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 MEMORANDUM IN SUPPORT OF HIS MOTION TO DISMISS

Date: August 23, 2024

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INTRODUCTION

In recent years, a minority of pharmaceutical industry members have wrought substantial and irreparable harm on Illinois residents by imposing egregious price increases on essential medications, notwithstanding the lack of any legitimate business need to do so. In 2023, the Illinois legislature responded to this exploitative conduct by enacting Public Act 103-367 (the "Act"), which prohibits excessive and unduly burdensome price increases for generic prescription drugs sold in Illinois. In January 2024, the Association for Accessible Medicines ("AAM") brought a sweeping, pre-enforcement complaint on behalf of members seeking complete invalidation of the Act. Dkt. 1 ("Compl."). In June, this Court dismissed the complaint for failure to allege the requisite injury-in-fact for facial, pre-enforcement challenges. Dkt. 32 at 3. In particular, it concluded that AAM had failed to allege that its members intended to engage in a course of conduct proscribed by Act or that a credible threat of enforcement existed. *Id.*

Shortly thereafter, AAM filed an amended complaint. Dkt. 34 ("Am. Compl."). But AAM fails to cure the two key deficiencies identified by this Court. As to the first, AAM rests on the same types of vague and generally applicable allegations about its members that this Court deemed insufficient to show an injury-in-fact. As to the second, AAM makes no effort to supplement the complaint with any factual allegations showing a credible threat of enforcement. Instead, it incorporates a legal argument that this Court has already rejected. Besides these continuing defects, dismissal is warranted for the additional reason that it would be premature for the Court to adjudicate the sweeping, facial challenge presented by AAM in its amended complaint.

BACKGROUND

A. Factual Background

In 2023, the Illinois General Assembly enacted a law to protect Illinois residents from price gouging of generic drugs. *See* Ill. Pub. Act 103-367 (eff. Jan 1, 2024). Generic prescription drugs are sold through a pharmaceutical supply chain that typically includes manufacturers, wholesale distributors, and pharmacies. Am. Compl. ¶ 25. Manufacturers produce the drug and set the baseline price, which is known as the "wholesale acquisition cost." *Id.* ¶¶ 25-26, 38-39, 47. In some instances, manufacturers sell the drug directly to pharmacies. *Id.* ¶ 46. In others, they sell the drug to wholesale distributors, which then resell to pharmacies. *Id.* ¶ 25.

As the General Assembly explained, there has been a "repeated pattern and practice of price gouging" by certain industry members, which has led patients to choose between "copayments exceeding tens of thousands of dollars per year and risking their health." 410 ILCS 725/2(b)–(c); *see also, e.g.*, Dkt. 26 at 2–6 (detailing these abuses). The Act thus prohibits manufacturers and wholesale drug distributors from engaging in "price gouging in the sale of an essential off-patent or generic drug that is ultimately sold in Illinois." *Id.* 725/10(a).

Relevant here, the Act contains limitations to ensure that it applies only to those industry members making egregious pricing increases. To start, the Act is limited to regulating drugs that are manufactured by three or fewer manufacturers, *id.* 725/5, and thus may not be subject to robust competition in the marketplace. The drugs also must be designated "essential medicines" by the World Health Organization or the U.S. Department of Health and Human Services. *Id.*

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

> An unconscionable increase in price that:
>
> (1) would result in the wholesale acquisition cost of a 30 day supply of

> the essential off-patent or generic drug exceeding $20 and would result in an increase in the wholesale acquisition cost of the essential off-patent or generic drug of:
>
> (A) 50% or more within the preceding year;
> (B) 50% of more within the preceding 3 years; or
> (C) 75% or more within the preceding 5 years;

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

The Act notably does not restrict price increases that are necessary to meet a legitimate business need. The Act makes clear that a price increase does not constitute price gouging when it is reasonably justified by either "an increase in the cost of producing the essential off-patent or generic drug," or "the cost of appropriate expansion of access to the essential off-patent or generic drug to promote public health." *Id.* Thus, a price increase that satisfied the quantitative component and would otherwise be demonstrably excessive and burdensome is *not* price gouging under the Act when that increase is based on increased production costs or corporate efforts to promote access to their drug for the sake of public health.

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

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

B. Procedural Background

On January 22, 2024, AAM filed this action seeking to invalidate the Act in its entirety, alleging that it violates the dormant Commerce Clause, the Due Process Clause, and the Constitution's horizontal separation of powers. Dkt. 1. AAM brought this suit on behalf of its members, which are "manufacturers and distributors of generic and biosimilar medicines." *Id.* ¶ 14. AAM alleged that its members are harmed by the Act because they "intend, or intended until the Act's adoption, to make competitively reasonable price adjustments to the wholesale acquisition cost for certain 'essential off-patent or generic drugs' during the first half of the 2024 calendar year." *Id.* ¶ 37. The complaint did not, however, contain allegations about any of its members' specific plans to do so, or any enforcement actions pending against them. *Id.* ¶¶ 37–45. AAM later filed a motion for a preliminary injunction, based only on the theory that the Act violates the dormant Commerce Clause. Dkt. 18 at 1. As support for this request, AAM submitted a declaration from Timothy DeGavre, the Chief Commercial Officer for Sandoz, Inc. Dkt. 20.

Defendant (the Illinois Attorney General, named in his official capacity) moved to dismiss AAM's complaint for lack of jurisdiction and opposed AAM's motion for preliminary injunction. Dkt. 26. He argued, first, that the Court lacks subject-matter jurisdiction because AAM failed to plausibly allege an injury-in-fact and because AAM's complaint sought to prematurely adjudicate fact-intensive theories. Dkt. 26 at 11-20. Second, he asserted that preliminary injunctive relief was

unwarranted because AAM was unlikely to prevail on the merits of its dormant Commerce Clause claim, had failed to show irreparable harm, and that the balance of hardships favors Illinois and the public interest. Dkt. 26 at 20–30.

This Court dismissed the complaint for lack of subject-matter jurisdiction and denied AAM's motion for preliminary injunction as moot. Dkt. 32. It concluded that AAM had not sufficiently alleged an injury-in-fact for two reasons. First, "AAM [did] not allege that its members intend to violate the Act in a manner that is proscribed by the Act." *Id.* at 3. Second, "AAM . . . fail[ed] to allege that a credible threat of prosecution exists." *Id.*

On July 9, AAM filed an amended complaint that largely tracks the initial complaint, with discrete additions related to the two bases of the district court's dismissal order. Dkt. 34. As to the way its membership purports to violate the Act, AAM has integrated the contents of the de Gavre Declaration—primarily allegations about AAM member Sandoz, Inc.—into the body of its amended complaint. *Compare* Dkt. 20, *with* Am. Compl. ¶¶ 38–54. With respect to imminent enforcement, the complaint still contains no factual allegations about an imminent threat of enforcement, but AAM has incorporated the legal argument that the Attorney General's failure to disavow an enforcement action is dispositive. Dkt. 33 ¶ 8; Am. Compl. ¶¶ 44, 48.

LEGAL STANDARD

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

The Article III case-or-controversy requirement "limits federal courts to resolving concrete disputes between adverse parties." *Sweeney v. Raoul*, 990 F.3d 555, 559 (7th Cir. 2021). To meet the Article III requirement, a plaintiff must satisfy the justiciability doctrines of standing and ripeness. *Id*. As the Seventh Circuit recently reiterated in the context of associational standing, these jurisdictional requirements are essential to foundational 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)." *Parents Protecting Our Children v. Eau Claire Area School District*, 95 F.4th 501, 504, 506 (7th Cir. 2024). "[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977).

For a plaintiff to establish standing in its own right, it "must demonstrate (i) that [it] has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024). Plaintiff's injury must be "concrete"—i.e., "real and not abstract"—and "particularized"—i.e., an injury that "affects the plaintiff in a personal and individual way." *Id.* at 381 (cleaned up). The injury must also "be actual or imminent, not speculative—meaning that the injury must have already occurred or be likely to occur soon." *Id.* "Allegations of possible future injury do not satisfy the requirements of Art. III." *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990). "By requiring the plaintiff to show an injury in fact, Article III screens out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action." *FDA*, 602 U.S. at 381.

In pre-enforcement challenges, review is permitted only "under circumstances that render the threatened enforcement sufficiently imminent." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014). Plaintiffs may satisfy this standard by alleging "an intention to engage in a course of conduct arguably affected by [the challenged statute], and that he faces a credible threat the [statute] will be enforced against him when he does." *Speech First v. Killeen*, 968 F.3d 628, 638 (7th Cir. 2020). But "the 'chilling effect' associated with a potentially unconstitutional law being 'on the books' is insufficient to 'justify federal intervention' in a pre-enforcement suit." *Whole Woman's Health v. Jackson*, 595 U.S. 30, 50 (2021). Accordingly, the Supreme Court "has always required proof of a more concrete injury and compliance with traditional rules of equitable practice" in pre-enforcement cases, whether "the challenged law in question is said to chill the free exercise of religion, the freedom of speech, the right to bear arms, or any other right." *Id.*

The ripeness doctrine involves similar considerations, "as claims premised on uncertain or contingent events present justiciability problems." *Church of Our Lord & Savior Jesus Christ v. City of Markham, Illinois*, 913 F.3d 670, 676 (7th Cir. 2019). Indeed, the "doctrine's underlying objective is to avoid premature adjudication and judicial entanglement in abstract disagreements." *Id.* Accordingly, a "case is ripe when it is 'not dependent on contingent future events that may not occur as anticipated, or indeed may not occur at all.'" *Mathis v. Metro. Life Ins. Co.*, 12 F.4th 658, 664 (7th Cir. 2021) (quoting *Trump v. New York*, 141 S. Ct. 530, 535 (2020)). "A case is not ripe when the parties point only to hypothetical, speculative, or illusory disputes as opposed to actual, concrete conflicts." *Id.* (internal quotations omitted); *see also Parents Protecting Our Children*, 95 F.4th at 506 (judiciary's "role is limited to awaiting concrete disputes between adverse parties").

When these questions of standing and ripeness are "otherwise close, the distinction between criminal and civil sanctions might tip the balance." 13B Charles Alan Wright *et al.*,

Federal Practice and Procedure § 3532.5 (3d ed. 2023). Also relevant is whether private parties may enforce the law being challenged, since "the risk of enforcement is greater when private parties can enforce the law," and "lower when enforcement is 'restricted to state officials who are constrained by explicit guidelines or ethical obligations.'" *NSSF v. New Jersey*, 80 F.4th 215, 221 (3d Cir. 2023) (quoting *Susan B. Anthony*, 573 U.S. at 164).

Finally, "[w]arnings against premature adjudication of constitutional questions bear heightened attention when a federal court is asked to invalidate a State's law, for the federal tribunal risks friction-generating error when it endeavors to construe a novel state Act not yet reviewed by the State's highest court." *Arizonans for Off. Eng. v. Arizona*, 520 U.S. 43, 79 (1997). Speculation about the scope of a state law is "particularly gratuitous" in "the absence of prior state adjudication." *Id*. Similar concerns arise where plaintiffs bring facial, rather than as-applied, challenges. *Washington State Grange v. Wash. State Republican Party,* 552 U.S. 442, 450–51 (2008). Facial challenges are "disfavored" because they "often rest on speculation" and thus "raise the risk of premature interpretation of statutes on the basis of factually barebones records." *Id.* at 450; *Parents Protecting Our Children*, 95 F.4th at 506 (jurisdictional principles particularly important where plaintiff seeks "sweeping pre-enforcement facial invalidation of a law").

ARGUMENT

This case should be dismissed (again, and this time with prejudice) at the outset because AAM's amended complaint does not present a "case" or "controversy" fit for resolution by a federal court. *Sweeney*, 990 F.3d at 559. In particular, AAM has failed to satisfy the justiciability doctrines of standing and ripeness for at least two reasons. First, the amended complaint does not overcome the injury-in-fact deficiencies identified by the Court in its order dismissing the original complaint. Second, resolution of AAM's facial challenge to the Act would be premature.

I. AAM fails to cure the injury-in-fact deficiencies identified by the Court's recent dismissal order and thus lacks Article III standing.

To start, the amended complaint should be dismissed because it does not cure either deficiency identified by this Court in its order dismissing the original complaint. As this Court explained, AAM "must allege that . . . its members have standing to sue in their own right," which includes showing that its members have suffered an injury-in-fact. Dkt. 32 at 2. The Court held that AAM did not allege an injury-in-fact for two, independent reasons: (1) "AAM [did] not allege that its members intend to violate the Act in a manner that is proscribed by the Act"; and (2) AAM failed "to allege that a credible threat of prosecution exists." *Id.* at 3. Because AAM has made no meaningful attempt to remedy these deficiencies with additional factual allegations, its amended complaint should be dismissed.

A. AAM fails to allege that its members intend to engage in a proscribed course of conduct under the Act.

As this Court explained, a plaintiff raising a constitutional, pre-enforcement challenge to a statute must allege "an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute." Dkt. 32 at 2. The Court concluded that AAM's original complaint failed to meet this standard because while AAM alleged that its members planned to increase drug prices, it did not "allege that its members intend to violate the Act in a manner that is proscribed by the Act." *Id.* at 3. Specifically, AAM failed to allege that the price increases would "be otherwise excessive and unduly burden consumers," as is required by the Act. *Id.* (cleaned up); 410 ILCS 725/5. On the contrary, it "repeatedly describes the contemplated price increases as 'reasonable' and 'necessary.'" Dkt. 32 at 3.

The allegations in AAM's amended complaint still fail to satisfy this threshold requirement 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). In fact, AAM has not provided any material facts

related to its members' course of conduct beyond those already submitted to the Court in conjunction with its initial complaint and preliminary injunction motion. On the contrary, the amended complaint contains the same types of vague and generally applicable allegations about its members that were insufficient to satisfy this standard in the initial complaint, Am. Compl. ¶¶ 39-45; Dkt. 32 at 3, as well as allegations about a price increase for a product manufactured by Sandoz, Inc. that are virtually identical to the averments contained in the deGavre declaration submitted in support of AAM's preliminary injunction motion, Am. Compl. ¶¶ 46-47; Dkt. 20. And the amended complaint contains no allegations about distributors, despite seeking relief on their behalf.

For starters, AAM's allegations about unidentified manufacturers who intend to raise unidentified drug prices do not show that its members intend to engage in conduct proscribed by the Act. Although AAM alleges that these planned price increases satisfy the Act's quantitative requirement, Am. Compl. ¶ 39, it is insufficient for purposes of associational standing to make generalized allegations about a group of individuals or entities, *see, e.g.*, *Prairie Rivers Network v. Dynegy Midwest Generation*, 2 F.4th 1002, 1010 (7th Cir. 2021). Moreover, the amended complaint, like the initial complaint, fails to provide factual allegations showing how any of these planned price increases would meet the Act's other components—that the increases be excessive, unduly burdensome, or not attributable to production costs or costs that increase access to the drug. 410 ILCS 725/5. In fact, with respect to the third factor, the amended complaint (like the initial complaint) admits that at least some of the planned price increases are necessitated by factors excepted by the Act. *Id.* ¶¶40, 45; Compl. ¶ 39. To be sure, AAM has removed (without explanation) the allegations from its initial complaint that these increases will be "reasonable" and "necessary." But AAM does not replace these admissions with factual allegations showing that

these price increases will run afoul of the Act's requirements that the price increases not be excessive or unduly burdensome. *See* Am. Compl. ¶¶ 40–45. Instead, it appears to admit that it cannot make such a showing. *Id.* In other words, AAM's allegations about its membership as a group do not show a sufficient course of conduct proscribed by the Act.

AAM's allegations about Sandoz likewise fail to cure the deficiencies identified by this Court. According to the amended complaint, Sandoz plans to increase the wholesale acquisition cost of an essential medication in an amount that is "substantially more than the Act's 30% threshold." Am. Compl. ¶ 47. AAM further alleges that "a majority" of Sandoz's proposed increase is attributable to factors other than the cost of producing the drug, such as "regulatory approval costs, costs incurred due to product inventory loss, and inflation," and that this increase is "necessary to meet the company's long-term growth strategy." *Id.* But the amended complaint provides no specific facts demonstrating how the vague justifications for the price increase, even if substantial, would render it excessive—i.e., more than necessary—or unduly burdensome to consumers. On the contrary, AAM admits that the increase in cost for this drug is "necessary" for its long-term growth strategy, which includes expanding its portfolio of products and ultimately reducing the price of prescription drugs. *Id.* AAM also admits that this increase in cost is due in part to factors exempted by the Act, such as production costs and expanding access to the drug. *Id.* In short, given these admissions and without further information, it is not possible to discern whether Sandoz's proposed course of conduct would be proscribed by the Act.

Finally, to the extent that AAM seeks to satisfy the injury-in-fact requirement by alleging that some of its members are refraining from implementing price increases due to the Act, Am. Compl. ¶¶ 50–51, those allegations are deficient for many of the same reasons just discussed. Perhaps most obviously, the complaint does not identify a specific member who, but for the Act,

would be raising its prices. It also does not identify any prescription drugs that would be affected by such increases, let alone the justifications for, or amount of, the price increase. As explained, it is insufficient for purposes of associational standing to make generalized allegations about a group of individuals or entities, without providing a specific example of a member with standing. *Parents Protecting Our Children*, 95 F.4th at 505 (association must allege that "one of the association's members—any particular [member]—has experienced an actual or imminent injury").

B. AAM fails to allege a credible threat of prosecution.

This Court should dismiss the amended complaint for the additional reason that it has not cured its failure to allege a credible threat of prosecution, which, as this Court explained in its dismissal order, is another prerequisite for facial, pre-enforcement challenges. Dkt. 32 at 3. In that order, the Court concluded that AAM failed to satisfy this standard because it "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.*; *Parents Protecting Our Children*, 95 F.4th at 505 (rejecting associational standing because "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]").

The amended complaint does not even attempt to cure that deficiency: it contains no factual allegations describing any investigatory or enforcement action taken by the Attorney General against one of its members, let alone one that indicates a credible and imminent threat of enforcement. Am. Compl. ¶¶ 44, 48. Instead, the amended complaint rests on the same general allegations that it raised in the original complaint—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." Am. Compl. ¶ 44; *see also id.* ¶ 48 (making conclusory statement that it is "likely" that the Attorney General would determine that the Sandoz price increase constitutes price gouging). But as the Seventh Circuit recently recognized, such generalized allegations about potential harm in the future "fall short of establishing a Case or Controversy." *Parents Protecting Our Children*, 95 F.4th at 506.

AAM also suggests in the amended complaint that there is a "substantial risk" of enforcement because "[t]he Attorney General has not *disavowed* bringing an enforcement action against an AAM member." Am. Compl. ¶ 44 (emphasis added). But this is not a factual allegation; it is a legal argument that AAM unsuccessfully raised in its opposition to defendant's motion to dismiss the original complaint. Dkt. 27 at 9. Furthermore, that legal argument is incorrect. As defendant has explained, Dkt. 28 at 9-10, the existence or absence of a disavowal of enforcement does not establish a credible threat of enforcement; rather, it is just one of many considerations that a court may weigh when assessing whether there is a credible threat of enforcement. *E.g.*, *Susan B. Anthony List*, 573 U.S. at 160–61 (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 existence of recent prosecutions and State's Attorney's failure to disavow enforcement against the plaintiff). And here, those factors weigh against a threat of enforcement, since there are no allegations that the Attorney General, who is the sole enforcer under the Act, has conducted or brought an investigation against anyone.

II. Alternatively, dismissal is warranted because AAM seeks premature adjudication of fact-intensive theories best reserved for as-applied challenges.

Even if the complaint clears the injury-in-fact bar outlined by this Court, it would be premature for the Court to adjudicate the facial challenge presented by AAM in its amended

complaint. As in the original complaint, AAM seeks sweeping declaratory and injunctive relief that would invalidate the Act in its entirety. Am. Compl. at 37–38. Resolving such a broad case at this juncture would be improper for several reasons.

To start, notwithstanding that AAM has raised a facial challenge to the Act, it has also recognized in its complaint the existence of constitutional applications of the Act. *Id.* ¶¶ 28, 41. This alone renders the Act unsuitable for a facial challenge. *Ezell v. City of Chicago*, 651 F.3d 684, 698–99 (7th Cir. 2011) ("a successful facial attack means the statute is wholly invalid and cannot be applied *to anyone*," that is, it must be unconstitutional "*in all* its applications, as *Salerno* requires"). In particular, AAM recognizes that some of its manufacturer members are either located in Illinois or sell generic prescription drugs to entities in Illinois, Am. Compl. ¶¶ 28, 41, which of course would present no extraterritoriality problem—Commerce Clause or otherwise. In other words, even if AAM's theories were correct (which they are not), the Act cannot be facially unconstitutional.

Additionally, AAM's claims are best resolved on a case-by-case basis. As explained above, the application of the Act itself is inherently fact-bound, and whether the Attorney General would even bring an enforcement action will depend on the specific circumstances of each case. Furthermore, AAM's legal theory (to the extent it is valid, which the State has disputed, *see* Dkt. 26 at 20–29)—in effect, that the Act is impermissibly unconstitutional because it regulates "transactions" that lack sufficient contacts with Illinois, Am. Compl. ¶ 3—necessarily depends on the factual circumstances of those transactions and the scope of contacts with Illinois. Reserving premature adjudication of AAM's broad claims would allow courts to assess these constitutional issues on an incremental basis and with full context. *Washington State Grange*, 552 U.S. at 450 (declining facial challenge "frees the Court not only from unnecessary pronouncement on

constitutional issues, but also from premature interpretations of statutes in areas where their constitutional application might be cloudy").

Finally, AAM or its members will have ample opportunity to challenge the Act in the future if and when a concrete dispute concerning them actually arises, whether it be in the context of an as-applied challenge or as an affirmative defense to an enforcement action. *E.g.*, *Whole Woman's Health*, 595 U.S. at 49–50 ("many federal constitutional rights are as a practical matter asserted typically as defenses to state-law claims, not in federal pre-enforcement cases like this one"); *Parents Protecting Our Children*, 95 F.4th at 506 (reserving ability of litigants to bring as-applied challenges "in a particular instance," while rejecting a "sweeping, pre-enforcement" challenge). As explained, the Act contains substantial procedural protections providing manufacturers and distributors the opportunity to show that the relevant price increase was made due to legitimate business needs.

In short, "[t]he benefits of awaiting a concrete and particularized dispute—a Case or Controversy—are plain." *Sweeney*, 990 F.3d at 561. Among others, this approach allows "all involved an opportunity to fully probe" the factual and legal issues presented by that case, as opposed to being "explored—legally, practically, or otherwise—in the abstract." *Id.* This is especially true where, as here, there remains much to be seen about the nature of the planned price increases, as well as the Attorney General's enforcement practices under the Act. *Washington State Grange,* 552 U.S. at 450. AAM's request to adjudicate the constitutionality of the Act is premature and should be dismissed for this independent reason.

CONCLUSION

For the foregoing reasons, the Attorney General requests that AAM's amended complaint be dismissed for lack of subject-matter jurisdiction.

Dated: August 23, 2024

Respectfully submitted,

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