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

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

DEFENDANT'S COMBINED MEMORANDUM IN SUPPORT OF HIS MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

Date: March 8, 2024

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INTRODUCTION

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

In January 2024, the Association for Accessible Medicines ("AAM") brought suit on behalf of its manufacturer and distributor members seeking complete invalidation of the Act. Dkt. 1 ("Compl."). AAM's sweeping pre-enforcement complaint, however, alleges no imminent injury-in-fact to any of its members and presents claims based solely on speculation, as opposed to concrete disputes. AAM also seeks facial invalidation of the Act, notwithstanding its apparent recognition of constitutional applications of the Act. Accordingly, the complaint should be dismissed for lack of Article III standing and ripeness. At the very least, the Court should deny AAM's request for preliminary injunctive relief, which it seeks solely on the basis of a dormant

Commerce Clause theory that was recently rejected by the Supreme Court in *National Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023). Furthermore, AAM's assertions that its members will suffer financial harm absent an injunction does not constitute irreparable harm, and the equities here weigh heavily in favor of the State.

BACKGROUND

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

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

Although the wholesale acquisition cost serves as a benchmark for the price of a specific drug, manufacturers often ultimately sell the drug to distributors at prices reached through negotiations with the entire supply chain, including distributors and pharmacies.[5] In these negotiations, distributors may leverage, for example, their ability to drive market share or sales

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

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

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

[4] *Id.* at 4.

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

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

Manufacturers and distributors, moreover, typically have a number of contacts with Illinois and the other States where their products are sold. For starters, some manufacturers (as AAM recognizes), as well as many distributors (by virtue of the nature of their business), sell products directly into Illinois. Compl. ¶¶ 28, 40; Dkt. 20 ¶ 4.[9] And, subject to certain exceptions, entities that distribute generic drugs to pharmacies in Illinois—whether they be manufacturers or distributors—must obtain a license under the Wholesale Drug Distribution Licensing Act, 225 ILCS 120 *et seq*. Licensure in Illinois obligates distributors to, for example, consent to search by pharmacy inspectors, *id.* 120/50, and develop an electronic system to track and trace drugs through the distribution process, *id.* 120/57.

Furthermore, manufacturers know, or have the technology to easily find out, whether their products are ultimately sold in any given State, including Illinois. *E.g.*, Dkt. 20 ¶ 4. Starting in 2015, the United States Drug Supply Chain Security Act has required manufacturers to apply increasingly specific product identifiers to certain prescription drugs and trace product information

[6] *Id.* at 18.

[7] *Id.* at 19.

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

[9] *Id.* at 16.

including name, strength and dosage, size and number of containers, lot number, transaction date, shipment date, and shipment address.[10] Pub. L. 113-54, 127 Stat. 599; 21 U.S.C. §360eee(26), §360eee-1(b)(1). The FDA characterizes the legislation as a way to "build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States."[11] Manufacturers like AAM member Sandoz have invested in developing electronically tagged medicines to automate restocking in hospitals.[12] In other words, Sandoz believes it has the technology to know the *exact quantity* of medication available at a given hospital, and the ability to automatically ship medication to that hospital when it runs low.

And even before passage of the legislation, manufacturers were fully aware, or capable of being fully aware, of where many of their drugs ended up. For instance, manufacturers that seek coverage from state Medicaid programs must offer rebates to those programs.[13] Outside of Medicaid, manufacturers regularly offer rebates to pharmacies who are able to direct consumers to certain products.[14] In short, this continued monitoring of the supply chain, which already occurs as a matter of course for pharmaceutical manufacturers, shows that manufacturers do not wash their hands of the product after selling drugs to a distributor.

B. Industry members engage in price gouging.

Sixty percent of Americans, and 90% of seniors, take prescription drugs. 410 ILCS 725/2(a). Approximately 90% of these prescriptions are filled with generic, as opposed to brand

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

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

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

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

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

name, drugs.[15] In the ordinary course, generic drugs save Americans a substantial amount of money on medication.[16] Indeed, when there is genuine competition in the generic-drug marketplace, generic drugs are typically 80–85% less expensive than brand-name drugs.[17]

In recent years, however, some industry members have implemented "extraordinary price increases" for generic drugs.[18] A Senate subcommittee examining this issue noted that between 2010 and 2015, a time period when generic drug prices declined overall, 48 generic drugs were hiked in price by more than 500% in a single year.[19] These actions are not justified by legitimate business needs. On the contrary, reports have shown that these price increases are motivated by efforts to extract maximum value from inelastic consumer markets where there is a lack of genuine competition. For instance, the drug Seromycin has been on the market since 1964, has no generic competitors, is the only drug that treats multi-drug resistant tuberculosis, and has a very small market of hundreds of cases per year.[20] Nevertheless, in 2015, Rodelis Therapeutics raised the price of Seromycin from $500 to $10,800 for 30 capsules—an increase of 2,060% overnight.[21] Other recent examples include Martin Shkreli's infamous decision to raise the price of the anti-

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

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

[17] *Id.*

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

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

[20] *Id.* at 6, 72–84.

[21] *Id.* at 6.

parasitic medication Daraprim from $13.50 to $750 per tablet.[22] Similarly, the manufacturer of Tetracycline, a general antibiotic, recently raised prices by more than 17,000% in a single year.[23]

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

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

C. The General Assembly regulates price gouging.

In response to these abuses, the legislature enacted a law to protect Illinois residents from price gouging of generic drugs. *See* Ill. Pub. Act 103-367 (eff. Jan 1, 2024). As the legislature explained, there was a "repeated pattern and practice of price gouging by certain prescription drug manufacturers," which has led patients to choose between "copayments exceeding tens of

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

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

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

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

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

thousands of dollars per year and risking their health." 410 ILCS 725/2(b)–(c). And "this choice has led patients to delay or forgo necessary medications creating greater health risks and complications." *Id.* 725/2(d). Accordingly, it concluded that a legislative response to this crisis was "a matter of health, safety, and welfare for the People of the State of Illinois." *Id.* 725/2(e).

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

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

> An unconscionable increase in price that:
>
> (1) would result in the wholesale acquisition cost of a 30 day supply of the essential off-patent or generic drug exceeding $20 and would

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

[28] Chih-Cheng Hsu, Cheng-Hua Lee, Mark L. Wahlqvist et al., *Poverty Increases Type 2 Diabetes Incidence and Inequality of Care Despite Universal Health Coverage*, Diabetes Care (Oct 2012), https://bit.ly/3Ih7Y3v; Peter Hotez, *Hookworm and Poverty*, Ann. NY Acad. Sci. (Oct. 2007), https://bit.ly/3wJVBu0; Cameron Scott, *Study Attributes 60-70% of Excess Heart Disease Among Low-Income Americans to Poverty Rather Than Traditional Risk Factors*, UCSF Department of Epidemiology & Biostatistics (May 2020), https://bit.ly/48Bcpko.

> result in an increase in the wholesale acquisition cost of the essential off-patent or generic drug of:
>
> (A) 50% or more within the preceding year;
> (B) 50% of more within the preceding 3 years; or
> (C) 75% or more within the preceding 5 years;

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

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

Consistent with the legislature's goal of restricting only undue price increases, the Act is enforced through an iterative process that provides substantial opportunity for manufacturers and distributors to demonstrate that their price increases were due to legitimate business expenses, do not unduly burden consumers, and are not otherwise excessive. Under the Act, the Illinois Department of Healthcare and Family Services is tasked with monitoring the price of generic drugs that are covered by the Illinois Medicaid program. *Id.* 725/10(a). If the Department discovers a price increase that may be covered by the Act, it notifies the Attorney General. *Id.* If the Attorney

General "has reason to believe" that a manufacturer or distributor has violated the Act, he may send a notice requesting a statement containing information about the price increase, including the components of the cost of producing the drug; the circumstances and timing of an increase in materials, manufacturing costs, or expenditures made to expand access; any communications with competitors; and any other information the manufacturer or distributor deems relevant. *Id.* 725/10(b). Upon receipt of the statement, the Attorney General may exercise his discretion to investigate the price increase, and if necessary, petition a court for remedial action. *Id.* 725/10(c).

D. AAM files suit in federal court.

On January 22, 2024, AAM filed this action seeking to invalidate the Act in its entirety, alleging that it violates the dormant Commerce Clause, the Due Process Clause, and the Constitution's horizontal separation of powers. Dkt. 1. AAM brings this suit on behalf of its members, which are "manufacturers and distributors of generic and biosimilar medicines." *Id.* ¶ 14. Although some members are located in Illinois and/or transact business with Illinois entities, others are incorporated or headquartered outside of Illinois. *Id.* ¶¶ 28, 40. AAM alleges that its members are harmed by the Act because they "intend, or intended until the Act's adoption, to make competitively reasonable price adjustments to the wholesale acquisition cost for certain 'essential off-patent or generic drugs' during the first half of the 2024 calendar year." *Id.* ¶ 37. The complaint does not, however, contain allegations about any of its members' specific plans to do so, or any enforcement actions pending against them. *Id.* ¶¶ 37–45.

AAM later filed a motion for a preliminary injunction, based on the sole theory that the Act violates the Commerce Clause by regulating transactions between manufacturers and distributors that occur wholly outside of Illinois. Dkt. 18 at 1. Based on that theory, AAM seeks to enjoin the Attorney General from "implementing or enforcing [the Act] against AAM's members,

or their agents and licensees, based on their sales of generic drugs or biosimilars that occur outside Illinois." Dkt. 17 at 1. As support for this sweeping request, AAM submits a single declaration from Timothy DeGavre, the Chief Commercial Officer for Sandoz, Inc. Dkt. 20.

LEGAL STANDARDS

Under Rule 12(b)(1), a party may move to dismiss a case based on "lack of subject matter jurisdiction." Fed. R. Civ. P. 12(b)(1). When a plaintiff lacks standing to bring an action, federal jurisdiction cannot attach and the court lacks subject matter jurisdiction. *Walters v. Edgar*, 163 F.3d 430, 432 (7th Cir. 1998). Pursuant to Rule 12(h)(3), "[i]f the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." Fed. R. Civ. P. 12(h)(3).

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

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

ARGUMENT

I. This court lacks subject-matter jurisdiction.

At the threshold, this case should be dismissed, and the preliminary injunction denied, because AAM's complaint is not a "case" or "controversy" fit for resolution by a federal court. *Sweeney v. Raoul*, 990 F.3d 555, 559 (7th Cir. 2021). The Article III case-or-controversy requirement "limits federal courts to resolving concrete disputes between adverse parties." *Id*. To meet the Article III requirement, a plaintiff must satisfy the justiciability doctrines of standing and ripeness. *Id*. Without satisfying both doctrines, this Court is "left with a request for an advisory opinion" despite the fact that "federal courts do not deal in advice." *Id*. at 561. As now explained, AAM's prematurely-filed complaint establishes neither standing nor ripeness.

A. To establish subject-matter jurisdiction in a pre-enforcement challenge, AAM must allege an imminent injury in a concrete dispute.

AAM purports to bring this suit based on associational standing. "[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977). For a plaintiff to establish standing in its own right, it "must show (1) an injury in fact, (2) a sufficient causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157–58 (2014) (cleaned up). Plaintiff's injury "must be concrete and particularized, as well as actual or imminent." *Carney v. Adams*, 141 S. Ct. 493, 498 (2020)

(cleaned up). An "imminent" injury is one that is "certainly impending" and therefore "not too speculative for Article III purposes." *Clapper v. Amnesty Int'l*, 568 U.S. 398, 409 (2013) (cleaned up). "Allegations of possible future injury do not satisfy the requirements of Art. III." *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990).

In pre-enforcement challenges, the Supreme Court permits review only "under circumstances that render the threatened enforcement sufficiently imminent." *Susan B. Anthony*, 573 U.S. at 159; *see also Whole Woman's Health v. Jackson*, 595 U.S. 30, 49 (2021) ("This Court has never recognized an unqualified right to pre-enforcement review of constitutional claims in federal court."). A plaintiff may satisfy this standard by alleging "an intention to engage in a course of conduct arguably affected by [the challenged statute], and that he faces a credible threat the [statute] will be enforced against him when he does." *Speech First v. Killeen*, 968 F.3d 628, 638 (7th Cir. 2020). But "the 'chilling effect' associated with a potentially unconstitutional law being 'on the books' is insufficient to 'justify federal intervention' in a pre-enforcement suit." *Whole Woman's Health*, 595 U.S. at 50. As the Supreme Court recently reiterated, it "has always required proof of a more concrete injury and compliance with traditional rules of equitable practice" in pre-enforcement cases, whether "the challenged law in question is said to chill the free exercise of religion, the freedom of speech, the right to bear arms, or any other right." *Id.*

The ripeness doctrine involves similar considerations, "as claims premised on uncertain or contingent events present justiciability problems." *Church of Our Lord & Savior Jesus Christ v. City of Markham, Illinois*, 913 F.3d 670, 676 (7th Cir. 2019). Indeed, the "doctrine's underlying objective is to avoid premature adjudication and judicial entanglement in abstract disagreements." *Id.* Accordingly, a "case is ripe when it is 'not dependent on contingent future events that may not occur as anticipated, or indeed may not occur at all.'" *Mathis v. Metro. Life Ins. Co.*, 12 F.4th 658,

664 (7th Cir. 2021) (quoting *Trump v. New York*, 141 S. Ct. 530, 535 (2020)). "A case is not ripe when the parties point only to hypothetical, speculative, or illusory disputes as opposed to actual, concrete conflicts." *Id.* (internal quotations omitted).

When these questions of standing and ripeness are "otherwise close, the distinction between criminal and civil sanctions might tip the balance." 13B Charles Alan Wright *et al.*, *Federal Practice and Procedure* § 3532.5 (3d ed. 2023). Also relevant is whether private parties may enforce the law being challenged, since "the risk of enforcement is greater when private parties can enforce the law," and "lower when enforcement is 'restricted to state officials who are constrained by explicit guidelines or ethical obligations.'" *NSSF v. New Jersey*, 80 F.4th 215, 221 (3d Cir. 2023) (quoting *Susan B. Anthony*, 573 U.S. at 164).

Finally, "[w]arnings against premature adjudication of constitutional questions bear heightened attention when a federal court is asked to invalidate a State's law, for the federal tribunal risks friction-generating error when it endeavors to construe a novel state Act not yet reviewed by the State's highest court." *Arizonans for Off. Eng. v. Arizona*, 520 U.S. 43, 79 (1997). Speculation about the scope of a state law is "particularly gratuitous" in "the absence of prior state adjudication." *Id*. Similar concerns arise where plaintiffs bring facial, rather than as-applied, challenges. *Washington State Grange v. Wash. State Republican Party,* 552 U.S. 442, 450–51 (2008). As the Supreme Court explained, facial challenges are "disfavored" because they "often rest on speculation" and thus "raise the risk of premature interpretation of statutes on the basis of factually barebones records." *Id.* at 450. Facial challenges thus may also "run contrary to the fundamental principle of judicial restraint that courts should neither anticipate a question of constitutional law in advance of the necessity of deciding it nor formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied." *Id.*

B. AAM fails to plausibly allege an injury-in-fact.

This case is not justiciable because AAM has not established any threatened enforcement action that is sufficiently imminent to satisfy either the injury-in-fact requirement for Article III standing or the ripeness requirement to show the existence of an actual, concrete conflict. In particular, AAM has failed to set forth plausible allegations of its intended course of conduct or a substantial and credible threat of enforcement at this time. Each of these deficiencies provides an independent basis for dismissal under the doctrines of standing and ripeness.

The requirement that a plaintiff sufficiently identify a course of conduct in its complaint is critical. Without knowing what the pre-enforcement plaintiff intends to do, it is impossible to determine whether that conduct is arguably proscribed by the challenged statute, much less whether it subjects the plaintiff to a credible threat of enforcement. *See Ind. Right to Life Victory Fund v. Morales*, 66 F.4th 625, 630 (7th Cir. 2023) ("It is a threshold requirement to establish a credible threat of enforcement that the statute actually cover the plaintiff's desired conduct."). AAM's complaint contains only vague and conclusory allegations about the intent of unidentified manufacturers in its membership "to make competitively reasonable price adjustments . . . for certain 'essential off-patent or generic drugs.'" Compl. ¶ 37. And although AAM purports to bring this action on behalf of the manufacturers and distributors in its membership (both of which are covered by the Act), the complaint makes no attempt to allege that the distributors intend to engage in a course of conduct proscribed by the statute. On the contrary, it describes only the proposed course of conduct of its manufacturing members. *Id.* ¶¶ 7, 40.

With respect to manufacturers, the complaint makes the conclusory assertion that the price increases of these unidentified drugs would meet the "quantitative elements of 'price gouging' under the Act" because they "constitut[e] substantially more than a 30% increase of the wholesale

acquisition cost for those medicines over one year." *Id.* ¶ 38. But it is insufficient for purposes of associational standing to make generalized allegations about a group of individuals or entities, without providing a specific example of a member with standing. *See, e.g.*, *Prairie Rivers Network v. Dynegy Midwest Generation*, 2 F.4th 1002, 1010 (7th Cir. 2021) (insufficient allegations where complaint "speaks of its individual members only as a collective" and "presum[es] that at least one of these individual members has standing to sue on their own").

In any event, the complaint contains no factual allegations about the other components of the Act: that the price increase be excessive, unduly burdensome to consumers, and not attributable to production costs or costs that increase access to the drug. 410 ILCS 725/5. For example, rather than allege that the planned price increases are "excessive," AAM repeatedly describes the increases as "reasonable" and "necessary." Compl. ¶¶ 11, 37, 48. The complaint similarly fails to explain how any of the planned price increases—which again, are unidentified—would "unduly burden consumers because of the importance of the [drug] to their health and because of insufficient competition in the marketplace." 410 ILCS 725/5. And finally, AAM admits that at least some of the planned price increases are necessitated by factors "excepted by the Act." Compl. ¶ 39. For the remainder, AAM alleges that they "are necessitated, at least in part, by economic or cost factors other than those excepted by the Act." *Id.* But this vague statement provides no factual basis to support that conclusion. In other words, it is impossible to know, based on the factual allegations in the complaint, whether any of AAM's members intend to participate in a course of conduct that is actually proscribed by the statute.

AAM's complaint also fails to identify any credible enforcement threat against any of its members. It does not even attempt to satisfy that standard. It provides no allegations that the Attorney General—who is the sole enforcer under the Act, 410 ILCS 725/10(b)—has sent a notice,

begun an investigation, or brought an enforcement action against anyone, let alone an AAM member. AAM likewise provides no allegations that the Attorney General plans to do so. Instead, the complaint alleges only that, at some point in the future, there may be a "substantial risk the Attorney General and an Illinois court would determine that the contemplated price increases by AAM's members of their essential off-patent or generic drugs meet [the] elements of the definition of 'price gouging.'" Compl. ¶ 42. But the chance that the Attorney General or a court could someday decide that unidentified price increases satisfy the definition of price gouging does not amount to "actual or threatened *enforcement*." *California v. Texas*, 593 U.S. 659, 670 (2021).

In similar circumstances, the Third Circuit recently dismissed an associational plaintiff's pre-enforcement complaint for failure to show a threat of enforcement by the New Jersey Attorney General. *NSSF*, 80 F.4th at 220–22. There, the plaintiff challenged a new statute authorizing the attorney general to bring suit against gun-industry members that create a public nuisance by engaging in unlawful conduct related to the sale, manufacture, distribution, or marketing of firearms. *Id.* at 218. Like here, the New Jersey law had "not been enforced against anyone, let alone the Foundation or its members," *id*. at 220, and was only able to be enforced by the attorney general, *id.* at 221. In fact, it was not enough in *NSSF* that the association alleged that the attorney general had set up an office to enforce the law or that the State said it would be used against "bad actors in the gun industry." *Id.* at 222. AAM alleges neither here but, in any event, such generalized plans cannot provide a basis for a court to find a credible threat to a particular entity.

Indeed, the Supreme Court has required much more to establish injury in pre-enforcement cases. In *Susan B. Anthony List*, for example, the Court concluded "the threat of future enforcement of the [challenged] statute is substantial" because "there is a history of past enforcement here: [plaintiff] was the subject of a [recent] complaint" and prosecution. 573 U.S. at 164. Likewise, in

Holder v. Humanitarian Law Project, 561 U.S. 1 (2010), the Court found it relevant that the government had "charged about 150 persons with violating" the challenged statute, and "that several of those prosecutions involved the enforcement of the statutory terms at issue." *Id.* at 15–16. Here, by contrast, there is no evidence of the statute having been enforced against anyone. AAM thus fails to allege its members face an imminent risk of enforcement.

Finally, to the extent AAM seeks to rely on the Sandoz declaration to establish standing, that declaration is irrelevant on a facial challenge to jurisdiction, which looks exclusively at the allegations in the complaint. *Silha v. ACT, Inc.*, 807 F.3d 169, 173 (7th Cir. 2015). In any event, the declaration does not cure the Article III defects for several reasons. First, it provides no information about distributors; like the complaint, it describes only manufacturer conduct. Dkt. 20. Additionally, it includes no threat of enforcement, let alone an imminent or credible one. *Id.* As with the complaint, the declaration makes no statements that the Attorney General has sent Sandoz a notice, opened an investigation, or otherwise threatened to enforce the Act against Sandoz. *Id.* Instead, it describes a generalized fear of liability, *id.* ¶ 16, which does not constitute an Article III injury, *Speech First*, 968 F.3d at 638–39 & n.1.

The described course of conduct in the declaration, moreover, lacks sufficient detail to determine whether Sandoz would even be subject to an enforcement action by the Attorney General. As explained, price gouging occurs when the price increase meets a quantitative standard, is "otherwise excessive," and "unduly burdens consumers." 410 ILCS 725/5. Price gouging does not include price increases that are "reasonably justified by" increases in the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health. *Id.* According to the declaration, the "majority" of the planned increase "is attributable to factors other than an increase in the cost of producing" the drug, including "regulatory approval costs, costs

incurred due to product inventory loss, . . . inflation[,] and Sandoz's assessment of current market dynamics." Dkt. 20 at ¶ 15. But the declaration provides no specific information about these costs, or why Sandoz has concluded that they would be considered "otherwise excessive" and outside the scope of the exemptions. *Id.* At the same time, the declaration admits that the increase in cost is due in part to the increase in production costs, *id.* ¶ 13, and explains that it is necessary in order to keep the drug on the market, *id.* ¶ 26. All told, without further information, it is not possible to discern whether Sandoz's proposed course of conduct would be proscribed by the Act.

C. AAM's sweeping complaint seeks premature adjudication of fact-intensive theories best reserved for as-applied challenges.

Even if the complaint clears the injury-in-fact bar, it would be premature for this court to adjudicate the facial challenge presented by AAM in its complaint. AAM seeks sweeping declaratory and injunctive relief that would invalidate the Act in its entirety. Compl. at 33-34. Resolving such a broad complaint at this juncture would be improper for several reasons. To start, notwithstanding that AAM has raised a facial challenge to the Act, it has also recognized in its complaint the existence of constitutional applications of the Act. *See* Compl. ¶¶ 28, 40. This alone renders the Act unsuitable for a facial challenge. *Ezell v. City of Chicago*, 651 F.3d 684, 698–99 (7th Cir. 2011) ("a successful facial attack means the statute is wholly invalid and cannot be applied *to anyone*," that is, it must be unconstitutional "*in all* its applications, as *Salerno* requires"). In particular, AAM recognizes that some of its manufacturer members are either located in Illinois or sell generic prescription drugs to entities in Illinois, Compl. ¶¶ 28, 40, which of course would present no extraterritoriality problem—Commerce Clause or otherwise. In other words, even if AAM's theories were correct (which they are not), the Act cannot be facially unconstitutional.

Additionally, AAM's claims are best resolved on a case-by-case basis. As explained, *see supra* pp. 6-9, 15-18, the application of the Act itself is inherently fact-bound, and whether the

Attorney General would even bring an enforcement action will depend on the specific circumstances of each case. Furthermore, AAM's legal theory (to the extent it is valid, which the State disputes, *infra* Section II)—in effect, that the Act is impermissibly unconstitutional because it regulates "transactions" that lack sufficient contacts with Illinois, Compl. ¶ 3—necessarily depends on the factual circumstances of those transactions and the scope of contacts with Illinois. Reserving premature adjudication of AAM's broad claims would allow courts to assess these constitutional issues on an incremental basis and with full context. *Washington State Grange*, 552 U.S. at 450 (declining facial challenge "frees the Court not only from unnecessary pronouncement on constitutional issues, but also from premature interpretations of statutes in areas where their constitutional application might be cloudy").

Finally, there is ample opportunity for AAM or its members to challenge the Act in the future if and when a concrete dispute concerning them actually arises, whether it be in the context of an as-applied challenge or as an affirmative defense to an enforcement action. *E.g.*, *Whole Woman's Health v. Jackson*, 595 U.S. 30, 49-50 (2021) ("many federal constitutional rights are as a practical matter asserted typically as defenses to state-law claims, not in federal pre-enforcement cases like this one"); *Sherwin-Williams Co. v. Cnty. of Delaware, Pennsylvania*, 968 F.3d 264, 270 (3d Cir. 2020) ("If the County sues, Sherwin-Williams can raise [due process and First Amendment] claims as affirmative defenses in state court."). And here, as explained, *supra* pp. 7-9, the Act contains substantial procedural protections providing manufacturers and distributors the opportunity to show that the relevant price increase was made due to legitimate business needs.

In short, as the Seventh Circuit has explained, "[t]he benefits of awaiting a concrete and particularized dispute—a Case or Controversy—are plain." *Sweeney*, 990 F.3d at 561. Among others, this approach allows "all involved an opportunity to fully probe" the factual and legal issues

presented by that case, as opposed to being "explored—legally, practically, or otherwise—in the abstract." *Id.* This is especially true where, as here, there remains much to be seen about the nature of the planned price increases, as well as the Attorney General's enforcement practices under the Act. *Washington State Grange,* 552 U.S. at 450. AAM's request to adjudicate the constitutionality of the Act is premature and should be dismissed.

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

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

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

drugs sold into Illinois, regardless of where they are manufactured. The Act "visits its effects equally upon both interstate and local business," and therefore does not discriminate against interstate commerce. *CTS*, 481 U.S. at 87.

Thus, AAM's motion challenges the Act solely on "extraterritoriality" grounds, claiming that it impermissibly regulates out-of-state transactions. Dkt. 18 at 8-15.[29] As discussed below, AAM's attempts to extract a viable extraterritoriality theory from a footnote in *Ross* are unavailing, and its dormant Commerce Clause claim is unlikely to succeed.

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

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

Previously, the lower courts reached varying conclusions regarding the reach of the extraterritoriality principle set forth in this trilogy of cases. While the Seventh Circuit applied the principle broadly, *see Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 665–68 (7th Cir. 2010),

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

other courts adhered to a "narrow interpretation, given the emphasis on protecting against discriminatory regulations in cases applying the Commerce Clause," *Mayo v. Titlemax of Del.*, No. 21-2964, 2022 U.S. Dist. Lexis 2573, at *11 (E.D. Pa. Jan. 4, 2022) (collecting cases).

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

AAM acknowledges *Ross*, Dkt. 18 at 12–13, but it ignores the recent decision's full import. *Ross* involved a challenge to a California law barring the in-state sale of pork meat from pigs "confined in a cruel manner." 143 S. Ct. at 1150. The plaintiffs alleged that the law would require substantial changes to their operations, and that the costs of compliance would be borne primarily by out-of-state firms. *Id.* at 1152. Relying on *Baldwin*, *Brown-Forman*, and *Healy*, the plaintiffs argued for an "almost *per se*" rule prohibiting state laws that have the "practical effect of controlling commerce outside the state," regardless of whether there is discrimination. *Id.* at 1153–54. The Court rejected this proposition, noting that the plaintiffs "read too much into too little." *Id.* at 1154. The plaintiff's position was legally unsupported, would "cast a shadow over laws long understood to represent valid exercises of the States' constitutionally reserved powers," and would "invite endless litigation and inconsistent results." *Id.* at 1154–56.

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

issue in *Baldwin* "plainly discriminated against out-of-staters" by "erecting an economic barrier protecting a major local industry against competition from without the State." *Id.* And the laws at issue *in Brown-Forman* and *Healy* similarly amounted to "simple economic protectionism." *Id.* As *Ross* made clear, these cases should not be extended beyond their facts; they merely reflect the rule against protectionist state laws that discriminate against out-of-state interests in favor of their in-state counterparts. *Id.* at 1155.

AAM concedes the first point, agreeing that the Supreme Court has rejected the "practical effects" argument. Dkt. 18 at 13. But it does not account for the second point, that the extraterritoriality rule of *Baldwin*, *Brown-Forman*, and *Healy* has a limited reach. AAM relies on these cases both explicitly, *see id.* at 8–9, and implicitly, by citing other decisions that rely on them, *id.* at 14–15. Yet *Baldwin* and its progeny do not apply here because the Act is not protectionist, does not discriminate against out-of-state-interests, and does not tie the price of drugs sold in Illinois to the price of drugs sold elsewhere. *Ross*, 143 S. Ct. at 1154-56. While AAM calls the Act a "price control" statute, this is incorrect. The Act does not control the prices for out-of-state sales "either by its express terms or by its inevitable effect." *Pharm. Research & Mfrs. of Am.*, 538 U.S. at 669. An out-of-state manufacturer can sell a drug to an out-of-state wholesaler at whatever price those parties agree upon, provided that the drug is not sold into Illinois, 410 ILCS 725/10(a), and the Act does not tie the price of drugs sold into Illinois to out-of-state prices.

AAM's pre-*Ross* case law cannot sustain its claim here. Take, for example, *Midwest Title Loans*, AAM's lead Seventh Circuit case. Dkt. 18 at 9–10. There, an out-of-state lender asserted a Commerce Clause claim challenging an Indiana law that regulated car loans made to residents of Indiana. *Midwest Title Loans*, 593 F.3d at 662. Relying in part on *Healy*, the court invalidated Indiana's law based on its extraterritorial effects, since it could apply to out-of-state companies

issuing loans to Indiana residents. *Id.* at 669. But this application of *Healy* is incorrect under *Ross* because the statute at issue did not discriminate against out-of-state interests, nor was it a price control or price fixing statute. 143 S. Ct. at 1154–56.

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

The multiple issues with *Midwest Title* carry over to *Legato Vapors, LLC v. Cook*, 847 F.3d 825 (7th Cir. 2017), the other Seventh Circuit case that AAM emphasizes. Dkt. 18 at 8–10.[30] In *Legato Vapors*, the plaintiff challenged a law regulating the manufacture and distribution of vapor pens and the liquors used in e-cigarettes. *Id.* at 827. The law had an "unprecedented" extraterritorial reach, "imposing detailed requirements of Indiana law on out-of-state manufacturing operations." *Id.* And although the Seventh Circuit did not decide the case on this ground, the law raised "obvious concerns about protectionist purposes," as it appeared to be "a legislative grant of a monopoly to one favored in-state company in the security business." *Id.* at 833. In invalidating the law as an

[30] Many of AAM's out-of-jurisdiction cases, in addition to being non-binding, are unreliable because they invoke the "practical effect" test that the Supreme Court has now rejected. *See* Dkt. 18 at 14–15 (citing *Pharmaceutical Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 67–71 (D. D.C. 2005) (relying on the *Baldwin* line of cases and the "practical effect" test); *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 261 (S.D. N.Y. 2018) (relying on the "practical effect" test). AAM also cites to *Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001), but there, the court found that the challenged law did not violate the dormant Commerce Clause, explaining that the extraterritoriality principle from the *Baldwin* line of cases has a limited reach. *Id.* at 81–82.

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

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

As established above, *Ross* forecloses any challenge to the Act based on *Baldwin*, *Brown-Forman*, and *Healy* and other cases relying on them. AAM asserts that a separate strand of "extraterritoriality" jurisprudence remains intact. It points to single footnote in *Ross*, which cites *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), to argue that the Commerce Clause prohibits "state laws that directly regulate out-of-state commerce." Dkt. No. 18 at 13. But this footnote endorses no such principle. 143 S. Ct. 1157, n.1. The Court merely noted that the petitioners invoked *Edgar* and observed that in *Edgar*, a plurality declined to enforce a law that "*directly* regulated transactions which took place wholly outside the State and involved individuals having no connection with Illinois." *Id.* (cleaned up).

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

opinion of the Court"). While AAM banks its claim on extraterritoriality, at least for purposes of its preliminary injunction motion, the majority in *Edgar* relied on *Pike* balancing, an argument that AAM does not advance here. *Edgar*, 457 U.S. at 643–46; *Alliant*, 330 F.3d at 917.

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

The Act does not have this problem. Unlike the corporate takeover statute at issue in *Edgar*, which could block out-of-state transactions without protecting a single Illinois shareholder, every application of the Act necessarily promotes a legitimate local interest. That is because the Act applies only to prescription drugs that are "ultimately sold in Illinois," 410 ILCS 725/10(a), and Illinois indisputably has a strong interest in ensuring that its own residents are not subject to prescription drug price-gouging. *Id.* 725/2(e) (legislative finding that the Act addresses a "matter of health, safety, and welfare for the People of the State of Illinois"). Moreover, manufacturers set prices with input from the entire supply chain; distributors and some manufacturers sell products into Illinois; and any entities that distribute generic drugs to pharmacies in Illinois must be licensed by the State. *See supra* pp. 2-4.

The Act's limited application to prescription drugs ultimately sold into Illinois distinguishes it from the Maryland statute at issue in *Association for Accessible Medicines v. Frosh*,

887 F.3d 664 (4th Cir. 2018), which pre-dates *Ross*. Dkt. 18 at 11. In *Frosh*, the Fourth Circuit invalidated a Maryland price-gouging law drafted so broadly that it could be enforced "against parties to a transaction that did not result in a single pill being shipped to Maryland." *Id.* at 671; *id.* at 679 (dissent criticizing majority for construing the statute as extending to drugs "not ultimately sold in Maryland"). Illinois' law does not operate in this manner. Plus, *Frosh* is not persuasive because, contrary to *Ross*, the court applied the *Baldwin* line of cases and the "practical effect" test to a non-discriminatory consumer protection statute. *Id.* at 673.

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

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

While AAM cites a number of unreliable or inapposite cases, it ignores the Supreme Court's decision in *CTS*, which shows that state laws affecting out-of-state transactions should be

upheld where, as here, they necessarily promote a legitimate local interest. 481 U.S. at 93. *CTS*, decided five years after *Edgar*, involved a challenge to an anti-takeover statute that regulated the acquisition of "control shares" in Indiana businesses that had certain numbers of Indiana shareholders. *Id.* at 72–74. The district court found that the law violated the Commerce Clause and the appellate court affirmed, stating that the law could "impede transactions between residents of other states" and that Indiana was "depriving nonresidents of the valued opportunity to accept tender offers from other nonresidents." *Id.* at 77–78. But the Supreme Court reversed, noting that the law did not discriminate against out-of-state interests, that it applied to Indiana corporations, and that "every application" of the law would "affect a substantial number of Indiana residents, whom Indiana indisputably has an interest in protecting." *Id.* at 88, 93–94.

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

In sum, Illinois has authority to protect its own citizens from price gouging, regardless of whether drug manufacturers ship directly into Illinois or rely on wholesalers. States are not "powerless to regulate all transactions beyond their borders, including transactions involving their citizens." *IMS Health Inc.*, 616 F.3d at 29 n.29. "[I]t is inevitable that a state's law…will have

extraterritorial effects," and the Supreme Court has "never suggested that the dormant commerce clause requires Balkanization, with each state's law stopping at the border." *Instructional Sys. v. Computer Curriculum Corp.*, 35 F.3d 813, 825 (3d Cir. 1994).

III. AAM has failed to show irreparable harm.

AAM has also failed to establish that it will suffer irreparable harm if the Court denies its motion. *Winter*, 555 U.S. at 2. First, AAM makes a boilerplate argument that its members will suffer an irreparable injury from being subjected to an allegedly unconstitutional law. Dkt. 18 at 16. But the Supreme Court has never applied this principle outside the First Amendment context (*Elrod v. Burns*, 427 U.S. 347, 373–74 (1976)), and the Seventh Circuit has not applied it to dormant Commerce Clause claims. This argument is further undermined by AAM's delay in bringing this lawsuit. The Act was passed on July 28, 2023, nearly six months before AAM filed suit. Dkt. No. 1. This lack of urgency makes the extraordinary remedy of injunctive relief inappropriate. *Tranchita v. Callahan*, 511 F. Supp. 3d 850, 882 (N.D. Ill. Jan. 5, 2021).

AAM also asserts that its members will suffer monetary losses. Dkt. 18 at 17–19. But economic loss is irreparable in extenuating circumstances—for example, where the injunction is necessary to "save [a] plaintiff's business." *Gateway E. Ry. Co. v. Terminal R.R. Ass'n*, 35 F. 3d 1134, 1140 (7th Cir. 1994). AAM makes no such claims and cannot satisfy this factor.[31] In fact, as explained, *supra* pp. 7-9, 14-15, AAM has not established that its members will suffer substantial financial harm due to enforcement. The Act protects Illinois consumers from predatory pricing

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

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

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

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

Here, AAM's interests are significantly outweighed by the State's. As an initial matter, it is well-established that "[a]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (citation omitted). Additionally, however, AAM's purported interest stands in direct contrast with the public interest. AAM's argument focuses on the financial burden its members may encounter if they cannot engage in price gouging or are required to alter their current business practices. In contrast, the State's interest lies in preventing activity that will directly impact the health of its residents. As explained, *supra* pp. 4-8, the Act safeguards Illinois residents from abusive pricing tactics which primarily burden the elderly and poor. These tactics are proven to exist across a number of manufacturers and, at the extreme level the Act seeks to prohibit, have no purpose other than the accumulation of wealth at the expense of consumers. As such, the public interest weighs strongly in the State's favor.

CONCLUSION

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

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Respectfully submitted,

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