

No. 25-2960

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff-Appellant,

v.

KWAME RAOUL,

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

Defendant-Appellee.

On appeal from the United States District Court
for the Northern District of Illinois
No. 24-cv-00544 (Kendall, C.J.)

**OPENING BRIEF, ADDENDUM, AND REQUIRED
SHORT APPENDIX OF PLAINTIFF-APPELLANT
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Short Caption: Association for Accessible Medicines v. Kwame Raoul

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INTRODUCTION

This appeal concerns whether Illinois state law can set prices for the entire United States. Illinois has imposed massive civil penalties on any generic drug manufacturer that charges a wholesale price higher than a tight limit set by the Illinois General Assembly. But Illinois was not content to regulate prices charged in Illinois. The state’s new price-cap law applies even to out-of-state transactions between out-of-state manufacturers and out-of-state wholesalers, with no connection to Illinois—so long as the drug in question is eventually *re*-sold in Illinois, by anyone, no matter at what price. The Association for Accessible Medicines (“AAM”), the trade association for the generic industry, therefore brought suit to enjoin the law’s application to out-of-state transactions. Under settled precedent, Illinois has no power to directly regulate transactions outside its borders. As the Eighth Circuit recently held in invalidating an almost identical Minnesota law, “controlling the price of wholly out-of-state transactions” is wholly beyond a state’s power under the Constitution, even when the products sold in those out-of-state transactions are later re-sold in that state. *Ass’n for Accessible Medicines v. Ellison*, 140 F.4th 957, 961 (8th Cir. 2025).

The district court did not disagree that, under long-settled caselaw—including from this Court—Illinois’s law cannot survive. Indeed, the district court frankly acknowledged that this Circuit’s precedent “certainly support[s] AAM’s position.” A8. That was quite the understatement. This Court has long held that “[a] state cannot regulate sales that take place wholly outside it.” *E.g., In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997), *abrogated on other grounds by Rivet v. Regions Bank of La.*, 522 U.S. 470 (1998). But rather than follow that “long line of cases,” *Dean Foods Co. v. Brancel*, 187 F.3d 609, 615 (7th Cir. 1999), the district court held that they are no longer good law. A9.¹ That was plainly incorrect.

The district court’s decision to bypass decades of binding precedent stemmed from its misreading of *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). *Ross* involved a California law that regulated the sale of pork *in California*; it did not directly regulate or penalize pig farmers *outside* California at all. *Id.* at 363. For that reason, the challengers in *Ross* did not even argue that the California law implicated

¹ AAM cites documents in the Required Short Appendix and Appendix as “A.”

the constitutional prohibition on direct state regulation of out-of-state conduct. Their argument was that, despite regulating only in-state transactions, the California law had *indirect* effects on out-of-state commerce that were too severe. In rejecting that argument, the Supreme Court clarified that there is no “almost per se’ rule against state laws” that regulate *in-state* conduct and have *indirect* “effects” on “extraterritorial” commerce. *Id.* at 373. But that is not what this case is about. The Illinois law challenged here is not a law that regulates in-state conduct and just happens to have indirect effects on out-of-state commerce. It *directly* regulates out-of-state transactions. And the Supreme Court went out of its way in *Ross* to make clear that its holding should not be read to bless state laws like that—*i.e.*, state laws “that *directly* regulate[] out-of-state transactions by those with *no* connection to the State.” *Id.* at 376 n.1.

The district court here acknowledged that the Supreme Court’s decision “did not answer the precise question this case presents”—whether one state may directly regulate transactions in another. A7. Nevertheless, it concluded that it could now disregard this Court’s on-point precedents as having been based on a flawed “conception of the

dormant Commerce Clause.” A10. That is wrong as a reading of *Ross*, given that the Supreme Court expressly did not displace the longstanding body of law holding that states have no power to directly regulate out-of-state transactions. It is wrong as a matter of *stare decisis*, because a perceived new “conception” does not justify disregarding on-point holdings. And most fundamentally, the district court’s new “conception” is wrong as a matter of constitutional structure. A single state may not regulate prices or conduct nationwide in this way—as decisions postdating *Ross* confirm. The decision below is the sole outlier.

Correcting the district court’s legal error compels reversing the denial of a preliminary injunction. The district court agreed that AAM had shown that its members would face “real harm”—irreparable harm—from the Illinois law. A15. And the harm to AAM’s members will harm the public interest as well. Generic medicines are the backbone of affordable healthcare in America, accounting for 90 percent of prescriptions filled while representing only 12 percent of spending on prescription drugs. These medications saved the U.S. healthcare system \$467 billion in 2024 alone. Yet generic manufacturers operate on razor-thin margins in an increasingly challenging economic environment.

Increasing costs have already driven manufacturers to withdraw generic drugs from the market, contributing to drug shortages that are approaching record levels. Illinois’s law would accelerate that problem by preventing manufacturers from adjusting their prices to maintain profitability in the face of considerations like inflation, regulatory costs, or overhead—forcing them to choose between operating at a loss, risking the Act’s draconian penalties, or withdrawing their products from the market altogether. The district court found the balance of equities to be “a wash” solely because it concluded that AAM’s constitutional claim was not “colorable.” A15. This Court therefore should both correct the district court’s legal error on AAM’s likelihood of success and reverse the denial of a preliminary injunction.

STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1343 because AAM’s claims arise under the Constitution (principally the Commerce Clause and Due Process Clause) and 42 U.S.C. § 1983. The district court denied AAM’s motion for a preliminary injunction in an order entered September 26, 2025. A1-16. AAM timely filed a notice of appeal from that order on October 16, 2025. A159. This Court has

jurisdiction to hear this interlocutory appeal under 28 U.S.C. § 1292(a)(1) because the appeal is from an order expressly refusing an injunction, *see* A16. AAM's claims remain pending in the district court, which has stayed the case pending resolution of this appeal. D.Ct. ECF 95.

ISSUES PRESENTED

1. Whether AAM is likely to succeed on the merits of its argument that the Act violates the dormant Commerce Clause by directly regulating the prices that out-of-state manufacturers can charge for generic medicines in transactions that occur entirely outside of Illinois.

2. Whether in light of AAM's likelihood of success, the district court's finding that AAM has established irreparable harm, and the remaining preliminary-injunction factors, this Court should reverse the denial of a preliminary injunction.

STATEMENT OF THE CASE

I. The Dormant Commerce Clause

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 v. Beer Inst., Inc.*, 491 U.S. 324, 335-36 (1989) (footnotes omitted). 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).

A state law violates the Commerce Clause when it (1) “directly regulates” commerce occurring wholly outside the state, (2) “discriminates against interstate commerce,” or (3) imposes a “burden on interstate commerce [that] clearly exceeds the local benefits” secured. *Wiesmueller v. Kosobucki*, 571 F.3d 699, 703 (7th Cir. 2009) (citation omitted); accord *Nat’l Solid Wastes Mgmt. Ass’n v. Meyer*, 63 F.3d 652,

657 (7th Cir. 1995); *Ellison*, 140 F.4th at 960; *New York v. Mountain Tobacco Co.*, 942 F.3d 536, 542 (2d Cir. 2019); *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 644 (6th Cir. 2010).²

This appeal involves a challenge under the first line of authority, which prohibits “law[s] that *directly* regulate[] out-of-state transactions by those with *no* connection to the State.” *Ross*, 598 U.S. at 376 n.1. As this Court has put it, “direct extraterritorial regulation” is “invalid.” *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 830 (7th Cir. 2017); *accord*, e.g., *Alliant Energy Corp. v. Bie*, 336 F.3d 545, 547 (7th Cir. 2003) (identifying the “well established” and “unsurprising principle that a *direct or facial* regulation of wholly extraterritorial transactions is *per se* invalid.”). Under that direct-regulation doctrine, this Court has struck down multiple laws, including (as particularly relevant here) a “state law that attempted to regulate loan transactions entered into entirely out-of-

² This Court has described the rules against direct regulation and overt discrimination as together comprising one “tier” of Commerce Clause scrutiny, in which laws are “struck down ... without further inquiry” because they are *per se* invalid. *Wiesmueller*, 571 F.3d at 703. The second “tier” of the analysis, for laws that involve neither direct extraterritorial regulation nor discrimination, applies a lower degree of scrutiny under a balancing test. *Id.*; *Nat’l Solid Wastes Mgmt. Ass’n*, 63 F.3d at 657; *see generally Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).

state” and a state law that “regulate[d] the price of sales of milk produced in Wisconsin but where the sales took place outside the state, after the producers had transported the milk beyond the state boundary.” *Legato Vapors*, 847 F.3d at 831; *Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 667-69 (7th Cir. 2010).

II. Generic and Biosimilar Competition Lowers Drug Prices Nationwide

As U.S. healthcare costs continue to rise, generic and biosimilar medicines play a pivotal role in controlling drug prices.³ See U.S. Dep’t of Health & Hum. Servs., *Drug Competition Series: Analysis of New Generic Markets, Effect of Market Entry on Generic Drug Prices: Medicare Data 2007-2022*, ASPE Issue Brief, 1-2 (January 16, 2025).⁴ Generics lower prescription drug prices by increasing competition when they enter the market, resulting in prices that “are consistently lower than brand-name prices across all market sizes and time periods.” *Id.* at 1. Their influence in driving down drug prices is profound: Generics made up 90 percent of all prescriptions filled in the U.S. in 2024 but only 12 percent

³ Although there are regulatory differences between generic drugs and biosimilars, they are not pertinent to this case, and this brief refers to them collectively as “generics.”

⁴ <https://tinyurl.com/5n6b6jks>.

of total spending on prescription drugs. *See* Ass’n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report 2*, 10 (Sept. 2025).⁵ The savings from these price differentials are substantial. Generic and biosimilar medicines generated \$467 billion in savings for the U.S. healthcare system in 2024—a \$27 billion increase in savings over 2023. *Id.* at 10-11. And over the last decade, generics and biosimilars have generated \$3.4 trillion in savings. *Id.*

AAM is the leading trade association for manufacturers of generic and biosimilar medicines. AAM’s manufacturer members do not sell their medicines directly to patients. Rather, these medicines travel along an extensive supply chain. Manufacturers generally sell their medications to large national wholesale distributors, which then resell those products to retail pharmacies, hospitals, or other healthcare facilities. *See* Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp., 4-5 (2021)⁶; Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 1-2

⁵ <https://tinyurl.com/rfapueh6>.

⁶ <https://tinyurl.com/np9nbxsz>.

(Mar. 2005).⁷ Finally, those providers sell or otherwise dispense the medications to patients. *Id.*

Three companies—Cencora (formerly known as AmerisourceBergen), Cardinal Health, and McKesson, none based in Illinois—control over 90 percent of the wholesale market. *See* A77 ¶ 28; Eastern Research Group, Inc., *An Examination of Pharmaceutical Supply Chain Intermediary Margins in the U.S. Retail Channel* 8 (Sept. 27, 2024).⁸ Nearly all sales from generic manufacturer to wholesaler occur outside of Illinois. *See* A55 ¶¶ 5-8; A77 ¶ 28; A80 ¶ 41; A112 ¶¶ 5-8. Manufacturers do not sell their medications on a state-by-state basis—rather, they pre-negotiate bulk contracts with wholesale distributors that cover a range of products for resale nationwide. *See* A55 ¶¶ 5-6; A76 ¶ 26; A112 ¶¶ 5-6. As a result, manufacturers control neither the prices that wholesalers or retailers set for their drugs nor the location where the drugs are later sold. *See* A54-55 ¶ 4; A58-59 ¶ 21; A76 ¶ 26; A112 ¶ 5; A116 ¶ 23.

⁷ <https://tinyurl.com/yvd5ep5n>.

⁸ <https://tinyurl.com/5efhuanp>; *see* Cencora, Inc., SEC Form 8-K (Sept. 3, 2025), <https://tinyurl.com/2uw568bn>; Cardinal Health, Inc., SEC Form 8-K (Aug. 27, 2025), <https://tinyurl.com/44w2k6pw>; McKesson Corp., SEC Form 8-K (Aug. 6, 2025), <https://tinyurl.com/4eskx7s9>.

Generic and biosimilar manufacturers face challenging economic conditions that can “drive existing manufacturers out of the market, and deter potential market entrants.” U.S. Dep’t of Health & Hum. Servs., *White Paper: Policy Considerations to Prevent Drug Shortages and Mitigation Supply Chain Vulnerabilities in the United States* 3 (Apr. 2, 2024).⁹ In contrast to their brand-name counterparts, which enjoy monopoly pricing for extended periods through patents and other exclusivity pathways, generic and biosimilar manufacturers face intense market competition, high investment requirements, supply chain vulnerabilities, regulatory complexity, and intellectual property challenges, all of which limit potential returns. See Sarah Ibrahim, Ph.D., *Unlocking Global Access to Generic Drugs*, FDA, 6 (2023-2024);¹⁰ FDA, *Drug Shortages: Root Causes and Potential Solutions* 22-23 (Feb. 21, 2020).¹¹ As a result of these conditions, generic manufacturers frequently operate on “unpredictable sales volumes, prices, and profit margins.” U.S. Dep’t of Health & Hum. Servs., *White Paper, supra*, at 3.

⁹ <https://tinyurl.com/3jwsfa69>.

¹⁰ <https://tinyurl.com/224uwb89>.

¹¹ <https://tinyurl.com/3vkzkuxr>.

In addition to the uncertain operational environment, the cost to manufacture generics has soared. The “raw material prices for essential drugs” have increased significantly, by as much as 140 percent in the post-COVID era. *See Active Pharmaceutical Ingredients Market Size*, Precedence Research (Jan. 2023).¹² “Most generic drug manufacturers rely on other companies to produce” the materials for the medications they develop, Mariana P. Socal et al., *Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients*, 42 *Health Affairs* 407, 407 (Mar. 2023),¹³ so generic manufacturers are at the whim of these raw material price increases. Escalating raw material costs further erode profit margins, intensifying the challenges generic and biosimilar manufacturers face in keeping their products on the market.

As a result of the increasing cost of manufacturing generic and biosimilar products and the uncertain market conditions described above, generic and biosimilar manufacturers have taken products off of the generics market. FDA, *Drug Shortages*, *supra*, at 21; Comm. on

¹² <https://tinyurl.com/5ey4tzan>.

¹³ <https://tinyurl.com/mvukatf3>.

Homeland Sec. & Governmental Affairs, U.S. Senate, *Short Supply: The Health and National Security Risks of Drug Shortages* 13 (Mar. 2023).¹⁴

Such exits from the market have resulted in supply shortages that are “approaching record levels” and depriving patients of access to life-saving, cost-effective treatments. Christina Jewett, *Drug Shortages Near an All-Time High, Leading to Rationing*, N.Y. Times, May 17, 2023.¹⁵

These shortages are particularly dangerous when they impact the supply of essential medications.

III. Illinois’ Price Control Law

This appeal challenges the constitutionality of an attempt by Illinois to impose price controls on out-of-state transactions. The relevant price-control statute—Public Act 103-0367, 2023 Ill. Legis. Serv. P.A. 103-367 (H.B. 3957) (West), codified at 410 Ill. Comp. Stat. 725/1 *et seq.* (“Act”)—regulates the prices that manufacturers and wholesale drug distributors may charge “in the sale of an essential off-patent or generic drug that *is ultimately sold* in Illinois.” Act § 10(a) (emphasis added).¹⁶

¹⁴ <https://tinyurl.com/5n8dwrw5>.

¹⁵ <https://tinyurl.com/7r9ttefx>.

¹⁶ The Act defines “[e]ssential off-patent or generic drug” as “any prescription drug sold within the State” (1) for which “all exclusive marketing rights” under federal drug approval and patent laws have

The regulated “sale” itself—by a manufacturer or a wholesaler—need not occur in Illinois. As confirmation that the Act reaches upstream transactions outside Illinois, the Act expressly states 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).

As the district court explained, “Illinois targets upstream sales rather than direct sales to Illinois consumers.” A2. For example, the Act targets the initial upstream sale of product X from the generic manufacturer to a wholesale drug distributor, which “will almost always involve two non-resident entities and occur entirely outside of Illinois.” A2. “[I]f the wholesaler sells product X to a pharmacy that, in turn, sells product X in Illinois, the Act can be enforced against the manufacturer

expired; (2) “that appears on the model list of essential medicines most recently adopted by the World Health Organization” or “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 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.

based on the price of the initial sale”—which, again, took place in another state. A2-3.

By narrowly targeting generic manufacturers and wholesale distributors, the Act exempts large segments of the pharmaceutical marketplace. The Act exempts *brand-name* drugs, because it applies only to drugs “for which *all* exclusive marketing rights” have expired, including all rights under “federal patent law.” Act § 5 (defining “Essential off-patent or generic drug”) (emphasis added). Nor does the Act apply to *entities downstream in the supply chain*, such as pharmacies or hospitals. *Id.* § 10(a). Indeed, it does not even matter what price a person actually pays in Illinois. The only thing the Act regulates is “the sale of an essential off-patent or generic drug” by “[a] manufacturer or wholesale drug distributor.” *Id.*

Exactly what price increases Illinois will tolerate is left vague. The price-control provision begins with a formula that defines a covered price increase (termed “price gouging”) as one that: (1) would result in the wholesale acquisition cost (“WAC”)¹⁷ for a “30-day supply” of the drug

¹⁷ The term “wholesale acquisition cost” means “the manufacturer’s list price ... to wholesalers or direct purchasers in the United States, not including ... discounts, rebates or reductions in price, for the most recent

exceeding \$20; and (2) would result in an increase in the WAC for the medicine of (a) 30% or more over the preceding year, (b) 50% or more over the preceding 3 years, or (c) 75% or more over the preceding 5 years. *Id.*

§ 5. If that formula is met, then a price increase will be prohibited if it is both “unconscionable” and “otherwise excessive and unduly burdens consumers because of [1] the importance of the [medicine] to their health and ... [2] insufficient competition.” *Id.*

The Act then adds a caveat to this definition, stating that price gouging “does not include a price increase that can be reasonably justified by: (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 essential off-patent or generic drug to promote public health.” *Id.* What can be “reasonably justified” presumably is up to the court. And this exception does not allow a court to take into consideration the manufacturer’s non-production costs or profit margin. *See* A145 (counsel for Defendant expressly exempts the cost of production and of increasing production, and nothing further); *see also* A141. Thus, the Act fails to

month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.” 42 U.S.C. § 1395w-3a(c)(6)(B); *see* Act § 5 (incorporating federal definition).

take into account the many costs faced by drug manufacturers that are outside “the cost of produc[tion],” such as rising regulatory and overhead costs. These significant costs erode manufacturers’ profit margins on a product, threatening to make the product unprofitable and leading to its withdrawal from the market. A56-58 ¶¶ 13, 17; A60 ¶ 27; A113-115 ¶¶ 14, 18-19; A118 ¶ 29.

Wholesalers get more favorable treatment. The Act exempts wholesale distributors from liability for any price increase that “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). The Act provides no similar defense for manufacturers who raise the price of their medications as a result of market conditions beyond their control.

A manufacturer found in violation of the Act faces catastrophic financial liability. Upon “petition of the Attorney General,” an Illinois court may order a manufacturer to relinquish “any money acquired as a result of a price increase” that the court deems unlawful; impose a “civil penalty of up to \$10,000 *per day* for each violation” on top of the

disgorgement of revenues; and “enjoin[]” the manufacturer from charging prices that violate the Act. *Id.* § 10(c)(2), (3), (5) (emphasis added).

IV. District Court Proceedings

In light of the Act, AAM members that had planned price increases on generic drugs faced a lose-lose-lose scenario. If they went forward with their price increases, they would be forced to disgorge any revenue from them, *plus* forced to pay civil penalties of up to \$3.65 million per year *per product*. If they adhered to the unconstitutional Illinois cap in all their transactions throughout the United States, they would forgo potentially millions of dollars in revenue and potentially lose money on products that Illinois’s cap makes unprofitable. If they took the money-losing products off the market, they would face unrecoverable sunk costs. No matter which path they chose, Illinois’s sovereign immunity would preclude them from suing to recover money damages for their constitutional injury. A55-57 ¶¶ 9-10, 14; A113-114 ¶¶ 10-11, 15.

Thus, for example, one AAM member intended to increase the price of a generic drug subject to the Act’s price control, to account for numerous rising costs, including rising production costs, product ingredient costs, product validation costs, testing costs, regulatory

approval costs, overhead costs, and elevated product inventory loss. A55-57 ¶¶ 9-10, 14; A113-115 ¶¶ 10-11, 15, 19. But because of the Act's prohibition, the member company has forgone the planned price increase—and the associated revenue. *Id.*

Accordingly, AAM brought this lawsuit on January 22, 2024, promptly after the Act took effect on January 1, 2024. A17; Act § 99. The Complaint sought declaratory relief and injunctive relief on the grounds that the Act violates the dormant Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and the horizontal separation of powers implicit in the Constitution's design. A44-49. AAM moved for a preliminary injunction to enjoin the Attorney General from enforcing the Act against its members based on their sale of generics or biosimilars outside of Illinois. D.Ct. ECF 17.

The Attorney General moved to dismiss for lack of jurisdiction, arguing that AAM failed to plausibly allege Article III standing or ripeness and insisting that, for these purposes, the Court could not consider the sealed declarations submitted with the preliminary-injunction motion because they were not attached to the complaint. D.Ct. ECF 26, at 11-18. Although the district court initially concluded that

AAM had not yet pleaded the type of imminent injury to a member that would support standing, A62-64, the court allowed AAM to amend its complaint. *See* A80-87.¹⁸

AAM submitted an amended complaint on July 9, 2024, that added further detail regarding the intent of AAM members to raise the price of a regulated medicine in a manner that is arguably proscribed by the Act, including facts previously set out in the declaration from an AAM member company. A65-105. The court concluded that the amended complaint cured any standing deficiency. A106-110. The court recognized (at A108-09) that a “plaintiff[] need not ‘violate the [law] and risk prosecution in order to challenge it.’” *Ezell v. City of Chi.*, 651 F.3d 684, 695 (7th Cir. 2011). It sufficed that a member of AAM had “alleged an intention to engage in a course of conduct arguably protected by federal law, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.” *520 S. Mich. Ave. Assocs., Ltd. v. Devine*, 433 F.3d 961, 963 (7th Cir. 2006) (alterations and citation omitted). The threat of prosecution comes from the statute itself: A “preenforcement

¹⁸ Neither the Attorney General nor the district court disputed that, if one or more AAM members has standing to sue, AAM has associational standing to sue on behalf of its members. *See* A63.

plaintiff ‘need not show that the authorities have threatened to prosecute him’ because ‘the threat is latent in the existence of the statute.’” *ACLU of Ill. v. Alvarez*, 679 F.3d 583, 591 (7th Cir. 2012) (quoting *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003)); accord *Ezell*, 651 F.3d at 695-96 (“The very ‘existence of a statute implies a threat to prosecute, so pre-enforcement challenges are proper.” (citation omitted)).

Upon denial of the Attorney General’s motion to dismiss, AAM promptly renewed its motion for preliminary injunction. D.Ct. ECF 51.

The district court denied the preliminary injunction on September 26, 2025. A1-16. The court acknowledged that prior precedent from this Court “certainly support[s] AAM’s position” regarding the Act’s invalidity under the Commerce Clause. A8-9. But the Court explicitly declined to follow that precedent based on *National Pork Producers Council v. Ross*. The court acknowledged that “*Ross* did not answer” the question presented in this case, A7, namely “whether the dormant Commerce Clause itself prohibits a state from regulating out-of-state transactions based on their downstream consequences,” A6. And the district court did not deny that there is a “long line of cases” from this Court “holding that states violate the Commerce Clause by regulating or controlling

commerce occurring wholly outside their own borders.” *Dean Foods*, 187 F.3d at 615. But the district court held that *Ross* had rejected the “conception” of the dormant Commerce Clause that underlay all existing precedent on that question, and that, following *Ross*, the dormant Commerce Clause *only* invalidates state laws with a discriminatory or protectionist purpose. A9-10. And because the court found that the Act at issue does not discriminate against out-of-state interests, it held that AAM failed to make a strong showing of its likelihood of success on the merits of its claim. A12.

Turning to the remaining preliminary injunction factors, the district court found that AAM had carried its burden in establishing irreparable harm. A12-13. The court found unrecoverable economic losses as a result of Illinois’ sovereign immunity and the costs of complying with the Act, possible penalties for any violations, and the detrimental business positions AAM members have already had to take as a result of the Act. *Id.*

In weighing the balance of the equities and public interest, the district court noted that AAM’s members “face real harm because of the Act” in the form of unrecoverable penalties, but “absent a colorable

constitutional violation,” the balance of harms favors the Attorney General A15. The court reasoned that both parties made substantial arguments regarding the public interest, noting AAM’s position that the Act could force generic manufacturers out of the market all together and exacerbate drug shortages. *Id.* But the court found that the public interest considerations were “a wash” at this stage, given its conclusion that AAM had a “low” likelihood of success on the merits, and the district court held that was not sufficient. A15-16.

Based on these four factors, the district court denied AAM’s preliminary injunction. A16. AAM timely appealed. A159.

SUMMARY OF ARGUMENT

The application of Illinois’s Act to out-of-state transactions should be preliminarily enjoined because AAM is likely to succeed on the merits of its claim that those applications of the Act violate the Commerce Clause, the Act inflicts irreparable harm on AAM’s members, and the balance of the equities and public interest favor AAM.

I. AAM is likely to succeed on its claim that the Act violates the Commerce Clause by directly regulating transactions that occur entirely

outside Illinois’s borders. The dormant Commerce Clause prohibits states from directly regulating wholly out-of-state transactions.

This principle is well-established in both Supreme Court precedent and this Court’s decisions. The Supreme Court has consistently held that states cannot project their regulatory authority to control commerce occurring wholly in other states. This Court has faithfully applied that principle, striking down—on numerous occasions—state laws that attempted to regulate out-of-state sales. These precedents establish a clear rule: Direct extraterritorial regulation is invalid under the Commerce Clause.

The district court’s only justification for departing from that clear rule was its perception that the Supreme Court’s decision in *Ross* announced a new “conception” of the dormant Commerce Clause. But *Ross* expressly did not disturb the fundamental prohibition on one state regulating transactions in another: It took pains to distinguish laws that “*directly* regulate[] out-of-state transactions by those with *no* connection to the State.” 598 U.S. at 376 n.1. No such direct regulation was at issue in *Ross*: The California law at issue regulated only *in-state* sales of pork products, and did not directly regulate or penalize out-of-state producers.

The district court therefore erred in reading *Ross* to abrogate the longstanding rule against direct regulation of wholly out-of-state transactions.

Both before and after *Ross*, other federal courts have consistently invalidated price control laws materially identical to the Act. The Fourth Circuit struck down a similar Maryland law that regulated prices in transactions occurring wholly outside Maryland. The Fourth Circuit's decision was cited favorably in *Ross* as correctly interpreting Supreme Court precedent. 598 U.S. at 374. Most recently, the Eighth Circuit affirmed a preliminary injunction against a nearly identical Minnesota law, expressly holding that *Ross* did not overturn precedent invalidating statutes that control prices in wholly out-of-state transactions. Numerous other courts have read *Ross* the same way. The district court's decision here stands alone as an outlier.

The district court not only misread *Ross* and misapplied *stare decisis*, but also erred as a matter of first principles by disregarding the fundamental considerations of horizontal federalism that animate the Commerce Clause's prohibition on direct out-of-state regulation. The Commerce Clause was adopted to prevent economic balkanization and

preserve a national marketplace. Allowing one state to regulate transactions occurring entirely in other states would create regulatory overlap, foster interstate antagonism, and undermine democratic accountability of state regulators—precisely the evils the Framers sought to prevent by adopting the Commerce Clause.

There is no doubt whatsoever that the Act directly regulates prices charged by out-of-state manufacturers in out-of-state transactions. Under settled law, those applications of the Act violate the Commerce Clause.

II. The remaining preliminary injunction factors also weigh decisively in AAM's favor. The district court correctly found that AAM's members will suffer irreparable harm absent an injunction. AAM's members face unrecoverable economic loss because they must choose between violating the Act and facing draconian financial liability; withdrawing their products from the Illinois market and losing all associated revenue; or complying with an unconstitutional law and losing significant revenue as a result of forgone price increases. Moreover, the enforcement of an unconstitutional statute constitutes irreparable harm in itself.

The balance of the equities and public interest also favor granting an injunction. It is always in the public interest to prevent constitutional violations. Furthermore, the Act threatens to exacerbate drug shortages by imperiling the profitability of generic drugs and therefore causing generic manufacturers to withdraw those products from the market—harming the very patients Illinois purports to protect.

This Court should reverse the district court’s denial of AAM’s motion for a preliminary injunction.

STANDARD OF REVIEW

When evaluating a preliminary-injunction decision, this Court “review[s] the district court’s ... legal conclusions de novo,” its “findings of fact for clear error,” and “its balancing of the factors for a preliminary injunction for abuse of discretion.” *Reporters Comm. for Freedom of the Press v. Rokita*, 147 F.4th 720, 729 (7th Cir. 2025) (citation omitted). “[I]f a district court bases an exercise of discretion on a legal error, it turns out to abuse its discretion.” *Common Cause Ind. v. Lawson*, 978 F.3d 1036, 1039 (7th Cir. 2020) (citation omitted).

A party seeking a preliminary injunction must demonstrate “a likelihood of success on the merits, a likelihood of suffering irreparable

harm in the absence of preliminary relief, that the balance of equities tips in the plaintiff's favor, and that an injunction is in the public interest.” *Minocqua Brewing Co. LLC v. Hess*, 160 F.4th 849, 855 (7th Cir. 2025); *see also Mahmoud v. Taylor*, 606 U.S. 522, 523 (2025). The last two factors “merge when the Government is the opposing party.” *Nken v. Holder*, 556 U.S. 418, 435 (2009).

ARGUMENT

I. AAM is Likely To Succeed on the Merits Because the Act Violates the Commerce Clause’s Prohibition on State Laws that Directly Regulate Wholly Out-of-State Transactions.

AAM is likely to succeed on its claim that the Act violates the Commerce Clause by directly regulating transactions that occur entirely outside of Illinois. Other circuits, including most recently the Eighth Circuit addressing materially identical state legislation, have held these laws unconstitutional. That conclusion is consistent with this Court’s established precedent and with longstanding Supreme Court precedent. Contrary to the district court’s view, *Ross* did not address the issue presented in this case and did not silently overrule well-established Commerce Clause precedent. Indeed, the Court went out of its way to make clear that it was not disturbing the fundamental prohibition on

states' directly regulating out-of-state parties' out-of-state transactions. This Court should therefore hold that the Act violates the Commerce Clause.

A. The Commerce Clause Prohibits States from Directly Regulating Sales that Occur Entirely Outside of Their Borders.

While state legislation that regulates *in*-state conduct may have *indirect* effects on out-of-state conduct without violating the Commerce Clause, a state law that *directly* regulates wholly out-of-state transactions is fundamentally different. This Court's cases reflect that critical distinction. *See, e.g., Legato Vapors*, 847 F.3d at 830 (“When a state directly regulates interstate commerce, it ‘exceeds the inherent limits of the enacting State’s authority and is invalid.’” (citation omitted)); *Midwest Title Loans*, 593 F.3d at 667-69 (invalidating application of an Indiana law to loan contracts “made and executed in Illinois”); *Dean Foods*, 187 F.3d at 617 (“We have held ... that extraterritoriality principles ban a state from regulating ‘sales that take place wholly outside it.’” (citation omitted)); *In re Brand Name Prescription Drugs*, 123 F.3d at 613 (“State A cannot use its antitrust law to make a seller in State B charge a lower price to a buyer in C. Insofar

as the Alabama suit challenges sales from plants or offices in other states to pharmacies in other states, it exceeds the constitutional scope of the Alabama antitrust law.”).

Far from overturning that rule, the Supreme Court reaffirmed it in *National Pork Producers Council v. Ross*, reiterating that it was not validating a state law that “*directly* regulate[s] out-of-state transactions by those with *no* connection to the State.” 598 U.S. at 376 n.1. The Act is just such a direct regulation. It was and is unconstitutional.

- 1. The Supreme Court and This Circuit Have Consistently Held that States Are Prohibited from Directly Regulating Wholly Out-Of-State Transactions.**

The rule that state laws may not directly regulate out-of-state commerce is deeply rooted in authoritative and binding precedent. Indeed, this Circuit has numerous on-point cases invalidating state laws under that rule, and those decisions in turn faithfully apply more than a century of Supreme Court precedent.

In *Midwest Title Loans, Inc. v. Mills*, this Court held that an Indiana law regulating loans to Indiana residents, including loans made entirely outside the state, violated the dormant Commerce Clause. 593 F.3d at 662, 669. Under the Indiana law at issue there, the loan

transaction was “deemed to occur in Indiana” (and thus be subjected to Indiana’s regulatory ambit) as long as the creditor had advertised its loans in Indiana. *Id.* at 662. Applying the Commerce Clause’s mandate “that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another,” this Court held that the law could not be applied to Midwest, a company with no offices in Indiana that made loans only in Illinois. *Id.* at 665, 669 (citation omitted). “The contract was, in short, made and executed in Illinois, and that [wa]s enough to show that” the law “violate[d] the commerce clause.” *Id.* at 669.

The principle against direct state regulation of out-of-state transactions applied in *Midwest Title Loans* even though Indiana was not “trying to protect its title lenders from the competition of title lenders in other states.” *Id.* at 665. As this Court explained, the direct-regulation prohibition is well grounded in the Commerce Clause because that Clause “protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State.” *Id.* at 667 (quoting *Healy*, 491 U.S. at 337). In addition, allowing “Indiana to apply its law against title loans when its residents transact

in a different state that has a different law would be arbitrarily to exalt the public policy of one state over that of another.” *Id.* at 667-68.

In *Dean Foods Co. v. Brancel*, this Court considered a Commerce Clause challenge to the enforcement of “Wisconsin milk-pricing regulations against transactions [the plaintiff] Dean Foods claimed took place in Illinois.” 187 F.3d at 610. This Court upheld the district court’s conclusion that, under principles of constitutional avoidance, the law could not be enforced against those out-of-state transactions because “[n]o state can legislate except with reference to its own jurisdiction.” *Id.* at 614-15 (quoting *Bonaparte v. Tax Court*, 104 U.S. 592, 594 (1882)). And *Dean Foods* made clear that “the fact that a particular transaction may affect or impact a state does not license that state to regulate commerce which occurs outside of its jurisdiction.” *Id.* at 619-20.

This Court again applied the constitutional prohibition on direct regulation of out-of-state conduct to sustain a challenge to an Indiana law regulating the sale of e-cigarettes in *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 830 (7th Cir. 2017). The state law at issue regulated sales of e-liquids between out-of-state companies—sales by an out-of-state manufacturer to either an out-of-state distributor or an out-of-state

online retailer—if the purchaser then resold the e-liquids to buyers in Indiana. *Id.* at 836. It also imposed restrictions on how the manufacturers were to operate their businesses in other states. *Id.* at 834, 835. In relevant part, this Court held that these forms of regulation were “impermissible extraterritorial regulation[s]” because they directly regulated transactions that occurred “entirely outside the regulating state.” *Id.* at 836.

This Court in *Midwest Title Loans*, *Dean Foods*, and *Legato Vapors* faithfully applied a century’s worth of Supreme Court cases. In *Davis v. Farmers Co-Operative Equity Co.*, the Supreme Court applied the Commerce Clause to invalidate a Minnesota law requiring out-of-state companies to submit to suit involving a “transaction [that] was in no way connected with Minnesota.” 262 U.S. 312, 314-17 (1923). Cases like *Shafer v. Farmers’ Grain Co. of Embden*, 268 U.S. 189, 199 (1925), and *Shaffer v. Heitner*, 433 U.S. 186, 197 (1977), also stand for the proposition that the Commerce Clause “precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders, whether or not the commerce has effects within the State.” *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion). And in

Baldwin v. G.A.F. Seelig, Inc., the Supreme Court recognized that one state “has no power to project its legislation into [another state] by regulating the price to be paid in that state for [a product] acquired there,” even if the product will later be resold in the regulating state. 294 U.S. 511, 521 (1935).

Applying that same principle, a plurality in *Edgar* held invalid an Illinois law regulating certain tender offers (*i.e.*, offers to buy shares of a corporation) affecting Illinois corporations. 457 U.S. at 642-43 (plurality opinion). Under the law at issue in *Edgar*, the Illinois government was vested with authority to block any tender offer made by an out-of-state buyer to current shareholders if it did not meet Illinois’s standards of fairness. *Id.* at 626-28. A plurality concluded that the Illinois law violated the Commerce Clause because “it directly regulate[d] transactions which take place across state lines, even if wholly outside the State of Illinois.” *Id.* at 641.¹⁹ MITE Corporation, the plurality observed, had “shareholders scattered around the country,” with only

¹⁹ A fifth Justice joined a section of the opinion holding the law independently invalid under the Commerce Clause’s balancing test for legislation that unduly burdens interstate commerce. 457 U.S. at 643-646.

“27% of [them] liv[ing] in Illinois.” *Id.* at 642. By blocking the tender offer, the Illinois law prevented the prospective buyer “from making its offer and concluding interstate transactions ... with those [stockholders] living in other States and having no connection with Illinois.” *Id.* In fact, “the Act could be applied to regulate a tender offer which would not affect a single Illinois shareholder,” *id.*, violating the Commerce Clause by “purport[ing] to regulate directly and to interdict interstate commerce, including commerce wholly outside the State.” *Id.* at 643.

Subsequent Supreme Court majority opinions have characterized the *Edgar* plurality as “significantly illuminat[ing] the contours of the constitutional prohibition on extraterritorial legislation.” *Healy*, 491 U.S. at 333 n.9. Citing that plurality, the Court has repeatedly recognized that a state law is unconstitutional if it “directly regulates or discriminates against interstate commerce,” *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578-79 (1986) (citing, *inter alia*, *Edgar*, 457 U.S. at 640-43 (plurality opinion)), including through direct “application ... to commerce that takes place wholly outside of the State’s borders,” *Healy*, 491 U.S. at 336 (quoting *Edgar*, 457 U.S. at 642-43 (plurality opinion)). This Court has adopted the same reading. *See*,

e.g., *Legato Vapors*, 847 F.3d at 829, 830, 834.

The district court brushed aside the *Edgar* plurality, A10-11 & n.2, but only because the decision was a plurality and without reckoning with the numerous post-*Edgar* decisions in which the Supreme Court and this Court have agreed with the plurality's reasoning. In fact, the one case from this Court that the district court cited actually supports AAM's position: On rehearing in *Alliant Energy*, this Court recognized "that direct regulation of interstate commerce is virtually *per se* unconstitutional"—it called that point "well established." 336 F.3d at 547. And while that proposition was "not at issue" in *Alliant Energy* because the state law in question *was not a direct regulation* and the challengers were instead asking for an indirect "effects" test (like the one later rejected in *Ross*), this Court recognized that *Brown-Forman* had relied on the *Edgar* plurality for that same proposition. *Id.*

The district court mistakenly perceived support for its approach in *Alliant Energy's* references to the "two-tiered" approach to Commerce Clause scrutiny—one tier that invalidates state laws virtually *per se*, and one that applies a more deferential balancing test. A11 n.2; *see* note 2, *supra*. But this Court was clear: "direct or facial regulation of wholly

extraterritorial transactions is *per se* invalid under the two-tiered approach.” *Alliant Energy*, 336 F.3d at 547. That rule controls here.

2. *Ross* Did Not Lift the Constitutional Prohibition on States’ Directly Regulating Transactions That Occur Entirely In Other States.

Ross did not alter either the Supreme Court’s own longstanding caselaw or this Court’s precedent addressing direct regulation of wholly out-of-state transactions. Three points make that abundantly clear: First, *Ross* upheld a state law that regulated *in-state* conduct. Second, the Supreme Court went out of its way in its opinion to make clear that it was not disturbing the longstanding prohibition on direct extraterritorial regulation. Third, in addressing some of the alternative arguments in *Ross*, the Court conclusively refuted the notion that *only* intentional discrimination is actionable under the Commerce Clause. The district court therefore erred in relying on *Ross* (and only *Ross*) as displacing the precedent under which it recognized that AAM must otherwise prevail.

The California law that the Supreme Court reviewed in *Ross* imposes liability only for “the *in-state sale* of whole pork meat” from a pig housed under conditions that California prohibited. 598 U.S. at 365

(emphasis added) (citing Cal. Health & Safety Code Ann. § 25990(b)(2)). The law had an indirect *effect* on pork producers outside of California—in that they had to either alter their practices so that their products could be sold in California or accept that their products could not lawfully be sold in the California market—but it did not regulate them directly. Out-of-state producers incurred no liability as a result of their out-of-state conduct. And if a retailer sold non-compliant pork meat in California, it would be the retailer, not the upstream pork producer, that would violate the statute.

The *Ross* plaintiffs, recognizing as much, did not argue that the law directly regulates wholly out-of-state transactions. They instead argued that the law violates the dormant Commerce Clause “almost *per se*” because (they said) it has the *indirect effect* of controlling behavior outside of California. 598 U.S. at 371, 373-74. The Supreme Court rejected that argument. At the outset, the Court made clear that it had never previously countenanced an “almost *per se*’ rule against” state laws that regulate only in-state conduct but have the indirect, “practical effect’ of ‘controlling’ extraterritorial commerce.” *Id.* at 375. And the Court declined to adopt any such rule going forward, because such a

broad prohibition would have “cast a shadow over laws long understood to represent valid exercises of the States’ constitutionally reserved powers.” *Id.* The Court thus ended its analysis by stating that, in rejecting the challengers’ proposed broad rule, it was “say[ing] nothing new”: It had not previously adopted any such broad rule, and it “s[aw] no reason to change course now.” *Id.* at 374, 376.

At the same time, however, the Court took pains to caution against reading its decision in a way that would “trivialize the role territory and sovereign boundaries play in our federal system.” *Id.* at 375. And one critical role those boundaries play is defining the scope of states’ power. State laws that regulate only *in-state* conduct, but have “incidental” effects out of state, are typically valid; but “direct regulation” of out-of-state acts “is prohibited,” even if those out-of-state acts produce in-state consequences. *Edgar*, 457 U.S. at 640 (plurality opinion). Thus, the Court in *Ross* underscored that nothing in its opinion should be read to in any way validate state laws, like the Act here, that *directly* regulate out-of-state parties’ out-of-state conduct.²⁰

²⁰ In the decision that the Supreme Court affirmed in *Ross*, the Ninth Circuit provided a similar explanation distinguishing the law at issue from laws found unconstitutional under the Commerce Clause. *Nat’l*

Discussing why the *Edgar* plurality opinion did not help the challengers in *Ross*, the Court repeatedly emphasized that *Edgar* involved direct regulation whereas *Ross* did not. The statute in *Edgar*, the Court explained, “‘*directly* regulate[d] transactions which [took] place ... wholly outside the State’ and involved individuals ‘having no connection with Illinois.’” *Ross*, 598 U.S. at 376 n.1 (quoting *Edgar*, 457 U.S. at 641-43) (emphasis, brackets, and ellipsis in *Ross*). By contrast, the California law directly regulated only “the in-state sale of certain pork products.” *Id.* at 363; *see id.* at 376 n.1 (noting the challengers’ “acknowledge[ment] that Proposition 12 regulates only products that companies choose to sell ‘within’ California”).

Simply put, nothing in *Ross* even remotely suggests, let alone holds, that a state could “*directly* regulate[] out-of-state transactions by those with *no* connection to the State.” *Id.* at 376 n.1. On the contrary, any attempt for a state to do so still exceeds “the territorial limits of state authority under the Constitution’s horizontal separation of powers,” *id.*—

Pork Producers Council v. Ross, 6 F.4th 1021, 1030 (9th Cir. 2021) (distinguishing *Ross* from cases “in which [the Ninth Circuit] determined that a state law had an impermissibly extraterritorial effect because it directly regulated transactions conducted entirely out of state”).

just as has always been the case. Because the Act here does exactly that, it is unconstitutional.

The district court’s contrary decision is plainly incorrect. The district court seemed to think that *Ross* overruled all of the Supreme Court’s (and this Court’s) prior direct-regulation caselaw. A9. *Ross* did no such thing. Quite the opposite: The Court reiterated in *Ross* that its prior cases such as *Baldwin* and *Healy* remain good law, but that they had never stood for the broad proposition the challengers in *Ross* pressed—*i.e.*, that any state law with *indirect* effects on out-of-state commerce is invalid. 598 U.S. at 374.

In fact, *Ross* expressly cited a case almost identical to this one as correctly understanding and applying its precedent. *See id.* (citing *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664, 669 (4th Cir. 2018), *cert. denied*, 586 U.S. 1145 (2019), as an example of the “[m]any lower courts [who] have read [*Baldwin* and *Healy*] in exactly the same way” as *Ross*). As explained further below, *Frosh* held unconstitutional a Maryland “price control statute” that (just like the Act here) prohibited “unconscionable” price increases of certain generic prescription drugs because that law directly regulated the “prices ... in transactions that

[did] not take place in Maryland.” *Frosh*, 887 F.3d at 672-73. The district court here agreed with Judge Wynn’s *dissent* in *Frosh*, A10, making it all the odder that it read a Supreme Court decision praising the *Frosh majority* as validating the *Frosh dissent*.

And there is more. Another line of Commerce Clause caselaw invalidates nondiscriminatory state legislation that is too burdensome on interstate commerce. (This is the so-called *Pike* balancing test, after *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970)). The district court’s narrow focus on discrimination (A7-A8) cannot be squared with the continued viability of the *Pike* balancing test. The Supreme Court explicitly considered in *Ross* whether to dispense with the *Pike* balancing test, and it just as explicitly concluded that it should not. The Court acknowledged that it has “left the ‘courtroom door open’ to challenges premised on ‘even nondiscriminatory burdens.’” *Ross*, 598 U.S. at 379 & n.2 (citation omitted). And Justices Sotomayor and Kagan, whose votes provided majority support for the disposition, noted the Court’s “acknowledge[ment]” of that point and concluded that a “failure to allege discrimination or an impact on the instrumentalities of commerce does not doom” a claim under the Commerce Clause. *Id.* at 392 (Sotomayor,

J., joined by Kagan, J., concurring in part). All told, a total of six Justices confirmed their agreement that discrimination is not required to state a claim under the Commerce Clause. *Accord id.* at 396 (Roberts, C.J., joined by Alito, Kavanaugh, and Jackson, JJ., concurring in part and dissenting in part); *id.* at 403 (Kavanaugh, J., concurring in part and dissenting in part). The district court acknowledged that *Pike* continues to invalidate nondiscriminatory laws, A11-12 & n.2, but did not explain how it could treat the extraterritoriality analysis as now beginning and ending with whether the Act “discriminate[s] on out-of-state interests.” A8.

* * *

In sum, nothing in *Ross* remotely suggests that a state may violate the fundamental principle prohibiting one state from “*directly* regulat[ing] out-of-state transactions by those with *no* connection to the State.” *Id.* at 376 n.1. But even if this Court were to conclude otherwise, the Supreme Court has repeatedly cautioned that even if one of its precedents is in tension with “some other line of decisions,” lower courts “should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions.” *E.g., Rodriguez de Quijas v.*

Shearson/Am. Express, Inc., 490 U.S. 477, 484 (1989). Indeed, at the same time he was working on the Court’s opinion in *Ross*, Justice Gorsuch was authoring a decision in another case reiterating exactly that point. *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 136 (2023) (plurality opinion of Gorsuch, J.) (explaining that “the Pennsylvania Supreme Court clearly erred” in declining to follow Supreme Court precedent on the theory that “intervening decisions from this Court had ‘implicitly overruled [that precedent]’”) (citation omitted). The district court did not “follow the case which directly controls” here.²¹

This error alone would be reason enough to reverse even if the district court were not wrong as an original matter. But the district court fundamentally misunderstood *Ross* and dormant Commerce Clause doctrine more generally. *Ross*’s careful distinction of the cases involving

²¹ The district court committed a like error in concluding that a 2018 Supreme Court decision that *did not mention* the prohibition on direct extraterritorial regulation “severely undercuts the doctrine’s continuing viability.” A11-12 (discussing *South Dakota v. Wayfair, Inc.*, 585 U.S. 162, 173 (2018)). In *Wayfair* the Court simply summarized “two *primary* principles” of Commerce Clause jurisprudence and explicitly did not catalog all the “exceptions and variations.” 585 U.S. at 173. That was no silent overruling. What the Court did overrule in *Wayfair*, it overruled explicitly. *See id.* at 188 (overruling a tax-specific principle not relevant here).

direct extraterritorial regulation—and its explicit praise of cases like *Frosh*—would make no sense if it were simultaneously overruling all of those cases. For this reason, no other court has (mis)read *Ross* to mean what the district court here read it to mean. *See infra* pp. 47-48.

3. Other Federal Courts Have Repeatedly Invalidated Price Controls like the Act, both Pre- And Post- *Ross*.

Other courts that have considered materially identical drug-pricing laws—both before and after *Ross*—have invalidated extraterritorial regulation of generic drug prices.

As mentioned, the Fourth Circuit invalidated a similar Maryland “price control statute that instruct[ed] manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland.” *Frosh*, 887 F.3d at 672. Like the Illinois Act here, the Maryland law there prohibited any “unconscionable increase in the price of a prescription drug” for certain generic “essential medicine[s].” *Id.* at 677. Also like the Illinois Act here, the Maryland law there applied only to drugs “made available for sale” in the state (there, Maryland). *Id.* at 674. The Fourth Circuit nonetheless held that the Maryland law violated the dormant Commerce Clause, because it was

not “limit[ed] ... to sales that actually occur[red] within Maryland.” *Id.* at 671. Instead, “if a drug from a transaction addressed to another state were later made available for sale in Maryland, the Act would permit Maryland to penalize the manufacturer.” *Id.* at 674. The Maryland law thus unconstitutionally sought “to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland.” *Id.* at 671-72.

Two years after the Supreme Court’s decision in *Ross*, the Eighth Circuit affirmed a preliminary injunction against a Minnesota law essentially identical to the Illinois Act here and the Maryland law in *Frosh. Ellison*, 140 F.4th 957. In trying to defend its law, Minnesota took the position that *Ross* interred the constitutional prohibition on state laws directly regulating out-of-state parties’ out-of-state transactions. The Eighth Circuit rejected that argument in no uncertain terms. “[T]he [*Ross*] Court,” the Eighth Circuit explained, “did not overturn its cases that applied the dormant Commerce Clause to invalidate statutes that have the specific impermissible extraterritorial effect of controlling prices.” *Id.* at 961. And, for good measure, the Eighth Circuit added that “discrimination is not required when a statute has the

specific extraterritorial effect of controlling the price of wholly out-of-state transactions.” *Id.* at 961.

Those two court of appeals decisions bearing AAM’s name do not stand alone. District courts have also held similar laws to be unconstitutional post-*Ross*. See, e.g., *Interlink Prods. Int’l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. 2023) (“[I]n clarifying that such laws with extraterritorial effects are not prohibited under the dormant Commerce Clause, the Supreme Court [in *Ross*] distinguished them from those in which ‘a law [] *directly* regulated out-of-state transactions” (citation omitted)); *Nat’l Shooting Sports Found. v. Bonta*, 718 F. Supp. 3d 1244, 1256 (S.D. Cal. 2024) (“*Ross* did not disturb the constitutional bar on state laws that ‘*directly* regulate[] out-of-state transactions by those with *no* connection to the State.” (citation omitted)). Indeed, notably, these two decisions came from district courts within the Ninth Circuit—the same circuit whose decision the Supreme Court affirmed in *Ross*—precisely because that circuit correctly understood that *Ross* did not implicate the rule against extraterritorial regulation. See note 20, *supra*.

4. **The Rule Against Direct Extraterritorial Regulation Is an Important Principle of Our Constitution’s System of Horizontal Federalism.**

From the Founding, the Commerce Clause been read in accordance with the constitutional structure that it helped to constitute. In *Gibbons v. Ogden*, Chief Justice Marshall, speaking for the Court, applied structural reasoning to elucidate several aspects of the Commerce Clause, including the federal government’s power to regulate “within the territorial jurisdiction” of each state and early identifications of the dormant aspect of the Commerce Clause. 22 U.S. 1, 196, 199-200 (1824).

Horizontal separation of powers is just as innate in a federation, which depends on the proper balance of power—not only between the central government and the sub-national states, but also among the sister states that make up the federation. That balance requires limits on the territorial bounds of each state’s regulatory power, “a feature of our constitutional order that allows ‘different communities’ to live ‘with different local standards.’” *Ross*, 598 U.S. at 375 (citation omitted). Such limits further democratic accountability, because the targets of extraterritorial regulation often have no way to oppose it through the democratic process. Ruth Mason & Michael S. Knoll, *Bounded*

Extraterritoriality, 122 Mich. L. Rev. 1623, 1636 (2024). The limits reflected in horizontal separation of powers also reduce regulatory overlap, which can overburden interstate commerce, and mitigate antagonism, rivalry, and reprisals between states. *Id.* at 1637; *Edgar*, 457 U.S. at 643; *Shaffer*, 433 U.S. at 197. The horizontal separation of powers thus safeguards a national marketplace by dampening interstate rivalries that undermine federal unity and disrupt the national marketplace.

The Supreme Court has long recognized that structural principle and identified it in both Commerce Clause cases and cases touching on other clauses of the Constitution. *See Ogden v. Saunders*, 25 U.S. 213, 358, 369 (1827) (Justice Johnson, “instructed by the majority of the Court finally to dispose of this cause,” holding that when “States pass beyond their own limits ... and act upon the rights of citizens of other States, there arises a conflict of sovereign power ... which renders the exercise of such a power incompatible with the rights of other States, and with the constitution of the United States.”); *Bonaparte*, 104 U.S. 592 (“No State can legislate except with reference to its own jurisdiction.”); *N.Y. Life Ins. Co. v. Head*, 234 U.S. 149, 161 (1914) (“[W]e think ... it

would be impossible to permit the statutes of Missouri to operate beyond the jurisdiction of that State and in the State of New York ... without throwing down the constitutional barriers by which all the States are restricted ... and upon the preservation of which the Government under the Constitution depends.”). This structural principle “is so obviously the necessary result of the Constitution that it has rarely been called in question.” *N.Y. Life*, 234 U.S. at 161.

Horizontal separation-of-powers concerns have a home in the Commerce Clause because they seek to safeguard the national marketplace, a crucial component of our federalism and a core reason why the Constitutional Convention adopted the Commerce Clause. *Mason & Knoll*, *supra*, at 1650. Thus, although there are reflections of horizontal separation-of-powers principles in other sections of the Constitution, in cases implicating the national market the Commerce Clause is the natural source of the limits on state power. *Mallory*, 600 U.S. at 154, 157 (Alito, J., concurring in part and concurring in the judgment). “[A]t this point in the Court’s history, no provision other than the Commerce Clause could easily do the job.” *Tenn. Wine & Spirits Retailers Ass’n v. Thomas*, 588 U.S. 504, 516 (2019); see *Mallory*, 600 U.S.

at 158 n.4 (Alito, J., concurring in part and concurring in the judgment).²² Nothing in the Supreme Court’s decisions suggests a willingness to abandon those limits.

B. The Act Is Unconstitutional Because It Directly Regulates Generic Drug Sales that Occur Entirely Outside the State.

The Act is unconstitutional for the same reason that the Fourth and Eighth Circuits have found similar laws unconstitutional: It regulates “commerce that takes place wholly outside [Illinois’] borders.” *Legato Vapors*, 847 F.3d at 830 (citation omitted). The Act’s price regulation applies even when a regulated drug is sold outside the state of Illinois, so long as the drug is “ultimately sold in Illinois” by anyone, not necessarily the manufacturer. Act § 10(a), (c). The Act explicitly states that it is not a defense that a manufacturer “did not *directly* sell a product to a consumer residing in Illinois.” *Id.* § 10(c) (emphasis added). As the district court recognized, AAM members outside of Illinois who sell their product to a large national wholesaler also outside of Illinois are subject

²² For that reason, although AAM also pleaded claims invoking the Due Process Clause and the horizontal separation of powers more broadly, A96-97, the Commerce Clause is the most straightforward basis on which to invalidate Illinois’s regulation of out-of-state commerce.

to the Act (and its crippling financial penalties) any time that someone down the lengthy drug supply chain—someone who was not a party to the initial transaction—sells the drug to a consumer in Illinois.

The mere fact of an in-state sale *down* the chain does not give Illinois the unfettered ability to impose price controls on out-of-state transactions *up* the chain. The fact that Illinois is attempting to regulate the nationwide market, not anything actually happening in Illinois, is clear from the structure of the statute. The only price that matters is the price charged by the manufacturer (and any further increase imposed by the wholesaler). The price charged *in Illinois* by the retailer does not matter; retailers are not even subject to the statute. Nor did Illinois try to do what California did in the law at issue in *Ross*—ban a product from sale within its borders based on aspects of its production out-of-state. It explicitly set out to regulate transactions involving manufacturers and wholesalers—and *only* those transactions, wherever they occur.

And where they occur is overwhelmingly out-of-state. Generic drug manufacturers are mostly based outside Illinois. So are the national wholesalers to which they sell their products. While some such transactions may take place in Illinois, AAM did not seek to enjoin any

such in-state transactions. What it sought was only an as-applied injunction, barring enforcement against *out-of-state* transactions. Thus, the district court's decision explicitly allows Illinois to regulate prices charged in other states. And because the Illinois market cannot be segregated from the rest of the nation, the nationwide generic price ceiling is now set in Springfield, Illinois.

II. The Remaining Preliminary Injunction Factors Weigh in Favor of Granting the Preliminary Injunction.

Not only does the likelihood-of-success factor weigh decisively in AAM's favor, but the irreparable-harm factor, the balance of the equities, and the public interest also favor granting AAM an injunction. As the district court correctly concluded, absent an injunction, AAM (through its members) will suffer irreparable economic harm for which there is no adequate remedy at law. A14. AAM will also suffer irreparable harm from the continued constitutional violation described *supra* Section I.B. The balance of the equities and the public interest also favor granting an injunction because of the Act's unconstitutionality and its negative impact on the availability of generic drugs to patients in Illinois.

A. Absent an Injunction, AAM Members Will Suffer Irreparable Harm.

1. The Act Will Cause Irreparable Economic Harm.

As the district court correctly found, AAM's members will suffer irreparable economic losses that they will not be able to recover absent an injunction. A13-14. Without a preliminary injunction in place, AAM's members must choose between violating the Act and facing draconian financial liability; withdrawing their products from the Illinois market and losing all associated revenue; or complying with an unconstitutional law and losing significant revenue as a result. A58-60 ¶¶ 21-27. The district court expressly acknowledged that AAM's members have forgone planned drug price increases due to the penalties they would face under the Act, resulting in "real business losses that must be taken into consideration." A14.

The district court correctly noted that these serious economic losses are irreparable. Illinois's sovereign immunity will prevent AAM's members from recovering any damages. *Id.*; *Gateway E. Ry. Co. v. Terminal R.R. Ass'n of St. Louis*, 35 F.3d 1134, 1140 (7th Cir. 1994). AAM has therefore established irreparable harm based on the unrecoverable

financial injury the Act has inflicted and continues to inflict on AAM's members.

2. The Act Unconstitutionally Regulates AAM's Members.

The Act subjects AAM's members to another form of irreparable harm through the continued unconstitutional regulation of AAM members. It is well-established that “the existence of a continuing constitutional violation constitutes proof of an irreparable harm and its remedy certainly would serve the public interest.” *Preston v. Thompson*, 589 F.2d 300, 303 n.3 (7th Cir. 1978). This principle applies to violations of the Commerce Clause. *See, e.g., Kendall-Jackson Winery, Ltd. v. Branson*, 82 F. Supp. 2d 844, 878 (N.D. Ill. 2000) (violation of the dormant Commerce Clause constitutes irreparable injury); *Ind. Fine Wines & Spirits, LLC v. Cook*, 459 F. Supp. 3d 1157, 1170 (S.D. Ind. 2020). And there is no adequate remedy at law for this constitutional harm for the same reason that there is no adequate remedy at law for the Act's economic harm: AAM's members cannot pursue compensatory damages against Illinois because of sovereign immunity. *Smith v. Wis. Dep't of Agric., Trade & Consumer Prot.*, 23 F.3d 1134, 1138 (7th Cir. 1994).

The district court erroneously dismissed the existence of this continuing constitutional harm based on its misreading of *Ross*, described *supra* Section I.A.2. Regardless, as the district court correctly found, AAM has carried its burden in establishing irreparable harm based solely on the significant economic harm its members will suffer as a result of the Act. A13-14.

B. The Balance of the Equities Supports an Injunction.

The irreparable harm that AAM's members will suffer as a result of the Act's economic and constitutional injuries significantly outweighs any harm that the Attorney General can claim from a preliminary injunction barring enforcement of an unconstitutional statute. The district court abused its discretion by holding otherwise.

Most plainly, the district court premised its balancing of the equities on the erroneous legal conclusion that AAM's likelihood of success on the merits is low. A14 ("Since AAM's likelihood of success on the merits is low, the balance of harms must weigh decisively in its favor to justify preliminary relief."). Because AAM has demonstrated that it is likely to succeed on its constitutional claim, Part I, *supra*, the district court's balancing of the equities rests on legal error.

The district court weighed AAM members' economic harms against the Attorney General's purported interest in enforcing the Act. A15. But, as established *supra* Section I.B., the Act impermissibly violates the dormant Commerce Clause, and "it is always in the public interest to prevent the violation of a party's constitutional rights." *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114, 1145 (10th Cir. 2013), *aff'd sub nom. Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014) (citation omitted).

Even setting aside AAM's likelihood of success on the merits, the district court improperly weighed the equities. The tremendous economic losses that AAM's members would suffer at the hands of the Act are harmful both to AAM's members who will lose revenue and the patients whose access to medications will be impacted. The generics industry has already exhibited "severe financial strain," causing some generic and biosimilar manufacturers to shutter entirely. *See Jewett, Drug Shortages, supra*. By preventing manufacturers from implementing price increases, the Act threatens to make certain products unprofitable. And if products become unprofitable enough, manufacturers may be

forced to withdraw their products from the market entirely. *See* A58 ¶ 17; A60 ¶¶ 25-27; A118 ¶¶ 28-29.

The resulting drug shortages have grave effects on patients and the public at large. By reducing the supply of affordable generic and biosimilar products, the Act also increases demand for these medications and drives their prices higher. This unintended effect undermines the Act's goal of increasing access to affordable medications, and is certainly not to the public's benefit. Based on these significant downstream effects on patients, the district court erred by concluding that public interest considerations were at a wash. A15.

The irreparable harm that AAM's members will suffer as a result of the Act's economic and constitutional injuries, together with the public's interest in avoiding the downstream effects of these harms on patient access to affordable medications, significantly outweighs any harm that Appellees can claim from a preliminary injunction. The district court abused its discretion by holding otherwise.

CONCLUSION

For the foregoing reasons, the district court's denial of AAM's motion for a preliminary injunction should be reversed.

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CERTIFICATE OF SERVICE

I hereby certify that on February 9, 2026, I electronically filed the foregoing OPENING BRIEF, ADDENDUM, AND REQUIRED SHORT APPENDIX OF PLAINTIFF-APPELLANT ASSOCIATION FOR ACCESSIBLE MEDICINES with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system

Dated: February 9, 2026

s/William M. Jay _____

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CIRCUIT RULE 30(d) STATEMENT

Pursuant to 7th Cir. R. 30(d), I hereby state that the following Required Short Appendix attached to the foregoing brief and the separately bound appendix contain all materials required by Rule 30(a) and Rule 30(b) of the Circuit Rules.

Dated: February 9, 2026

s/William M. Jay _____

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ADDENDUM

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Ill. Public Act 103-0367 (2023) (H.B. 3957), codified at 410 Ill. Comp. Stat. 725/1 <i>et seq.</i>	Add. 1

AN ACT concerning regulation.

**Be it enacted by the People of the State of Illinois,
represented in the General Assembly:**

Section 1. Short title. This Act may be cited as the Pharmaceutical and Health Affordability: Restrictions on Manufacturers' Amoral Behavior through Reasonable Oversight Act.

Section 2. Legislative Findings.

(a) The General Assembly finds that public reports by Congress and the news media have demonstrated the devastating impact that increasing drug prices can have on the 60% of Americans and 90% of seniors that take prescription drugs.

(b) The General Assembly further finds that public reports describe a repeated pattern and practice of price gouging by certain prescription drug manufacturers once they acquire the ownership rights for a new generic drug.

(c) The General Assembly further finds that price gouging has forced patients to choose between copayments exceeding tens of thousands of dollars per year and risking their health to find a more affordable drug.

(d) The General Assembly further finds that this choice has led patients to delay or forgo necessary medications creating greater health risks and complications.

(e) The General Assembly concludes that addressing accessibility of these life-saving medications is a matter of health, safety, and welfare for the People of the State of Illinois.

Section 5. Definitions. As used in this Act:

"Essential off-patent or generic drug" means any prescription drug sold within the State:

(1) for which all exclusive marketing rights, if any, granted under the Federal Food, Drug, and Cosmetic Act, Section 351 of the federal Public Health Service Act, 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 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.

"Essential off-patent or generic drug" includes any drug-device combination product used for the delivery of a drug for which all exclusive marketing rights, if any, granted under the Federal Food, Drug, and Cosmetic Act, Section 351 of

the federal Public Health Service Act, and federal patent law have expired.

"Manufacturer" has the meaning provided in Section 15 of the Wholesale Drug Distribution Licensing Act. "Manufacturer" does not include an entity operating as a wholesale drug distributor as defined in Section 15 of the Wholesale Drug Distribution Licensing Act.

"Price gouging" means an unconscionable increase in a prescription drug's 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) 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

(2) is otherwise excessive and unduly burdens consumers because of the importance of the essential off-patent or generic drug to their health and because of insufficient competition in the marketplace.

"Price gouging" does not include a price increase that can be reasonably justified by:

- (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

essential off-patent or generic drug to promote public health.

"State health plan" means the program of health benefits under the State Employees Group Insurance Act of 1971.

"Wholesale acquisition cost" has the meaning provided in 42 U.S.C. 1395w-3a.

"Wholesale drug distributor" has the meaning provided in Section 15 of the Wholesale Drug Distribution Licensing Act.

Section 10. Price gouging prohibited.

(a) A manufacturer or wholesale drug distributor shall not engage in price gouging in the sale of an essential off-patent or generic drug that is ultimately sold in Illinois.

It is not a violation of this Act for a wholesale distributor to increase the price of an essential off-patent or generic drug if the 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.

For the purpose of the enforcement of this Act, the Director of Healthcare and Family Services shall notify the Attorney General of any increase in the price of any essential off-patent or generic drug under the Medical Assistance Program under Section V of the Illinois Public Aid Code that amounts to price gouging.

(b) If the Attorney General has reason to believe that a

manufacturer or wholesale drug distributor of an essential off-patent or generic drug has violated this Act, then the Attorney General may send a notice to the manufacturer or the wholesale drug distributor requesting a statement:

(1) itemizing the components of the cost of producing the essential off-patent or generic drug;

(2) identifying the circumstances and timing of an increase in materials or manufacturing costs that caused an increase in the wholesale acquisition cost of the essential off-patent or generic drug within the 5-year period preceding the date of the price increase;

(3) identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the essential off-patent or generic drug and explaining any improvement in public health associated with those expenditures;

(4) identifying any communications with competitors of distributors about that drug and any price changes; the request for a statement shall serve as a litigation hold regarding documents and communications about that drug; and

(5) providing any other information that the manufacturer or wholesale drug distributor believes to be relevant to a determination of whether a violation of this Act has occurred.

Within 45 days after receipt of the request, the

manufacturer or wholesale drug distributor shall submit the statement to the Attorney General.

To accomplish the objectives and carry out the duties prescribed in this Act, the Attorney General may issue subpoenas or examine under oath any person to determine whether a manufacturer or wholesale drug distributor has violated this Act.

(c) Upon petition of the Attorney General, a circuit court may issue an order:

(1) compelling a manufacturer or a wholesale drug distributor:

(A) to provide a statement required under subsection (b); or

(B) to produce specific records or other documents requested by the Attorney General that may be relevant to a determination of whether a violation of this Act has occurred;

(2) restraining or enjoining a violation of this Act;

(3) restoring to any consumer, including a third-party payor, any money acquired as a result of a price increase that violates this Act;

(4) requiring a manufacturer or wholesale drug distributor that has engaged in price gouging in the sale of an essential off-patent or generic drug to make the drug available to participants in the State health plan or Medical Assistance Program under Section V of the Illinois

Public Aid Code for a period of up to one year at the price at which the drug was made available to participants in Illinois immediately before the violation of this Act;

(5) imposing a civil penalty of up to \$10,000 per day for each violation of this Act;

(6) providing for the Attorney General's recovery of costs and disbursements incurred in bringing an action against a manufacturer found to be in violation of this Act, including the costs of investigation and reasonable attorney's fees; or

(7) granting any other relief.

In response to any petition brought by the Attorney General under this Section, a manufacturer or wholesale drug distributor who is alleged to have violated this Act 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.

(d) Any financial information provided by a manufacturer or a wholesale drug distributor to the Attorney General in accordance with this Section may not be disclosed to the public by the Attorney General. The financial information, while in the possession of the Attorney General, shall be exempt from disclosure by the Attorney General under the Freedom of Information Act. Notwithstanding the other provisions of this subsection, if it appears to the Attorney General that a manufacturer or wholesale drug distributor has

engaged in or is engaging in any practice declared to be in violation of this Act and that legal proceedings would be in the public interest, then the Attorney General may disclose any financial information provided in accordance with this Section in support of the filing of an action in the circuit court.

Section 99. Effective date. This Act takes effect January 1, 2024.

REQUIRED SHORT APPENDIX

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CIRCUIT RULE 30(d) STATEMENT: Plaintiff-Appellant's Required Short Appendix and Separate Appendix include all the materials required by Circuit Rule 30(a) and (b).

Required Short Appendix – Pursuant to 7th Cir. R. 30(a)

Dkt.	Document	Page
85	Memorandum Opinion and Order Denying Plaintiff's Motion for a Preliminary Injunction, issued on September 26, 2025	A1

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

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

MEMORANDUM OPINION AND ORDER

Plaintiff, Association for Accessible Medicines (“AAM”), seeks to enjoin the Illinois Attorney General’s enforcement of House Bill 3957 (“the Act”) against its members based on out-of-state transactions claiming the Act violates the dormant Commerce Clause’s prohibition against extraterritorial state legislation. (Dkt. 51). For the below reasons, the Court denies AAM’s Motion for Preliminary Injunction [51].

BACKGROUND

AAM is the leading trade association representing generic and biosimilar drug manufacturers and distributors. (Dkt. 35 ¶ 14). Several states—Illinois included—have passed laws regulating the price of generics and biosimilars. These measures have largely been responsive to skyrocketing drug prices, sometimes by more than 1,000%, and sometimes overnight. (*See* Dkt. 58 at 6). The Illinois legislature’s solution is to regulate the “wholesale acquisition cost” of certain generic and biosimilar products that are eventually sold in-state. (*Id.* at 7). Specifically, the Act—which took effect on January 1, 2024—prohibits manufacturers and wholesale drug distributors from “engag[ing] in price gouging.” 410 Ill. Comp. Stat. 725/10(a). The Act defines price gouging as:

[A]n unconscionable increase in a prescription drug's 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) 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 (2) is otherwise excessive and unduly burdens 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. § 5. Excluded from the definition are “reasonably justified” price hikes stemming from increased production costs or costs incurred to expand access to a specific drug. *Id.* The Act directs the Attorney General to investigate possible instances of price gouging and further provides that Illinois courts may order generic manufacturers to cease sales that violate the Act, disgorge money acquired because of a price increase that violates the Act, and pay a civil penalty of up to \$10,000 per day for each violation of the Act. *See id.* § 10(c)(2), (3), (5).

In regulating the wholesale acquisition cost of these drugs, Illinois targets upstream sales rather than direct sales to Illinois consumers. This is largely a function of how the U.S. prescription drug industry is structured. Drug manufacturers rarely sell their products directly to patients; indeed, they rarely even sell to pharmacies. (Dkt. 52 at 3). Instead, manufacturers ordinarily “sell nationally, to wholesale distributors, who resell to pharmacies, who in turn resell to patients.” (Dkt. 52 at 3). The price of that first sale, from manufacturer to distributor, is the wholesale acquisition cost and “serves as a benchmark for the price of a specific drug.” (Dkt. 58 at 2).

Three companies control over 90% of the wholesale distribution market, and none of them are based in Illinois. (Dkt. 52 at 3). So, when an out-of-state generic manufacturer sells product X to a wholesale drug distributor, that transaction will almost always involve two non-resident entities and occur entirely outside of Illinois. But if the wholesaler sells product X to a pharmacy that, in turn, sells product X in Illinois, the Act can be enforced against the manufacturer based on

the price of the initial sale. *See* 410 Ill. Comp. Stat. 725/10(c) (“[A] manufacturer or wholesale drug distributor who is alleged to have violated this Act 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.”).

AAM claims the Act violates the dormant Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and the Constitution’s horizontal separation of powers. (Dkt. 35 ¶¶ 78–108). The Court granted the Attorney General’s first Motion to Dismiss because AAM failed to allege facts sufficient to confer standing and likewise failed to allege a credible threat of prosecution. (Dkt. 32). The Court subsequently found that AAM’s First Amended Complaint cured these deficiencies. (Dkt. 46). While AAM’s Complaint alleges six independent causes of action, the throughline is whether the Constitution permits Illinois to regulate the prices of wholly out-of-state sales. (Dkt. 46 at 5).

Now, in its renewed Motion for Preliminary Injunction, AAM asks the Court to enjoin the Act based on Count One of its Complaint, which alleges the Act violates the dormant Commerce Clause’s prohibition against extraterritorial state legislation. (*See* Dkt. 52 at 8; Dkt. 62 at 2). Touching on the remaining Counts in its Complaint, AAM suggests that other parts of the Constitution prohibit “direct state regulation of out-of-state transactions.” (Dkt. 52 at 8 n.15). But AAM does not advance any of those separate theories in its Motion for Preliminary Injunction—they are thus surrendered for the purposes of this motion. *See Cassell v. Snyders*, 990 F.3d 539, 551 (7th Cir. 2021); *see also Halgren v. City of Naperville*, 577 F. Supp. 3d 700, 726–27 (N.D. Ill. 2021).

DISCUSSION

“A preliminary injunction is ‘an exercise of a very far-reaching power, never to be indulged in except in a case clearly demanding it.’ ” *Finch v. Treto*, 82 F.4th 572, 578 (7th Cir. 2023) (quoting *Cassell*, 990 F.3d at 544). To obtain a preliminary injunction, the moving party must show that (1) it is reasonably likely to succeed on the merits; (2) no adequate remedy at law exists; and (3) it will suffer irreparable harm absent an injunction. *Speech First, Inc. v. Killeen*, 968 F.3d 628, 637 (7th Cir. 2020). If the moving party establishes these threshold requirements, the Court will balance the equities, “weighing the harm to the moving party if the requested injunction is denied against the harm to the nonmoving party and the public—including third parties—if it is granted.” *Finch*, 82 F.4th at 578; *see also Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Likelihood of success on the merits is often the decisive factor. *Braam v. Carr*, 37 F.4th 1269, 1272 (7th Cir. 2022).

I. Likelihood of Success on the Merits

AAM contends Illinois’s direct regulation of out-of-state commerce is plainly unconstitutional under the dormant Commerce Clause.

Congress has the power to “regulate Commerce . . . among the several states.” U.S. Const. art. I, § 8, cl. 3. But the Commerce Clause has long been understood to include a negative command, one that prohibits states from passing laws that “unduly restrict interstate commerce.” *Tenn. Wine & Spirits Retailers Ass’n v. Thomas*, 588 U.S. 504, 514 (2019). The dormant Commerce Clause’s existence is uncontroversial; its boundaries are not.

Two primary dormant Commerce Clause strands “guide the courts in adjudicating cases challenging state laws[.]” *South Dakota v. Wayfair*, 585 U.S. 162, 173 (2018). First, state laws may not “discriminate against interstate commerce.” *Id.* Second, state laws may not “impose undue

burdens on interstate commerce.” *Id.* The “antidiscrimination principle lies at the ‘very core’ of . . . dormant Commerce Clause jurisprudence.” *Nat’l Pork Prods. Council v. Ross*, 598 U.S. 356, 369 (2023) (quoting *Camps/Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 581 (1997)). It serves to ward off state laws and regulations that are designed to “benefit in-state economic interests by burdening out-of-state competitors.” *Dep’t of Rev. of Ky. v. Davis*, 553 U.S. 328, 338 (2008) (quoting *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273–74 (1988)). Laws that impose burdens on interstate commerce without facially discriminating against it, on the other hand, are subject to a more flexible test set forth in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). Under *Pike*, a facially neutral state law that serves a legitimate local interest may nonetheless violate the dormant Commerce Clause if the burden it imposes on out-of-state commerce is “clearly excessive in relation to the putative local benefit.” *Id.* at 142. AAM does not invoke either principle in its Motion for Preliminary Injunction. Instead, it argues the Act is unconstitutional under a third dormant Commerce Clause precept, one that prohibits “state laws that directly regulate out-of-state commerce.” (Dkt. 52 at 13).

Courts have referred to this third dormant Commerce Clause strand as the “extraterritoriality principle.” *See, e.g., Energy & Env’t Legal Inst. v. Epel*, 793 F.3d 1169, 1172 (10th Cir. 2015) (Gorsuch, J.) (referring to the “extraterritoriality principle” as the “least understood” and “most dormant” strand of commerce clause jurisprudence). It was featured most recently in a Supreme Court case involving a California law that prohibited the in-state sale of pork products if they came from pigs that were cruelly confined. *Ross*, 598 U.S. at 365–66. Out-of-state pork producers advanced an “almost *per se* rule forbidding enforcement of state laws that have the practical effect of controlling commerce outside the State, even when those laws do not purposely discriminate against out-of-state economic interests.” *Id.* at 371 (citation modified). The

Court unanimously rejected this “practical effects” argument and eventually upheld the California law regardless of its out-of-state consequences.¹ *Id.* at 371–76. This case, however, presents an inverse of *Ross*. Where the California law in *Ross* regulated in-state commerce based on upstream conduct, the Act regulates upstream commerce based on downstream effects. Accordingly, AAM contends the Act is unconstitutional before and after *Ross*—at least to the extent it applies to wholly out-of-state sales between non-residents of Illinois. (Dkt. 52 at 13–14). This basic premise has some force. Indeed, the *Ross* majority was careful not to “trivialize the role territory and sovereign boundaries play in our federal system” and emphasized the need for courts to “referee disputes about where one State’s authority ends and another’s begins.” *Ross*, 598 U.S. at 378. But AAM’s reliance on dormant Commerce Clause extraterritoriality presents several complex issues.

One key to AAM’s argument is the Supreme Court’s plurality opinion in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982). There, four justices signed onto the proposition that the dormant Commerce Clause prohibits a state from directly regulating transactions that take place “wholly outside the State.” *Edgar*, 457 U.S. at 641–43. The *Ross* majority stopped short of recognizing this theory as a continuing strand of dormant Commerce Clause jurisprudence. Instead it elided *Edgar* considering the California law only targeted in-state sales. *See Ross*, 598 U.S. at 376 n.1. But the majority simultaneously noted that commentators have questioned whether the state law at issue in *Edgar* “posed a dormant Commerce Clause question as much as one testing the territorial limits of state authority under the Constitution’s horizontal separation of powers.” *Id.* In other words, *Ross* does not squarely address whether the dormant Commerce Clause itself prohibits a state from regulating out-of-state transactions based on their downstream consequences. *See Bradley W. Joondeph, The “Horizontal Separation of Powers” After National Pork Producers Council v. Ross*,

¹ The more fractured portion of the Court’s decision in *Ross* focused on the continuing viability, force, and scope of *Pike* balancing, but that analysis is irrelevant to the extraterritoriality challenge AAM raises in this case.

61 San Diego L. Rev. 45, 78–79 (2024) (noting *Ross* “glided past” issues concerning “the substantive content of the Constitution’s prohibition on extraterritorial state legislation”).

While *Ross* did not answer the precise question this case presents, it offered a robust discussion on three cases that have long been linked to the extraterritoriality principle. Those cases—*Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573 (1986); and *Healy v. Beer Instit.*, 491 U.S. 324 (1989)—all involved state price control or price affirmation laws that the Court held violated the dormant Commerce Clause. *Baldwin* struck down a New York price control law barring out-of-state producers from selling milk in New York unless they charged the minimum price guaranteed to in-state producers. *See Baldwin*, 294 U.S. at 519–22. *Brown-Forman* and *Healy* involved laws that required out-of-state distillers and brewers to affirm their in-state prices were no higher than out-of-state prices. *See Brown-Forman*, 476 U.S. at 576–78; *Healy*, 491 U.S. at 326–29. The pork producers in *Ross* relied on language from all three opinions that suggested, in isolation, the Court decided the *Baldwin-Healy* cases on the grounds that the state laws they addressed impermissibly controlled commerce occurring wholly beyond each state’s boundaries. *Ross*, 598 U.S. at 373. But the *Ross* Court unanimously agreed that the petitioners’ “read too much into too little” from the *Baldwin-Healy* cases. *Ross*, 598 U.S. at 373. Instead, the Court clarified that these cases did not prohibit extraterritorial legislation writ large, but only legislation with a “*specific* impermissible extraterritorial effect” tracing directly back to the antidiscrimination principle. *Id.* at 374. Indeed, a closer examination of the cases reveals three laws that were plainly designed either to protect an in-state industry (*Baldwin*) or to hoard commerce for in-state merchants (*Brown-Forman* and *Healy*). *See id.* at 372–73.

The problem this poses for AAM is that the Act does not discriminate on out-of-state interests. It regulates the price of drugs sold in Illinois, without regard for where they are manufactured. (Dkt. 58 at 11). And the Act in no way favors Illinois corporations or manufacturers, or discourages consumers from engaging with merchants across state lines. Without a protectionist tilt, the *Baldwin–Healy* cases are of virtually no use to AAM in its attack on the Act under the dormant Commerce Clause. As far as Supreme Court cases go, that leaves AAM to rely entirely on the *Edgar* plurality—and perhaps the footnote in *Ross* discussing it—for the proposition that the dormant Commerce Clause prohibits nondiscriminatory state laws that directly regulate out-of-state commerce. Against this murky backdrop, AAM contends that two Seventh Circuit cases relying on the extraterritoriality principle control the outcome.

Read in a vacuum, the Seventh Circuit’s decisions in *Legato Vapors v. Cook*, 847 F.3d 825 (7th Cir. 2017) and *Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660 (7th Cir. 2010), certainly support AAM’s position. In *Legato Vapors*, the court struck down an Indiana law that imposed significant regulatory burdens on out-of-state e-cigarette liquid manufacturers and distributors. *Legato Vapors*, 847 F.3d 827–28. The court reasoned the law was unconstitutional for the sole reason that it governed transactions that “occur[ed] entirely outside the regulating state.” *Id.* at 836. This was so despite “obvious concerns about [the law’s] protectionist purposes.” *Id.* at 833. The court declined to rest its decision on the antidiscrimination principle because, in its view, the law was clearly unconstitutional extraterritorial legislation. *Id.* *Legato Vapors* followed *Midwest Title*, which struck down another Indiana law that regulated out-of-state title companies making loans to Indiana residents. *Midwest Title*, 593 F.3d at 664–68. There again, the court found the state statute ran afoul of the dormant Commerce Clause, not because of any discriminatory

purpose, but because Indiana was attempting to directly “regulate activities in other states.” *Id.* at 665.

Before *Ross*, *Legato Vapors* and *Midwest Title* would probably control this Court’s likelihood of success on the merits analysis. But both cases heavily relied on *Baldwin* and its progeny to support one major legal proposition: that, protectionism aside, the dormant Commerce Clause prohibits the direct regulation of wholly out-of-state commerce. *See Legato Vapors*, 847 F.3d at 829–30; *Midwest Title*, 593 F.3d at 665–66. After *Ross*, this conception of the *Baldwin–Healy* cases is no longer accurate, and casts doubt the court’s conclusions in both cases.

Nonetheless, AAM points to a handful of nearly identical state laws that courts have struck down both pre- and post-*Ross* as violating the dormant Commerce Clause. *See, e.g., Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018); *Ass’n for Accessible Meds. v. Ellison*, 140 F.4th 957 (8th Cir. 2025); *Ass’n for Accessible Meds. v. Bonta*, 766 F. Supp. 3d 1020 (E.D. Cal. 2025). The Court has carefully considered these out-of-circuit cases and finds their reasoning unpersuasive. By way of example, the Eighth Circuit’s decision in *Ellison* upheld an injunction on a similar Minnesota law regulating generic drug pricing. *Ellison*, 140 F.4th at 961. It reasoned that, under *Ross*, *Baldwin*, and *Healy*, the Minnesota law had the “specific impermissible extraterritorial effect of controlling the price of wholly out-of-state transactions” and that, under these circumstances, no showing of discrimination or protectionism was required. *Id.* at 961. This is a misreading of *Ross*. *See N.J. Staffing Alliance v. Fais*, 110 F.4th 201, 207 (3d Cir. 2024) (“[T]he dormant Commerce Clause does not prohibit laws solely because they have extraterritorial reach absent protectionist intent or effect.”); *Ass’n des Eleveurs de Canards et d’Oies du Quebec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013) (finding *Healy* and *Baldwin* only applicable to protectionist price control and price affirmation statutes). The “specific impermissible

extraterritorial effect” *Ross* observed of the state laws at issue in the *Baldwin–Healy* cases was that each “deliberately prevented out-of-state firms from undertaking competitive pricing or deprived businesses and consumers in other States of whatever competitive advantages they may possess.” *Ross*, 598 U.S. at 374 (quoting *Healy*, 491 U.S. at 338–39) (citation modified). In other words, they were discriminatory and protectionist. Thus, the *Ellison* court’s conclusion that the Minnesota law was unconstitutional simply because it impacted the price of out-of-state transactions again “reads too much” into the *Baldwin–Healy* cases. *Id.* at 373.

Judge Wynn’s dissent from the Fourth Circuit’s pre-*Ross* majority opinion in *Frosh* is further illustrative of this point. The majority in *Frosh* struck down a materially similar Maryland law regulating generic drug prices and, in doing so, read *Baldwin* and *Healy* broadly to stand for the proposition that “the extraterritoriality principle is violated” whenever a state law regulates the price of an out-of-state transaction. *Frosh*, 887 F.3d at 670. This is the very reading of the *Baldwin–Healy* cases that the Supreme Court rejected in *Ross*. Anticipating that decision, Judge Wynn noted in dissent that the *Baldwin–Healy* cases could not be reduced to forbidding the regulation of out-of-state transactions, but rather turned on “the principle concerns animating the Supreme Court’s dormant Commerce Clause jurisprudence: economic protectionism, discrimination against interstate commerce, and State regulation of a stream of transactions that never crosses through the State’s borders.” *Id.* at 684 (Wynn, J., dissenting). Like *Legato Vapors* and *Midwest Title*, *Frosh* was decided based on a conception of the dormant Commerce Clause that the Supreme Court has now rejected.

One final question demands an answer: does the *Edgar* plurality alone provide enough support for AAM’s position? There are several reasons why this Court believes the answer is “no.” First, the language in *Edgar* on which AAM relies did not “draw support from a majority of the

Court,” and the Seventh Circuit has declined to follow it, even in in situations where “th[e] language, if controlling, would mean victory” for the plaintiff. *See Alliant Energy Corp. v. Bie*, 330 F.3d 904, 916 (7th Cir. 2003);² *see also CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 81 (1987) (“As the plurality opinion in *MITE* did not represent the views of a majority of the Court, we are not bound by its reasoning.”). Second, this Court disagrees with AAM’s suggestion that *Ross* somehow endorsed or preserved the extraterritoriality principle as conceptualized in *Edgar*. To the contrary, the lone footnote in *Ross* discussing *Edgar* distinguished the cases on their facts and went on to cast doubt on whether the state law in *Edgar* posed a dormant Commerce Clause issue at all, or if it instead implicated horizontal separation of powers more broadly. *Ross*, 598 U.S. at 376 n.1. This view of *Edgar* and the extraterritoriality principle has long been percolating among scholars studying the penumbra surrounding the dormant Commerce Clause. *See* Donald H. Regan, *Siamese Essays: (I) CTS Corp. v. Dynamics Corp. of America and Dormant Commerce Clause Doctrine; (II) Extraterritorial State Legislation*, 85 Mich. L. Rev. 1865, 1884–97, 1904 (1987); Joondeph, *supra*, at 49, 62–70. Finally, the modern Supreme Court cases discussing the dormant Commerce Clause frame the inquiry as a two-principle approach. Plaintiffs can either challenge a state law because it (1) “discriminate[s] against interstate commerce” or (2) “impose[s] an undue burden on interstate commerce” and flunks *Pike* balancing. *Wayfair*, 585 U.S. at 173; *see also Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 160 (2023) (Alito, J., concurring in part and concurring in the judgment) (“Under our modern framework, a state law may offend the Commerce Clause’s negative restrictions in two circumstances: when the law discriminates against

² The Seventh Circuit’s opinion upon rehearing in *Bie* does not increase AAM’s likelihood of success on the merits. If anything, that opinion reinforces this Court’s conclusion that, after *Ross*, the appropriate analysis for any dormant Commerce Clause case involves only two theories: the antidiscrimination principle and *Pike* balancing. *See Alliant Energy Corp. v. Bie*, 336 F.3d 545, 547 (7th Cir. 2003) (concluding a “two-tiered test” applies to all dormant Commerce Clause challenges, including challenges to extraterritorial regulations).

interstate commerce or when it imposes ‘undue burdens’ on interstate commerce.”). The Supreme Court’s omission of extraterritoriality from the discussion severely undercuts the doctrine’s continuing viability.

While the Court is not persuaded by AAM’s extraterritoriality argument under the dormant Commerce Clause, the Act may well be unconstitutional for some other reason. For example, it may fail *Pike* balancing, violate the Due Process Clause, or run afoul of horizontal separation of powers. *See Frosh*, 887 F.3d at 681 (Wynn, J., dissenting) (noting the “the availability of potentially more appropriate constitutional provisions, like the Due Process Clause, to ensure that States do not unduly extend their regulatory authority beyond their borders”). AAM raises these arguments in separate counts of its Complaint, but did not present them in support of its Motion for Preliminary Injunction. Thus, they will have to be addressed on another day. *Cf. Epel*, 793 F.3d at 1172 (“[W]hether Colorado’s law survives the *Pike* or *Philadelphia* tests may be interesting questions, but they are ones that will have to await resolution[.]”).

In summary, the Court finds that that AAM has failed to make a “strong showing” of its likelihood of success on the merits. *Bevis v. City of Naperville, Ill.*, 85 F.4th 1175, 1188 (7th Cir. 2023) (citation modified). This alone counsels against the entry of a preliminary injunction. *See Doe v. Univ. of S. Ind.*, 43 F.4th 784, 791 (7th Cir. 2022) (noting likelihood of success on the merits is “often decisive,” eliminating the need to address the remaining elements). Nonetheless, the Court addresses the remaining preliminary injunction factors briefly below.

II. Irreparable Harm

In its Order denying the Attorney General’s second motion to dismiss, this Court addressed many of the relevant facts pertaining to the harm AAM and its members face. (*See* Dkt. 46 at 3–4). At this stage, AAM must show that harm is “irreparable”—i.e., “legal remedies are inadequate

to cure it.” *Life Spine, Inc. v. Aegis Spine, Inc.*, 8 F.4th 531, 545 (7th Cir. 2021). AAM offers two theories on irreparable harm: (1) the existence of a “continuing constitutional violation” and (2) unrecoverable economic losses. (Dkt. 52 at 16–17). Having failed to advance a theory that persuasively demonstrates the Act’s constitutional infirmity, AAM’s first theory is insufficient to establish irreparable harm. AAM has, however, demonstrated more than a mere possibility of irreparable economic harm.

Rodney Emerson, the Vice President of Pricing and Contracts for Sandoz, Inc. (“Sandoz”), one of AAM’s members, submitted a declaration describing the company’s decision to forego specific drug price increases it had planned for calendar year 2024 because of the “significant penalties and other monetary liability” it could face under the Act. (*See* Dkt. 54 ¶¶ 15–17). This foregone revenue, Emerson avers, presents a real risk to Sandoz’s business and could force the company to withdraw certain “generic or biosimilar products it currently sells nationwide.” (*Id.* ¶ 29). Sandoz attributes its previously planned price increases for one of its products to a variety of factors, some tied to increased production costs and expanding access to the drug, and others driven by “overall profit margins . . . and provid[ing] a greater return on investment for [Sandoz] shareholders.” (*Id.* ¶ 18). AAM’s members have further demonstrated that they face a credible threat of prosecution based on the existence of the Act alone. (*See* Dkt. 46 at 3–4); *Bell v. Keating*, 697 F.3d 445, 451 (7th Cir. 2012) (“The existence of the statute constitutes the government’s commitment to prosecute in accordance with it and, thus, a concrete prospect of future harm for one who would flout it.”).

The Court harbors some skepticism about the true scope of harm AAM’s members face considering the Act excludes from the definition of price gouging “reasonably justified” price increases tied to “an increase in the cost of producing the essential off-patent or generic drug” or

“appropriate expansion of access” to the drug. 410 Ill. Comp. Stat. 725/5. While Emerson suggests that there are several factors relevant to Sandoz’s price increases that fall outside of these categories, AAM has not offered any legal argument as to why, for example, “regulatory approval costs” or “inflation” would not be excludable production costs. (Dkt. 54 ¶ 18). Nonetheless, there are certain categories of price increases that certainly do fall outside these categories—like driving shareholder value. In any event, the money AAM’s members are losing right now by way of foregone price increases represent real business losses that must be taken into consideration. And while economic losses alone are ordinarily insufficient to demonstrate irreparable harm, they may be enough to justify injunctive relief when a post-merits damage remedy would be inadequate. *Gateway E. Ry. Co. v. Terminal R.R. Ass’n of St. Louis*, 35 F.3d 1134, 1140 (7th Cir. 1994). That is the case here, because AAM’s members will not be able to recover economic losses sustained during the pendency of this litigation if they eventually prevail on the merits due to sovereign immunity. *See Staffing Servs. Ass’n of Illinois v. Flanagan*, 720 F. Supp. 3d 627, 641 (N.D. Ill. 2024).

Considering the costs of complying with the Act, the possible penalties for violating the Act, and detrimental business positions AAM’s members have already taken in response to the Act, coupled with sovereign immunity, the Court finds that AAM has carried its burden in establishing irreparable harm.

III. Balance of the Equities

Finally, the Court considers the balance of the equities and public interest. Since AAM’s likelihood of success on the merits is low, the balance of harms must weigh decisively in its favor to justify preliminary relief. *Valencia v. City of Springfield*, 883 F.3d 959, 966 (7th Cir. 2018). It does not. *See NetChoice, LLC v. Fitch*, 2025 WL 2350189, at *1 (U.S. Aug. 14, 2025) (Kavanaugh,

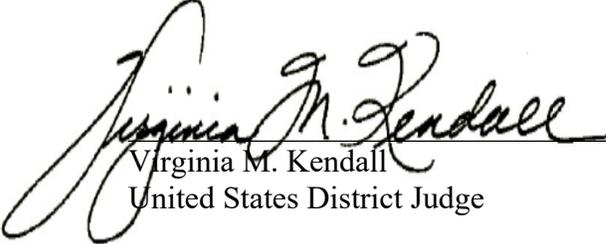
J., concurring) (explaining a plaintiff must “sufficiently demonstrate[] that the balance of harms and equities favor it” in justifying interim relief, even if it has shown a likelihood that the state law at issue is unconstitutional).

AAM’s members face real harm because of the Act. It will undoubtedly burden their bottom lines, may force them to make challenging business decision, and could result in significant unrecoverable penalties. But it should go without saying that a state law’s impact on corporate profits alone will never be enough to enjoin that law. This is especially true when compared to the Attorney General’s strong interest in enforcing a statute that was duly enacted by the representatives of the people of Illinois. *See Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (“[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.”). Thus, absent a colorable constitutional violation, the balance of harms favors the Attorney General. Both parties make compelling arguments on the competing public interest considerations. Ballooning drug prices are a significant concern for Illinoisans of all stripes, but especially for the most vulnerable among us. The Attorney General has emphasized the public’s interest in having affordable access to generic and biosimilar drugs and argues the Act is specifically designed to protect that access. (*See* Dkt. 58 at 7–9). AAM posits the Act is harmful to the interest it is ostensibly designed to protect because it may force generic manufacturers out of the market all together and “exacerbate the drug-shortage problem.” (Dkt. 52 at 20). At best for AAM, the public interest considerations are a wash at this early stage of the litigation. And a wash is not enough considering AAM’s low

likelihood of success on the merits, the competing harms, and the extraordinary form of relief AAM seeks.

CONCLUSION

For the reasons set forth above, Plaintiffs' Motion for Preliminary Injunction [51] is denied.


Virginia M. Kendall
United States District Judge

Date: September 26, 2025