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

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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 posing an immediate, concrete, and irreparable injury to generic manufacturers. And absent an injunction, that harm to the generic industry will impede the public's access to life-saving generic medicines.

Defendant does not challenge the sufficiency of AAM's allegations under Rule 12(b)(6)—only standing and ripeness under Rule 12(b)(1). That motion lacks merit. The Complaint plausibly alleges that at least one AAM member has concrete plans to engage in conduct proscribed by the Act and faces a credible threat of an enforcement action. That allegation is not just plausible: the sealed declaration from an AAM member company substantiates it with specific facts, identifying the company, product, price, and increase. Defendant urges the Court to consider only the Complaint and to ignore the declaration, but the declaration is proper evidence on both a Rule 12(b)(1) motion *and* a preliminary-injunction motion. Defendant's standing argument otherwise amounts to a demand for conclusive proof that Illinois would deem AAM's members' price increases "excessive." But AAM need only show that its members' intended course of conduct is "*at least arguably* proscribed by the challenged statute." *Brown v. Kemp*, 86 F.4th 745, 764 (7th Cir. 2023) (emphasis added). AAM's claims are also ripe: this case turns not on "uncertain or contingent events," *Wis. Right to Life State PAC v. Barland*, 664 F.3d 139, 148 (7th Cir. 2011), but on the pure legal question whether the Commerce Clause invalidates Illinois's unapologetic attempt to directly regulate wholly out-of-state transactions.

Defendant's defense of the Act on the merits rests on a core error: that the Supreme Court

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

in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), ruled out Commerce Clause challenges *except* to state laws that discriminate against interstate commerce. No court has accepted that strained reading of *Ross*, and for good reason. *Ross* held that if a state law regulates only *in-state* conduct, it does not become *per se* invalid just because it has extraterritorial *effects*. *Ross* did not disturb—indeed, it expressly preserved—existing case law invalidating 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 confirmed that a deprivation of rights under the Commerce Clause is no exception. Defendant argues that only a *First Amendment* violation is an 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 Defendant's sovereign immunity makes recovering those losses impossible. 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.

LEGAL STANDARD

When deciding a Rule 12(b)(1) motion, the court must consider the complaint's allegations, as well as any other evidence either party has submitted regarding the plaintiff's standing. *See Marszalek v. Kelly*, No. 20-cv-4270, 2022 WL 225882, at *3 (N.D. Ill. Jan. 26, 2022) (citation omitted). The sufficiency of a complaint's standing allegations is evaluated under the same

plausibility standard that governs whether a complaint states a claim for relief. *Silha v. ACT, Inc.*, 807 F.3d 169, 174 (7th Cir. 2015). Under that standard, "the Court accepts all well-pleaded facts as true[,] … draws all reasonable inferences in favor of the non-moving party," *Laborers' Pension Fund v. Midwest Milling & Paving Co.*, No. 20-cv-00908, 2021 WL 292849, at *2 (N.D. Ill. Jan. 28, 2021), and "presum[es] that general allegations embrace those specific facts that are necessary to support the claim,'" *Prairie Rivers Network v. Dynegy Midwest Generation, LLC*, 2 F.4th 1002, 1008 (7th Cir. 2021). The factual allegations "need not prove" standing but "show only that" the plaintiff's claim of standing "is 'plausible on its face.'" *G.G. v. Salesforce.com, Inc.*, 76 F.4th 544, 551 (7th Cir. 2023). "This pleading standard is not demanding." *Id.*

ARGUMENT

I. AAM has Article III standing and its claims are ripe.

AAM has standing and ripe claims because at least one member company has concrete plans to adopt a price increase that "arguably" violates the Act. The plans are not just alleged, but substantiated with a sworn declaration identifying the company, product, price, and increase. That is sufficient: the member is not required to actually violate the Act *and* receive a threat of suit from Defendant in order to obtain redress from unconstitutional applications of the law.

A. AAM has established injury-in-fact.

An association may sue in federal court to vindicate its members' rights, "even without a showing of injury to the association itself." *Prairie Rivers Network*, 2 F.4th at 1008 (citation omitted). Defendant disputes only one prong of associational standing: whether "at least one of [AAM's] members would 'have standing to sue in [its] own right.'" *Id.* (citation omitted). Standing requires "a concrete and particularized injury that is both fairly traceable to the challenged conduct and likely to be redressed by a favorable judicial decision." *Bazile v. Fin. Sys. of Green Bay, Inc.*, 983 F.3d 274, 278 (7th Cir. 2020).

A plaintiff need not actually "violate the [law] and risk prosecution in order to challenge it." *Ezell v. City of Chi.*, 651 F.3d 684, 695 (7th Cir. 2011). Rather, a plaintiff has standing to bring a pre-enforcement challenge if it "has alleged an intention to engage in a course of conduct arguably protected by federal law, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." *520 Mich. Ave. Assocs., Ltd. v. Devine*, 433 F.3d 961, 963 (7th Cir. 2006) (alterations and citation omitted).

AAM has alleged that its members meet these requirements and has substantiated those allegations with a declaration from a member company. That is more than sufficient.

1. AAM has established its members' intent to engage in conduct prohibited by the Act.

The Rule 12(b)(1) pleading standard "is not demanding," *G.G.*, 76 F.4th at 551, and AAM's allegations readily clear it. The Complaint alleges that AAM's members "intend, or intended" to raise the prices for medicines in amounts that are "substantially more" than the Act's dollar and percentage thresholds, Compl. ¶ 38; that those medicines are "essential medicines" within the meaning of the Act, *id.* ¶ 41; and that some members are forgoing those price increases because of the threat of liability and others intend to implement those increases notwithstanding the Act, *id.* ¶¶ 43-44. Thus, the Complaint alleges that some AAM members intend to raise their prices for medicines subject to the Act "in a manner that satisfies every ascertainable element of the Act's definition of 'price gouging.'" *Id.* ¶ 43.

And what the Complaint alleges, the de Gavre Declaration (ECF No. 19) substantiates with concrete facts about AAM's member company Sandoz. AAM has therefore supported its standing sufficiently not just to withstand Defendant's Rule 12(b)(1) motion, but to establish a likelihood of success if the issue were further disputed.

Defendant argues (at 17) the declaration "is irrelevant" because he wishes to only challenge

the plausibility of AAM's standing *allegations*, rather than whether AAM has shown standing *in fact*. But the law does not allow Defendant that choice: "Courts evaluating Rule 12(b)(1) motions may look beyond the complaint to consider whatever evidence has been submitted on the issue to determine whether subject matter jurisdiction exists." *Marszalek*, 2022 WL 225882, at *3 (citation omitted). That includes supplemental "affidavits" that are "supportive of a plaintiff's standing." *Warth v. Seldin*, 422 U.S. 490, 501-02 (1975). In fact, a district court "not only [has] *the right*, but *the duty* to look beyond the allegations of the complaint to determine that it ha[s] jurisdiction to hear the plaintiffs' claim." *FHFA v. City of Chi.*, 962 F. Supp. 2d 1044, 1050, 1051 n.7 (N.D. Ill. 2013) (considering declarations submitted by plaintiff in opposition to Rule 12(b)(1) motion) (emphasis added; alterations omitted) (quoting *Hay v. Ind. State Bd. of Tax Comm'rs*, 312 F.3d 876, 879 (7th Cir. 2002)); *see also Int'l Union of Operating Eng'rs, Loc. 139, AFL-CIO v. Daley*, 983 F.3d 287, 293, 295 (7th Cir. 2020) (similar). Defendant cannot ignore this evidence of standing because he would rather attack the allegations.[2]

That established law dispenses with Defendant's assertion that the Complaint is deficient because it does not "provid[e] *a specific example* of a member with standing." Def. Br. 14-15 (emphasis added). The de Gavre Declaration identifies a specific AAM member (Sandoz) and the basis for that member's standing. Even if there were no declaration, associations are not required to plead their members' identity with such specificity. *See Luce v. Kelly*, No. 21-cv-1250, 2022

[2] Even if the Court were to ignore the de Gavre Declaration, that would accomplish nothing for Defendant. Courts freely grant parties leave to amend to cure defects in a complaint's jurisdictional allegations and AAM would ask this Court to exercise its discretion to provide AAM that opportunity if the Court were to grant Defendant's motion. *See Sapperstein v. Hager*, 188 F.3d 852, 855 (7th Cir. 1999). Amending the Complaint to include the facts in the de Gavre Declaration would eliminate even Defendant's objection to considering the declaration on the Rule 12(b)(1) motion. The de Gavre Declaration is dated before the Complaint and establishes facts that were true at the time the Complaint was filed. At a minimum it establishes a *likelihood* that AAM can plead and prove those facts.

WL 204373, at *5 (N.D. Ill. Jan. 24, 2022) ("the Seventh Circuit has not required organizations to name individual members who possess standing"); *Marszalek v. Kelly*, No. 20-cv-04270, 2021 WL 2350913, at *4 (N.D. Ill. June 9, 2021) (same). This Court recently upheld an association's standing based on six individual members identified only by their initials, noting that "the group may need to later establish these facts, likely by filing an addendum under seal." *Bevis v. City of Naperville*, 657 F. Supp. 3d 1052, 1061 n.4 (N.D. Ill. 2023) (Kendall, J.), *aff'd*, 85 F.4th 1175 (7th Cir. 2023). Here, AAM identified all its members when it filed suit, Compl. Ex. A (ECF No. 1-1), and it promptly detailed a member's standing in a declaration once it was able to meet-and-confer on and file the necessary motion to seal.

For those reasons, this case is nothing like the extreme example on which Defendant relies, Def. Br. 15—an environmental lawsuit in which the plaintiff organization "ha[d] more than 1000 members" but referred to "its individual members" in the complaint "only as a collective," *Prairie Rivers Network*, 2 F.4th at 1009. The court could not "know … who these members are or how exactly the alleged discharges will harm them individually." *Id.* Here, there is no doubt who AAM's members are or how the Act will harm them individually; the Complaint alleges that those "AAM members [who] refrain[] from raising their prices … [will] fac[e] economic harm in the form of lost revenues," Compl. ¶ 44, while those "AAM members [who] intend to proceed with their price adjustments notwithstanding the Act … [will] face severe economic harm from the potential enforcement of the Act." *Id.* ¶ 43.

Alternatively, Defendant argues the Complaint and de Gavre Declaration fail to *definitively* establish that AAM's members' price increases would violate the Act. But that misstates AAM's burden, which is only to show that one of its members' "intended course of conduct [is] *at least arguably* proscribed by the challenged statute." *Brown*, 86 F.4th at 764 (emphasis added). The

Complaint and the declaration easily meet that burden without "further information" (Def. Br. 18).

Defendant does not dispute that the Complaint's allegations meet the Act's quantitative formula, but contends that the price increases are not alleged to be "excessive, unduly burdensome to consumers, [or] not attributable to production costs or costs that increase access to the drug." Def. Br. 15 (citing Act § 5). That is incorrect as to all three prongs. First, "excessive": Defendant ignores the allegation that the anticipated increases "constitut[e] *substantially more* than a 30% increase … for those medicines over one year," Compl. ¶ 38 (emphasis added)—the threshold for triggering the Act's liability for a one-year increase, Act § 5.[3] And he also ignores that the planned increases are alleged to be "*competitively* reasonable," Compl. ¶ 37 (emphasis added)—meaning reasonable in light of existing market conditions, including that each product is manufactured by three or fewer companies, *id.* ¶ 41. The de Gavre Declaration goes even farther: it specifies the precise dollar and percentage amounts of Sandoz's anticipated price increase, which far exceed the Act's thresholds for an annual increase. *Compare* de Gavre Decl. ¶ 14, *with* Act § 5. That is more than sufficient to show that Sandoz's price increase would "arguably" be deemed "excessive" under the Act. *Cf.* Def. Br. 18.[4]

Second, "unduly burdensome": To be covered by the Act, as the Complaint alleges, a drug must be on a list of essential medicines and manufactured by three or fewer companies. Compl. ¶ 41; *see* Act § 5. Satisfying those factors *alone* suffices to plausibly allege that price increases for those medicines will "arguably" burden consumers "because of" the medicine's

[3] Of course, an AAM member's belief that a price increase is reasonable does not negate the possibility that an Illinois court or Defendant will deem it "excessive."

[4] Defendant posits that Sandoz's price increase might not be deemed "excessive" because it is "necessary … to keep the drug on the market." Def. Br. 18. What the declaration actually says is that the product will be unprofitable "[a]t its current price," de Gavre Decl. ¶ 17; that is no guarantee that Defendant will find the specific proposed increase appropriate.

"importance … to their health" and "insufficient competition." Act § 5.

Third, "not attributable to production costs": Defendant acknowledges the allegation that "[s]ome of the[] … planned price increases are necessitated, at least in part, by economic or cost factors other than those excepted by the Act," Compl. ¶ 39, but claims it is "vague" and lacking a "factual basis." Def. Br. 15. Again, that demands far too much of a pleading, as AAM "need not prove" its members' injuries in its Complaint. *G.G.*, 76 F.4th at 551. In any event, the de Gavre Declaration provides "factual support"—it identifies specific categories of costs partially responsible for the price increase: "regulatory approval costs, costs incurred due to product inventory loss, and inflation," as well as "Sandoz's assessment of current market dynamics …, including the pricing of competing generic products." de Gavre Decl. ¶ 15; *see also id.* ¶ 13 (describing costs "not directly associated with production"); Def. Br. 18 (acknowledging same).

The "pleading standard" under Rule 12(b)(1) "is not demanding," *G.G.*, 76 F.4th at 551, and the Complaint's allegations, coupled with the de Gavre Declaration, are more than adequate to show that at least one AAM member's "intended course of conduct [is] *at least arguably* proscribed by the challenged statute," *Brown*, 86 F.4th at 764 (emphasis added).

2. AAM has plausibly alleged a credible threat of enforcement.

The Complaint also alleges "a credible threat" of enforcement. *Devine*, 433 F.3d at 963. Defendant's contrary argument hinges nearly exclusively on the fact that he has not *yet* investigated or sued any company since the Act took effect on January 1. Def. Br. 15-16. But that is not necessary. The Supreme Court has found standing to challenge a "newly enacted law" in a lawsuit filed "before the statute became effective." *Virginia v. Am. Booksellers Ass'n, Inc.*, 484 U.S. 383, 392, 393 (1988); *see Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 302 (1979) (similar). Past enforcement actions and statements about enforcement priorities can help

substantiate an enforcement threat, but they are not *required* to show one.[5]

The rule is instead that a credible threat of enforcement exists when the plaintiff's intended conduct falls within a statute's plain terms because "*[t]he very 'existence of a statute* implies a threat to prosecute." *Ezell*, 651 F.3d at 695-96 (emphasis added) (citation omitted); *accord Bauer v. Shepard*, 620 F.3d 704, 708 (7th Cir. 2010) (similar). Here, the Complaint alleges that AAM's members plan to engage in conduct that falls squarely within the Act. *See* pp. 4-8, *supra*. Moreover, Defendant has not disavowed enforcement actions against AAM's members, or Sandoz's specific price increase—nor could he, realistically, considering the Act targets the generic industry. "Seventh Circuit law" is clear that "there is a credible threat of enforcement when the defendants don't expressly disavow enforcement of a law that clearly applies to the plaintiffs." *Carey v. Wis. Elections Comm'n*, 624 F. Supp. 3d 1020, 1030-31 (W.D. Wis. 2022) (collecting cases); *see Brown*, 86 F.4th at 769-70 ("[T]he absence of a clear disavowal tends to support finding a credible threat of prosecution."); *Susan B. Anthony List*, 573 U.S. at 165 (noting that the government "ha[d] not disavowed enforcement"); *Am. Booksellers Ass'n*, 484 U.S. at 393 (same). AAM has alleged a credible threat of enforcement.[6]

National Shooting Sports Foundation v. Attorney General of New Jersey, 80 F.4th 215 (3d Cir. 2023) (*"NSSF"*), does not support Defendant's argument. There, a firearms organization established only that the organization's "members plan to make, market, and sell guns"—lawful

[5] Defendant says (at 16-17) that *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 164 (2014), and *Holder v. Humanitarian Law Project*, 561 U.S. 1, 15-16 (2010), hold otherwise, but those cases found past enforcement *relevant*, not necessary. In fact, *Susan B. Anthony List* cited both *Babbitt* and *American Booksellers* approvingly, though neither one involved prior enforcement.

[6] AAM's standing is premised on far more than an abstract "chilling effect." Def. Br. 12 (quoting *Whole Women's Health v. Jackson*, 595 U.S. 30, 50 (2021)). The Act threatens economic loss or liability to AAM's members with concrete plans to engage in conduct that would violate the Act. *See* pp. 4-8, *supra*. That is "concrete injury" under *Whole Women's Health*, 595 U.S. at 50.

conduct—and the Attorney General "disavowed prosecuting" any member just for participating in lawful commerce. *Id.* at 219-20, 221. The organization "never explain[ed] how simply making, marketing, or selling guns w[ould] inevitably trigger th[e] law" and invite prosecution. *Id.* at 221. By contrast, AAM has alleged exactly what its members plan to do and how that conduct will violate the Act, Compl. ¶¶ 37-44, and Defendant has not denied that conduct would violate the Act. *NSSF* also acknowledged that when a law "is new," a mere "lack of enforcement does not tell us much either way," 80 F.4th at 220—undercutting Defendant's emphasis on the fact that he has not (yet) threatened to sue.

B. AAM's claims are ripe for review.

AAM's claims are also ripe. The *constitutional* ripeness inquiry merges with standing in a pre-enforcement case, and any prudential ripeness inquiry is irrelevant given that AAM "ha[s] alleged a sufficient Article III injury." *Susan B. Anthony List*, 573 U.S. at 167 (citation omitted); *see, e.g.*, *Martinez v. City of Chi.*, 534 F. Supp. 3d 936, 948-49 (N.D. Ill. 2021). In any event, AAM satisfies the ripeness doctrine, which looks to "first, whether the relevant issues are sufficiently focused … to permit judicial resolution without further factual development; and, second, whether the parties would suffer any hardship by the postponement of judicial action." *Triple G Landfills, Inc. v. Bd. of Comm'rs of Foundation Cnty.*, 977 F.2d 287, 289 (7th Cir. 1992); *see Barland*, 664 F.3d at 148 (same).

Defendant does not meaningfully address the latter point—the hardship to AAM from delaying review. That does not require "an actual enforcement action"; the "threat of enforcement is sufficient because the law is in force the moment it becomes effective." *Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 656 F.3d 580, 586 (7th Cir. 2011). As shown above, AAM has alleged and substantiated a credible risk of enforcement. *See* pp. 8-10, *supra*. Members are also refraining from previously planned price increases due to the Act, which

will result in economic loss. Compl. ¶ 44. No more hardship is needed.

Focusing on the first ripeness concern, Defendant argues that applying the Act to AAM's claims "is inherently fact-bound" and will "necessarily depend[] on the factual circumstances" of a given sale. Def. Br. 18, 19; *see also id.* at 12-13. But the Complaint alleges all the relevant details: (a) "all but two of AAM's members are located outside Illinois," Compl. ¶ 38; (b) those members "located outside Illinois sell their medicines overwhelmingly to large wholesale distributors … also located outside Illinois," *id.* ¶ 40; and (c) some of those AAM members' products are eventually resold into Illinois by third parties, *id.* ¶ 41. Moreover, AAM has alleged its members' price increases are encompassed by the Act. *See* pp. 6-8, *supra*. These allegations, which must be accepted as true, *Silha*, 807 F.3d at 174, show that resolving the legality of the Act as-applied to these circumstances will not turn on "uncertain or contingent events," *Barland*, 664 F.3d at 148, nor require "further factual development," *Triple G Landfills, Inc.*, 977 F.2d at 289. Rather, AAM's claims present a purely legal issue: whether the Constitution permits Illinois to regulate the prices charged in sales by AAM's out-of-state members to other out-of-state entities. Such "purely legal issues are normally fit for judicial decision." *Barland*, 664 F.3d at 148. Defendant repeatedly insists that this is a "facial" challenge (citing nothing) and urges the Court to wait for an "as-applied" one, Def. Br. 18-19, but he misses that AAM has brought Commerce Clause and due process claims challenging the Act *as applied* to transactions outside Illinois. Compl. ¶¶ 73, 78, 81; *see* AAM Prelim. Inj. Mot. (ECF No. 17).

Equally flawed is Defendant's argument that AAM's lawsuit is not ripe because of a need to interpret the Act. Def. Br. 18-19. The parties *agree* the Act regulates specified prices charged by out-of-state manufacturers to other out-of-state entities, Def. Br. 6-8, and applying those provisions will not require "[s]peculation about the scope of [the] state law," Def. Br. 13; *see Gov't*

Suppliers Consolidating Servs., Inc. v. Bayh, 975 F.2d 1267, 1275-76 (7th Cir. 1992) (case ripe when "what the statutes authorize is clear"). Defendant's argument sounds more like *Pullman* abstention, but that is appropriate only when there is a "reasonable probability" that "clarification of state law might obviate the need for a federal constitutional ruling." *Barland*, 664 F.3d at 150 (citation omitted). Here, there is no dispute that the Act applies to out-of-state transactions.

The law is clear that Article III does not require AAM's members to live under the Act and wait for an enforcement action before asserting their constitutional claims. *Contra* Def. Br. 19. AAM has shown "an intention to engage in a course of conduct arguably" proscribed by law, "a credible threat" of enforcement," *Devine*, 433 F.3d at 963 (citation omitted), and the absence of "uncertain or contingent events," *Barland*, 664 F.3d at 148. This is a "live, focused case of real consequence," and it is justiciable. *Triple G Landfills, Inc.*, 977 F.2d at 291.

II. 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 both the Supreme Court and the Seventh Circuit. AAM Br. 8-12. Defendant's only response is to argue that the law changed in 2023: that *National Pork Producers Council v. Ross* loosened the Commerce Clause's limits on extraterritorial legislation and held that only discriminatory laws are unconstitutional. Def. Br. 21-23.[7] That position cannot withstand scrutiny. And Defendant has no other argument that AAM is unlikely to succeed on its Commerce Clause extraterritoriality claim.

1. *Ross* left undisturbed the Commerce Clause's prohibition on direct regulation of

[7] Defendant has not moved to dismiss under Rule 12(b)(6), and does not even 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.

out-of-state commerce. AAM Br. 12-14. The California law in *Ross* regulates only the "*in-state* sale of whole pork." 598 U.S. at 365 (emphasis added). The plaintiffs therefore did not argue that the law was an unconstitutional *direct* regulation of out-of-state commerce; instead, they argued that it was unconstitutional 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* Commerce Clause claim, but nothing in *Ross* goes further to limit Commerce Clause claims exclusively to discriminatory state laws, as Defendant claims. Def. Br. 22-23. 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* 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). In particular, *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 that "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). *Id.*

Defendant insists that *Ross* did not "endorse[]" a direct-regulation prohibition. Def. Br. 25. That is changing the question. 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* chose instead to distinguish the California law from the law in *Edgar* confirms that the Court left 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*, No. 23-cv-2024, --- F. Supp. ---, 2023 WL 8374586, at *3 (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*, No. 23-cv-0945, --- F. Supp. 3d.---, 2024 WL 710892, at *7 n.1 (S.D. Cal. Feb. 21, 2024) (similar); *Interlink Prods. Int'l, Inc. v. Crowfoot*, No. 20-cv-02277, --- F. Supp. 3d ---, 2023 WL 4187496, at *4 (E.D. Cal. June 26, 2023) (similar); AAM Br. 12-13.

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.

The Indiana law in *Midwest Title* 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. *Id.* at 667-68.

Defendant tries (at 23) 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. Rather, *Midwest Title* cited the Supreme Court'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 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. 24. 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. 24-25 (arguing that *Legato Vapors* "relied heavily on *Midwest Title*, which is no longer reliable" (citation omitted)). *Legato Vapors* struck down a law whose regulatory hook closely resembles the Act's—it regulated the sales of, and imposed extensive regulations on, e-cigarette "manufacturer[s]" that "s[old] e-liquids" either to "a distributor who is located outside of Indiana *who then sells or distributes the product to a retailer located in Indiana*," or "an out-of-state retailer *who then sells the product to a consumer or end user in Indiana over the Internet*." *Legato Vapors LLC v. Cook*, 193 F. Supp. 3d 952, 960 n.4 (S.D. Ind. 2016) (emphases added); *see Legato Vapors*, 847 F.3d at 836. The Seventh Circuit held this law unconstitutional, not because of extraterritorial effects, but because it "directly regulate[d]" transactions "entirely outside the regulating state." 847 F.3d at 836, 837. 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.[8]

[8] 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. 14-15. 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. 24 n.30, which is just as untrue of these cases as it is of *Midwest Title* and *Legato Vapors*.

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. 25. 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 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. 25. The exact opposite is true: reconsidering a prior decision on rehearing, the court *endorsed* the *Edgar* plurality. Just like in *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. 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.* Thus, far from disavowing the direct-regulation rule, *Alliant* drew the same distinction as *Ross*, and as AAM's briefs here.[9]

[9] 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.

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)—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. *Id.* 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. Rather, it regulated matters of "corporate 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.[10] Dynamics thus did *not* argue the law was impermissible extraterritorial legislation. It asserted an entirely different claim—that the law was unconstitutional under the *Pike* balancing test 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)). Far from undermining the *Edgar* plurality, *CTS* reaffirmed its 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

[10] Defendant cites *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010), for this reading of *CTS*, Def. Br. 28, 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 infirmities as the law at issue in *Edgar*," which "allow[ed] Illinois to block out-of-state transactions without advancing *any* local interest." Def. Br. 26. 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,[11] and 27% of MITE Corporation's shareholders lived in Illinois. 457 U.S. at 642 (plurality opinion). Thus, the Illinois law certainly 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. 26, 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. 26. 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, 26.[12] 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*

[11] It applied where (1) "shareholders located *in Illinois* own[ed] 10% of the class of equity securities subject to the offer"; or (2) "any two of the following three conditions are met: [a] the corporation ha[d] its principal executive office *in Illinois*, [b] [was] organized under the laws *of Illinois*, or [c] ha[d] at least 10% of its stated capital and paid-in surplus represented *within the State*." *Edgar*, 457 U.S. at 626-27 (emphases added).

[12] 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).

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").

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. 3. In fact, 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*, 2023 WL 8374586, at *4. That conclusion is reinforced by the uncontroverted de Gavre Declaration 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." de Gavre Decl. ¶ 4.

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. 2-3, 26. 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)[13] ("[Manufacturers] develop algorithms … and 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 manufacturer, *see* Act § 5, which confirms 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. 27 (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 [Minnesota]." *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

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

"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.

So, too, is *Ellison*. The 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." 2023 WL 8374586, at *3, *9. That is the precise relief AAM seeks here (ECF No. 17). Defendant says *Ellison* should be "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. 27 (quoting *Ellison*, 2023 WL 8374586, at *3). 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. 27. 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 employed in *Midwest Title* and *Legato Vapors* under which the Act is invalid.

Against the 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. Just as in *Ellison*—a decision postdating every case Defendant cites—AAM is likely to succeed on the merits.

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

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. 29, 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), and this Court has 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); AAM Br. 16 (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 AAM's members cannot show irreparable harm because

AAM did not file this lawsuit until six months after the Act's passage. Def. Br. 29. But Defendant ignores that the Act did not take effect until January 1, 2024. AAM Br. 5 (citing Act § 99, 410 Ill. Comp. Stat. Ann. § 725/99). AAM's members were not facing injury-in-fact until they developed their pricing plans for 2024, subject to the Act's unconstitutional regulation.

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 (collecting cases). He insists, however, that economic loss is irreparable only if "the injunction is necessary to 'save [a] plaintiff's business.'" Def. Br. 29 (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.[14]

Otherwise, Defendant's assertion that AAM's members will not "suffer substantial financial harm" due to the Act depends on his arguments challenging AAM's Article III standing, which are wrong for the reasons already provided. *See* pp. 3-8, *supra*.

C. A preliminary injunction is in the public interest.

The balance of hardships and public interest also support an injunction. AAM Br. 19-20.

[14] 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").

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. 30 (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 omitted).

Defendant argues the public interest disfavors an injunction because the Act seeks to prevent "price gouging" and "abusive pricing." Def. Br. 30. He does not dispute that generics and biosimilars "save Americans a substantial amount of money on medication," Def. Br. 4-5, 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 motion for a preliminary injunction and deny Defendant's motion to dismiss.

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Respectfully submitted,

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