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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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