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

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff,

v.

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

Defendant.

Case No. 1:24-cv-00544

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Constitutional and Statutory Provisions:

Other Authorities:

INTRODUCTION

The Association for Accessible Medicines ("AAM") is dedicated to making medicine more affordable. AAM's members make generic and biosimilar medications, which lower prices by introducing competitive alternatives to brand-name drugs. Yet despite the generic industry's commitment to providing access to affordable medications, the State of Illinois has targeted generic and biosimilar manufacturers—but *not* the brand-name drugmakers—with a new price-control statute. *See* Pub. L. No. 103-0367, 410 Ill. Comp. Stat. Ann. §§ 725/1-725/99 (2023) ("the Act") (attached hereto). The new law threatens massive penalties for selling many generics and biosimilars, anywhere in the country, if Illinois thinks the price is too high. By regulating transactions that occur entirely outside Illinois, the Act violates the U.S. Constitution. Every court that has considered similar state price-control legislation has held it unconstitutional; AAM won decisions against materially identical drug-pricing laws in both Maryland and Minnesota. *See Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019); *Ass'n for Accessible Meds. v. Ellison*, No. 23-cv-2024, 2023 WL 8374586 (D. Minn. Dec. 4, 2023), *appeal docketed*, No. 24-1019 (8th Cir. Jan. 3, 2024). In its most recent Commerce Clause decision, *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), the Supreme Court reaffirmed "that a state may not directly regulate transactions that take place wholly outside the state." *Ellison*, 2023 WL 8374586, at *3; *see Ross*, 598 U.S. at 376 n.1 (reiterating that a state law that "*directly* regulate[s] out-of-state transactions by those with *no* connection to the State" exceeds "the territorial limits of state authority under the Constitution[]"). This Court should apply that precedent and enjoin this unconstitutional law.

"When a state directly regulates interstate commerce, it 'exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature.'" *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 830 (7th Cir. 2017)

(citation omitted). Here, the legislature has not only directly but *expressly* regulated prices in transactions outside Illinois, such as between AAM's non-Illinois members and the non-Illinois wholesalers that buy their products. The Act specifically sweeps in sales that are not directly made to anyone in Illinois. That is unconstitutional.

The remaining preliminary-injunction factors support granting AAM's motion. If not enjoined, the Act will irreparably injure AAM's members by depriving them of their constitutional rights and by causing them severe economic losses—and neither injury can be remedied through an action for damages against the State. By contrast, Illinois will not be injured if prohibited from enforcing an unconstitutional law. Enjoining the law also will serve the public interest: generic and biosimilar medications are enormously beneficial to the healthcare system—making lifesaving medicines available to more patients while saving hundreds of billions of dollars annually. Yet the Illinois law targets *only* generic and biosimilar manufacturers, exempting brand-name drugs from price regulation even though they cost exponentially more. The Act's price control and draconian penalties threaten generic and biosimilar manufacturers' ability to market their products—especially given the thin profit margins for a number of generic and biosimilar products. In the end, the Act will only exacerbate the already severe drug-shortage problem plaguing the U.S. healthcare system.

The Court should enjoin enforcement of the Act against AAM's members based on their out-of-state transactions, pending litigation of this case on the merits.

STATEMENT OF FACTS

I. The Importance Of Generic And Biosimilar Medicines

AAM is the leading trade association for generic and biosimilar medicines, which play a critical role in controlling healthcare costs. *See* U.S. Dep't of Health & Hum. Servs., *ASPE Issue*

Brief: Understanding Recent Trends in Generic Drug Prices, 1 (Jan. 27, 2016).[1] Through vigorous competition, generic and biosimilar products "offer[] relief from rising prescription drug costs" by "driv[ing] prices for generic drugs to be a fraction of that of the corresponding brand name drug." *Id*. As a result, generic and biosimilar medicines account for 90% of all prescriptions dispensed in the United States, but only 17.5% of the money spent on prescriptions. Ass'n for Accessible Meds., The U.S. Generic & Biosimilar Medicines Savings Report 7-8, 10 (Sept. 2023).[2] Over the last decade, generic and biosimilar medicines have produced nearly $2.9 trillion in savings for the U.S. healthcare system, with $408 billion in 2022 alone, *id*. at 7-8; they saved Illinois $15.3 billion that year, *id*. at 16.

Drug manufacturers typically do not sell their medicines directly to patients. Rather, they generally sell nationally, to wholesale distributors, who resell to pharmacies, who in turn resell to patients. *See* Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp., 4-5 (2021).[3] Three companies—Cencora, Cardinal Health, and McKesson, none based in Illinois—control over 90% of the wholesale distribution market.[4] These sales (*i.e.*, wholesale sales from generic or biosimilar manufacturers to one of the big wholesalers) overwhelmingly occur outside Illinois. *E.g.*, Declaration of Timothy de Gavre ("de Gavre Decl.") ¶¶ 4-7.

Wholesale prices are set not on a state-by-state or drug-by-drug basis, but typically in pre-

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

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

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

[4] Adam J. Fein, PhD., *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, Drug Channels (Oct. 2, 2019), https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html.

negotiated—frequently long-term—bulk contracts covering a range of products for resale nationwide. de Gavre Decl. ¶¶ 5-6, 18. Manufacturers do not control the prices at which wholesalers or retailers resell their drugs, nor where those drugs are resold. *Id*. ¶¶ 4, 21.

Generic and biosimilar manufacturers face significant "barriers … to both enter and remain in the market." Comm. on Homeland Sec. & Governmental Affairs, U.S. Senate, *Short Supply: The Health and National Security Risks of Drug Shortages*, 13 (Mar. 2023).[5] Manufacturers typically "face intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns." U.S. Food & Drug Admin., Drug Shortages: Root Causes and Potential Solutions, 22 (Feb. 21, 2020)[6]; *see* de Gavre Decl. ¶ 24. At the same time, the cost to manufacture generics and biosimilars has risen sharply, which has driven up prices. For example, "[m]ost generic drug manufacturers rely on other companies to produce" the ingredients "for the drugs they produce," Mariana P. Socal, et al., Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients, 42 Health Affairs 407, 407 (Mar. 2023),[7] and the "raw material prices for essential drugs" have continued to rise sharply, by as much as 140% in the post-COVID era, Active Pharmaceutical Ingredients Market Size, Report 2023 to 2032, Precedence Research (Jan. 2023).[8] Moreover, manufacturers of biosimilars and some off-patent drugs[9] must spend considerable sums on clinical or other studies

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

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

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

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

[9] Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2), creates a streamlined pathway for approval of a drug meant to build on an existing drug that has already received FDA approval—such as by creating a new dosage form for that brand drug. Because 505(b)(2) drugs, unlike typical generic drugs, are not identical copies of a brand-name drug, they do not benefit from state laws that require or allow pharmacists to substitute a generic drug for a

to obtain FDA approval, to market their drugs once approved, and to provide patient support or outreach services; each of these costs affects prices. de Gavre Decl. ¶ 23. Combined, these factors have forced products out of the market and resulted in supply shortages that are "approaching record levels" and reducing patient access to lifesaving medicines. Christina Jewett, *Drug Shortages Near an All-Time High, Leading to Rationing*, N.Y. Times, May 17, 2023.[10]

Drug shortages are particularly harmful when they occur in the supply of an essential medication. Both the World Health Organization and the U.S. Department of Health and Human Services have published lists of "essential medicines" deemed necessary to meet priority health care needs, *see* World Health Organization, *The Selection and Use of Essential Medicines 2023: World Health Organization Model List of Essential Medicines – 23rd list* (2023)[11], and to protect society from outbreaks of infectious diseases and other threats, *see* U.S. Food & Drug. Admin., Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs (May 23, 2022).[12]

II. Illinois' New Price-Control Law

The Act took effect January 1, 2024. Act § 99, 410 Ill. Comp. Stat. Ann. § 725/99. The Act prohibits "manufacturer[s]," as well as "wholesale drug distributor[s]," from "engag[ing] in price gouging in the sale of an essential off-patent or generic drug that is ultimately sold in Illinois." *Id.* § 10(a), 410 Ill. Comp. Stat. Ann. § 725/10(a).[13] "Price gouging" combines a rigid formula

---

prescribed brand-name drug. Thus, manufacturers of 505(b)(2) drugs must expend additional resources to market these products.

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

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

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

[13] The Act defines "[e]ssential off-patent or generic drug" to encompass "any prescription drug sold within the State" (1) for which any "exclusive marketing rights" under the federal patent laws

with a nebulous consideration of other factors. Specifically, "[p]rice gouging" is defined as a price increase that: (1) would result in the wholesale acquisition cost ("WAC")[14] for a "30-day supply" of the drug 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's prohibition is not limited to prices charged in Illinois. Although the law's prohibition is *triggered* when a drug is "ultimately sold in Illinois," Act § 10(a), the Act regulates the *upstream* sales of essential medicines that occur entirely outside Illinois. Indeed, the Act expressly provides 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).

The Attorney General may demand price-related information from manufacturers and may sue to enforce the Act. Act § 10. An Illinois court may order a manufacturer to relinquish "any money acquired as a result of a price increase" deemed unlawful, *and* impose a "civil penalty of

---

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." Act § 5, 410 Ill. Comp. Stat. Ann. § 725/5.

[14] 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 month for which the information is available." 42 U.S.C. § 1395w-3a(c)(6)(B); *see* Act § 5 (incorporating federal definition).

up to $10,000 per day for each violation," *and* "restrain[] or enjoin[]" the manufacturer from charging prices that violate the Act. *Id.* § 10(c)(2), (3), (5).

STANDING

Some AAM members intend to make, or but for the Act would make, competitively reasonable price adjustments that satisfy the Act's definition of "price gouging," in transactions entirely outside Illinois, for one or more products that satisfy the Act's definition of "essential off-patent or generic drug." *See* de Gavre Decl. ¶¶ 8-17; Compl. ¶¶ 37-45. The prices charged for those products by AAM's members will become subject to the Act as a result of those products being resold into Illinois by third parties. *See* de Gavre Decl. ¶¶ 4-8, 17; Compl. ¶ 41. The Act therefore is causing AAM members injury-in-fact, which an injunction would redress. *See Ezell v. City of Chicago*, 651 F.3d 684, 695, 696 (7th Cir. 2011). This case is germane to AAM's mission, *e.g.*, *Frosh*, 887 F.3d at 667, and does not require participation of AAM's members, as AAM seeks only equitable relief. Accordingly, AAM has associational standing to bring this lawsuit. *See, e.g.*, *Prairie Rivers Network v. Dynegy Midwest Generation, LLC*, 2 F.4th 1002, 1008 (7th Cir. 2021).

ARGUMENT

A party seeking a preliminary injunction must demonstrate "(1) some likelihood of succeeding on the merits, and (2) that it has 'no adequate remedy at law' and will suffer 'irreparable harm' if preliminary relief is denied"; the Court also considers (3) "the irreparable harm the non-moving party will suffer if preliminary relief is granted, balancing that harm against the irreparable harm to the moving party if relief is denied," and (4) "the public interest, meaning the consequences of granting or denying the injunction to non-parties." *Int'l Ass'n of Fire Fighters, Loc. 365 v. City of E. Chicago*, 56 F.4th 437, 446 (7th Cir. 2022) (citation omitted). The Court analyzes these factors on a sliding scale: "the more likely the plaintiff will succeed on the merits, the less the balance of irreparable harms need favor the plaintiff's position." *Ty, Inc. v. Jones Grp.,*

Inc., 237 F.3d 891, 895 (7th Cir. 2001).

All the relevant factors weigh decisively in favor of granting a preliminary injunction here.

I. AAM Is Likely To Succeed On Its Claims That The Act's Direct Regulation Of Out-Of-State Transactions Is Unconstitutional.

AAM is likely to succeed on its claims that the Act violates the Constitution, including the Commerce Clause,[15] by directly regulating prices charged in transactions wholly outside of Illinois. Courts addressing materially similar state legislation have repeatedly held such laws unconstitutional. This Court should do the same.

A. The Commerce Clause Prohibits States From Directly Regulating Transactions That Occur Wholly Out Of State.

The "dormant" Commerce Clause refers to the rule that the power to regulate interstate commerce is primarily for the national government, not states. State laws may have an incidental effect on interstate commerce, but a state law that "directly regulates" commerce that "takes place wholly outside of the State's borders…. 'exceeds the inherent limits of the enacting State's authority and is invalid." *Legato Vapors*, 847 F.3d at 830 (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)). Accordingly, states may not "force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another," *Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 665 (7th Cir. 2010) (citation omitted), and, in particular, may not "project [their] legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there," *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). This constraint follows from the "inherent limits [on] the State's power" under the Constitution—"any attempt

[15] The constitutional prohibition against direct state regulation of out-of-state transactions is not limited to the Commerce Clause but is also inherent in the Constitution's structure and implicit in its other provisions. *See Ross*, 598 U.S. at 376 n.1; *id.* at 404, 408-10 (Kavanaugh, J., concurring in part and dissenting in part); *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 154 (2023) (Alito, J., concurring in part and concurring in the judgment); *see also* Compl. ¶¶ 8, 59-64.

directly to assert extraterritorial jurisdiction over persons or property would offend sister States" and therefore "must be held invalid." *Edgar v. MITE Corp.*, 457 U.S. 624, 643 (1982) (plurality opinion) (citation and quotation marks omitted); *accord* *Davis v. Farmers Co-operative Equity Co.*, 262 U.S. 312, 314-17 (1923) (holding that Minnesota law requiring out-of-state companies to submit to suit involving a "transaction [that] was in no way connected with Minnesota" violated the Commerce Clause).

In the more than 150 years of dormant Commerce Clause jurisprudence, "the Supreme Court has never held that a state may impose truly direct and burdensome state regulation of commerce beyond the state's boundaries." *Legato Vapors*, 847 F.3d at 829. Rather, "the 'Commerce Clause precludes the application of a state statute 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) (alteration omitted); *accord* *Baldwin*, 294 U.S. at 521; *Brown-Forman Distiller Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578 (1986).

A plurality of the Supreme Court applied this prohibition in *Edgar* to invalidate an Illinois law regulating tender offers that would have "prevent[ed]" the defendant company from "concluding interstate transactions … with those living in other States and having no connection with Illinois." 457 U.S. at 642-43 (plurality opinion). The plurality concluded that the Illinois statute "must be held invalid" because it "directly" regulated "commerce wholly outside the State." *Id.*; *accord* *Ross*, 598 U.S. at 376 n.1 (recognizing that *Edgar* "spoke to a law that *directly* regulated out-of-state transactions by those with *no* connection to the State"); *Healy*, 491 U.S. at 333 n.9 (characterizing the *Edgar* plurality opinion as "significantly illuminat[ing] the contours of the constitutional prohibition on extraterritorial legislation").

The Seventh Circuit has likewise repeatedly applied the Commerce Clause's prohibition

on state laws directly regulating out-of-state transactions. In *Midwest Title Loans, Inc. v. Mills*, the court invalidated an Indiana law that regulated "the making of title loans" to residents of Indiana, even loans made entirely outside Indiana. 593 F.3d at 662, 666, 669. The Seventh Circuit reiterated that "[t]he Commerce Clause dictates that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another." *Id.* at 665 (citation omitted). Indiana therefore could not apply its law where "contract[s] w[ere] … made and executed in Illinois. *Id.* at 669. As the court explained, "to allow Indiana to apply its law against title loans when its residents transact in a different state … would be arbitrarily to exalt the public policy of one state over that of another." *Id.* at 667-68.

Similarly, in *Legato Vapors*, the Seventh Circuit applied the prohibition on direct extraterritorial regulation to invalidate another Indiana law—this one regulating sales of e-cigarettes. That law directly regulated "sales by an out-of-state manufacturer to an out-of-state distributor" or "out-of-state online retailer" if the distributor or online retailer then "re[sold] the e-liquids to Indiana retailers." 847 F.3d at 836. The court held that these were "impermissible extraterritorial regulation[s]," because the covered sales "occur[red] entirely outside the regulating state." *Id.*; *see also, e.g.*, *Nat'l Solid Wastes Mgmt. Ass'n v. Meyer*, 63 F.3d 652, 655, 658-61 (7th Cir. 1995) (holding that a Wisconsin law requiring out-of-state entities to "adhere to the Wisconsin [recycling] standards whether or not they dump their waste in Wisconsin" violated the Commerce Clause because it "controls the conduct of those engaged in commerce occurring wholly outside the State of Wisconsin and therefore directly regulates interstate commerce").[16]

[16] *Accord* *Alliant Energy Corp. v. Bie*, 336 F.3d 545, 547, 548 (7th Cir. 2003) (stating that "there is no question" that a "direct … regulation" of out-of-state commerce "is *per se* invalid"); *Dean Foods Co. v. Brancel*, 187 F.3d 609, 611-12, 615-20 (7th Cir. 1999) (invalidating Wisconsin law prohibiting the payment of volume premiums by a dairy producer to wholesalers that occurred entirely outside Wisconsin and recognizing the "long line of cases holding that states violate the

B. Courts Have Applied The Rule Against Direct Extraterritorial Regulation To Invalidate State Price Control Laws.

Courts have consistently applied the Commerce Clause's prohibition on state laws directly regulating wholly out-of-state transactions to invalidate materially similar interstate restrictions on prescription-drug prices, including in AAM's successful challenges to nearly identical laws passed by Maryland and Minnesota. Like the Illinois law, the Maryland law at issue in *Frosh* prohibited "price gouging"—defined as an "unconscionable increase in the price of a prescription drug"—in the sale of "essential off-patent or generic drug[s]" that were "made available for sale in [Maryland]." 887 F.3d at 666 (citations omitted). The Fourth Circuit held the law unconstitutional because it regulated "conduct that occur[red] entirely outside Maryland's borders" and controlled the "prices … in transactions that [did] not take place in Maryland." *Id.* at 670-72. Although the law applied only to drugs "made available for sale" in Maryland (by anyone)—just like the Illinois law's application to essential medicines "ultimately sold in Illinois," Act § 10(a)—the Maryland law did not "limit [its] application to sales that actually occur[red] within Maryland, nor [did] it restrict [its] operation to the context of a resale transaction with a Maryland consumer." 887 F.3d at 671. Thus, the Maryland law sought "to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland." *Id.* at 672. "This," the Fourth Circuit held, Maryland "cannot do." *Id.*

The District of Minnesota followed the same reasoning to enjoin a Minnesota law that closely resembles the Illinois law, prohibiting any generic or biosimilar manufacturer from "impos[ing], or caus[ing] to be imposed, an excessive price increase, whether directly or through

---

Commerce Clause by regulating or controlling commerce occurring wholly outside their own borders"); *K-S Pharmacies, Inc. v. Am. Home Prods. Corp.*, 962 F.2d 728, 730-31 (7th Cir. 1992) (interpreting Wisconsin drug price discrimination statute "to apply to sales within Wisconsin" in part because "States lack any … power to reach outside their borders").

a [third party], on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in [Minnesota]." *Ellison*, 2023 WL 8374586, at *1 (quoting Minn. Stat. Ann. § 62J.842, subd. 1). Like the Illinois law, which regulates out-of-state prices of essential medicines solely because they are "ultimately sold in Illinois," Act § 10(a), the Minnesota law "target[ed] … the upstream pricing and sale of prescription drugs," by imposing liability on out-of-state manufacturers for wholly out-of-state sales simply because "somehow, someday, in some way, someone who is *not* a party to the transaction … sell[s], dispense[s], or deliver[s] the drug to a[] consumer in Minnesota." 2023 WL 8374586, at *4, *5 (citation omitted). The court held the Minnesota law was likely unconstitutional for the same reasons articulated by *Frosh*: "the dormant Commerce Clause prohibits states from regulating out-of-state transactions," and "[j]ust as in *Frosh*, the [Minnesota law] 'effectively s[ought] to compel manufacturers … to act in accordance with [Minnesota] law outside of [Minnesota]," *id.* at *2, *5 (quoting *Frosh*, 887 F.3d at 672) (first alteration added). As the court recognized, there is no "support for the notion that the dormant Commerce Clause permits [a state] to directly regulate a sale that occurs in another state simply because the product eventually makes its way into [that state]." *Id.* at *3.[17]

C. *Ross* Confirms That States May Not Directly Regulate Prices In Out-Of-State Transactions.

The Supreme Court's decision in *Ross* confirms this settled precedent holding that state laws that *directly* regulate wholly out-of-state transactions are unconstitutional.

The California law at issue in *Ross* did not *directly* regulate any out-of-state conduct, but instead prohibited only "the *in-state* sale of whole pork meat" from any pig that had been housed

[17] These are only a few of the many decisions invalidating state laws under the Commerce Clause that directly regulated out-of-state transactions. *See, e.g.*, *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1321-24 (9th Cir. 2015) (en banc); *Styczinski v. Arnold*, 46 F.4th 907, 913 (8th Cir. 2022); *Am. Beverage Ass'n v. Snyder*, 735 F.3d 362, 366-76 (6th Cir. 2013).

under conditions deemed cruel. 598 U.S. at 365 (emphasis added). Unsurprisingly, the plaintiffs did not attempt to premise their Commerce Clause claim on a "direct-regulation" theory, either: they argued that the law violated the Commerce Clause *per se*, because the law had "the '*practical effect* of controlling commerce outside [California].'" *Id*. at 371 (emphasis added).

The Supreme Court rejected the "practical effects" argument, but in doing so did not disturb the distinct prohibition against state laws that *directly* regulate out-of-state commerce. Indeed, the Court expressly distinguished the California law from the Illinois tender-offer law invalidated in *Edgar*, reasoning that the Illinois law (unlike the California law) "*directly* regulated out-of-state transactions." 598 U.S. at 376 n.1; *see also Interlink Prods. Int'l, Inc. v. Crowfoot*, --- F. Supp. 3d ---, 2023 WL 4187496, at *4 (E.D. Cal. June 26, 2023) ("[I]n clarifying that 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). As the court in *Ellison* concluded, "[*Ross*] did not change the rule that a state may not directly regulate transactions that take place wholly outside the state and have no connection to it." 2023 WL 8374586, at *3; *see also id*. at *5 (distinguishing *Ross* because the Minnesota law "directly regulates upstream sales that take place wholly outside Minnesota," whereas *Ross* addressed a law that "regulates in-state actors who engage in in-state conduct"). In fact, *Ross* approvingly cited the Fourth Circuit's decision in *Frosh*, which invalidated a law nearly identical to the Act because it directly regulated out-of-state drug prices. 598 U.S. at 374.

Ross thus confirms what settled precedent from the Supreme Court, the Seventh Circuit, and other federal courts have made crystal clear: under the Commerce Clause and the Constitution's "horizontal separation of powers," 598 U.S. at 376 n.1, laws that directly regulate

wholly out-of-state transactions are invalid.

D. The Act Is Unconstitutional Because It Directly Regulates Prices Charged In Transactions Entirely Outside Illinois.

The Act "directly regulates interstate commerce" that "takes place[] wholly outside the State's borders" and is therefore "invalid." *Legato Vapors*, 847 F.3d at 830 (citation omitted). Its price regulation applies wherever a regulated drug is sold, so long as the drug is "ultimately sold in Illinois" by *someone*—not just the manufacturer. Act § 10(a), (c). The Act leaves no doubt on this point: "a manufacturer … *may not* assert as a defense that the manufacturer … did not *directly* sell a product to a consumer residing in Illinois." *Id.* § 10(c) (emphasis added). Thus, when AAM's members *outside* Illinois sell generics or biosimilars to the dominant national wholesalers, who are also located *outside* Illinois and take title to the medicines *outside* Illinois, they become subject to the Act, even though the manufacturers do not control whether their products end up being resold in Illinois in separate transactions between third parties. *See* p. 4, *supra.* The Act thus regulates the prices manufacturers charge in transactions with *no* Illinois connection.

Illinois is not the first state to try to regulate the prices charged for prescription drugs in out-of-state transactions. As discussed above, AAM won decisions in the Fourth Circuit and the District of Minnesota against laws that sought to regulate the prices charged in wholly out-of-state transactions. *See* pp. 11-12, *supra* (discussing *Frosh* and *Ellison*). Consistent with these decisions, every other court that has considered such price-control laws has found them unconstitutional.

For instance, in *Pharmaceutical Research & Manufacturers of America v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005), *aff'd sub nom., Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007), the court enjoined a District of Columbia law prohibiting sales "that result[] in [a] prescription drug being sold in the District for an excessive price." *Id.* at 60 (citation omitted). The court held that the District law impermissibly "regulate[d]

transactions that occur[red] wholly out of state" because the "plaintiffs' members s[old] 'the overwhelming bulk' of their … drugs in out-of-state transactions to wholesalers or large retail chains." *Id.* at 68, 70. The fact that the law's penalties were triggered by the drug's eventual resale in the District—just like the Illinois law's requirement that the medicine be "ultimately sold in Illinois"—made no constitutional difference, because "as soon as that drug [wa]s sold in the District, the manufacturer's out-of-state sale bec[a]me[] the [law's] primary target." *Id.* at 69.

The same fate befell a Maine law prohibiting drug manufacturers (all "located outside the State of Maine") from "exact[ing] or demand[ing] an unconscionable price" or "exact[ing] or demand[ing] prices or terms that lead to any unjust or unreasonable profit." *Pharm. Rsch. & Mfrs. of Am. v. Comm'r, Maine Dep't of Hum. Servs.*, 2000 WL 34290605, at *2 (D. Me. Oct. 26, 2000) (citation omitted), *rev'd on other grounds sub nom., Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001). The court found the law unconstitutional because it attempted to regulate prices in wholly out-of-state transactions. *Id.*

So too with a New York law that imposed an opioid-related fee on pharmaceutical manufacturers and others and prohibited them from "passing through" any portion of it to their customers. *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 246 (S.D.N.Y. 2018), *rev'd in part on other grounds sub nom. Ass'n for Accessible Meds. v. James*, 974 F.3d 216 (2d Cir. 2020). The court held that the statute "violate[d] the Commerce Clause's prohibition on extraterritorial state legislation," because its bar on "pass-through" charges was not limited to New York transactions. *Id.* at 261-62.

The Act violates the Constitution for the same reasons as these other laws: by its terms, the Act applies Illinois law "to commerce that takes place wholly outside [Illinois'] borders." *Legato Vapors*, 847 F.3d at 830 (citation omitted). Therefore, it "must be held invalid." *Edgar*,

457 U.S. at 643 (plurality opinion).

II. AAM's Members Have No Adequate Remedy At Law And Will Suffer Irreparable Harm Absent An Injunction.

Without a preliminary injunction, AAM members will suffer irreparable harm while this case is litigated for which they have no adequate remedy at law. *See H-D, U.S.A., LLC v. P'ships & Unincorporated Ass'ns Identified on Schedule "A"*, 2021 WL 4459472, at *3 (N.D. Ill. Sept. 24, 2021) ("The irreparable harm and adequate remedy factors tend to merge" and courts often "consider them together"). First, AAM's members will be irreparably injured by the imposition of unconstitutional regulation. Second, they will incur unrecoverable monetary losses—a classic form of irreparable injury.

A. The Act Subjects AAM's Members To Unconstitutional Regulation.

The Act subjects AAM's members to unconstitutional regulation, which is an irreparable injury with no remedy at law. *See Preston v. Thompson*, 589 F.2d 300, 303 n.3 (7th Cir. 1978) ("The existence of a continuing constitutional violation constitutes proof of an irreparable harm").

This Court, and other courts within the Seventh Circuit, have repeatedly held that a violation of constitutional rights, including "under … the dormant Commerce Clause[,] … constitutes irreparable injury." *Kendall-Jackson Winery, Ltd. v. Branson*, 82 F. Supp. 2d 844, 878 (N.D. Ill. 2000) (collecting cases); *see also Ind. Fine Wine & Spirits, LLC v. Cook*, 459 F. Supp. 3d 1157, 1170 (S.D. Ind. 2020) (principle that "a continuing constitutional violation constitutes proof of an irreparable harm … applies to violations of the Commerce Clause") (citation omitted).

Moreover, there is "no adequate remedy at law" for these constitutional harms, "because [AAM's members] cannot pursue compensatory damages against [Defendant] because of sovereign immunity." *Ind. Fine Wine & Spirits*, 459 F. Supp. 3d at 1170; *accord Kendall-Jackson Winery*, 82 F. Supp. 2d at 878 (same).

B. The Act Will Cause Irreparable Economic Harm.

The Act will also cause AAM's members to suffer significant economic losses they will not be able to recoup if AAM prevails in this lawsuit. They face a no-win scenario: AAM's members must either violate the law and face significant financial liability, including the loss of revenue plus penalties; comply with an unconstitutional law and lose substantial revenues, potentially rendering their products no longer economically viable; or attempt to withdraw their products from the Illinois market, again losing revenue and potentially not even escaping the law's reach. de Gavre Decl. ¶¶ 21-27.

As with constitutional violations, financial or economic losses are irreparable when they are unrecoverable after successful litigation—which is the case here, where Illinois' sovereign immunity will prevent any recovery. *See* *Tranchita v. Callahan*, 511 F. Supp. 3d 850, 881 (N.D. Ill. 2021) (party lacked adequate remedy to collect damages in light of sovereign immunity); *Ind. Fine Wine & Spirits*, 459 F. Supp. 3d at 1170 (monetary harm irreparable where "state defendants have immunity from compensatory damages in federal court"); *NA Main St. LLC v. Cook*, 508 F. Supp. 3d 320, 331-32 (S.D. Ill. 2020) (similar); *Methodist Hosps. Inc. v. Ind. Fam. & Soc. Servs. Admin.*, 860 F. Supp. 1309, 1318-19 (N.D. Ind. 1994) (holding that loss of income was irreparable injury where "Plaintiffs do not have [] an adequate remedy at law in this Court because the Eleventh Amendment bars federal courts from awarding retrospective money judgments against the states"); *accord* *Ellison*, 2023 WL 8374586, at *6 ("There is no dispute that the financial injuries that [AAM's] members will suffer as a result of foregoing the intended price increases are not recoverable from the State or anyone else. These members are therefore facing a threat of irreparable harm.").

Complying with the Act's unconstitutional price control will reduce AAM members' revenues, resulting in significant financial loss. de Gavre Decl. ¶¶ 17, 22-25. That is a particular

danger where price increases are necessary to recover costs not directly caused by production, such as clinical studies, marketing, or patient outreach or support services. *Id.* ¶¶ 23-25. Barring the necessary price increases on such products could mean not just less profit, but no profit at all. Those manufacturers sometimes operate on thin profit margins and are often unable to both absorb such increased costs and maintain existing prices while also remaining profitable. *Id.* ¶¶ 25-26. AAM members will also incur separate costs in complying with the Act's mandatory notice-and-reporting regime—none of which will be recoverable. *Id.* ¶ 24.

AAM's members would also suffer unrecoverable financial injury if they were to try to avoid these economic losses. A manufacturer that managed to withdraw a product from the Illinois market would suffer the resulting loss of revenues from sales of that product. de Gavre Decl. ¶¶ 17, 26. And a manufacturer that keeps its product on the market and raises prices despite the Act, including to preserve product profitability (and, therefore, viability), faces a dual threat: any additional revenue would be subject to disgorgement, *and* the company would expose itself to crippling civil penalties—up to $10,000 per day for every sale. *See id.* ¶¶ 16, 27; *see* p. 7, *supra*.

The Act thus makes unrecoverable economic loss a certainty. de Gavre Decl. ¶ 27. AAM's members must either comply with its unconstitutional command and lose revenue, or violate the Act and suffer massive, financial penalties. Such unrecoverable economic loss is quintessential irreparable harm. *See* p. 17, *supra*. That harm is only exacerbated by the Act's nationwide reach, forcing AAM's members to make this choice on a national scale, as there is no way to comply with the Act without changing practices out of state. de Gavre Decl. ¶¶ 4-7, 21; *see also* pp. 3-4, *supra*. This type of no-win scenario is the paradigm of irreparable harm. *See* *Am. Trucking Ass'ns, Inc. v. City of L.A.*, 559 F.3d 1046, 1058 (9th Cir. 2009) (finding irreparable harm from regulatory agreements because plaintiff could either "refuse to sign" and suffer "a loss of customer goodwill"

or "sign[]" and be subject to "conditions which are likely unconstitutional" and "incur large costs"); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (finding irreparable injury where plaintiffs faced "choice" to either "continually violate the [challenged] law and expose themselves to potentially huge liability, or violate the law once as a test case and suffer the injury of obeying the law during the pendency of the proceedings and any further review").

III. The Balance Of Hardships And Public Interest Support An Injunction.

The balance of hardships and public interest also favor an injunction.

The irreparable harm to AAM's members far outweighs any harm the Attorney General can claim from a preliminary injunction. "It is always in the public interest to prevent the violation of a party's constitutional rights." *Mitchell v. Baker*, 2015 WL 278852, at *7 (S.D. Ill. Jan. 21, 2015) (alterations and citation omitted); *see also Ellison*, 2023 WL 8374586, at *7 (same). Conversely, a "State has no interest in enforcing laws that are unconstitutional … and an injunction preventing the State from enforcing the challenged statute does not irreparably harm the State." *Pavek v. Simon*, 467 F. Supp. 3d 718, 762 (D. Minn. 2020) (alterations and citation omitted).

In addition, a preliminary injunction would serve the public interest by preventing the damaging consequences the Act will inflict on patients and the market for generics and biosimilars. The generic industry is currently undergoing "severe financial strain," with some generic and biosimilar manufacturers shutting down completely, *see* Jewett, *Drug Shortages*, *supra*. As a result, "drug shortages in the United States" have "approach[ed] record levels," *id.*, producing "devastating consequences for patients and healthcare providers," Comm. on Homeland Sec. & Governmental Affairs, *Short Supply*, *supra*, at 5.

The Act's draconian penalties will only exacerbate the drug-shortage problem. By forbidding price increases on the rarest of essential medicines, including those price increases necessary to keep certain products profitable, and threatening generic and biosimilar

manufacturers with severe civil penalties for making other reasonable price adjustments, the Act will place increasing pressure on generic and biosimilar manufacturers to withdraw their products from the market entirely. *See* de Gavre Decl. ¶¶ 17, 25-27. And that outcome is all the more likely because the Act expressly targets those medicines produced by the *fewest* number of manufacturers. *See* note 13, *supra*. So in the end, the Illinois law's price control will not only reduce the supply of affordable generic alternatives, but also increase demand for those medicines that competed with the discontinued generics or biosimilars—driving prices for those medicines even higher. Ultimately, the Act will only make generics and biosimilars *less* available to patients in Illinois, directly undermining the Act's goal of increasing access to affordable medications.

CONCLUSION

The Court should grant AAM's motion for a preliminary injunction.

February 2, 2024

Respectfully submitted,

s/ Andrianna D. Kastanek

Andrianna D. Kastanek
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654
(312) 840-7285
akastanek@jenner.com

William M. Jay
Benjamin Hayes
GOODWIN PROCTER LLP
1900 N Street, NW
Washington, DC 20036
(202) 346-4000
wjay@goodwinlaw.com
bhayes@goodwinlaw.com

Counsel for Plaintiff