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

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. KWAME RAOUL, in his official capacity as Attorney General of the State of Illinois, *Defendant*.	Case No. 1:24-cv-00544

PLAINTIFF'S REPLY IN SUPPORT OF
RENEWED MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

The Act[1] directly regulates the prices charged in transactions that take place entirely outside Illinois. That is unconstitutional. The Act's threat of massive penalties for charging any price Illinois thinks too high is imposing an immediate, concrete, and irreparable injury on generic manufacturers. And absent an injunction, that harm to the generic industry will impede the public's access to life-saving generic medicines.

Defendant's defense of the Act rests on a core error: that the Supreme Court in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), foreclosed Commerce Clause challenges *except* to state laws that discriminate against interstate commerce. No court has accepted that distorted reading of *Ross*, and for good reason. *Ross* held that state laws that regulate only *in-state* conduct are not *per se* invalid just because they have extraterritorial *effects*. *Ross* did not disturb—indeed, it expressly preserved—existing case law invalidating state laws that "*directly* regulate[]" out-of-state commerce, whether or not discriminatory. *Id.* at 376 n.1. That is precisely what the Act does, as Defendant does not seriously dispute. Under binding Seventh Circuit precedent, the Act is unconstitutional as applied to out-of-state transactions, as every court that has considered the constitutionality of similar drug price-control laws has held. This Court should do the same.

Defendant's cursory arguments on the remaining preliminary-injunction factors fare no better. A deprivation of constitutional rights is irreparable harm, and this Court has repeatedly confirmed that a deprivation of rights under the Commerce Clause is no exception. Defendant argues that only a *First Amendment* violation produces irreparable injury, but that argument has no support in precedent or logic. And in any event, the *financial* injury AAM's members will suffer from the Act is certain and irreparable. The Act is costing regulated companies money, and

[1] Defined terms have the same meaning as in AAM's memorandum of law ("AAM Br.").

Defendant's sovereign immunity makes recovering those losses impossible. Defendant does not seriously dispute either point. The public interest is also served by enjoining a constitutional violation and preventing the Act from exacerbating already severe drug shortages, making life-saving drugs *less* available and, perversely, *more* expensive.

ARGUMENT

I. The Court should enjoin the Act's unconstitutional application to AAM's members.

A. AAM is likely to succeed on its extraterritorial Commerce Clause claim.

As AAM explained in its opening memorandum, a state law that *directly* regulates commerce outside the State is invalid, under settled precedent from the Supreme Court, the Seventh Circuit, and multiple other federal courts. AAM Br. 8-16. Defendant's only response is to argue that the law fundamentally changed in 2023: that *Ross* relaxed the Commerce Clause's limits on extraterritorial legislation and held that only discriminatory laws are unconstitutional. Def. Br. 12-14.[2] That is wrong. And Defendant's other arguments that AAM is unlikely to succeed on its extraterritoriality claim equally lack merit.

1. *Ross* left undisturbed the Commerce Clause's prohibition on direct regulation of out-of-state commerce. AAM Br. 13-14. The California law in *Ross* regulates only the "*in-state* sale of whole pork." 598 U.S. at 365 (emphasis added). As a result, the plaintiffs there did not argue that the California law was unconstitutional because it *directly* regulated out-of-state commerce, but because its regulation of *in-state* conduct had "the '*practical effect* of controlling commerce outside the State.'" *Id.* at 371 (emphasis added); *see also id.* at 373, 374; AAM Br. 13.

Ross rejected that *specific* "practical effect" claim, but nothing in *Ross* rejected *other*

[2] Defendant has not moved to dismiss under Rule 12(b)(6), and does not address any claim other than Count I. Therefore, even if the Court were to hold that AAM has not shown a likelihood of success on its extraterritoriality claim, the case would proceed.

Commerce Clause claims or held that only *discriminatory* state laws can violate the Commerce Clause, as Defendant claims. Def. Br. 13-14. To start, five Justices rejected limiting the dormant Commerce Clause to discriminatory state laws. *Ross*, 598 U.S. at 392 (Sotomayor, J., concurring in part); *id*. at 396 (Roberts, C.J., concurring in part and dissenting in part). More fundamentally, *Ross* expressly distinguished the type of *in-state* regulation it was reviewing from laws that *directly* regulate out-of-state activity. *Id*. at 376 n.1 (majority opinion). *Ross* noted that the plaintiffs had invoked the plurality opinion in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), but concluded that "the *Edgar* plurality opinion does not support the rule petitioners propose." *Ross*, 598 U.S. at 376 n.1. Why not? Because unlike the California law, which "regulate[d] only products that companies choose to sell *'within'* California," *Edgar* "spoke to a law that *directly* regulated out-of-state transactions by those with *no* connection to the State." *Id.* (first emphasis added). *Ross* thus recognized the constitutional difference between laws that regulate *in-state* conduct but have extraterritorial effects (at issue in *Ross*) and laws that "*directly* regulate[] out of state transactions" (not at issue), and it limited its holding exclusively to the former. *Id.*

Defendant insists that *Ross* did not "endorse[]" a direct-regulation prohibition. Def. Br. 16. That is changing the question. Especially in light of the robust circuit precedent on this subject, *see* AAM Br. 9-12, 14-16, Defendant needs *Ross* to have *overturned* the prohibition on direct regulation of out-of-state conduct. It did not. Indeed, if *Ross* had truly meant to foreclose *all* extraterritoriality claims involving non-discriminatory laws, it would have rejected the plaintiffs' reliance on the *Edgar* plurality on that basis. That *Ross* instead chose to distinguish the California law from the law in *Edgar* confirms that the Court was consciously leaving intact the rule that direct regulation of transactions in another State is unconstitutional—which is exactly what every court to interpret *Ross* has concluded. *See Ass'n for Accessible Meds. v. Ellison*, 704 F. Supp. 3d

947, 953 (D. Minn. Dec. 4, 2023) ("[*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."), *appeal docketed*, No. 24-1019 (8th Cir. Jan. 3, 2024); *Nat'l Shooting Sports Found. v. Bonta*, 718 F. Supp. 3d 1244, 1256 n.1 (S.D. Cal. Feb. 21, 2024) (similar); *Interlink Prods. Int'l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. June 26, 2023) (similar); AAM Br. 13-14.

2. The upshot of *Ross* and the *Edgar* plurality is clear: laws that directly regulate out-of-state commerce violate the Commerce Clause. The Seventh Circuit has applied this prohibition repeatedly. *See Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660 (7th Cir. 2010); *Legato Vapors, LLC v. Cook*, 847 F.3d 825 (7th Cir. 2017); AAM Br. 10. Defendant misreads these cases as addressing laws like the one in *Ross*—regulating only in-state activity, though with extraterritorial effects. That characterization is plainly incorrect. And he makes almost no effort to explain how the Act could survive under *Midwest Title* and *Legato Vapors*, as properly understood. Defendant certainly does not identify any Seventh Circuit decision that has *upheld* a state law like this one.

Start with *Midwest Title*. The Indiana law in that case directly regulated loans issued *outside* Indiana to an Indiana resident, so long as the lender advertised in Indiana at some point. 593 F.3d at 662. Midwest itself "had no offices in Indiana" and its loans were "made only in person, at Midwest's offices in Illinois." *Id.* The Seventh Circuit invalidated the law, not because of its effects, but because it directly regulated conduct outside Indiana's boundaries by "apply[ing] its law against title loans when its residents transact in a different state." *Id.* at 667-68; *see* AAM Br. 10.

Defendant tries (at 15) to convert *Midwest Title* into a case about extraterritorial effects by noting that *Midwest Title* cited *Healy v. Beer Institute*, 491 U.S. 324 (1989), but that single citation does not change the facts or the Seventh Circuit's holding. *Midwest Title* did not cite *Healy* for its

discussion of extraterritorial effects—the aspect that *Ross* later clarified; it cited *Healy*'s separate statement that "no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another." 593 F.3d at 665 (quoting *Healy*, 491 U.S. at 337). That is a correct statement of the law, before and after *Ross*. The Seventh Circuit also recognized that Midwest's claim was "stronger" than the specific claim in *Healy* because the Indiana law directly regulated out-of-state transactions by "forbid[ding]" out-of-state businesses from "making … title loans in Illinois to residents of Indiana." *Id.* at 666.

Unable to avoid *Midwest Title*, Defendant says it is no longer valid because it "significantly relies" on *Quill Corporation v. North Dakota*, 504 U.S. 298 (1992), a case about collection of sales taxes that was later overruled. Def. Br. 15. Defendant is wrong for multiple reasons. First, *Midwest Title* did not "significantly rel[y]" on *Quill*; it cited *Quill* once in support of its Commerce Clause holding, and only as an "example" of an "extraterritorial regulation held to violate the commerce clause" despite the regulating state's interest in the transaction. 593 F.3d at 666. Second, in cutting back on a *per se* rule announced in *Quill*, *see* *South Dakota v. Wayfair, Inc.*, 585 U.S. 162, 168 (2018), the Supreme Court did not authorize regulation of wholly out-of-state commerce. "All agree[d]" in *Wayfair* that "South Dakota had the authority to tax" the relevant transactions, because the South Dakota law applied solely to "sales … *for delivery into South Dakota*." *Id.* at 168, 176. *Quill* had held that a State could not force a merchant to collect *even a constitutionally valid sales tax* (on sales into that State) unless the merchant *also* had a physical presence in the State. *Wayfair* dispensed with the requirement that the merchant have a physical presence. *Id.* at 176-77. It did not change which taxes and other regulations a State may lawfully impose. *See id.* at 179 (States may compel collection of "lawful taxes").

Defendant's effort to distinguish *Legato Vapors* fails for the same reasons as his effort to

distinguish *Midwest Title*. Def. Br. 15-16 (arguing that *Legato Vapors* "relied heavily on *Midwest Title*, which is no longer reliable" (citation omitted)). Defendant does not dispute that the putative regulatory hook in the Indiana law under review in *Legato Vapors* is indistinguishable from the Act's. *See* AAM Br. 10. The Seventh Circuit held this law unconstitutional, not because of extraterritorial effects, but because it "directly regulate[d]" transactions occurring "entirely outside the regulating state." 847 F.3d at 836, 837. It did so, even though the law's regulation was triggered by the resale of e-cigarettes into Indiana in a subsequent transaction, because the regulated sales "occur[red] entirely outside [Indiana]." *Id.* at 836; *see Legato Vapors LLC v. Cook*, 193 F. Supp. 3d 952, 960 n.4 (S.D. Ind. 2016). As with *Midwest Title*, the handful of citations in *Legato Vapors* to *Healy*, *Quill*, or *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573 (1986), does not alter the nature of the e-cigarette law or the Seventh Circuit's rationale for striking it down.[3]

The most Defendant suggests is that the Act differs from the law in *Legato Vapors* because it "does not seek to impose detailed and invasive requirements on out-of-state manufacturing operations." Def. Br. 16. But whether the Act imposes "detailed and invasive requirements" on wholly out-of-state "operations" (as in *Legato Vapors*) or regulates individual out-of-state sales (as in *Midwest Title* and *Legato Vapors*), the constitutional infirmity is the same: the law "regulate[s] directly … commerce wholly outside the State" and therefore "must be held invalid." *Edgar*, 457

[3] The same is true of *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), and *Healthcare Distributors Alliance v. Zucker*, 353 F. Supp. 3d 235 (S.D.N.Y. 2018), *rev'd in part on other grounds sub nom. Association for Accessible Medicines v. James*, 974 F.3d 216 (2d Cir. 2020). Those decisions, like *Midwest Title* and *Legato Vapors*, invalidated laws because they directly regulated out-of-state transactions. *See* AAM Br. 14-16. Defendant offers no response other than to say these cases are "non-binding" and "unreliable because they invoke the 'practical effect' test" *Ross* rejected, Def. Br. 15 n.30, which is just as untrue of these cases as it is of *Midwest Title* and *Legato Vapors*.

U.S. at 643 (plurality opinion).

3. These decisions also refute Defendant's claim that an *earlier* Seventh Circuit decision, *Alliant Energy Corporation v. Bie*, 336 F.3d 545 (7th Cir. 2003), somehow "declin[ed] to follow" the *Edgar* plurality's "discussion of extraterritoriality." Def. Br. 16-17. The exact opposite is true: reconsidering a prior decision on rehearing, the Seventh Circuit *endorsed* the *Edgar* plurality. Just like *Ross*, *Alliant* rejected the argument that the Commerce Clause "mandates the *per se* invalidation of *every* state regulation that has any extraterritorial effect." 336 F.3d at 546. But it distinguished that mistaken theory from "the unsurprising principle that a *direct or facial* regulation of wholly extraterritorial transactions is *per se* invalid"—a principle it characterized as an "unremarkable application" of "traditional" Commerce Clause jurisprudence. *Id.* at 547. *Alliant* then concluded that the *Edgar* plurality stood for this "well established" rule that "direct regulation of interstate commerce is virtually *per se* unconstitutional"—a rule "not at issue" in *Alliant*. *Id.* So, far from disavowing the direct-regulation prohibition, *Alliant* drew the same distinction as *Ross*, and as AAM here.[4]

Defendant fares no better in claiming that the Supreme Court disavowed the *Edgar* plurality in *CTS Corporation v. Dynamics Corporation of America*, 481 U.S. 69 (1987). Def. Br. 19-20. The opposite is true. *CTS* involved an Indiana law that regulated the voting rights of shares *of an Indiana corporation* by "provid[ing] regulatory procedures" for a change of control. 481 U.S. at 72-74, 91, 93-94. The law did not regulate Dynamics' tender offer to anyone (in Indiana or elsewhere), or otherwise regulate out-of-state transactions; it regulated matters of "corporate

[4] An earlier decision had declined to endorse the plaintiff's claim that the *Edgar* plurality required it to invalidate laws with extraterritorial *effects*. *Alliant Energy Corp. v. Bie*, 330 F.3d 904, 916 (7th Cir. 2003). On rehearing, the court observed that "[i]nasmuch as [the plaintiff's] interpretation was the view of the plurality in [*Edgar*]," it was not controlling. 336 F.3d at 548. But as discussed, the court on rehearing made clear that it did not agree with that reading of the *Edgar* plurality.

governance," which fall squarely within states' power to "create corporations, to prescribe their powers, and to define the rights that are acquired by purchasing their shares." *Id.* at 91.[5] For that reason, Dynamics did *not* argue the law was impermissible extraterritorial legislation. It asserted an entirely different claim—that the law was unconstitutional under *Pike* because it unduly burdened interstate commerce. *Id.* at 76-77. It was in the context of rejecting that *Pike* claim that *CTS* distinguished the *Edgar* majority's holding that the Illinois law was unconstitutional under *Pike*. *Id.* at 89-93. But while *CTS* distinguished the *Edgar* majority, it *reaffirmed* the rationale in the *Edgar* plurality; it explained that the Indiana law was not unconstitutional for "subjecting activities" in interstate commerce "to inconsistent regulations" because under laws like Indiana's, corporations "will be subject to the law of only one State." *See id.* at 88-89 (citing, *inter alia*, *Edgar*, 457 U.S. at 642 (plurality opinion)). *CTS* reaffirmed, rather than undermined, the *Edgar* plurality's rationale.

4. Unable to avoid the principle applied by the *Edgar* plurality and repeatedly endorsed by the Supreme Court and the Seventh Circuit, Defendant argues the Act "does not suffer the same infirmities as the law at issue in *Edgar*," which supposedly "allow[ed] Illinois to block out-of-state transactions without advancing *any* local interest" and where "not … a single Illinois shareholder" was affected. Def. Br. 17. That is not what was "infirm" about the Illinois law. To the contrary, that law applied only to tender offers with substantial ties to Illinois, *see* AAM Br. 9

[5] Defendant cites *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010), for this reading of *CTS*, Def. Br. 20, but does not acknowledge that the decision was vacated by the Supreme Court, *IMS Health Inc. v. Schneider*, 564 U.S. 1051 (2011), and never reinstated (the law in question independently violated the First Amendment). In any event, if *IMS Health* understood *CTS* to have involved direct regulation of out-of-state commerce, it misread that decision. The same is true of the law review article on which Defendant relies, whose sole footnote reference to *CTS* offers no analysis of the facts or reasoning of that decision. *See* Def. Br. 17 (citing R. Feldman, *Lochner Revenant: The Dormant Commerce Clause & Extraterritoriality*, 16 N.Y.U. J. LAW & LIBERTY 209, 242 n.98 (2002)).

& n.16, and 27% of MITE Corporation's shareholders *lived in Illinois*, *Edgar*, 457 U.S. at 642 (plurality opinion). The Illinois law plainly advanced local interests to some degree. Nonetheless—and what matters for this case—the plurality concluded those "local interests" did not license Illinois to regulate offers made to shareholders "living in other States and having no connection with Illinois." *Id.* at 642-43.

So too here. That the Act purportedly "promotes a legitimate local interest" by tying its regulation to "drugs that are 'ultimately sold in Illinois,'" Def. Br. 17, does not cure the Act's unconstitutional reach. It also makes no difference that "some manufacturers sell products into Illinois" and manufacturers "must be licensed" in Illinois to sell their medicines there. Def. Br. 18. Illinois is free to regulate the prices charged in sales *into Illinois*, just like it was free to regulate tender offers *to Illinois residents* in *Edgar*; but that narrow authority does not create a sweeping power to regulate other transactions *unconnected* with Illinois. 457 U.S. at 642 (plurality opinion). Nor does the fact that some manufacturers may be licensed in Illinois. Def. Br. 3, 18, 20.[6] Residency is a stronger connection to a State than mere licensure, but as the Seventh Circuit made clear in *Midwest Title*, States cannot regulate the transactions their residents (or anyone else) enter into *in other States*. 593 F.3d at 662, 667-68; *accord* *Styczinski v. Arnold*, 46 F.4th 907, 914 (8th Cir. 2022) (States do not have "*carte blanche* to regulate all conduct of residents regardless of where it occurs"); *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1321-24 (9th Cir. 2015) (en banc) (invalidating law requiring art sellers to pay into artists' fund if "the seller resides in California *or* the sale takes place in California," because the law regulated "sales hav[ing] no necessary connection with the state other than the residency of the seller").

[6] The Illinois law Defendant cites (the Wholesale Drug Distribution Licensing Act) applies only to manufacturers that also operate as wholesalers and "distribut[e] [] prescription drugs *into, out of, or within the State*." 225 Ill. Comp. Stat. Ann. § 120/15 (emphasis added).

That principle dispenses with Defendant's suggestion that Illinois can regulate prices charged in out-of-state sales because manufacturers "know" or can "easily find out" whether their products are ultimately sold in Illinois. Def. Br. 4. The District of Minnesota rejected a materially identical argument in striking down a Minnesota price-control statute, concluding that because "out-of-state sales to actual Minnesota residents d[o] not have a sufficient connection to Minnesota to be regulated" under the Commerce Clause, "a non-Minnesota manufacturer's knowledge that some of the drugs that it sells to a non-Minnesota distributor may someday find their way into Minnesota [does not] validate Minnesota's direct regulation of that out-of-state sale." *Ellison*, 704 F. Supp. 3d at 955. That conclusion is reinforced by the uncontroverted Declaration of Rodney Emerson, stating that manufacturers "do[] not control the prices at which [] drugs are resold by other entities in the supply chain, nor … where those drugs are resold." Emerson Decl. (ECF No. 53) ¶ 5.

Finally, Defendant suggests the Act is unlike the law in *Edgar* because "manufacturers set prices with input from the entire supply chain," including "distributors and pharmacies." Def. Br. 3, 18. That argument, however, conflates the price a distributor, pharmacy, or payor *ultimately pays* and a medicine's wholesale acquisition cost ("WAC"). As Defendant recognizes, the WAC is the "baseline price" of a medicine, Def. Br. 2; through negotiations with manufacturers, distributors, pharmacies, or other entities often pay a discounted price from the WAC—but that price is distinct from the WAC itself, which is set *by manufacturers*. Def. Br. 2 ("Manufacturers … set[] the [WAC]."); *see also* *Follow the Pill: Understanding the U.S. Commercial Supply Chain*, The Kaiser Family Foundation, at 17 (Mar. 2005)[7] ("[Manufacturers] develop algorithms … and

[7] https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

use those algorithms to establish the [WAC]"). That difference matters, because the Act does not target the price distributors, pharmacies, or patients *actually* pay; it is indifferent to those prices. Rather, the Act *exclusively* targets increases in the WAC set by the out-of-state manufacturer, *see* Act § 5, 410 Ill. Comp. Stat. Ann. § 725/5, which confirms that the Act regulates conduct "with *no* connection to [Illinois]," *Ross*, 598 U.S. at 376 n.1.

5. Under this precedent, the Act's regulation of AAM members' out-of-state sales violates the Commerce Clause. That is why courts have consistently applied the prohibition on direct extraterritorial legislation to invalidate nearly identical price-control laws. AAM Br. 11-12 (discussing *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018), and *Ellison*).

Defendant argues that the Maryland law in *Frosh* was "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,'" whereas the Act requires an in-state sale to trigger liability. Def. Br. 18 (quoting *Frosh*, 887 F.3d at 671). That distinction is irrelevant. That the Act is *triggered* by an in-state sale or distribution does not change the fact that it *regulates* wholly out-of-state sales—and *those* wholly out-of-state sales likewise "d[o] not result in a single pill being shipped [in]to [Illinois]." *Frosh*, 887 F.3d at 671.

In any event, *Frosh* did not stop there; it went on to hold that the Maryland law still violated the Commerce Clause "*[e]ven if* [it] … require[d] a nexus to an actual sale in Maryland," as the district court had believed, because the Maryland statute "measured" the lawfulness of a sale "according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*" outside Maryland. 887 F.3d at 671 (first emphasis added); *accord Pharm. Rsch. & Mfrs. of Am.*, 406 F. Supp. 2d at 69-70 (invalidating D.C. price-control law triggered by a drug's eventual resale

in the District). *Frosh* is thus directly on point.[8]

Unable to distinguish *Frosh*'s holding, Defendant relies on the dissent in that case for the proposition that "a State regulates 'wholly outside of its borders'"—and so violates the direct-regulation rule—"only if 'no transactions *in that stream* take place within the State's borders." Def. Br. 18 (quoting *Frosh*, 887 F.3d at 683 (Wynn, J., dissenting)). That position is not only incompatible with *Legato Vapors*, *see* p. 6, *supra*, but it also conflicts with the earlier Seventh Circuit decision the *Frosh* dissent cites—*In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599 (7th Cir. 1997). *See* Def. Br. 18 (citing same). There, the Seventh Circuit held that Alabama could not use its antitrust laws to regulate "sales from plants or offices in other states to pharmacies in other states," but could regulate "sales from other states *to pharmacies in Alabama*." 123 F.3d at 613 (emphasis added). That is AAM's position—even if State *A* may regulate sales from an out-of-state manufacturer *into* that State, "State *A* cannot use its … law to make a seller in State *B* charge a lower price to a buyer in [State] *C*." *Id.*

Ellison applied that same rule. That court held the Minnesota law unconstitutional because it could "find [no] support for the notion that the dormant Commerce Clause permits Minnesota to directly regulate a sale that occurs in another state simply because the product eventually makes its way into Minnesota," and it enjoined "enforc[ement]" of the law "based on any [AAM] member's sale of generic or off-patent drugs outside Minnesota." 704 F. Supp. 3d at 954, 960. That is the precise relief AAM seeks here. *See* ECF No. 51. Defendant says *Ellison* should be

[8] Defendant argues that *Frosh* was wrong to label the Maryland law a "'price control' statute" because the law "did not insist on a 'certain price.'" Def. Br. 18 (quoting *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003)). That is irrelevant. *Walsh* did not hold that *only* statutes that dictate "a certain price" violate the direct-regulation rule, *see* 538 U.S. at 669, and both *Midwest Title* and *Legato Vapors* applied the direct-regulation rule to invalidate non-pricing statutes after *Walsh* was decided.

"give[n] little weight" because the Minnesota Attorney General conceded "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.'" Def. Br. 19 (quoting *Ellison*, 704 F. Supp. 3d at 954). But that was not the basis for the court's holding. Here, as in *Ellison*, it is undisputed that the Act applies to manufacturers' out-of-state transactions as long as the product ends up in the State—no matter how it gets there. And AAM is not seeking to enjoin the Act's application to any sales made by its members directly into Illinois.

Defendant also criticizes *Ellison* for relying on the Eighth Circuit decision in *Styczinski*, based on the now-familiar refrain that it "employed the 'practical effect' test … rejected" in *Ross*. Def. Br. 19. That critique is as untrue of *Styczinski* as of *Midwest Title* and *Legato Vapors*. *Styczinski* addressed a Minnesota law that regulated "transaction[s] anywhere in the world between a bullion trader and a Minnesota resident," without requiring "a single transaction in Minnesota." 46 F.4th at 913. The Eighth Circuit held this violated the Commerce Clause, because it "applie[d] Minnesota law to commerce wholly outside Minnesota," *id.*—the same rationale that was employed in *Midwest Title* and *Legato Vapors* and renders the Act invalid.

Nothing in *New Jersey Staffing Alliance v. Fais*, 110 F.4th 201 (3d Cir. 2024), undermines this mountain of case law. *Cf.* Def. Br. 14. That out-of-circuit decision involved a constitutional challenge to a New Jersey law regulating the temporary worker staffing industry. 110 F.4th at 204. Although the plaintiffs challenged the New Jersey law on Commerce Clause grounds, the Third Circuit did not address whether that law *directly* regulated out-of-state transactions. It considered and rejected two very different arguments: first, whether the law was discriminatory, and second, whether the law was invalid because of its "extraterritorial *effects*," an argument that failed under *Ross*. *Id.* at 206-07 (emphasis added). The Third Circuit never addressed whether the law was

invalid as a *direct* regulation of out-of-state commerce, which is why it never cited or discussed either the plurality opinion in *Edgar* or *Ross*'s explicit language distinguishing the *Edgar* plurality from the California law.

* * *

Against this overwhelming weight of authority—Supreme Court decisions, Seventh Circuit decisions, and decisions nationwide invalidating indistinguishable price-control laws—Defendant essentially stakes everything on the notion that *Ross*, *CTS*, or *Alliant* somehow got rid of the rule that one State may not directly regulate prices in another. None of those cases even *involved* such a direct regulation, and Defendant cites no case that upholds one. As in *Ellison*—a decision postdating each of those cases—AAM is likely to succeed on the merits.

B. AAM has established that the Act will irreparably harm its members.

The Act imposes unconstitutional regulations and makes AAM's members bear unrecoverable economic harms. Both are irreparable injuries. AAM Br. 16-19.

1. AAM's members will suffer irreparable harm as a result of being subject to an unconstitutional law. AAM Br. 16-17. Defendant argues this principle applies only to First Amendment violations, Def. Br. 21, but that is demonstrably incorrect: the Seventh Circuit has found irreparable injury for non-First Amendment violations, *see* *Preston v. Thompson*, 589 F.2d 300, 303 & n.3 (7th Cir. 1978) (due process claim), and this Court has repeatedly held that violations of "the dormant Commerce Clause … constitute[] irreparable injury," *Kendall-Jackson Winery, Ltd. v. Branson*, 82 F. Supp. 2d 844, 878 (N.D. Ill. 2000) (collecting cases), *appeal dismissed*, 212 F.3d 995 (7th Cir. 2000); AAM Br. 16-17 (citing additional cases). Defendant neither engages with these cases nor cites any authority making his proposed distinction. Nor would it make sense to treat Commerce Clause violations differently than any other constitutional claim: the Constitution's allocation of authority over interstate commerce is just another example

of how "federalism secures to citizens the liberties that derive from the diffusion of sovereign power." *Bond v. United States*, 564 U.S. 211, 221 (2011) (citation omitted).

Separately, Defendant says that the harm to AAM's members must not be irreparable because AAM did not file suit until January 2024. Def. Br. 21. But Defendant ignores that the Act *did not take effect* until January 1, 2024. Act § 99, 410 Ill. Comp. Stat. Ann. § 725/99. AAM's members were not facing imminent injury-in-fact until they developed their pricing plans for 2024 (which typically occurs at or near the beginning of a calendar year) and became subject to the Act's unconstitutional regulation. By identifying plans for a specific price increase *in 2024*, AAM overcame Defendant's arguments on standing and ripeness, all of which were premised on the notion that AAM had sued *too soon*; Defendant cannot now credibly argue that AAM sued *too late*. AAM's decision to file suit promptly after the law's effective date is nothing like the circumstances in *Tranchita v. Callahan*, 511 F. Supp. 3d 850 (N.D. Ill. 2021), in which an assertion of irreparable injury was "undermine[d]" by the plaintiff's unexplained several-month delay in requesting a preliminary injunction. *See id.* at 882. Here, if AAM had sued before being able to identify plans for a specific price increase *in 2024*, Defendant no doubt would have trumpeted that fact to support its now-rejected arguments on standing and ripeness. Defendant cannot have it both ways.

2. AAM's members also will suffer irreparable economic harm. Defendant does not engage with the case law holding that economic losses that are unrecoverable due to sovereign immunity count as irreparable harm. AAM Br. 17-19 (collecting cases). He insists, however, that economic loss is irreparable only if "the injunction is necessary to 'save [a] plaintiff's business.'" Def. Br. 21 (quoting *Gateway E. Ry. Co. v. Terminal R.R. Ass'n of St. Louis*, 35 F.3d 1134, 1140 (7th Cir. 1994)). *Gateway* does not say that: it concluded that "although economic loss generally

will not sustain an injunction," it will if a "damages remedy [is] inadequate." 35 F.3d at 1140. Damages were "inadequate" in *Gateway*—which did not involve sovereign immunity—because any award would "come[] too late to save the plaintiff's business." *Id.* (citation and quotation marks omitted). Sovereign immunity is a *stronger* reason for finding economic loss irreparable, because it means a damages remedy will not "come[] too late," *id.*; it will never come at all.[9]

Otherwise, Defendant's assertion that AAM's members will not "suffer substantial financial harm" due to the Act is refuted by the declaration that AAM submitted in support of its preliminary injunction motion. Emerson Decl. ¶¶ 19, 25-29. Defendant has not disputed that declaration, nor submitted any contrary evidence of his own.

C. A preliminary injunction is in the public interest.

In addition to establishing likelihood of success and irreparable harm—"[t]he two most important" preliminary injunction factors, *Bevis v. City of Naperville*, 85 F.4th 1175, 1188 (7th Cir. 2023)—AAM also has shown that the balance of hardships and public interest support an injunction. AAM Br. 19-20. Defendant invokes the inapposite principle that a State "suffers a form of irreparable injury" if a court enjoins one of its duly enacted laws. Def. Br. 22 (quoting *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers)). That principle may help the State when seeking a stay, but it does not immunize state laws from being enjoined. Instead, 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 in original; citation

[9] In both the other decisions Defendant cites, the courts found no irreparable injury from economic loss because the plaintiff failed to show it could not recover the lost funds some other way. *See McHenry Cnty. v. Raoul*, No. 21-cv-50341, 2021 WL 8344241, at *2 (N.D. Ill. Dec. 27, 2021) (county "ha[d] the authority to raise taxes and make budgetary cuts to adjust to the loss of revenue"); *McHenry Cnty. v. Raoul*, No. 21-3334, 2022 WL 636643, at *1 (7th Cir. 2022) ("loss of revenue" had not been shown to be "permanent").

omitted).

Defendant argues the public interest disfavors an injunction because the Act seeks to prevent "price gouging" and "abusive pricing." Def. Br. 22. He does not dispute that generics and biosimilars "save Americans a substantial amount of money on medication," Def. Br. 5, nor that the Act will exacerbate the severe drug shortages plaguing the U.S. healthcare system, forcing withdrawal of generics and *reducing* patient access to affordable medicines, AAM Br. 19-20. Defendant also makes no effort to justify targeting *only* generic and biosimilar manufacturers—the entities that are *most* responsible for *lowering* prescription drug prices, which generate *tens of billions* of dollars in savings every year for Illinois patients. AAM Br. 3.

CONCLUSION

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

February 7, 2025

Respectfully submitted,

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