistrate Judge the Honorable Jeannice W. Appenteng. Case assignment: Random assignment. (Civil Category 2). (jcm) (Entered: 01/22/2024)
	01/22/2024	CLERK'S NOTICE: Pursuant to Local Rule 73.1(b), a United States Magistrate Judge of this court is available to conduct all proceedings in this civil action. If all parties consent to have the currently assigned United States Magistrate Judge conduct all proceedings in this case, including trial, the entry of final judgment, and all post-trial proceedings, all parties must sign their names on the attached Consent To form. This consent form is eligible for filing only if executed by all parties. The parties can also express their consent to jurisdiction by a magistrate judge in any joint filing, including the Joint Initial Status Report or proposed Case Management Order. (jcm) (Entered: 01/22/2024)
	01/22/2024	SUMMONS Issued as to Defendant Kwame Raoul (jcm) (Entered: 01/22/2024)
4	01/22/2024	ATTORNEY Appearance for Plaintiff Association for Accessible Medicines by Andrianna Deanne Kastanek (Kastanek, Andrianna) (Entered: 01/22/2024)
5	01/22/2024	ATTORNEY Appearance for Plaintiff Association for Accessible Medicines by William Jay (Jay, William) (Entered: 01/22/2024)
6	01/22/2024	ATTORNEY Appearance for Plaintiff Association for Accessible Medicines by Benjamin Hayes (Hayes, Benjamin) (Entered: 01/22/2024)
7	01/23/2024	SUMMONS Returned Executed by Association for Accessible Medicines as to Kwame Raoul on 1/23/2024, answer due 2/13/2024. (Kastanek, Andrianna) (Entered: 01/23/2024)
8	01/26/2024	MINUTE entry before the Honorable Virginia M. Kendall. Initial status hearing set for 2/27/2024 at 9:00 a.m. Joint Status Report due by 2/21/2024. The parties are directed to Judge Kendall's web page found at www.ilnd.uscourts.gov for information about the Initial Status Report and for information regarding all standing orders for cases on Judge Kendall's docket. The parties shall follow all of the standing orders for Judge Kendall and all Local Rules which can be found at the

#	Date	Proceeding Text
		same web page. For the Initial Status Report, the parties are to report on the following: (1) Possibility of settlement in the case; (2) if no possibility of settlement exists, the nature and length of discovery necessary (with specific dates) to get the case ready for trial; 3) whether the parties jointly consent to proceed before the Magistrate Judge. At the Initial Status Hearing, the Parties shall be prepared to inform the Court about the extent of monetary damages in order for the Court to address the proportionality of discovery as required by Fed. R. Civ. P. 26. Lead counsel is directed to appear at this status hearing. Virtual hearings must be pre-approved by the Court. If you need to appear virtually, send the attached form to Judge Kendall's courtroom deputy. The courtroom deputy will inform you as to whether your request has been approved. Mailed notice (lk,) (Entered: 01/26/2024)
9	01/26/2024	ATTORNEY Appearance for Defendant Kwame Raoul by Michael T. Dierkes (Dierkes, Michael) (Entered: 01/26/2024)
10	01/26/2024	MOTION by Plaintiff Association for Accessible Medicines to Exceed Page Limits for Memorandum of Law (Unopposed) (Kastanek, Andrianna) (Entered: 01/26/2024)
11	01/26/2024	NOTICE of Motion by Andrianna Deanne Kastanek for presentment of motion for miscellaneous relief 10 before Honorable Virginia M. Kendall on 1/31/2024 at 09:00 AM. (Kastanek, Andrianna) (Entered: 01/26/2024)
12	01/29/2024	ATTORNEY Appearance for Defendant Kwame Raoul by Mary Alice Johnston (Johnston, Mary) (Entered: 01/29/2024)
13	01/30/2024	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Motion to exceed page limits 10 is granted. Motion hearing set for 1/31/2024 is stricken. Mailed notice (lk,) (Entered: 01/30/2024)
14	01/31/2024	MOTION by Plaintiff Association for Accessible Medicines to set a briefing schedule / Unopposed Motion for Entry of Briefing Schedule and to set Page Limits for Memorandum of Law (Kastanek, Andrianna) (Entered: 01/31/2024)
15	01/31/2024	NOTICE of Motion by Andrianna Deanne Kastanek for presentment of motion by filer to set a briefing schedule 14 before Honorable Virginia M. Kendall on 2/5/2024 at 09:00 AM. (Kastanek, Andrianna) (Entered: 01/31/2024)
16	02/02/2024	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Unopposed Motion to set a briefing schedule and to set page limits 14 is granted. Plaintiff's Motion for Preliminary Injunction and Memorandum of Law in Support of the Motion (20 pages) shall be filed by 2/2/2024. Defendant's Combined Motion to Dismiss, Memorandum of Law in Support of the Motion, and Opposition to Plaintiff's Preliminary Injunction Motion (total 30 pages) due by 3/8/2024. Plaintiff's Combined Opposition to Defendant's Motion to Dismiss and Reply in Support of its Motion for Preliminary Injunction (total 25 pages) due by 4/5/2024. Defendant's Reply in Support of its Motion to Dismiss (15 pages) due by 4/26/2024. Motion hearing set for 2/5/2024 is stricken. Status hearing is reset for 6/4/2024 at 9:00 AM. Mailed notice (lk,) (Entered: 02/02/2024)
17	02/02/2024	MOTION by Plaintiff Association for Accessible Medicines for preliminary injunction (Kastanek, Andrianna) (Entered: 02/02/2024)
18	02/02/2024	MEMORANDUM by Association for Accessible Medicines in support of motion for preliminary injunction 17 (Attachments: # 1 Attachment A - Illinois Law)(Kastanek, Andrianna) (Entered: 02/02/2024)
19	02/02/2024	SEALED DOCUMENT by Plaintiff Association for Accessible Medicines / Declaration of Timothy de Gavre (Kastanek, Andrianna) (Entered: 02/02/2024)
20	02/02/2024	DECLARATION of Timothy de Gavre regarding motion for preliminary injunction 17 (Kastanek, Andrianna) (Entered: 02/02/2024)
21	02/02/2024	MOTION by Plaintiff Association for Accessible Medicines to seal / Plaintiff's Unopposed Motion to Seal and Maintain Confidentiality of Document in Support of Motion for Preliminary Injunction (Kastanek, Andrianna) (Entered: 02/02/2024)
22	02/02/2024	NOTICE of Motion by Andrianna Deanne Kastanek for presentment of motion for preliminary injunction 17 before Honorable Virginia M. Kendall on 2/7/2024 at 09:00 AM. (Kastanek, Andrianna) (Entered: 02/02/2024)
23	02/02/2024	CORRECTED NOTICE of Motion by Andrianna Deanne Kastanek for presentment of motion to seal 21 before Honorable Virginia M. Kendall on 2/7/2024 at 09:00 AM. (Kastanek, Andrianna) (Entered: 02/02/2024)
24	02/05/2024	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Unopposed Motion to seal and maintain confidentiality of document in support of Motion for Preliminary Injunction 21 is granted. Motion hearing set for 2/7/2024 is stricken. Briefing schedule as set in Minute Entry 16 stands.

#	Date	Proceeding Text
		Defendant's Combined Motion to Dismiss, Memorandum of Law in Support of the Motion, and Opposition to Plaintiff's Preliminary Injunction Motion (total 30 pages) due by 3/8/2024. Plaintiff's Combined Opposition to Defendant's Motion to Dismiss and Reply in Support of its Motion for Preliminary Injunction (total 25 pages) due by 4/5/2024. Defendant's Reply in Support of its Motion to Dismiss (15 pages) due by 4/26/2024. Status hearing set for 6/4/2024 at 9:00 AM stands. Mailed notice (lk,) (Entered: 02/05/2024)
25	03/08/2024	MOTION by Defendant Kwame Raoul to dismiss for lack of jurisdiction (Dierkes, Michael) (Entered: 03/08/2024)
26	03/08/2024	MEMORANDUM by Kwame Raoul in support of motion to dismiss/lack of jurisdiction 25 and in opposition to Plaintiff's motion for a preliminary injunction (Dkt. 17) (Dierkes, Michael) (Entered: 03/08/2024)
27	04/05/2024	RESPONSE by Association for Accessible Medicines to MOTION by Defendant Kwame Raoul to dismiss for lack of jurisdiction 25 / Plaintiff's Combined Reply in Support of Motion for a Preliminary Injunction and Opposition to Defendant's Motion to Dismiss (Kastanek, Andrianna) (Entered: 04/05/2024)
28	04/25/2024	REPLY by Kwame Raoul to response to motion, 27 (Dierkes, Michael) (Entered: 04/25/2024)
29	05/28/2024	STATUS Report (JOINT) by Association for Accessible Medicines (Kastanek, Andrianna) (Entered: 05/28/2024)
30	05/30/2024	MINUTE entry before the Honorable Virginia M. Kendall. On the Court's own Motion, Status hearing set for 6/4/2024 is reset for 6/17/2024 at 9:00 AM. Mailed notice (lk,) (Entered: 05/30/2024)
31	06/17/2024	MINUTE entry before the Honorable Virginia M. Kendall. Status hearing held on 6/17/2024. The Court orally addressed the Motion for Preliminary Injunction 17 and Motion to Dismiss 26 on the record in open Court indicating a written Opinion is forthcoming. Parties are given three weeks to file a response to Opinion, if able, three weeks after entry of Opinion. Mailed notice (lk,) (Entered: 06/17/2024)
32	06/18/2024	ORDER signed by the Honorable Virginia M. Kendall on 6/18/2024. The Attorney General's motion to dismiss 25 is granted and AAM's motion for preliminary injunction 17 is denied as moot. See Order for further details. Mailed notice(lk,) (Entered: 06/18/2024)
33	07/09/2024	MOTION by Plaintiff Association for Accessible Medicines for leave to file First Amended Complaint and to Enter Briefing Schedule (Unopposed) (Kastanek, Andrianna) (Entered: 07/09/2024)
34	07/09/2024	Proposed Amended Complaint for Declaratory and Injunctive Relief by Association for Accessible Medicines RE: 33 (Kastanek, Andrianna) (Entered: 07/09/2024)
35	07/09/2024	SEALED DOCUMENT by Plaintiff Association for Accessible Medicines / Proposed Amended Complaint for Declaratory and Injunctive Relief (Kastanek, Andrianna) (Entered: 07/09/2024)
36	07/09/2024	MOTION by Plaintiff Association for Accessible Medicines to seal Amended Complaint (Unopposed) (Kastanek, Andrianna) (Entered: 07/09/2024)
37	07/11/2024	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Unopposed Motion for leave to file First Amended Complaint and to enter Briefing schedule 36 is granted. Motion to Dismiss shall be filed by 8/23/2024. Response due by 9/20/2024; Reply due by 10/4/2024. Status hearing set for 11/20/2024 at 9:30 AM. Plaintiff's Motion for leave to file under seal 36 is granted. Mailed notice (lk,) (Entered: 07/11/2024)
38	08/23/2024	MOTION by Defendant Kwame Raoul to dismiss for lack of jurisdiction (Dierkes, Michael) (Entered: 08/23/2024)
39	08/23/2024	MEMORANDUM by Kwame Raoul in support of motion to dismiss/lack of jurisdiction 38 (Dierkes, Michael) (Entered: 08/23/2024)
40	09/20/2024	RESPONSE by Association for Accessible Medicinesin Opposition to MOTION by Defendant Kwame Raoul to dismiss for lack of jurisdiction 38 (Kastanek, Andrianna) (Entered: 09/20/2024)
41	10/03/2024	MOTION by Defendant Kwame Raoul for extension of time to file response/reply as to response in opposition to motion 40 (Dierkes, Michael) (Entered: 10/03/2024)
42	10/03/2024	NOTICE of Motion by Michael T. Dierkes for presentment of motion for extension of time to file response/reply 41 before Honorable Virginia M. Kendall on 10/9/2024 at 09:30 AM. (Dierkes, Michael) (Entered: 10/03/2024)
43	10/07/2024	MINUTE entry before the Honorable Virginia M. Kendall. Defendant's Unopposed Motion for extension of time to file Reply 41 regarding Motion to Dismiss 38 is granted. Reply shall be filed by 10/18/2024. Status hearing is reset for 12/12/2024 at 9:30 AM. Motion hearing set for

#	Date	Proceeding Text
		10/9/2024 is stricken. Mailed notice (lk,) (Entered: 10/07/2024)
44	10/18/2024	REPLY by Kwame Raoul to response in opposition to motion 40 (Dierkes, Michael) (Entered: 10/18/2024)
45	12/12/2024	MINUTE entry before the Honorable Virginia M. Kendall. Status hearing held on 12/12/2024. The Court orally addressed the Motion to Dismiss 38 on the record in open Court indicating a written Opinion is forthcoming. Renewed Motion for Preliminary Injunction shall be filed by 1/3/2025. Response due by 1/24/2025; Reply due by 2/7/2025. Mailed notice (lk,) (Entered: 12/13/2024)
46	12/13/2024	ORDER (Redacted) signed by the Honorable Virginia M. Kendall on 12/13/2024. The Attorney General's motion to dismiss 38 is denied. See Order for further details. Mailed notice(lk,) (Main Document 46 replaced on 12/13/2024 with redacted Order) (lk,). (Entered: 12/13/2024)
47	12/13/2024	SEALED ORDER (Unredacted) signed by the Honorable Virginia M. Kendall on 12/13/2024. Mailed notice(lk,) (Entered: 12/13/2024)
48	12/18/2024	MOTION by Plaintiff Association for Accessible Medicines to Exceed Page Limits for Memorandum of Law (Kastanek, Andrianna) (Entered: 12/18/2024)
49	12/23/2024	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Motion to exceed page limits 48 is granted. Mailed notice (lk,) (Entered: 12/23/2024)
50	12/27/2024	ANNUAL REMINDER: Pursuant to Local Rule 3.2 (Notification of Affiliates), any nongovernmental party, other than an individual or sole proprietorship, must file a statement identifying all its affiliates known to the party after diligent review or, if the party has identified no affiliates, then a statement reflecting that fact must be filed. An affiliate is defined as follows: any entity or individual owning, directly or indirectly (through ownership of one or more other entities), 5% or more of a party. The statement is to be electronically filed as a PDF in conjunction with entering the affiliates in CM/ECF as prompted. As a reminder to counsel, parties must supplement their statements of affiliates within thirty (30) days of any change in the information previously reported. This minute order is being issued to all counsel of record to remind counsel of their obligation to provide updated information as to additional affiliates if such updating is necessary. If counsel has any questions regarding this process, this LINK will provide additional information. Signed by the Honorable Virginia M. Kendall on 12/27/2024: Mailed notice. (tg,) (Entered: 12/31/2024)
51	01/03/2025	MOTION by Plaintiff Association for Accessible Medicines for preliminary injunction / Plaintiff's Renewed Motion for Preliminary Injunction (Kastanek, Andrianna) (Entered: 01/03/2025)
52	01/03/2025	MEMORANDUM by Association for Accessible Medicines in support of motion for preliminary injunction 51 (Attachments: # 1 Illinois Law)(Kastanek, Andrianna) (Entered: 01/03/2025)
53	01/03/2025	SEALED DOCUMENT by Plaintiff Association for Accessible Medicines / Declaration of Rodney Emerson (Kastanek, Andrianna) (Entered: 01/03/2025)
54	01/03/2025	DECLARATION of Rodney Emerson regarding motion for preliminary injunction 51 (Kastanek, Andrianna) (Entered: 01/03/2025)
55	01/03/2025	MOTION by Plaintiff Association for Accessible Medicines to seal / Plaintiff's Unopposed Motion to Seal and Maintain Confidentiality of Document in Support Renewed Motion for Preliminary Injunction (Kastanek, Andrianna) (Entered: 01/03/2025)
56	01/03/2025	NOTICE of Motion by Andrianna Deanne Kastanek for presentment of motion to seal 55 before Honorable Virginia M. Kendall on 1/9/2025 at 09:30 AM. (Kastanek, Andrianna) (Entered: 01/03/2025)
57	01/07/2025	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Unopposed Motion to Seal and Maintain Confidentiality of Document in Support Renewed Motion for Preliminary Injunction 55 is granted. Motion hearing set for 1/9/2025 is stricken. Mailed notice (lk,) (Entered: 01/07/2025)
58	01/24/2025	RESPONSE by Kwame Raoulin Opposition to MOTION by Plaintiff Association for Accessible Medicines for preliminary injunction / Plaintiff's Renewed Motion for Preliminary Injunction 51 (Dierkes, Michael) (Entered: 01/24/2025)
59	01/24/2025	MOTION by Defendant Kwame Raoul for leave to file excess pages (Unopposed) (Dierkes, Michael) (Entered: 01/24/2025)
60	01/24/2025	NOTICE of Motion by Michael T. Dierkes for presentment of motion for leave to file excess pages 59 before Honorable Virginia M. Kendall on 1/30/2025 at 09:30 AM. (Dierkes, Michael) (Entered: 01/24/2025)
61	01/28/2025	MINUTE entry before the Honorable Virginia M. Kendall. Defendant's Unopposed Motion for leave to file excess pages 59 is granted. Motion hearing set for 1/30/2025 is stricken. Mailed notice (lk,) (Entered: 01/28/2025)

#	Date	Proceeding Text
62	02/07/2025	REPLY by Association for Accessible Medicines to MOTION by Plaintiff Association for Accessible Medicines for preliminary injunction / Plaintiff's Renewed Motion for Preliminary Injunction 51 (Kastanek, Andrianna) (Entered: 02/07/2025)
63	02/07/2025	MOTION by Plaintiff Association for Accessible Medicines to Exceed Page Limits for Reply Memorandum of Law (Unopposed) (Kastanek, Andrianna) (Entered: 02/07/2025)
64	02/07/2025	NOTICE of Motion by Andrianna Deanne Kastanek for presentment of motion for miscellaneous relief 63 before Honorable Virginia M. Kendall on 2/13/2025 at 09:30 AM. (Kastanek, Andrianna) (Entered: 02/07/2025)
65	02/10/2025	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Unopposed Motion to exceed page limits 63 is granted. Motion hearing set for 2/13/2025 is stricken. Mailed notice (lk,) (Entered: 02/10/2025)
66	02/20/2025	MOTION by Plaintiff Association for Accessible Medicines for leave to file Notice of Supplemental Authority in Support of Renewed Motion for a Preliminary Injunction (Unopposed) (Attachments: # 1 Exhibit 1 - Notice of Supplemental Authority, # 2 Exhibit A - Copy of Case)(Kastanek, Andrianna) (Entered: 02/20/2025)
67	02/20/2025	NOTICE of Motion by Andrianna Deanne Kastanek for presentment of motion for leave to file, 66 before Honorable Virginia M. Kendall on 2/27/2025 at 09:30 AM. (Kastanek, Andrianna) (Entered: 02/20/2025)
68	02/24/2025	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Unopposed Motion for leave to file Notice of Supplemental Authority in Support of Renewed Motion for a Preliminary Injunction 66 is granted. Motion hearing set for 2/27/2025 is stricken. Mailed notice (lk,) (Entered: 02/24/2025)
69	05/07/2025	MOTION by Attorney Mary Johnston to withdraw as attorney for Kwame Raoul. No party information provided (Johnston, Mary) (Entered: 05/07/2025)
70	05/07/2025	NOTICE of Motion by Mary Alice Johnston for presentment of motion to withdraw as attorney 69 before Honorable Virginia M. Kendall on 5/20/2025 at 09:30 AM. (Johnston, Mary) (Entered: 05/07/2025)
71	05/12/2025	MINUTE entry before the Honorable Virginia M. Kendall. Attorney Mary Alice Johnston's Motion to withdraw as attorney 69 is granted. Motion hearing set for 5/20/2025 is stricken. Mailed notice (lk,) (Entered: 05/12/2025)
72	05/16/2025	MOTION by Attorney Benjamin Hayes to withdraw as attorney for Association for Accessible Medicines. No party information provided (Hayes, Benjamin) (Entered: 05/16/2025)
73	05/16/2025	NOTICE of Motion by Benjamin Hayes for presentment of motion to withdraw as attorney 72 before Honorable Virginia M. Kendall on 5/29/2025 at 09:30 AM. (Hayes, Benjamin) (Entered: 05/16/2025)
74	05/25/2025	MINUTE entry before the Honorable Virginia M. Kendall: Attorney Benjamin Hayes' request to appear virtually for motion presentment hearing set for 5/29/2025 at 9:30 a.m. is approved. Prior to the hearing, you are directed to cut and paste this hyper link into a browser: https://us-courts.webex.com/join/virginia_kendallilnd.uscourts.gov You can use the dial in option ONLY if you do not have access to a device with video capability: (650)-479-3207, the access code is: 180 698 4009. Emailed notice (cn). (Entered: 05/25/2025)
75	05/28/2025	MINUTE entry before the Honorable Virginia M. Kendall. Attorney Benjamin Hayes' Motion to withdraw as attorney 72 is granted. Motion hearing set for 5/29/2025 is stricken. Mailed notice (lk,) (Entered: 05/28/2025)
76	06/13/2025	MOTION by Plaintiff Association for Accessible Medicines for leave to file Notice of Supplemental Authority in Support of Renewed Motion for a Preliminary Injunction (Attachments: # 1 Exhibit 1 - Notice of Supplemental Authority)(Kastanek, Andrianna) (Entered: 06/13/2025)
77	06/18/2025	MINUTE entry before the Honorable Virginia M. Kendall. Plaintiff's Motion for leave to file notice of supplemental authority 76 is granted. Mailed notice (lk,) (Entered: 06/18/2025)
78	07/30/2025	MINUTE entry before the Honorable Virginia M. Kendall. Status hearing set for 8/13/2025 at 9:30 AM which will proceed via Webex. Prior to the hearing, you are directed to cut and paste this hyper link into a browser: https://us-courts.webex.com/join/virginia_kendallilnd.uscourts.gov You can use the dial in option ONLY if you do not have access to a device with video capability: (650)-479-3207, the access code is: 180 698 4009. Mailed notice (lk,) (Entered: 07/30/2025)
79	08/11/2025	MINUTE entry before the Honorable Virginia M. Kendall. On the Court's own Motion, Status hearing set for 8/13/2025 is reset for 8/21/2025 at 9:30 AM which will proceed via Webex. Prior to the hearing, you are directed to cut and paste this hyper link into a browser: https://us-courts.webex.com/join/virginia_kendallilnd.uscourts.gov You can use the dial in option ONLY if

#	Date	Proceeding Text
		you do not have access to a device with video capability: (650)-479-3207, the access code is: 180 698 4009. Mailed notice (lk,) (Entered: 08/11/2025)
80	08/11/2025	MINUTE entry before the Honorable Virginia M. Kendall. By request of Counsel, Status hearing set for 8/21/2025 is reset for 9/10/2025 at 9:30 AM. Prior to the hearing, you are directed to cut and paste this hyper link into a browser: https://us-courts.webex.com/join/virginia_kendallilnd.uscourts.gov You can use the dial in option ONLY if you do not have access to a device with video capability: (650)-479-3207, the access code is: 180 698 4009. Mailed notice (lk,) (Entered: 08/11/2025)
81	08/14/2025	MINUTE entry before the Honorable Virginia M. Kendall. By agreement of Parties, In Court hearing for oral argument regarding Motion for Preliminary Injunction 51 is set for 9/22/2025 at 10:00 AM which will proceed in Courtroom 2541. Parties advised the hearing would take approximately one hour. Mailed notice (lk,) (Entered: 08/14/2025)
82	09/22/2025	MINUTE entry before the Honorable Virginia M. Kendall. In Court hearing held regarding oral argument for Motion for Preliminary Injunction 51 . Mailed notice (lk,) (Entered: 09/22/2025)
83	09/23/2025	MOTION for Leave to Appear Pro Hac Vice on behalf of Association for Accessible Medicines by Isabel Marin; Filing fee $ 150, receipt number AILNDC-24101166. (Marin, Isabel) (Entered: 09/23/2025)
84	09/24/2025	MINUTE entry before the Honorable Virginia M. Kendall. Attorney Isabel Marin's Motion to appear pro hac vice 83 is granted. Mailed notice (lk,) (Entered: 09/24/2025)
85	09/26/2025	MEMORANDUM Opinion and Order signed by the Honorable Virginia M. Kendall on 9/26/2025. Plaintiffs' Motion for Preliminary Injunction 51 is denied. Please refer to Opinion for further details. Mailed notice(lk,) (Entered: 09/26/2025)
86	09/26/2025	TRANSCRIPT OF PROCEEDINGS held on 09/22/2025 before the Honorable Virginia M. Kendall. Oral Argument. Order Number: 53061. Court Reporter Contact Information: Gayle A. McGuigan, CSR, RMR, CRR, Gayle_McGuigan@ilnd.uscourts.gov. IMPORTANT: The transcript may be viewed at the court's public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through the Court Reporter/Transcriber or PACER. For further information on the redaction process, see the Court's web site at www.ilnd.uscourts.gov under Quick Links select Policy Regarding the Availability of Transcripts of Court Proceedings. Redaction Request due 10/17/2025. Redacted Transcript Deadline set for 10/27/2025. Release of Transcript Restriction set for 12/25/2025. (McGuigan, Gale) (Entered: 09/26/2025)
87	10/08/2025	MINUTE entry before the Honorable Virginia M. Kendall. Status hearing set for 11/25/2025 at 9:30 AM. Mailed notice (lk,) (Entered: 10/08/2025)
88	10/16/2025	NOTICE of appeal by Association for Accessible Medicines regarding orders 85 Filing fee $ 605, receipt number AILNDC-24206267. Receipt number: n (Kastanek, Andrianna) (Entered: 10/16/2025)
89	10/16/2025	DOCKETING Statement by Association for Accessible Medicines regarding notice of appeal 88 (Kastanek, Andrianna) (Entered: 10/16/2025)
90	10/30/2025	NOTICE of Appeal Due letter sent to counsel of record regarding notice of appeal 88 . (jh,) (Entered: 10/30/2025)
91	10/30/2025	TRANSMITTED to the 7th Circuit the short record on notice of appeal 88 . Notified counsel. (jh,) (Entered: 10/30/2025)
92	10/30/2025	SEVENTH CIRCUIT transcript information sheet by Association for Accessible Medicines (Kastanek, Andrianna) (Entered: 10/30/2025)
93	11/18/2025	MOTION by Plaintiff Association for Accessible Medicines to stay of District Court Proceedings Pending Resolution of Plaintiff's Appeal (Joint Motion) (Kastanek, Andrianna) (Entered: 11/18/2025)
94	11/18/2025	NOTICE of Motion by Andrianna Deanne Kastanek for presentment of motion to stay 93 before Honorable Virginia M. Kendall on 11/25/2025 at 09:30 AM. (Kastanek, Andrianna) (Entered: 11/18/2025)
95	11/20/2025	ORDER Granting Stay of District Court Proceeding Pending Resolution of Plaintiff's Appeal signed by the Honorable Virginia M. Kendall on 11/20/2025. This action is hereby STAYED until the appeal has been resolved. Within one week after a decision by the Seventh Circuit, the parties shall file a joint report notifying the Court of the disposition of the appeal and setting forth their respective positions on the appropriate next steps in this matter. The status hearing set for November 25, 2025, is hereby vacated. Mailed notice(lk,) (Entered: 11/20/2025)
96	12/31/2025	ANNUAL REMINDER: Pursuant to Local Rule 3.2 (Notification of Affiliates), any

#	Date	Proceeding Text
		nongovernmental party, other than an individual or sole proprietorship, must file a statement identifying all its affiliates known to the party after diligent review or, if the party has identified no affiliates, then a statement reflecting that fact must be filed. An affiliate is defined as follows: any entity or individual owning, directly or indirectly (through ownership of one or more other entities), 5% or more of a party. The statement is to be electronically filed as a PDF in conjunction with entering the affiliates in CM/ECF as prompted. As a reminder to counsel, parties must supplement their statements of affiliates within thirty (30) days of any change in the information previously reported. This minute order is being issued to all counsel of record to remind counsel of their obligation to provide updated information as to additional affiliates if such updating is necessary. If counsel has any questions regarding this process, this LINK will provide additional information. Signed by the Honorable Virginia M. Kendall on 12/31/2025: Mailed notice. (tg,) (Entered: 01/05/2026)

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