

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

ASSOCIATION FOR ACCESSIBLE  
MEDICINES,

Plaintiff,

v.

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

Defendant.

Case No. 24-cv-00544

Hon. Virginia M. Kendall

**DEFENDANT'S REPLY IN SUPPORT OF HIS MOTION TO DISMISS**

Date: April 25, 2024

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## INTRODUCTION

In 2023, the Illinois legislature enacted Public Act 103-367 (the “Act”) in response to reports of pharmaceutical industry members imposing egregious price increases on essential medications without any legitimate business need to do so. Relevant here, the Act prohibits excessive and unduly burdensome price increases for generic prescription drugs sold in Illinois, but does not restrict price increases that arise out of legitimate business needs. 410 ILCS 725/10. In other words, the Act’s provisions will protect Illinois residents from the abusive pricing tactics that have inflicted irreparable harm on their health and economic wellbeing, while allowing the pharmaceutical industry to raise prices in accordance with legitimate business needs.

The Association for Accessible Medicines (“AAM”), however, attempts to invalidate the entirety of the Act through a sweeping pre-enforcement complaint. But as outlined in the motion to dismiss, AAM has not established subject-matter jurisdiction in several respects, including by failing to allege an imminent injury-in-fact and seeking overbroad facial relief that is unwarranted at this juncture. In response, AAM does not meaningfully attempt to defend the sufficiency of the allegations in its complaint. It instead argues that its burden to establish subject-matter jurisdiction is “not demanding,” and, alternatively, that this Court should consider additional statements made in a declaration that it submitted in conjunction with its preliminary injunction motion. But when viewed under the correct standard, and even taking into account the improper declaration, AAM cannot succeed. In fact, the Seventh Circuit issued a decision last month confirming that sweeping, pre-enforcement challenges to state and local policies are improper where, as here, the organization bringing such challenges fails to identify a single instance of actual or imminent enforcement against any of its members. *Parents Protecting Our Children, UA v. Eau Claire Area Sch. Dist., Wisconsin*, 95 F.4th 501 (7th Cir. 2024). This Court should dismiss AAM’s complaint.

## ARGUMENT

### **I. AAM misstates its burden in establishing subject-matter jurisdiction.**

At the threshold, AAM’s various attempts to lessen its burden to establish standing are unpersuasive. As explained, Dkt. 26 at 11-13, AAM must establish that it has presented a “case” or “controversy” that is currently fit for resolution by a federal court. *Sweeney v. Raoul*, 990 F.3d 555, 559 (7th Cir. 2021). This inquiry is based on the allegations in the complaint itself, *Silha v. ACT, Inc.*, 807 F.3d 169, 173 (7th Cir. 2015), and is especially important in the context of broad, pre-enforcement challenges to a state statute that has yet to be interpreted by the State’s highest court, e.g., *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450–51 (2008); *Arizonans for Off. Eng. v. Arizona*, 520 U.S. 43, 79 (1997).

The Seventh Circuit very recently reiterated the importance of these foundational principles in a decision concluding that an associational plaintiff lacked Article III standing to bring a broad, pre-enforcement challenge to a local policy. The Seventh Circuit explained that because “[f]ederal courts are courts of limited jurisdiction,” they must “ensure the presence of a Case or Controversy” at the outset, “[n]o matter how important a legal question or how sincere a worry.” *Parents Protecting Our Children*, 95 F.4th at 504. This requirement “anchors itself in principles of separation of powers and federalism” because “[i]n limiting the authority of federal courts, the Constitution empowers other branches and actors (and by extension, the people).” *Id.* These principles are particularly important, the court explained, where the plaintiff seeks “sweeping pre-enforcement facial invalidation of a law” and where “the relief sought implicates a local policy and weighty principles of federalism.” *Id.* at 506; *see also id.* at 504 (Article III jurisdictional limitations ensure that federal courts do not encroach upon state or municipal authority). AAM’s complaint runs afoul of these principles because it seeks facial invalidation of a new state statute that has yet to be enforced by the Attorney General or interpreted by any state court.

Notwithstanding this controlling Seventh Circuit authority, AAM attempts to lessen its burden in several ways. None is persuasive. To start, AAM describes the inquiry under Rule 12(b)(1) as “not demanding,” requiring only “general allegations” demonstrating that the plaintiff’s standing is “plausible.” Dkt. 27 at 3 (cleaned up). But the Seventh Circuit has made clear that even in facial challenges to standing, which presume the veracity of plaintiff’s allegations, the complaint must ““contain sufficient factual matter”” to satisfy each element of the standing analysis. *Silha*, 807 F.3d at 173 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). And allegations that are “no more than conclusions” must be disregarded. *Id.* (cleaned up). AAM thus cannot rely solely on its general and conclusory allegations to support standing.

Furthermore, the cases AAM cites do not support its argument. Dkt. 3 (citing *G.G. v. Salesforce.com, Inc.*, 76 F.4th 544 (7th Cir. 2023), and *Prairie Rivers Network v. Dynegy Midwest Generation, LLC*, 2 F.4th 1002 (7th Cir. 2021)). In *G.G.*, the court addressed whether a victim of sex trafficking had sufficiently stated a claim under a federal statute. 76 F.4th at 548. It did not involve associational standing or pre-enforcement constitutional challenges to a state statute, and thus does not provide any useful governing principles to the challenge at issue here. In *Prairie Rivers Network*, a case addressing a facial attack on associational standing, the Seventh Circuit concluded that the organization failed to satisfy its burden because it spoke “of its individual members only as a collective” and failed to show “how exactly [the defendants’ conduct] will harm them individually.” 2 F.4th at 1005. In other words, the organization failed to “allege facts sufficient to show that at least one of its members could sue in their own right.” *Id.* at 1010. This case thus supports defendant’s position, and not AAM’s.

AAM’s argument that it may rely solely on general allegations under a “plausibility” standard is flawed for the additional reason that AAM places substantial weight on the Sandoz

declaration. Dkt. 27 at 3–5. This argument disregards the critical distinctions between facial and factual challenges to subject-matter jurisdiction, as well as the role of outside evidence in each. Where, as here, the defendant raises a facial challenge, “the court does not look beyond the allegations in the complaint, which are taken as true for purposes of the motion.” *Apex Digital, Inc. v. Sears, Roebuck & Co.*, 572 F.3d 440, 444 (7th Cir. 2009). In factual challenges, however, “the district court may properly look beyond the jurisdictional allegations of the complaint and view whatever evidence has been submitted on the issue to determine whether in fact subject matter jurisdiction exists.” *Id.* (cleaned up); see *Marszalek v. Kelly*, No. 20-CV-4270, 2022 WL 225882, at \*3 (N.D. Ill. Jan. 26, 2022) (same). But when materials outside of the complaint are presented and considered, “no presumptive truthfulness attaches to plaintiff’s allegations.” *Apex Digital, Inc.*, 572 F.3d at 444. Instead, “the plaintiff must support each controverted element of standing with ‘competent proof,’ which [the Seventh Circuit has] understood as a showing by a preponderance of the evidence, or proof to a reasonable probability, that standing exists.” *Bazile v. Fin. Sys. of Green Bay, Inc.*, 983 F.3d 274, 278 (7th Cir. 2020) (cleaned up). In other words, if AAM seeks to rely on the Sandoz declaration (which, as explained, it cannot), then it does not receive the benefit of the “plausibility” standard that otherwise attaches at the pleading stage.

Relatedly, AAM is incorrect that this Court has a “duty” to consider the Sandoz declaration. Dkt. 27 at 5. To be sure, it is well within a court’s discretion “to allow or to require the plaintiff to supply, by amendment to the complaint or by affidavits, further particularized allegations of fact deemed supportive of plaintiff’s standing.” *Warth v. Seldin*, 422 U.S. 490, 501 (1975). But courts typically request this additional information when a defendant, in raising a factual challenge to standing, has “proffer[ed] evidence that calls the court’s jurisdiction into question,” *Hay v. Indiana State Bd. of Tax Comm’rs*, 312 F.3d 876, 878 (7th Cir. 2002), or where the court itself has



“determined it required more information to fulfill [its] obligation” to confirm jurisdiction, *Int’l Union of Operating Engineers, Loc. 139, AFL-CIO v. Daley*, 983 F.3d 287, 294–95 (7th Cir. 2020).

Either way, this Court is not bound to consider AAM’s supplemental material.

Finally, AAM disputes its obligation to identify, in its complaint, a specific example of a member with standing. Dkt. 27 at 5. According to AAM, it has satisfied this obligation by providing a list of its members and by alleging that the Act will harm “those AAM members who refrain from raising their prices” as well as “those AAM members who intend to proceed with their price adjustments notwithstanding the Act.” *Id.* at 6. But, as explained, Dkt. 26 at 15, referring to members in the collective is insufficient under Seventh Circuit law. While it is not necessary to name the member when describing their proposed course of conduct, the association must describe individual members and describe their basis for standing with “specific allegations.” *Prairie Rivers Network*, 2 F.4th at 1009; *Goldman v. City of Highland Park, Illinois*, No. 22 C 4774, 2024 WL 98429, at \*5 (N.D. Ill. Jan. 9, 2024) (rejecting associational standing where the organization “merely refers to its members in the collective”). The complaint alleges an injury only at the highest level of generality, *see infra* Section II, and without any details about what any specific member actually intends to do. That AAM has attached a list of its members (without connecting any of those members to any particular course of conduct) does not cure those deficiencies. *Prairie Rivers Network*, 2 F.4th at 1010 (without allegations about individual members, “associational standing allegations are akin to impermissible speculation rather than permissible presumption”).

## **II. AAM fails to establish subject-matter jurisdiction.**

Because AAM has failed to satisfy its burden to establish subject-matter jurisdiction, its complaint should be dismissed for lack of Article III standing and ripeness. *See* Dkt. 26 at 11–20. In particular, AAM has not plausibly alleged an intended course of conduct or credible threat of enforcement, and thus has not demonstrated an injury-in-fact. Furthermore, AAM’s complaint

requests premature adjudication of constitutional questions that would be better suited for as-applied challenges. AAM attempts to rebut these points, but none of its arguments is persuasive.

**A. AAM fails to plausibly allege an intended course of conduct.**

To start, AAM cannot establish an injury-in-fact for the threshold reason that its complaint does not provide plausible allegations of its members' intended course of conduct. *See* Dkt. 26 at 14–15. It is thus impossible to determine whether that conduct is “arguably affected by” the Act or whether any member faces a “credible threat the [Act] will be enforced against him when he does.” *Speech First v. Killeen*, 968 F.3d 628, 638 (7th Cir. 2020). The complaint merely contains vague and conclusory allegations about how some, unidentified manufacturers intend, at an unidentified point in the future, to “raise the prices of one or more essential off-patent or generic drugs,” Dkt. 1 ¶ 43, while other, unidentified members will refrain from raising prices for unidentified generic drugs, *id.* ¶ 44. The complaint also does not identify any intended course of conduct for distributors, even though it purports to seek a remedy on their behalf. *Id.* ¶¶ 7, 40. And although the complaint alleges that these unidentified price increases would meet the quantitative element of price gouging under the Act, it makes no attempt to allege enough to plausibly show that these price increases would satisfy the other components of the Act: that the prices increases be otherwise excessive, unduly burdensome to consumers, and not attributable to production costs or costs that increase access to the drug. Dkt. 26 at 15.

AAM does not meaningfully contest the lack of detail in the complaint itself. Instead, it claims that this level of detail is unnecessary and, in any event, that the requisite detail could be satisfied through some combination of the Sandoz declaration and its allegations in the complaint. Dkt. 27 at 4–8. Neither is correct. First, AAM wrongly asserts that it satisfied the course-of-conduct requirement by alleging that “some AAM members intend to raise their prices for medicines subject to the Act ‘in a manner that satisfied every ascertainable element of the Act’s definition of

price gouging.” Dkt. 27 at 4 (quoting Dkt. 1 ¶ 43). This allegation is a legal conclusion, and AAM provides no support for its view that such a conclusory allegation would suffice. Nor could it. It is “a threshold requirement to establish a credible threat of enforcement that the statute actually cover the plaintiff’s desired conduct.” *Ind. Right to Life Victory Fund v. Morales*, 66 F.4th 625, 630 (7th Cir. 2023). The plaintiff thus must provide factual allegations showing that its intended conduct (or the conduct of one of its members) would arguably violate every aspect of the challenged statute. *E.g.*, *National Shooting Sports Foundation v. Lopez*, No. 23-00287, 2024 WL 1703105, at \*5 (D. Haw. Apr. 19, 2024) (addressing each aspect of a statute when determining whether associational plaintiff has alleged a sufficient course of conduct).

Second, AAM asserts that it has addressed each element of the Act through a combination of the complaint and Sandoz declaration. Dkt. 27 at 6–8. But neither the complaint nor the Sandoz declaration (assuming it is considered, *supra* p. 4) provides sufficient detail on an intended course of conduct. AAM does not even attempt to identify an allegation (or statement in the Sandoz declaration) that would address the “unduly burdensome” element of the Act. Instead, it argues that it has satisfied the “unduly burdensome” element because a drug is only covered by the Act if it is “on a list of essential medicines and manufactured by three or fewer companies.” Dkt. 27 at 7. Therefore, AAM argues, “[s]atisfying those factors *alone* suffices to plausibly allege that price increases for those medicines will arguably burden consumers ‘because of’ the medicine’s importance to their health and insufficient competition.” *Id.* (cleaned up). But this interpretation cannot be true, since it would render the “unduly burdensome” element entirely superfluous. *Wittman v. Koenig*, 831 F.3d 416, 422 (7th Cir. 2016) (“Statutory language is read where possible to give reasonable effect to every word, in order to avoid surplusage.”).

With respect to the “otherwise excessive” element, AAM points to its allegation that “the

anticipated increases ‘constitute *substantially more* than a 30% increase for those medicines over one year—the threshold for triggering the Act’s liability for a one-year increase.’” Dkt. 27 at 7 (quoting Dkt. 1 ¶ 38) (cleaned up) (emphasis in original). AAM has cherry-picked this language. When viewed in context, this allegation addresses the quantitative formula: “AAM members intend, or intended until the Act’s adoption to raise the wholesale acquisition cost of certain generic or other off-patent drugs in a manner that meets the quantitative elements of ‘price gouging’ under the Act—*e.g.*, constituting substantially more than a 30% increase of the wholesale acquisition cost for those medicines over one year. The wholesale acquisition cost for these medicines would exceed \$20 for a 30-day supply.” Dkt. 1 ¶ 38. Furthermore, neither this language nor the Sandoz declaration provides any explanation as to why such increases, even if substantial, would be *excessive* in nature—*i.e.*, that they are more than necessary. On the contrary, both AAM and Sandoz claim that these price increases would be necessary to cover production costs, maintain productivity, or be competitive in the marketplace. Dkt. 1 ¶¶ 11, 37, 48; Dkt. 20 ¶ 26.

Finally, AAM incorrectly asserts that it has demonstrated that the price increases are not attributable to production costs because it has alleged that “some of the planned price increases are necessitated, at least in part, by economic or cost factors other than those excepted by the Act” and because the Sandoz declaration “identifies specific categories of costs partially responsible for the price increase.” Dkt. 27 at 8. According to AAM, these “allegations, coupled with the [Sandoz] declaration, are more than adequate” to satisfy the Rule 12(b)(1) pleading standard. *Id.* But as explained, the “plausibility” standard does not apply to evidence presented in an attempt to supplement the complaint. In any event, these materials provide insufficient details to discern whether the price increases (especially the unidentified increases referenced in the complaint) would run afoul of this provision of the Act.

**B. AAM fails to plausibly allege a credible threat of enforcement.**

Furthermore, AAM has not identified a credible threat of enforcement: it provided no allegations that the Attorney General has sent a notice, begun an investigation, or brought an investigation against anyone, or that he has plans to do so. Instead, it speculates that, at some point in the future, there may be a “substantial risk the Attorney General and an Illinois court would determine that the contemplated price increases by AAM’s members of their essential off-patent or generic drugs meet [the] elements of the definition of ‘price gouging.’” Dkt. 1 ¶ 42.

As the Seventh Circuit recently recognized in *Parents Protecting Our Children*, however, such concerns over a new policy are insufficient to confer standing “[u]nless that policy operates to impose an injury or to create an imminent risk of injury.” 95 F.4th at 503. There, the Seventh Circuit rejected an organization’s claim of associational standing because, while the “allegations punch[ed] with conviction and concern[,] . . . nowhere does the complaint allege that even one of the association’s members—any particular parent—has experienced an actual or imminent injury attributable to the [policy].” *Id.* at 505. And though the court recognized that the organization’s members may “experience[ ] actual injury or face . . . imminent harm” in the future, the allegations “today . . . fall short of establishing a Case or Controversy.” *Id.* at 506.

For its part, AAM appears to concede the lack of such allegations by failing to identify an allegation, or even a statement in the Sandoz declaration, that shows any such credible threat. Dkt. 27 at 8–10. Instead, AAM asserts that this Court should presume that a credible threat exists unless the Attorney General disavows enforcement against it. Dkt. 27 at 9. But this is not the law. On the contrary, the existence or absence of a disavowal of enforcement is just one of many factors that a court may weigh when assessing whether there is a credible threat of enforcement. *E.g.*, *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 160–61 (2014) (considering government’s decision not “to disavow prosecution” as one factor among others); *ACLU of Illinois v. Alvarez*, 679 F.3d 583,

592–93 (7th Cir. 2012) (assessing credible threat of enforcement by reviewing totality of the circumstances, including recent prosecutions and failure to disavow enforcement against plaintiff); *see also, e.g., Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 607 (8th Cir. 2022) (considering government’s past “pursuit of [several] enforcement actions” coupled with “its failure to disavow”); *Fischer v. Thomas*, 52 F.4th 303, 307–08 (6th Cir. 2022) (describing four factors: “(1) Does the relevant prosecuting entity have a prior history of enforcing the challenged provision against the plaintiffs or others? (2) Has that entity sent warning letters to the plaintiffs regarding their conduct? (3) Does the challenged regulatory regime make enforcement easier or more likely? and (4) Did the prosecuting entity refuse to disavow enforcement of the challenged provision against the plaintiffs?”); *LSO, Ltd. v. Stroh*, 205 F.3d 1146, 1155 (9th Cir. 2000) (“failure to disavow ‘is an attitudinal factor’” rather than a requirement).

If AAM’s proposed rule were the standard (it is not), then the course of conduct and credible threat of enforcement prongs of injury-in-fact would effectively merge into a single inquiry: whether the challenged statute arguably covers the plaintiff’s intended conduct, regardless of any threat of enforcement. It also would call into question the recent Seventh Circuit decision *Parents Protecting Our Children*, among others, which did not apply such a presumption or require the government to affirmatively disavow enforcement.

AAM cites several cases in support of its presumption theory, but none stands for that proposition. In *Ezell v. City of Chicago*, 651 F.3d 684 (7th Cir. 2011), for example, the Seventh Circuit did not impose a presumption of a credible threat based on the existence of a statute, as AAM suggests. Dkt. 27 at 9. Rather, the court merely explained that the reason pre-enforcement challenges are proper (as a general matter) under Article III is because “[t]he very existence of a statute implies a threat to prosecute,” and “the probability of future injury counts as ‘injury’ for

purposes of standing.” *Ezell*, 651 at 695–96. Accordingly, a plaintiff need not violate a law “and risk prosecution in order to challenge it.” *Id.* at 695; *see also Bauer v. Shepard*, 620 F.3d 704, 708 (7th Cir. 2010) (similar). In *Brown v. Kemp*, 86 F.4th 745 (7th Cir. 2023), as AAM appears to recognize, the court considered many factors when assessing whether a credible threat of enforcement exists, including “the absence of a clear disavowal” of prosecution, as well as “the history of attempted prosecutions against [the plaintiffs] for similar conduct, the active enforcement of [the regulation], and the statute’s grant of widely distributed and broad enforcement discretion.” *Id.* at 769. And in *Carey v. Wisconsin Elections Comm’n*, 624 F. Supp. 3d 1020 (W.D. Wis. 2022), the court considered other factors in addition to the defendants’ failure to clearly disavow enforcement, such as past incidents showing that other local officials were enforcing the law in the manner alleged by the plaintiff. *Id.* at 1030.

Finally, AAM is incorrect that this Court should disregard *National Shooting Sports Foundation v. Attorney General of New Jersey*, 80 F.4th 215 (3d Cir. 2023), in which the Third Circuit dismissed an associational plaintiff’s pre-enforcement complaint for its failure to sufficiently allege a credible threat of enforcement. Dkt. 27 at 9. On the contrary, this case is even more relevant now that the Seventh Circuit has applied a similar analysis in the *Parents Protecting Our Children* decision, and other courts across the country have followed suit. *See, e.g., National Shooting Sports Foundation v. Lopez*, 2024 WL 1703105 (D. Haw. Apr. 19, 2024); *National Shooting Sports Foundation, Inc. v. Ferguson*, --- F. Supp. 3d ---, No. 2:23-cv-113, 2024 WL 1040673 (E.D. Wash. Mar. 8, 2024). Its holding applies directly here, where AAM has failed to allege a credible threat of enforcement under a statute that had not yet “been enforced against anyone, let alone the [association] or its members,” and where it “says little about what it plans to do.” *National Shooting Sports Foundation v. Attorney General of New Jersey*, 80 F.4th at 220.

And the fact that the court considered a limited disavowal by the New Jersey Attorney General's Office as one factor among many in the threat-of-enforcement inquiry also does not distinguish it in any meaningful way from this case. *Id.* at 221.

**C. AAM's complaint seeks premature adjudication of fact-intensive challenges.**

AAM's complaint should be dismissed for the alternative reason that it seeks premature adjudication of complex, fact-intensive issues that are best assessed in as-applied challenges involving a specific price increase. *See* Dkt. 26 at 18–20. And as currently presented, AAM asks this Court to enter declaratory and injunctive relief invalidating a law in its entirety based on vague and conclusory allegations and without an actual, concrete dispute between the parties. *Id.*

As the Seventh Circuit recently confirmed, such a request is improper. In *Parents Protecting Our Children*, the court noted that while the members of the association were certainly concerned with how the law would be implemented in the future, it remained the case that not “even one of the association’s members . . . has experienced an actual or imminent injury attributable to the [policy].” 95 F.4th at 505. In other words, all the court had “before [it] is a policy on paper without concrete facts about its implementation.” *Id.* at 505–06. In those circumstances, notwithstanding the “sensitivity, delicacy, and difficulty of the subject matter addressed by the [policy]”—in that case, a policy providing direction and resources to schools about gender identity—the court’s decision dismissing the action “affords the [local government] the opportunity to devise responses in each individual circumstance as it arises.” *Id.* at 506. And, the court made clear, if “resort to the federal courthouse proves necessary in a particular instance, so be it.” *Id.* But while “the ink was still drying on [the challenged policy],” the association could not “pull a federal court into a range of complex” issues in the context of a “sweeping, pre-enforcement” challenge seeking invalidation of the law. *Id.* The same is true here: notwithstanding AAM’s concerns about how the Act may be implemented or enforced, it has failed to identify a



single instance of either, let alone one that has negatively affected one of its members. And notwithstanding the lack of any concrete dispute, it seeks complete invalidation of the Act. Dkt. 1 at 33–34. Such a request, like the one in *Parents Protecting Our Children*, is premature.

AAM contends, however, that its claims are ripe for review because it has shown that the relevant issues are sufficiently focused for judicial resolution and that it would suffer hardship if judicial action were postponed. Dkt. 27 at 10. AAM is incorrect. At the threshold, AAM wrongly focuses this inquiry on prudential ripeness to the exclusion of broader standing and ripeness principles. As explained, the Seventh Circuit, as well as other courts across the country, have not limited their assessment of considerations regarding prematurity to the prudential ripeness doctrine; rather, it is an essential component of constitutional standing and ripeness. But even through the lens of prudential ripeness, AAM’s arguments are unpersuasive.

AAM’s primary argument is that the legal issues are ripe for judicial review because the complaint “alleges all the relevant details” to resolve 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.” Dkt. 27 at 11. According to AAM, there is no need for additional factual development or interpretation of the scope of the Act. *Id.* AAM’s argument rests on an oversimplification of the Act and the constitutional provisions that it invokes. As explained, determining whether a price increase falls within the scope of the Act is a fact-intensive question resting on a number of different variables, including the reason for the price increase and its effect on consumers within the State. Dkt. 26 at 7–9. The Act also requires the Attorney General (the sole enforcer under the Act) to engage in an individualized analysis of the specific price increase, with input from the manufacturer or distributor, before investigating or bringing an enforcement action against the company. *Id.*; 410 ILCS 725/10(b)–(c). Resolving the constitutionality of the Act before

allowing this process to play out would be premature. *E.g., Disability Rts. Wisc., Inc. v. Walworth Cnty. Bd. of Supervisors*, 522 F.3d 796, 802–03 (7th Cir. 2008) (suit was premature where each student would receive an individualized process applying the statute to his or her circumstances).

AAM’s position also ignores how the specific facts of a particular price increase—especially in a complex, interconnected market like the generic drug industry—could affect the outcome in any given case if its own extraterritoriality theory were applied. According to AAM’s theory (which defendant disputes, Dkt. 26 at 20–29), the Act would violate the dormant Commerce Clause and the Due Process Clause when the regulated transaction occurs wholly out-of-state. Dkt. 27 at 11. This would require the Court to assess myriad fact-intensive considerations to determine whether that transaction occurred wholly out-of-state, such as where the transaction occurred, which could be disputed in transactions involving companies with a national presence; whether the generic drugs were sold or distributed in Illinois, and which company (or its subsidiary) effectuated the sale or distribution; and whether the companies engaged in the regulated transaction have any presence in, or contacts with, Illinois. In other words, it is no simple task to identify, on a sweeping, pre-enforcement basis, which categories of transactions would violate the Constitution under AAM’s theory.

AAM next asserts that there is no need to await an as-applied challenge to resolve these questions because part of AAM’s complaint includes “claims challenging the Act *as applied* to transactions outside Illinois.” Dkt. 27 at 11 (emphasis in original). But as just discussed, that category encompasses a wide range of potential transactions that cannot easily be sorted at this stage. Indeed, if this Court were to enter an injunction using AAM’s language, there would almost certainly be follow-on litigation to determine whether any particular transaction occurred out-of-state. And that is because, contrary to its suggestions otherwise, AAM is not actually bringing an

as-applied challenge; instead, it seeks complete (or, alternatively, near-complete) invalidation of the Act in a case untethered to the specific circumstances of any particular company or transaction.

Finally, AAM asserts that it has shown its members will suffer hardship if judicial resolution is postponed because some of its members are subject to enforcement, while others have refrained from imposing “previously planned price increases due to the Act, which will result in economic loss.” Dkt. 27 at 10–11. But as explained, AAM has not demonstrated a credible threat of prosecution as to any of its members, and thus cannot show that it would suffer hardship absent judicial resolution. *See, e.g., Transit, Inc. v. Cook*, 878 F.3d 606, 610 (7th Cir. 2018) (assessing credibility of enforcement threat as part of hardship inquiry). And with respect to those members that have allegedly refrained from increasing the prices of generic drugs, AAM has provided insufficient information to evaluate the extent of any purported hardship stemming from that decision. Dkt. 1 ¶ 44. By contrast, as explained, Dkt. 27 at 30, the hardship to defendant and the public interest would be substantial if the Act were prematurely enjoined. Indeed, the State has a compelling and significant interest in preventing the kind of egregious price increases that harmed its residents and led to the Act’s passage in the first place. *Id.*

### **CONCLUSION**

For the foregoing reasons, the Attorney General requests that the complaint be dismissed.

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