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 OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

Illinois' new drug price-control law ("the Act")[1] targets generic and biosimilar manufacturers, including members of the Association for Accessible Medicines ("AAM")—those most responsible for reducing prescription drug prices—and imposes draconian punishment for charging prices Illinois does not like, even in sales *entirely* outside Illinois. That is unconstitutional as applied to the out-of-state transactions that AAM members undertake. The Act inflicts that liability, moreover, through vague and nebulous terms that fail to give manufacturers fair notice of what the law forbids and fail to curb the unbridled enforcement discretion the Act confers on Defendant, the Attorney General of Illinois.

That unconstitutional regulation is inflicting immediate, concrete harm on AAM's members who intend, or intended but for the Act, to raise prices on their regulated medicines in a manner that violates the Act. This Court held that the original complaint did not sufficiently allege that any AAM member is being injured by the Act. ECF No. 32 at 3. The Amended Complaint cures any such deficiency with detailed allegations of that harm: it identifies a specific AAM member (Sandoz, Inc.) that intends to raise the price of one of its regulated medicines; discloses the medicine's name and the exact amount of the price increase (to the penny); and specifies the business-centric reasons for the intended increase, none of which is exempted. It also alleges that other AAM members intended, but for the Act, to raise the prices of their regulated medicines in a manner and for reasons that would trigger liability under the Act. AAM has plausibly alleged that these increases are "'arguably' proscribed by the [Act]," which is all standing requires. *Brown v. Kemp*, 86 F.4th 745, 762 (7th Cir. 2023). Either the threat of penalties (for violating the Act) or the forgone revenue (from refraining from violating it) creates a concrete injury-in-fact.

[1] Pub. L. No. 103-0367, 410 ILCS §§ 725/1-725/99 (2023).

At Defendant's urging, this Court previously declined to consider the details of Sandoz's proposed price increase when included in a declaration, not the complaint; the Court should not countenance Defendant's opportunistic insistence that the Court actually did consider Sandoz's price increase and hold it insufficient. As for Defendant's attempts to flyspeck the alleged reasons for Sandoz's intended price increase, they flout Rule 12(b)'s mandate that "all reasonable inferences" be drawn "in favor of the [non-moving party]." *Prairie Rivers Network v. Dynegy Midwest Generation, LLC*, 2 F.4th 1002, 1007, 1008 (7th Cir. 2021).

Defendant also has *no response* to AAM's vagueness claim: the Amended Complaint plausibly alleges that AAM has standing to assert its claim that the Act's vague terms and lack of enforcement guidance violate due process. That deprivation *alone* is injuring AAM's members. This Court did not separately address that claim in its previous decision.

Defendant objects that he has not yet signaled an enforcement action against any AAM member, but Seventh Circuit law is clear that "[a] preenforcement plaintiff 'need not show that the authorities have threatened to prosecute him' because 'the threat is latent in the existence of the statute.'" *ACLU of Ill. v. Alvarez*, 679 F.3d 583, 591 (7th Cir. 2012) (quoting *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003)). The Amended Complaint details a member's price increase that at least arguably violates the Act. Despite repeated opportunities, Defendant has refused to disavow enforcing the Act against that price increase. That is enough.

Finally, AAM's claims are 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' unapologetic attempt to directly regulate wholly out-of-state transactions.

BACKGROUND

I. Illinois' New Price Control Law

The Act prohibits "manufacturer[s]" and "wholesale drug distributor[s]" from "engag[ing] in price gouging in the sale of an essential off-patent or generic drug that is ultimately sold in Illinois." 410 ILCS § 725/10(a).[2] The Act is not limited to sales in Illinois. To the contrary, the law provides that "a manufacturer or wholesale drug distributor … may not assert as a defense that the manufacturer or wholesale drug distributor did not directly sell a product to a consumer residing in Illinois." *Id.* § 725/10(c).

"Price gouging" is defined as a price increase that would result: (1) in the wholesale acquisition cost ("WAC") for a "30-day supply" of the drug exceeding $20; and (2) in an increase in the WAC for the medicine of (a) 30% or more over the preceding year, (b) 50% or more over the preceding 3 years, or (c) 75% or more over the preceding 5 years. 410 ILCS § 725/5. If that formula is met, then a price increase will be prohibited if it is "unconscionable" and "otherwise excessive and unduly burdens consumers because of [1] the importance of the [medicine] to their health and … [2] insufficient competition." *Id.* Price-gouging "does not include a price increase" that can be "reasonably justified" by either (1) "an increase in the cost of producing the essential off-patent or generic drug"; or (2) "the cost of appropriate expansion of access to the [drug] to promote public health." *Id.*

The Act creates a reporting mechanism to aid Defendant in identifying violative price increases. Specifically, the Director of Healthcare and Family Services may notify Defendant "of any increase in [] price … that amounts to price gouging" for an essential medicine made available

[2] The Act defines "[e]ssential off-patent or generic drug" as a drug designated as "essential" by the World Health Organization or Secretary of Health and Human Services, sold in the United States "by 3 or fewer manufacturers," and that is no longer covered by any exclusive federal marketing rights (such as a patent). 410 ILCS § 725/5.

through an Illinois Medication Assistance Program. 410 ILCS § 725/10(a).

The Act also authorizes Defendant to independently investigate violations and bring enforcement actions. If Defendant has "reason to believe" a violation has occurred, he "may," but is not required to, "send a notice to the manufacturer … requesting a statement" providing information "relevant to a determination of whether a violation … has occurred." 410 ILCS § 725/10(b). He also may investigate potential violations by issuing subpoenas or "examin[ing] under oath any person." *Id.* Defendant may bring suit in Illinois court to remedy any violation, and a court may order a manufacturer to relinquish "any money acquired as a result of a price increase" deemed unlawful, impose a "civil penalty of up to $10,000 per day for each violation," and "[r]estrain[] or enjoin[]" the manufacturer from charging prices that violate the Act. *Id.* § 725/10(c)(2), (3), (5).

II. Procedural History

AAM's original complaint alleged that the Act is unconstitutional under (a) the dormant Commerce Clause; (b) the Due Process Clause; and (c) the horizontal separation of powers. ECF No. 1 ¶¶ 70-100. Defendant moved to dismiss the complaint on standing and ripeness grounds. ECF Nos. 25, 26. Relevant here, Defendant argued that the Court could not consider the planned price increase of a particular AAM member (Sandoz), because it was detailed not in the complaint, but in the Declaration of Timothy de Gavre (ECF No. 19) that AAM had submitted with a separate motion for a preliminary injunction. ECF No. 26 at 17; ECF No. 28 at 3-4.

The Court held that AAM had not alleged an injury-in-fact. ECF No. 32 at 3. First, the Court held that AAM had "not allege[d] that its members intend to violate the Act." *Id.* Without referencing the de Gavre Declaration, the Court reasoned that the complaint lacked sufficient "allegations" that AAM's members' "intended price increases would in fact be excessive and unduly burden consumers." *Id.* The Court did not separately address AAM's standing to assert a

void-for-vagueness claim. *See id.* Second, the Court held that AAM "fail[ed] to allege that a credible threat of prosecution exists," because AAM had not "allege[d] that its members' actions are guaranteed to violate the Act." *Id.* In addition, the Court noted that "AAM does not allege that any of its members have received a notice of investigation, or have been subject to an investigation or enforcement action." *Id.* The Court allowed AAM to re-plead. ECF No. 37.

LEGAL STANDARD

The sufficiency of a complaint's standing allegations is evaluated under the *Twombly/Iqbal* plausibility standard. *Silha v. ACT, Inc.*, 807 F.3d 169, 174 (7th Cir. 2015). Under that standard, courts "accept all well-pleaded factual allegations as true," "draw all reasonable inferences in favor of the plaintiff," and "presum[e] that general allegations embrace those specific facts that are necessary to support the claim." *Prairie Rivers Network*, 2 F.4th at 1007, 1008 (citation omitted). The allegations "need not prove" standing but need "show only that" the plaintiff's claim of standing "is 'plausible on its face.'" *Taylor v. Salvation Army Nat'l Corp.*, 110 F.4th 1017, 1035 (7th Cir. 2024) (citation omitted). "This standard is not demanding." *Id.* (citation and quotation marks omitted).

I. AAM has plausibly alleged injury-in-fact for this pre-enforcement challenge.

An association may sue 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 "violate the [law] and risk prosecution in order to challenge it." *Ezell*

v. City of Chicago, 651 F.3d 684, 695 (7th Cir. 2011). Rather, a plaintiff may 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). "To suffice for standing, and to avoid confusing standing with the merits, plaintiffs' intended course of conduct need only be … 'arguably' proscribed by the challenged statute." *Brown*, 86 F.4th at 762; *see also Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 162 (2014) (same).

A. AAM has plausibly alleged its members' intended conduct will violate the Act.

The Amended Complaint plausibly alleges that at least one AAM member intends to raise the price of a regulated medicine in a manner that is "'arguably' proscribed by the [Act]," and at least one other is refraining from doing so because of the Act. *Brown*, 86 F.4th at 762.

1. To address the concerns articulated in the Court's dismissal order, the Amended Complaint now identifies a specific intended price increase for a specific product by a specific AAM member. ECF No. 35 ("AC") ¶¶ 46-48. It alleges facts demonstrating that the Sandoz product is an "essential off-patent or generic drug," as defined, and details the exact dollar amount of the intended increase, as well as the percentage of that increase over the prior year's price. *Id.* ¶¶ 46-47. It also alleges the precise medical condition for which the Sandoz product is indicated—which is "both life threatening and chronic." *Id.* ¶ 46. Finally, the Amended Complaint alleges the specific reasons for the price increase: "regulatory approval costs, costs incurred due to product inventory loss, and inflation," as well as the need to "meet the company's long-term growth strategy, to increase or sustain its overall profit margins, and to provide a greater return on investment for its shareholders." *Id.* ¶ 47. Those factors, none of which is exempted from the Act's definition of price gouging, account for a "majority of the anticipated price increase." *Id.*

That is sufficient to allege Sandoz's intent to adopt a price increase that is "'*arguably*' proscribed by the [Act]." *Brown*, 86 F.4th at 762 (emphasis added). As Defendant acknowledges, conduct "arguably proscribed" is all that is required. *See* ECF No. 39 ("Def. Br.") 7.[3]

Defendant starts with the remarkable argument that the Court *already* found the details of Sandoz's price increase deficient. Def. Br. 1, 10. But those details were in the de Gavre Declaration, which the Court's dismissal order never mentions—*just as Defendant urged*. Defendant insisted that the Court *could not* consider the facts in the de Gavre Declaration when evaluating Defendant's "facial challenge" to AAM's standing, ECF No. 26 at 17, and the Court looked only "to the complaint," ECF No. 32 at 2 (citation omitted); *see id.* at 1, 3. Having previously persuaded the Court *not* to consider the facts of Sandoz's price increase because they were not in the complaint, Defendant cannot now argue that the Court has already considered those facts and found them insufficient.

Defendant's substantive attacks on the Amended Complaint's new allegations of Sandoz's price increase fare no better. Defendant disputes neither that the Sandoz product is regulated by the Act, nor that Sandoz's intended price increase satisfies the Act's quantitative thresholds. *See* Def. Br. 10-11. Instead, in the single paragraph Defendant devotes to the Sandoz price increase, Defendant asserts that the Amended Complaint "provides no specific facts demonstrating" that Sandoz's intended price increase is "excessive—i.e., more than necessary—or unduly burdensome

[3] AAM thus need not establish that its members' "actions are *guaranteed* to violate the Act," as the Court's dismissal order stated. ECF No. 32 at 3 (emphasis added). Contrary to Defendant's subtle suggestion, nothing in *Indiana Right to Life Victory Fund v. Morales*, 66 F.4th 625 (7th Cir. 2023), imposes a heightened standard for alleging injury-in-fact for non-First Amendment claims. Notably, the Supreme Court's key case on the point upheld standing to assert a void-for-vagueness claim like AAM's based on past "arguabl[e]" violations of the vague statute. *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 303 (1979). Likewise, the Seventh Circuit has applied that standard to find standing to assert a non-First Amendment claim (preemption). *See Devine*, 433 F.3d at 962, 963.

to consumers." *Id.* That is demonstrably false. First, AAM now alleges the specific dollar and percentage amount of Sandoz's intended increase, AC ¶¶ 46-47, which Defendant concedes is "substantial," Def. Br. 11. Second, AAM identifies the potential burden on consumers—the medicine treats a condition that is "life-threatening and chronic," and there are only two other suppliers in the United States. AC ¶ 46. Third, as Defendant basically admits, AAM now alleges that Sandoz is implementing that increase largely for business-centric reasons that are not exempted from the Act—not only to cover overhead (such as "regulatory approval costs") but also to "increase or sustain its overall profit margins" and generate a "greater return on investment for its shareholders." *Id.* ¶ 47. That is more than sufficient to plausibly allege a price increase that an Illinois court would deem "excessive" and "unduly burden[some]" to consumers "because of" the medicine's "importance … to their health" and "insufficient competition." 410 ILCS § 725/5.

Defendant hints that perhaps AAM has not shown Sandoz's price increase to be excessive because it is alleged to be "'necessary' for [Sandoz's] long-term growth strategy," and because a *minority* of Sandoz's intended price increase is attributable to factors exempt from the Act. Def. Br. 11. Of course, if Defendant truly believed these features excluded Sandoz's intended price increase from liability, then he should have no trouble disclaiming an intent to bring an enforcement action against Sandoz—but he has consistently refused to do so. *See* p. 12, *infra*. In any event, Defendant's argument flouts Rule 12(b)'s mandate that "all reasonable inferences" be drawn "in favor of the plaintiff [non-moving party]." *Prairie Rivers Network*, 2 F.4th at 1007. Under that "not demanding" standard, *Taylor*, 110 F.4th at 1035 (citation omitted), it is at least *plausible* that a "substantial" (Def. Br. 11) price increase on an essential medicine that treats a life-threatening and chronic condition, a majority of which is attributable to non-exempt factors, including the goal of increasing a pharmaceutical company's profits, is "excessive" and will

"unduly burden[] consumers." 410 ILCS § 725/5.

2. Apart from the new allegations of Sandoz's intended price increase, the Amended Complaint now alleges, with greater detail, that other AAM members intend, or intended but for the Act, to raise the prices of their regulated medicines in a manner that would at least "'arguably' [be] proscribed by the [Act]." *Brown*, 86 F.4th at 762. The Amended Complaint plausibly alleges that these other AAM members' price increases satisfy the Act's quantitative requirements. AC ¶¶ 39, 45, 50. And it alleges that an Illinois court would consider these members' price increases to be "excessive" and "unduly burden[some]" to consumers because they: (1) will (or would) "substantially exceed[] a 30% increase over the prior year's wholesale acquisition cost for the medicine"; (2) affect medicines "indicated for the treatment of life-threatening or chronic health condition[s]," and (3) are (or were) motivated by factors not exempt under the Act, "including these companies' goals of increasing profitability and shareholder value and offsetting price reductions on other products that have reduced the companies' overall profitability." *Id.* ¶¶ 45, 50. By noting that "part" of these increases are for exempted costs, Def. Br. 11, Defendant only highlights that the lion's share are not.

Defendant complains that these manufacturers other than Sandoz are "unidentified," Def. Br. 10, 12, but the law does not require associations to plead the identity of each injured member, *see, e.g.*, *Luce v. Kelly*, No. 21-cv-1250, 2022 WL 204373, at *5 (N.D. Ill. Jan. 24, 2022) ("the Seventh Circuit has not required organizations to name individual members who possess standing")—a point Defendant has previously conceded, *see* ECF No. 28 at 5.

Nor are AAM's allegations too "generalized." Def. Br. 10, 12. This case is nothing like the extreme example on which Defendant relies—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. AAM identified all its members when it filed suit. ECF No. 35, Ex. A. The Amended Complaint alleges that those "AAM members [who] intend to raise the[ir] prices …. will face severe economic harm from the enforcement of the Act," AC ¶ 49, and those "AAM[] members who are refraining from raising their prices because of the Act are facing economic harm in the form of lost revenues they would otherwise realize but for the Act's prohibition," *id.* ¶ 52.

3. Defendant's litigation strategy of hiding behind the Act's vagueness—refusing to confirm that any conduct either violates the Act or does not—underscores that AAM has standing to pursue its void-for-vagueness claim. AC ¶¶ 98-103. Indeed, Defendant has no argument to the contrary. AAM has alleged that the Act violates due process because it (a) does not "provide any guidance for discerning" whether "the prices at which [AAM's members] sell their generic and biosimilar medicines" will satisfy the Act's qualitative thresholds, and (b) does not "cabin [Defendant's] discretion in deciding whether to initiate an investigation or bring an enforcement action." *Id.* ¶¶ 100, 102.[4] That vagueness and unbridled enforcement discretion "*independently* harm[s] AAM's members," *id.* ¶ 53 (emphasis added), causing them "economic harm in the form of lost revenues that they would otherwise realize" if not for "the chilling effect resulting from the Act's vague terms." *Id.* ¶ 52; *see also id.* ¶ 53. At a minimum, AAM has standing to assert its void-for-vagueness claim.

[4] Defendant notes that he *may* request information about a price increase from a manufacturer before suing, Def. Br. 3-4, but he is not required to do so. Nor is he required to wait for another state department to notify him of a potential violation; he can sue whenever he has reason to believe a violation has occurred. *See* 410 ILCS § 725/10(a)-(b); pp. 3-4, *supra*.

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

The Amended Complaint also alleges "a credible threat" of enforcement. *Devine*, 433 F.3d at 963 (citation omitted). It alleges that at least one AAM member intends to raise the price of a medicine regulated by the Act in a way that is at least "'arguably' proscribed by the [Act]." *Brown*, 86 F.4th at 762; *see* Part I.A, *supra*. That is sufficient to make out a credible threat of enforcement because "*[t]he very 'existence of a statute* implies a threat to prosecute.'" *Ezell*, 651 F.3d at 695-96 (emphasis added) (quoting *Bauer v. Shepard*, 620 F.3d 704, 708 (7th Cir. 2010)); *see Korte v. Sebelius*, 735 F.3d 654, 667 (7th Cir. 2013) (same); *Alvarez*, 679 F.3d at 591 (same); *Bell v. Keating*, 697 F.3d 445, 451 (7th Cir. 2012) (same). The credibility of that threat is only enhanced by the details of Sandoz's price increase now alleged in the Amended Complaint, which describe a price increase that falls squarely within the Act's prohibition.

The decision in *Parents Protecting Our Children, UA v. Eau Claire Area School District, Wisconsin*, 95 F.4th 501 (7th Cir. 2024), does not support a different outcome. *Cf.* Def. Br. 12, 13. That case involved an association of parents challenging a school district's policy that "provide[d] direction and resources to schools encountering students with questions about their gender identity." 95 F.4th at 503. No parent was regulated by the school district's policy, and so the Seventh Circuit did not consider whether there was a credible threat of enforcement. *See id.* at 504-06. Here, AAM's members are directly regulated by the Act, and their intent to adopt price increases that are arguably prohibited is what creates the enforcement threat.

Defendant's argument to the contrary 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. 12-13. The law requires no such thing: "A preenforcement plaintiff 'need not show that the authorities have threatened to prosecute him' because 'the threat is latent in the existence of the statute.'" *Alvarez*, 679 F.3d at 591 (quoting *Majors*, 317 F.3d at 721). For that reason, the Supreme Court has found

standing to challenge a "newly enacted law" in a lawsuit filed "before the statute became effective" and any threat of enforcement was possible. *Virginia v. Am. Booksellers Ass'n*, 484 U.S. 383, 392, 393 (1988) (emphasis added); *see Babbitt*, 442 U.S. at 302 (similar); *accord Hays v. City of Urbana*, 104 F.3d 102, 103 (7th Cir. 1997) (preenforcement plaintiff has standing "even if the threat of prosecution is not immediate—indeed, even if the law is not yet in effect"); *Devine*, 433 F.3d at 962 (similar). Past enforcement actions and statements about enforcement priorities can help *substantiate* an enforcement threat, but they are *not* required to show one. To the extent the Court previously deemed the absence of "an investigation or enforcement" by Defendant significant, ECF No. 32 at 3, the Amended Complaint's additional allegations, including those detailing Sandoz's price increase, suffice to plausibly allege a credible enforcement threat.

The Amended Complaint also alleges that Defendant has refused to disavow enforcement of the Act against any AAM member—including Sandoz, after having reviewed the details of its intended price increase in a sworn declaration. AC ¶¶ 44, 48. That confirms at least one AAM member faces a credible threat of enforcement, as "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). At a minimum, the absence of a disavowal—particularly with the details of Sandoz's price increase now alleged in the Amended Complaint—supports a credible threat of enforcement. *See 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); *Brown*, 86 F.4th at 769-70 ("[T]he absence of a clear disavowal tends to support finding a credible threat of prosecution."); *Morales*, 66 F.4th at 631 (similar). Defendant concedes this latter point, but only repeats that he has not "conducted or brought an investigation against anyone." Def. Br.

13. That Defendant has made a strategic decision to keep mum about his enforcement intentions for now, in hopes of getting this case dismissed, hardly suggests that a threat of enforcement is remote.[5]

The credibility of the enforcement threat is enhanced by the Act's vague terms and conferral of unbridled enforcement discretion on Defendant. *Brown*, 86 F.4th at 766 ("vagueness is also relevant in evaluating plaintiffs' fears of prosecution"). AAM has alleged that the Act provides "no meaningful guidance regarding when a price increase … will be deemed by [Defendant] to violate the Act," and does not "cabin [Defendant's] discretion in deciding whether to initiate an investigation or bring an enforcement action." AC ¶¶ 51, 102. That "vagueness," coupled with "[t]h[e] paucity of guidance and wealth of discretion" conferred on Defendant, makes it even more plausible that at least one AAM member is facing a credible threat of enforcement. *Brown*, 86 F.4th at 766-67.

* * *

The Amended Complaint therefore plausibly alleges that at least one member intends or intended to increase prices in a way arguably proscribed by the Act, and there is a credible threat that Defendant will institute an enforcement action. That is sufficient for injury-in-fact.

II. 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 Chicago*, 534 F. Supp. 3d 936, 948-49 (N.D. Ill. 2021). In any event,

[5] AAM's standing is premised on far more than an abstract "chilling effect." Def. Br. 7 (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. 6-10, *supra*. That is "concrete injury" under *Whole Women's Health*, 595 U.S. at 50.

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 Fountain 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 a credible risk of enforcement. *See* Section I.B, *supra*. AAM members are also refraining from previously planned price increases due to the Act, which will result in economic loss. AC ¶¶ 50, 52. 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 "depend on the specific circumstances" of a given sale. Def. Br. 14. But the Amended Complaint alleges all the relevant details: (a) "[a]ll but two of AAM's members are located outside Illinois," AC ¶¶ 28, 41; (b) those members "located outside Illinois sell their medicines overwhelmingly to large wholesale distributors … also located outside Illinois," *id.* ¶¶ 25, 28, 41; (c) the out-of-state "wholesale distributors take title to those products outside Illinois," *id.* ¶ 28; (d) some of those products are eventually resold into Illinois by third parties, *id.* ¶ 42; and (e) AAM's members "do not control the prices at which wholesale distributors resell their medicines or where those products are ultimately resold," *id.* ¶¶ 26, 42. Moreover, AAM has alleged its members' price increases are prohibited by the Act. Section I.A, *supra*. Thus, 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 wholly out-of-state sales. Such "purely legal issues are normally fit for judicial decision." *Barland*, 664 F.3d at 148. Defendant insists this is a "facial challenge" (citing nothing) and urges the Court to wait for an "as-applied" one, Def. Br. 14-15, but he misses that AAM has brought Commerce Clause and due process claims challenging the Act *as applied* to transactions outside Illinois, AC ¶¶ 80-81, 84-86.

Equally flawed is Defendant's argument that AAM's lawsuit is not ripe because of a need to interpret the Act. Def. Br. 14-15. The parties *agree* the Act regulates prices charged by out-of-state manufacturers to other out-of-state entities, Def. Br. 2, and so adjudicating the constitutionality of those provision will not require "[s]peculation about the scope of [the] state law," Def. Br. 8; *see Gov't Suppliers Consol. Servs., Inc. v. Bayh*, 975 F.2d 1267, 1275-76 (7th Cir. 1992) (case ripe when "what the statutes authorize is clear"). 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. 15. 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.

CONCLUSION

The Court should deny Defendant's motion to dismiss.

September 20, 2024

Respectfully submitted,

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