IN 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-00544 Hon. Virginia M. Kendall

DEFENDANT'S MEMORANDUM IN OPPOSITION TO PLAINTIFF'S RENEWED MOTION FOR A PRELIMINARY INJUNCTION

Date: January 24, 2025

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INTRODUCTION

In recent years, a minority of pharmaceutical industry members have wrought substantial and irreparable harm on Illinois residents by imposing egregious price increases on essential medications, notwithstanding the lack of any legitimate business need to do so. These price increases—which include markups as great as 17,000% in a single year—are designed to extract maximum profit in markets where there is little to no competition among industry members to produce and sell high-demand medications. In 2023, the Illinois legislature responded to this exploitative conduct by enacting Public Act 103-367 (the "Act"), which prohibits excessive and unduly burdensome price increases for generic prescription drugs sold in Illinois. The Act does not, however, restrict price increases that arise out of legitimate business needs; rather, it makes clear that a price increase does not constitute price gouging when it is reasonably justified by increased production costs or appropriate expansion of access to the drug. The Act's procedural protections also provide manufacturers and distributors an opportunity to explain why the price increase does not constitute price gouging—for example, because of increased production costs—before the Attorney General may file an enforcement action.

In January 2024, the Association for Accessible Medicines ("AAM") brought suit on behalf of its manufacturer and distributor members seeking complete invalidation of the Act. Dkt. 1. The Court dismissed AAM's sweeping pre-enforcement complaint for lack of standing, finding not only that AAM "fail[ed] to allege that its members intend to do what the Act prescribes," but also that AAM "fail[ed] to allege that a credible threat of prosecution exists." Dkt. 32 at 3. AAM amended its complaint, Dkt. 34, and Defendant again moved to dismiss on standing grounds. Dkts. 39, 44. The Court allowed the amended complaint to proceed, Dkt. 46, and AAM has now moved for a preliminary injunction. Dkts. 51, 52.

The Court should deny AAM's request for preliminary injunctive relief. Defendant preserves his argument that AAM lacks standing for the reasons set forth in his prior filings, see Dkts. 39, 44. Moreover, AAM's motion for a preliminary injunction relies solely on a dormant Commerce Clause theory that was recently rejected by the Supreme Court in *National Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023). Furthermore, AAM's assertions that its members will suffer financial harm absent an injunction does not constitute irreparable harm, and the equities here weigh heavily in favor of the State.

BACKGROUND

A. Illinois consumers purchase generic drugs sold through an interconnected pharmaceutical supply chain.

Generic prescription drugs are sold through a pharmaceutical supply chain that typically includes manufacturers, wholesale distributors, and pharmacies.[1] Manufacturers produce the drug, and accordingly have the most influence on prices by setting the "wholesale acquisition cost"—the baseline price at which wholesale distributors purchase products.[2] In some instances, manufacturers sell the drug directly to pharmacies.[3] In others, they sell the drug to wholesale distributors, which then resell to pharmacies.[4]

Although the wholesale acquisition cost serves as a benchmark for the price of a specific drug, manufacturers often ultimately sell the drug to distributors at prices reached through

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[1] *Follow the Pill: Understanding the U.S. Commercial Supply Chain*, The Kaiser Family Foundation, 17 (2005), https://bit.ly/3P570uG. All websites last visited on March 7, 2023. The Court may take judicial notice of this fact and the other information presented in this background section, as it provides context and is "not subject to reasonable dispute." *Ennenga v. Starns*, 677 F.3d 766, 774 (7th Cir. 2012); *Saccameno v. Ocwen Loan Servicing, LLC*, 372 F. Supp. 3d 609, 643 n.18 (N.D. Ill. 2019); Fed. R. Evid. 201(b)(2) (permitting judicial notice of facts "whose accuracy cannot reasonably be questioned").

[2] Follow the Pill, *supra* note 1 at 17.

[3] Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp., 16 (2021), https://bit.ly/4bZy4Wb.

[4] *Id.* at 4.

negotiations with the entire supply chain, including distributors and pharmacies.[5] In these negotiations, distributors may leverage, for example, their ability to drive market share or sales volume, or a competitive market for a particular drug, to set a more favorable price.[6] And pharmacies, which sell the drugs to consumers, may also negotiate discounts with the manufacturer based on their own ability to drive market share or sales volume.[7] Finally, when pharmacies purchase generic drugs from distributors, that negotiated price is necessarily based off of the wholesale acquisition cost.[8] In other words, not only is the consumer's price derived directly from the price set by the manufacturer, but the price set by the manufacturer is set with input from, and consideration of, the entire supply chain.

Manufacturers and distributors, moreover, typically have a number of contacts with Illinois and the other States where their products are sold. For starters, some manufacturers (as AAM recognizes), as well as many distributors (by virtue of the nature of their business), sell products directly into Illinois. Dkt. 34 ¶¶ 28, 41; Dkt. 54 ¶ 5.[9] And, subject to certain exceptions, entities that distribute generic drugs to pharmacies in Illinois—whether they be manufacturers or distributors—must obtain a license under the Wholesale Drug Distribution Licensing Act, 225 ILCS 120 *et seq*. Licensure in Illinois obligates distributors to, for example, consent to search by pharmacy inspectors, *id.* 120/50, and develop an electronic system to track and trace drugs through the distribution process, *id.* 120/57.

[5] Follow the Pill, *supra* note 1 at 17–21.

[6] *Id.* at 18.

[7] *Id.* at 19.

[8] Prescription Drug Supply Chains, *supra* note 3 at 12.

[9] *Id.* at 16.

Furthermore, manufacturers know, or have the technology to easily find out, whether their products are ultimately sold in any given State, including Illinois. *E.g.*, Dkt. 54 ¶ 5. Starting in 2015, the United States Drug Supply Chain Security Act has required manufacturers to apply increasingly specific product identifiers to certain prescription drugs and trace product information including name, strength and dosage, size and number of containers, lot number, transaction date, shipment date, and shipment address.[10] Pub. L. 113-54, 127 Stat. 599; 21 U.S.C. §360eee(26), §360eee-1(b)(1). The FDA characterizes the legislation as a way to "build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States."[11] Manufacturers like AAM member Sandoz have invested in developing electronically tagged medicines to automate restocking in hospitals.[12] In other words, Sandoz believes it has the technology to know the *exact quantity* of medication available at a given hospital, and the ability to automatically ship medication to that hospital when it runs low.

And even before passage of the legislation, manufacturers were fully aware, or capable of being fully aware, of where many of their drugs ended up. For instance, manufacturers that seek coverage from state Medicaid programs must offer rebates to those programs.[13] Outside of Medicaid, manufacturers regularly offer rebates to pharmacies who are able to direct consumers to certain products.[14] In short, this continued monitoring of the supply chain, which already occurs

[10] *DSCSA: Are You Ready for November 2024?*, Amerisource Bergen (Feb. 2023), https://bit.ly/49HUrOq.

[11] *FDA Provides New Guidance to Further Enhance the Security of Prescription Drugs in the U.S. Supply Chain*, U.S. Food and Drug Administration (Jun. 2021), https://bit.ly/3wzUbT4.

[12] Press Release, Sandoz, *Kit Check and Sandoz Agree to a Commercialization Collaboration That Helps Improve Hospital Medication Administration Safety* (June 2019), https://bit.ly/49YF2Jp.

[13] Prescription Drug Supply Chains, *supra* note 3 at 20.

[14] Follow the Pill, *supra* note 1 at 17.

as a matter of course for pharmaceutical manufacturers, shows that manufacturers do not wash their hands of the product after selling drugs to a distributor.

B. Industry members engage in price gouging.

Sixty percent of Americans, and 90% of seniors, take prescription drugs. 410 ILCS 725/2(a). Approximately 90% of these prescriptions are filled with generic, as opposed to brand name, drugs.[15] In the ordinary course, generic drugs save Americans a substantial amount of money on medication.[16] Indeed, when there is genuine competition in the generic-drug marketplace, generic drugs are typically 80–85% less expensive than brand-name drugs.[17]

In recent years, however, some industry members have implemented "extraordinary price increases" for generic drugs.[18] A Senate subcommittee examining this issue noted that between 2010 and 2015, a time period when generic drug prices declined overall, 48 generic drugs were hiked in price by more than 500% in a single year.[19] These actions are not justified by legitimate business needs. On the contrary, reports have shown that these price increases are motivated by efforts to extract maximum value from inelastic consumer markets where there is a lack of genuine competition. For instance, the drug Seromycin has been on the market since 1964, has no generic competitors, is the only drug that treats multi-drug resistant tuberculosis, and has a very small market of hundreds of cases per year.[20] Nevertheless, in 2015, Rodelis Therapeutics raised the

[15] Prescription Drug Supply Chains, *supra* note 3 at 2.

[16] *How to Get Generic Drugs and Low-Cost Prescriptions*, FTC (Oct. 2023), https://bit.ly/49z8qG1.

[17] *Id.*

[18] U.S. GAO *Generic Drugs Under Medicare* 2 (Aug. 2016), https://bit.ly/3V1ulkV.

[19] *Id.*, U.S. Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs* 28 (Dec. 2016), https://bit.ly/3Ij9QIK.

[20] *Id.* at 6, 72–84.

price of Seromycin from $500 to $10,800 for 30 capsules—an increase of 2,060% overnight.[21] Other recent examples include Martin Shkreli's infamous decision to raise the price of the anti-parasitic medication Daraprim from $13.50 to $750 per tablet.[22] Similarly, the manufacturer of Tetracycline, a general antibiotic, recently raised prices by more than 17,000% in a single year.[23]

Industry members have committed other, similar misdeeds that result in harm to Illinois consumers. As one example, Apotex, Glenmark, Sun (a/k/Taro), Sandoz, and Teva (five of AAM's members) recently admitted guilt to federal charges of conspiracy to fix drug prices.[24] They increased the price of medicines that treat conditions disproportionately experienced by the elderly and poor, like fungal infections, arthritis, hypertension, and blood clots.[25]

These unpredictable surges in price burden Illinois residents already struggling to get by—in 2022, nearly 50% of Illinoisans polled reported delaying or foregoing healthcare during the last 12 months due to cost, and more than 50% were "worried" or "very worried" about their ability to afford prescription drugs in the future.[26]

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[21] *Id.* at 6.

[22] *Drug Goes From $13.50 a Tablet to $750, Overnight*, The New York Times (Sept. 2015), https://bit.ly/3ImLNsu; Sudden Price Spikes, *supra* note 19 at 6.

[23] Department of Health and Human Services, *Understanding Recent Trends in Generic Drug Prices* 6 (Jan. 26, 2016), https://bit.ly/3T0mykH.

[24] Press Release, Office of Public Affairs, Department of Justice, *Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars to Resolve Price-Fixing Charges and Divest Key Drug at the Center of their Conspiracy* (Aug. 2023), https://bit.ly/3v4k7FL; Deferred Prosecution Agreement (Glenmark), https://www.justice.gov/d9/2023-08/415807.pdf.

[25] *Id.*; *Novartis Subsidiary Sandoz to Pay $195 Million Over Antitrust Allegations*, CNBC (Mar. 2020), https://bit.ly/3v4GOto.

[26] Healthcare Value Hub, *Illinois Residents Struggle to Afford High Healthcare Costs; Worry About Affording Future Care; Support Government Action Across Party Lines* (May 2022), https://bit.ly/3V5IlKE.

C. The General Assembly regulates price gouging.

In response to these abuses, the legislature enacted a law to protect Illinois residents from price gouging of generic drugs. *See* Ill. Pub. Act 103-367 (eff. Jan 1, 2024). As the legislature explained, there was a "repeated pattern and practice of price gouging by certain prescription drug manufacturers," which has led patients to choose between "copayments exceeding tens of thousands of dollars per year and risking their health." 410 ILCS 725/2(b)–(c). And "this choice has led patients to delay or forgo necessary medications creating greater health risks and complications." *Id.* 725/2(d). Accordingly, it concluded that a legislative response to this crisis was "a matter of health, safety, and welfare for the People of the State of Illinois." *Id.* 725/2(e).

The Act prohibits manufacturers and wholesale drug distributors from engaging in "price gouging in the sale of an essential off-patent or generic drug that is ultimately sold in Illinois." *Id.* 725/10(a). The Act contains a number of limitations to ensure that it applies only to those industry members making egregious pricing increases, like the conduct described above. To start, the Act is limited to regulating drugs that are manufactured by three or fewer manufacturers, *id.* 725/5, and thus may not be subject to robust competition in the marketplace. The drugs also must be designated "essential medicines" by the World Health Organization or the U.S. Department of Health and Human Services, *id.*—that is, the medicines necessary for a basic health-care system to operate.[27] Beyond the foundational medicines like antibiotics and anesthetics, these medicines also target diseases afflicting individuals who live in poverty: for example, insulin (for diabetes), albendazole (for hookworm), and lisinopril (for high blood pressure).[28]

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[27] World Health Organization Model List of Essential Medicines, Explanatory Notes (2023), https://bit.ly/3T3bhQM.

[28] Chih-Cheng Hsu, Cheng-Hua Lee, Mark L. Wahlqvist et al., *Poverty Increases Type 2 Diabetes Incidence and Inequality of Care Despite Universal Health Coverage*, Diabetes Care (Oct 2012), https://bit.ly/3Ih7Y3v; Peter Hotez, *Hookworm and Poverty*, Ann. NY Acad. Sci. (Oct. 2007), https://bit.ly/3wJVBu0; Cameron Scott, *Study Attributes 60-70% of Excess Heart Disease Among Low-*

Furthermore, the definition of "price gouging" itself contains several limitations. First, price gouging occurs only when the following quantitative metric is satisfied:

> An unconscionable increase in price that:
>
> (1) would result in the wholesale acquisition cost of a 30 day supply of the essential off-patent or generic drug exceeding $20 and would result in an increase in the wholesale acquisition cost of the essential off-patent or generic drug of:
>
> (A) 50% or more within the preceding year;
> (B) 50% of more within the preceding 3 years; or
> (C) 75% or more within the preceding 5 years;

410 ILCS 725/5. The price must also be "otherwise excessive and unduly burden[some to] consumers because of the importance of the essential off-patent or generic drug to their health and because of insufficient competition in the marketplace." *Id.*

The Act, however, does not restrict price increases that are necessary to meet a legitimate business need. The Act makes clear that a price increase does not constitute price gouging when it is reasonably justified by either "an increase in the cost of producing the essential off-patent or generic drug," or "the cost of appropriate expansion of access to the essential off-patent or generic drug to promote public health." *Id.* Thus, a price increase that satisfied the quantitative component and would otherwise be demonstrably excessive and burdensome is *not* price gouging under the Act when that increase is based on increased production costs or corporate efforts to promote access to their drug for the sake of public health. Finally, the Act applies only to products ultimately sold in Illinois. *Id.* But it is not a defense under the Act "that the manufacturer or wholesale drug distributor did not directly sell a product to a consumer residing in Illinois." *Id.* 725/10.

Income Americans to Poverty Rather Than Traditional Risk Factors, UCSF Department of Epidemiology & Biostatistics (May 2020), https://bit.ly/48Bcpko.

Consistent with the legislature's goal of restricting only undue price increases, the Act is enforced through an iterative process that provides substantial opportunity for manufacturers and distributors to demonstrate that their price increases were due to legitimate business expenses, do not unduly burden consumers, and are not otherwise excessive. Under the Act, the Illinois Department of Healthcare and Family Services is tasked with monitoring the price of generic drugs that are covered by the Illinois Medicaid program. *Id.* 725/10(a). If the Department discovers a price increase that may be covered by the Act, it notifies the Attorney General. *Id.* If the Attorney General "has reason to believe" that a manufacturer or distributor has violated the Act, he may send a notice requesting a statement containing information about the price increase, including the components of the cost of producing the drug; the circumstances and timing of an increase in materials, manufacturing costs, or expenditures made to expand access; any communications with competitors; and any other information the manufacturer or distributor deems relevant. *Id.* 725/10(b). Upon receipt of the statement, the Attorney General may exercise his discretion to investigate the price increase, and if necessary, petition a court for remedial action. *Id.* 725/10(c).

D. AAM files suit in federal court.

On January 22, 2024, AAM filed this action seeking to invalidate the Act in its entirety, alleging that it violates the dormant Commerce Clause, the Due Process Clause, and the Constitution's horizontal separation of powers. Dkt. 1; Dkt. 34 (amended complaint). AAM brings this suit on behalf of its members, which are "manufacturers and distributors of generic and biosimilar medicines." Dkt. 34 ¶ 14. Although some members are located in Illinois and/or transact business with Illinois entities, others are incorporated or headquartered outside of Illinois. *Id.* ¶¶ 28, 41. AAM alleges that its members are harmed by the Act because they "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." *Id.* ¶ 38. The complaint does not, however, contain allegations about any enforcement action pending against any of AAM's members. Dkt. 34.

AAM has filed a motion for a preliminary injunction, based on the sole theory that the Act violates the Commerce Clause by regulating transactions between manufacturers and distributors that occur wholly outside of Illinois. Dkts. 51, 52. Based on that theory, AAM seeks to enjoin the Attorney General from "implementing or enforcing [the Act] against AAM's members, or their agents, privies, or licensees, based on their sales of generic drugs or biosimilars that occur outside Illinois." Dkt. 51 at 1. As support for this sweeping request, AAM submits a single declaration from Rodney Emerson, the Vice President of Pricing and Contracts for Sandoz, Inc. Dkt. 54.

LEGAL STANDARDS

Injunctive relief is "an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). A preliminary injunction is "never awarded as of right" and "never to be indulged in except in a case clearly demanding it." *Orr v. Shicker*, 953 F.3d 490, 501 (7th Cir. 2020). A plaintiff "seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Ill. Republican Party v. Pritzker*, 973 F.3d 760, 762 (7th Cir. 2020). If the plaintiff satisfies these requirements, then the court must weigh the harm that the plaintiff will incur without an injunction against the harm to the defendant if one is entered, and "consider whether an injunction is in the public interest." *GEFT Outdoors, LLC v. City of Westfield*, 922 F.3d 357, 364 (7th Cir. 2019). This analysis is done on a "sliding scale"—if plaintiff is less likely to win on the merits, the balance of harms must weigh more heavily in his favor, and vice versa. *Id.* The court should pay "particular regard

for the public consequences in employing the extraordinary remedy of injunction." *Winter v. Nat. Res. Def. Counc.*, 555 U.S. 7, 24 (2008).

ARGUMENT

I. AAM is unlikely to succeed on the merits of its dormant Commerce Clause claim.

The Commerce Clause gives Congress the power to "regulate Commerce with foreign Nations, and among the several States." U.S. Const. art. I, § 8, cl. 3. "Reading between the Constitution's lines," the Supreme Court has inferred a "further, negative command" that prohibits a limited type of state economic regulations even when Congress has not legislated. *Ross*, 143 S. Ct. at 1152. The "principal objects of scrutiny" are state laws that "discriminate against interstate commerce." *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 88 (1987). In particular, the negative, or dormant, Commerce Clause "prohibits economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *New Energy Co. v. Limbach*, 486 U.S. 269, 308 (1988). To combat "state protectionism," the dormant Commerce Clause bars state laws that discriminate against interstate commerce unless they are narrowly tailored to advancing a legitimate, non-protectionist local purpose. *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2249, 2461 (2019).

As the Supreme Court recently emphasized in *Ross*, this "antidiscrimination principle" lies at the "very core" of dormant Commerce Clause jurisprudence. *Ross*, 143 S. Ct. at 1153. But here, AAM does not and cannot allege discrimination. The Act does not tie the price of drugs sold in Illinois to the price of drugs sold elsewhere. It does not distinguish between Illinois and out-of-state manufacturers, nor does it treat their products differently. Rather, it bars price gouging for drugs sold into Illinois, regardless of where they are manufactured. The Act "visits its effects

equally upon both interstate and local business," and therefore does not discriminate against interstate commerce. *CTS*, 481 U.S. at 87.

Thus, AAM's motion challenges the Act solely on "extraterritoriality" grounds, claiming that it impermissibly regulates out-of-state transactions. Dkt. 52 at 8-16.[29] As discussed below, AAM's attempts to extract a viable extraterritoriality theory from a footnote in *Ross* are unavailing, and its dormant Commerce Clause claim is unlikely to succeed.

A. Under *Ross*, the extraterritoriality doctrine does not apply because the Act does not discriminate against out-of-state companies.

Before *Ross*, extraterritoriality was considered the "least understood" of the strands of Commerce Clause doctrines. *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1172 (10th Cir. 2015) (Gorsuch, J.). And it has been the "most dormant," *id.*, with the Supreme Court invoking it on just three occasions—in *Baldwin*, *Brown-Forman*, and *Healy*—to strike down a state law. *See Baldwin v. G.A.F. Seeling, Inc.*, 294 U.S. 511 (1935) (law prohibiting out-of-state companies from selling their milk into New York if they paid less for the milk than the price guaranteed to New York dairy farmers); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 580-81 (1986) (law requiring liquor distillers to "affirm that they will make no sales anywhere in the United States lower than the posted price in New York"); *Healy v. Beer Inst.*, 491 U.S. 324, 335 (1989) (law requiring out-of-state beer shippers to affirm that the prices they charged Connecticut wholesalers were no higher than the prices they charged in border states).

Previously, the lower courts reached varying conclusions regarding the reach of the extraterritoriality principle set forth in this trilogy of cases. While the Seventh Circuit applied the principle broadly, *see Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 665–68 (7th Cir. 2010), other courts adhered to a "narrow interpretation, given the emphasis on protecting against

[29] AAM's renewed preliminary injunction motion does not advance a *Pike* balancing argument.

discriminatory regulations in cases applying the Commerce Clause," *Mayo v. Titlemax of Del.*, No. 21-2964, 2022 U.S. Dist. Lexis 2573, at *11 (E.D. Pa. Jan. 4, 2022) (collecting cases).

Now, after *Ross*, it is clear that the "narrow interpretation" prevails. Writing for a majority of the Supreme Court, Justice Gorsuch explained that *Baldwin*, *Brown-Foreman*, and *Healy* "must be read with a careful eye to context," and that this line of cases applies only to *specific* extraterritorial effects, *i.e.* those of "price control or price affirmation statutes that tie the price of in-state products to out-of-state products." *Ross*, 143 S. Ct. at 1155 (cleaned up).

AAM acknowledges *Ross*, Dkt. 52 at 13–14, but it ignores the recent decision's full import. *Ross* involved a challenge to a California law barring the in-state sale of pork meat from pigs "confined in a cruel manner." 143 S. Ct. at 1150. The plaintiffs alleged that the law would require substantial changes to their operations, and that the costs of compliance would be borne primarily by out-of-state firms. *Id.* at 1152. Relying on *Baldwin*, *Brown-Forman*, and *Healy*, the plaintiffs argued for an "almost *per se*" rule prohibiting state laws that have the "practical effect of controlling commerce outside the state," regardless of whether there is discrimination. *Id.* at 1153–54. The Court rejected this proposition, noting that the plaintiffs "read too much into too little." *Id.* at 1154. The plaintiff's position was legally unsupported, would "cast a shadow over laws long understood to represent valid exercises of the States' constitutionally reserved powers," and would "invite endless litigation and inconsistent results." *Id.* at 1154–56.

Two points emerge from the Supreme Court's recent decision. First, there is no *per se* rule against laws that have the "practical effect" of "controlling extraterritorial commerce." *Id.* at 1155. Second, and more fundamentally, *Baldwin* and its progeny merely reflect "the familiar concern with preventing purposeful discrimination against out-of-state interests." *Id.* at 1154. The law at issue in *Baldwin* "plainly discriminated against out-of-staters" by "erecting an economic barrier

protecting a major local industry against competition from without the State." *Id.* And the laws at issue in *Brown-Forman* and *Healy* similarly amounted to "simple economic protectionism." *Id.* As *Ross* made clear, these cases should not be extended beyond their facts; they merely reflect the rule against protectionist state laws that discriminate against out-of-state interests in favor of their in-state counterparts. *Id.* at 1155; *N.J. Staffing Alliance v. Fais*, 110 F. 4th 201, 207 (3d Cir. 2024) (explaining that under *Ross*, "the dormant Commerce Clause does not prohibit laws solely because they have extraterritorial reach absent protectionist intent or effect").

AAM concedes the first point, agreeing that the Supreme Court has rejected the "practical effects" argument. Dkt. 52 at 13. But it does not account for the second point, that the extraterritoriality rule of *Baldwin*, *Brown-Forman*, and *Healy* has a limited reach. AAM relies on these cases both explicitly, *see id.* at 8–9, and implicitly, by citing other decisions that rely on them. Yet *Baldwin* and its progeny do not apply here because the Act is not protectionist, does not discriminate against out-of-state-interests, and does not tie the price of drugs sold in Illinois to the price of drugs sold elsewhere. *Ross*, 143 S. Ct. at 1154-56. While AAM calls the Act a "price control" statute, this is incorrect. The Act does not control the prices for out-of-state sales "either by its express terms or by its inevitable effect." *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003) (upholding Maine law intended to address prescription drug prices). An out-of-state manufacturer can sell a drug to an out-of-state wholesaler at whatever price those parties agree upon, provided that the drug is not sold into Illinois, 410 ILCS 725/10(a), and the Act does not tie the price of drugs sold into Illinois to out-of-state prices.

AAM's pre-*Ross* case law cannot sustain its claim here. Take, for example, *Midwest Title Loans*, AAM's lead Seventh Circuit case. Dkt. 52 at 9–10. There, an out-of-state lender asserted a Commerce Clause claim challenging an Indiana law that regulated car loans made to residents of

Indiana. *Midwest Title Loans*, 593 F.3d at 662. Relying in part on *Healy*, the court invalidated Indiana's law based on its extraterritorial effects, since it could apply to out-of-state companies issuing loans to Indiana residents. *Id.* at 669. But this application of *Healy* is incorrect under *Ross* because the statute at issue did not discriminate against out-of-state interests, nor was it a price control or price fixing statute. 143 S. Ct. at 1154–56.

Midwest Title suffers from two other infirmities that also render it unreliable. First, it significantly relies on *Quill Corporation v. North Dakota*, 504 U.S. 298 (1992), as an "example of extraterritorial regulation held to violate the Commerce Clause even though the entity sought to be regulated received substantial benefits from the regulating state." 593 F.3d at 666. But *Quill* has been overruled. *See South Dakota v. Wayfair Inc.*, 138 S. Ct. 2080, 2099 (2018). (the "physical presence rule of *Quill* is unsound and incorrect"). Second, it does not adequately account for the Supreme Court's decision in *CTS*, 481 U.S. 69, and thus "gives insufficient weight to a state's interest in protecting its own citizens." *Mayo*, 2022 U.S. Dist. Lexis 2573.

The multiple issues with *Midwest Title* carry over to *Legato Vapors, LLC v. Cook*, 847 F.3d 825 (7th Cir. 2017), the other Seventh Circuit case that AAM emphasizes. Dkt. 52 at 8–10.[30] In *Legato Vapors*, the plaintiff challenged a law regulating the manufacture and distribution of vapor pens and the liquors used in e-cigarettes. *Id.* at 827. The law had an "unprecedented" extraterritorial reach, "imposing detailed requirements of Indiana law on out-of-state manufacturing operations." *Id.* And although the Seventh Circuit did not decide the case on this ground, the law raised "obvious

[30] Many of AAM's out-of-jurisdiction cases, in addition to being non-binding, are unreliable because they invoke the "practical effect" test that the Supreme Court has now rejected. *See* Dkt. 52 at 15–16 (citing *Pharmaceutical Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 67–71 (D. D.C. 2005) (relying on the *Baldwin* line of cases and the "practical effect" test); *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 261 (S.D. N.Y. 2018) (relying on the "practical effect" test). AAM also cites to *Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001), but there, the court found that the challenged law did not violate the dormant Commerce Clause, explaining that the extraterritoriality principle from the *Baldwin* line of cases has a limited reach. *Id.* at 81–82.

concerns about protectionist purposes," as it appeared to be "a legislative grant of a monopoly to one favored in-state company in the security business." *Id.* at 833. In invalidating the law as an impermissible extraterritorial regulation, the Seventh Circuit relied heavily on *Midwest Title*, *see id.* at 831, 836, which is no longer reliable, as discussed above. The Court's opinion is also replete with citations to *Brown-Forman*, *Healy*, and the overruled *Quill* decision. Finally, the law at issue in *Legato Vapors* was nothing like the Act, which does not seek to impose detailed and invasive requirements on out-of-state manufacturing operations (possibly for a protectionist purpose), but rather protects Illinois consumers from price gouging.

B. The Supreme Court's plurality opinion in *Edgar* is not binding and does not support AAM's Commerce Clause claim.

As established above, *Ross* forecloses any challenge to the Act based on *Baldwin*, *Brown-Forman*, and *Healy* and other cases relying on them. AAM asserts that a separate strand of "extraterritoriality" jurisprudence remains intact. It points to single footnote in *Ross*, which cites *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), to argue that the Commerce Clause prohibits "state laws that directly regulate out-of-state commerce." Dkt. No. 52 at 13. But this footnote endorses no such principle. 143 S. Ct. 1157, n.1. The Court merely noted that the petitioners invoked *Edgar* and observed that in *Edgar*, a plurality declined to enforce a law that "*directly* regulated transactions which took place wholly outside the State and involved individuals having no connection with Illinois." *Id.* (cleaned up).

Edgar offers no support for AAM's claim. To start, as the Supreme Court noted, the relevant portion of *Edgar* (Part V-A) is only a plurality opinion. *Id.*; *Edgar*, 457 U.S. at 641–643. It did not win the support of the majority of the Court and is not binding. *CTS*, 481 U.S. at 81 ("As the plurality opinion in *MITE* did not represent the views of a majority of the Court, we are not bound by its reasoning."); *Alliant Energy Corp. v. Bie*, 330 F.3d 904, 916 (7th Cir. 2003) (declining

to follow *Edgar*'s discussion of extraterritoriality because "the language, appearing in Part V-A of Justice White's opinion, did not draw support from a majority of the Court and is therefore not the opinion of the Court"). Moreover, although AAM banks its claim on extraterritoriality, at least for purposes of its preliminary injunction motion, the majority in *Edgar* relied on *Pike* balancing, an argument that AAM does not advance here. *Edgar*, 457 U.S. at 643–46; *Alliant*, 330 F.3d at 917. Finally, as discussed in Part I-C below, the Supreme Court "departed significantly" from the *Edgar* plurality's view in *CTS*, see R. Feldman, *Lochner Revenant: The Dormant Commerce Clause & Extraterritoriality*, 16 N.Y.U. J. LAW & LIBERTY 209, 242 n.98 (2022), a more recent Supreme Court case that AAM ignores.

In any event, the Act does not suffer from the same infirmities as the law at issue in *Edgar*, which could allow Illinois to block out-of-state transactions without advancing *any* local interest. The law challenged in *Edgar* allowed the Illinois Secretary of State to review and possibly prevent a corporate takeover offer for the shares of a "target company" having certain connections to Illinois. 457 U.S. at 626–27. Critically, the law "could be applied to regulate a tender offer which would not affect a single Illinois shareholder." *Id.* at 642. While the State asserted that the law sought to protect resident security holders, it had "no legitimate interest in protecting nonresident shareholders," so there was "nothing to be weighed in the balance to sustain the law." *Id.* at 644.

The Act does not have this problem. Unlike the corporate takeover statute at issue in *Edgar*, which could block out-of-state transactions without protecting a single Illinois shareholder, every application of the Act necessarily promotes a legitimate local interest. That is because the Act applies only to prescription drugs that are "ultimately sold in Illinois," 410 ILCS 725/10(a), and Illinois indisputably has a strong interest in ensuring that its own residents are not subject to prescription drug price-gouging. *Id.* 725/2(e) (legislative finding that the Act addresses a "matter

of health, safety, and welfare for the People of the State of Illinois"). Moreover, manufacturers set prices with input from the entire supply chain; distributors and some manufacturers sell products into Illinois; and any entities that distribute generic drugs to pharmacies in Illinois must be licensed by the State. *See supra* pp. 2-4.

The Act's limited application to prescription drugs ultimately sold into Illinois distinguishes it from the Maryland statute at issue in *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018), which pre-dates *Ross*. Dkt. 52 at 11-12. In *Frosh*, the Fourth Circuit invalidated a Maryland price-gouging law drafted so broadly that it could be enforced "against parties to a transaction that did not result in a single pill being shipped to Maryland." *Id.* at 671; *id.* at 679 (dissent criticizing majority for construing the statute as extending to drugs "not ultimately sold in Maryland"). Illinois' law does not operate in this manner, and thus *Frosh* is easily distinguishable.

Moreover, *Frosh* is not persuasive precedent. Contrary to the Supreme Court's decision in *Ross*, the court in *Frosh* applied the *Baldwin* line of cases and the "practical effect" test to a non-discriminatory consumer protection statute. *Id.* at 673. And contrary to the Supreme Court's earlier decision in *Walsh*, the court in *Frosh* considered Maryland's law to be a "price control" statute even though it did not insist on a "certain price," *Walsh*, 538 U.S. at 669, but rather forbid unconscionable price increases.

The *Frosh* majority also failed to recognize that a State regulates commerce "wholly outside of its borders" only if "no transactions *in that stream* take place within that State's borders." *Frosh*, 887 F.3d at 683 (dissent, emphasis added), citing *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997); *see also* R. Feldman, *supra* at p. 18, at 285 ("[D]oes the statute control commerce occurring wholly outside of the state if the transaction

stream ultimately enters the state? The Fourth Circuit says yes; the Seventh Circuit says no."). While the majority and dissent in *Frosh* disagreed about whether Maryland's statute extended to drugs not ultimately sold in Maryland, *Frosh*, 887 at 679, Illinois' law applies to price gouging for drugs "ultimately sold in Illinois," 410 ILCS 725/10(a), so it does not regulate commerce occurring wholly outside of the State.

Finally, this Court should give little weight to *Association for Accessible Medicines v. Ellison*, a Minnesota district court decision preliminarily enjoining that state's prescription drug price gouging statute. *See* No. 23-cv-2024, 2023 U.S. Dist. Lexis 214781 (D. Minn. Dec. 4, 2023). First, the court relied on a series of concessions that Minnesota made in response to hypothetical questions about the reach of its statute—for example, that the statute would apply to an out-of-state drug manufacturer that had done "everything in its power to *prevent* its drugs from being resold in Minnesota." *Id.* Here, AAM mounts a facial challenge to the Act and speculation about the Act's interpretation cannot sustain its claim. Dkt. 26 at 13. Second, the court relied on *Edgar*, *see id.* at *6–7, which does not support AAM's claim for all of the reasons detailed above. Third, the court placed heavy emphasis on a pre-*Ross* Eighth Circuit case, *Styczinski v. Arnold*, 46 F. 4th 907, 912–13 (8th Cir. 2022), *see id.* at *9–10, that employed the "practical effect" test the Supreme Court has now rejected. *Styczinski* primarily followed *Midwest Title*, the Seventh Circuit case that is inconsistent with *Ross* and that relied on *Quill*, as discussed above.

C. AAM's claim fails because Illinois has a substantial interest in protecting its residents from price-gouged prescription drugs.

While AAM cites a number of unreliable or inapposite cases, it ignores the Supreme Court's decision in *CTS*, which shows that state laws affecting out-of-state transactions should be upheld where, as here, they necessarily promote a legitimate local interest. 481 U.S. at 93. *CTS*, decided five years after *Edgar*, involved a challenge to an anti-takeover statute that regulated the

acquisition of "control shares" in Indiana businesses that had certain numbers of Indiana shareholders. *Id.* at 72–74. The district court found that the law violated the Commerce Clause and the appellate court affirmed, stating that the law could "impede transactions between residents of other states" and that Indiana was "depriving nonresidents of the valued opportunity to accept tender offers from other nonresidents." *Id.* at 77–78. But the Supreme Court reversed, noting that the law did not discriminate against out-of-state interests, that it applied to Indiana corporations, and that "every application" of the law would "affect a substantial number of Indiana residents, whom Indiana indisputably has an interest in protecting." *Id.* at 88, 93–94.

For similar reasons, the Act is constitutional. It does not discriminate against out-of-state entities, and every application of the Act advances Illinois' interest in protecting its citizens from prescription drug price gouging, because the Act applies only to drugs sold in Illinois. 410 ILCS 725/10(a). And as explained, *supra* p. 3, drug manufacturers and wholesalers must comply with Illinois' licensure requirements. Based on *CTS*, AAM's claim is unlikely to succeed. 481 U.S. at 93; *see also, e.g.*, *Alliant Energy Corp. v. Bie*, 336 F.3d 545, 549–50 (7th Cir. 2003) (en banc) (applying *CTS* to uphold various statutes regulating public utilities); *IMS Health Inc. v. Mills*, 616 F.3d 7, 31 (1st Cir. 2010) (noting that *CTS* "upheld a state statute that regulated out-of-state commercial transactions with a clear in-state nexus and impact").

In sum, Illinois has authority to protect its own citizens from price gouging, regardless of whether drug manufacturers ship directly into Illinois or rely on wholesalers. States are not "powerless to regulate all transactions beyond their borders, including transactions involving their citizens." *IMS Health Inc.*, 616 F.3d at 29 n.29. "[I]t is inevitable that a state's law…will have extraterritorial effects," and the Supreme Court has "never suggested that the dormant commerce

clause requires Balkanization, with each state's law stopping at the border." *Instructional Sys. v. Computer Curriculum Corp.*, 35 F.3d 813, 825 (3d Cir. 1994).

II. AAM has failed to show irreparable harm.

AAM has also failed to establish that it will suffer irreparable harm if the Court denies its motion. *Winter*, 555 U.S. at 2. First, AAM makes a boilerplate argument that its members will suffer an irreparable injury from being subjected to an allegedly unconstitutional law. Dkt. 52 at 16-17. But the Supreme Court has never applied this principle outside the First Amendment context (*Elrod v. Burns*, 427 U.S. 347, 373–74 (1976)), and the Seventh Circuit has not applied it to dormant Commerce Clause claims. This argument is further undermined by AAM's delay in bringing this lawsuit. The Act was passed on July 28, 2023, nearly six months before AAM filed suit. Dkt. No. 1. This lack of urgency makes the extraordinary remedy of injunctive relief inappropriate. *Tranchita v. Callahan*, 511 F. Supp. 3d 850, 882 (N.D. Ill. Jan. 5, 2021).

AAM also asserts that its members will suffer monetary losses. Dkt. 52 at 17–19. But economic loss is irreparable in extenuating circumstances—for example, where the injunction is necessary to "save [a] plaintiff's business." *Gateway E. Ry. Co. v. Terminal R.R. Ass'n*, 35 F. 3d 1134, 1140 (7th Cir. 1994). AAM makes no such claims and cannot satisfy this factor.[31] In fact, AAM has not established that its members will suffer substantial financial harm due to enforcement, see *supra* pp. 7-9. The Act protects Illinois consumers from predatory pricing

[31] Irreparable harm must be imminent and extend beyond a "disruption in cash flow" that does not threaten a plaintiff's existence. *McHenry Cnty v. Raoul*, No. 21-cv-20341, 2021 U.S. Dist. LEXIS 258576, at *6 (N.D. Ill. Dec. 27, 2021); *see also McHenry Cnty v. Raoul*, No. 21-3334, 2022 U.S. App. LEXIS 6097, at *3 (7th Cir. Jan. 12, 2022) (finding plaintiffs suing State had not shown feared economic losses were "imminent irreparable harm" because they had "not shown that they will lose substantial revenue absent an injunction or that this loss of revenue is permanent" and refusing to stay the statute's enforcement pending appeal). Furthermore, even in claims against state entities, the only irreparable economic injuries are those that are "certain, great and actual." *Nat'l Min. Ass'n v. Jackson*, 768 F. Supp. 2d 34, 52–53 (D.D.C. 2011).

practices, not from rises in prescription drug costs associated with changes to manufacturing or other legitimate needs.

III. The balance of hardships weighs strongly in favor of Illinois and the public interest.

AAM must also establish that "the harm [it] would suffer without the injunction is greater than the harm that preliminary relief would inflict on the defendant[]." *Mich. v. U.S. Army Corps of Eng'g*, 667 F.3d 765, 769 (7th Cir. 2011). The court also should consider whether a preliminary injunction would cause harm to the public interest. *Platinum Home Mort. Corp. v. Platinum Fin. Group, Inc*., 149 F.3d 722, 726 (7th Cir. 1998).

Here, AAM's interests are significantly outweighed by the State's. As an initial matter, it is well-established that "[a]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (citation omitted). Additionally, however, AAM's purported interest stands in direct contrast with the public interest. AAM's argument focuses on the financial burden its members may encounter if they cannot engage in price gouging or are required to alter their current business practices. In contrast, the State's interest lies in preventing activity that will directly impact the health of its residents. As explained, *supra* pp. 5-9, the Act safeguards Illinois residents from abusive pricing tactics which primarily burden the elderly and poor. These tactics are proven to exist across a number of manufacturers and, at the extreme level the Act seeks to prohibit, have no purpose other than the accumulation of wealth at the expense of consumers. As such, the public interest weighs strongly in the State's favor.

CONCLUSION

For the foregoing reasons, the Attorney General requests that AAM's renewed motion for a preliminary injunction be denied.

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Respectfully submitted,

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