

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

ASSOCIATION FOR ACCESSIBLE)	
MEDICINES,)	
)	No. 24 C 544
<i>Plaintiff,</i>)	
v.)	Judge Virginia M. Kendall
)	
KWAME RAOUL, in his official capacity as)	
Attorney General of the State of Illinois,)	
)	
<i>Defendant.</i>)	

ORDER

This matter is before the Court on Defendant Attorney General Kwame Raoul’s motion to dismiss Plaintiff Association for Accessible Medicines’ (“AAM”) First Amended Complaint. (Dkt. 38). For the reasons below, the Attorney General’s motion [38] is denied.

BACKGROUND

The Association for Accessible Medicines is a nonprofit association representing manufacturers and distributors of generic and biosimilar medicines. (Dkt. 35 at ¶ 14). AAM is concerned about the constitutionality of House Bill 3957 (“the Act”), which took effect on January 1, 2024. (*Id.* at ¶ 29). The Act prohibits manufacturers and wholesale drug distributors from engaging in “price gouging” in the sale of certain drugs that are “ultimately sold into Illinois.” (Dkt. 18-1 at 5). Price gouging is any price increase that meets certain metrics identified in the statute and is “otherwise excessive and unduly burdens consumers.” (*Id.* at 4). It does not include price increases that can be “reasonably justified” by reasons identified in the Act. (*Id.* at 4–5). If the Attorney General has reason to believe that a manufacturer or wholesale drug distributor is engaged in price gouging, the Act authorizes him to “send a notice to [the company] requesting a statement” of information relevant to determining whether a violation of the Act occurred. (*Id.* at 5–6). Upon determining that a company engaged in price-gouging, the Attorney General may ask a circuit court to impose various penalties, such as a fine or injunction. (*Id.* at 7–8).

In January 2024, AAM brought this pre-enforcement action seeking declaration that the Act is unconstitutional and moved for a preliminary injunction prohibiting the Attorney General from enforcing the Act against AAM’s members. (Dkt. 1 at ¶¶ 70–100; Dkt. 17). The Court granted the Attorney General’s motion to dismiss, explaining that AAM failed to allege facts sufficient to confer standing and, even if they had, AAM failed to allege that a credible threat of prosecution existed. (Dkt. 32). AAM then filed an Amended Complaint, (Dkt. 35), seeking the same relief as before. (*See generally* Dkt. 35 at ¶¶ 78–108). The Attorney General again moves to dismiss. (Dkt. 38).

LEGAL STANDARD

In reviewing a Federal Rule of Civil Procedure 12(b)(1) motion to dismiss for lack of subject-matter jurisdiction, the plaintiff must carry its burden of establishing that jurisdiction is proper. *Ctr. for Dermatology & Skin Cancer, Ltd. v. Burwell*, 770 F.3d 586, 588–89 (7th Cir. 2014). “Facial challenges require only that the court look to the complaint and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction.” *Apex Digital, Inc. v. Sears, Roebuck & Co.*, 572 F.3d 440, 443 (7th Cir. 2009). A court lacking subject-matter jurisdiction must dismiss the action without proceeding to the merits. *See MAO-MSO Recovery II, LLC v. State Farm Mut. Auto. Ins. Co.*, 935 F.3d 573, 581 (7th Cir. 2019).

DISCUSSION

The Attorney General argues that AAM’s complaint should be dismissed for lack of subject-matter jurisdiction because AAM lacks standing to bring this action, and the issues therein are not ripe for adjudication. Alternatively, he argues that this case should be dismissed because AAM seeks premature adjudication of fact-intensive theories best reserved for as-applied challenges. The Court will consider each argument in turn.

I. AAM has standing to bring this action.

Article III of the Constitution “confines the federal judicial power to the resolution of ‘Cases’ and ‘Controversies.’” *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021) (quoting U.S. Const. art. III, § 2). “For there to be a case or controversy under Article III, the plaintiff must have a ‘personal stake’ in the case—in other words, standing.” *Id.* (citing *Raines v. Byrd*, 521 U.S. 811, 819 (1997)). While organizations do not have standing to assert claims based on their particular concept of the public interest, they may, through associational standing, assert the rights of their members. To show that it has associational standing, AAM must allege that (1) its members have standing to sue in their own right; (2) the members’ interests are germane to the organization’s purpose; and (3) neither the claim asserted nor the relief requested requires the individual participation of the organizations’ members. *Milwaukee Police Ass’n v. Flynn*, 863 F.3d 636, 639 (7th Cir. 2017).

To establish that its members have standing to sue in their own right, AAM must allege that its members (1) suffered an injury in fact that is concrete, particularized, and actual or imminent; (2) the injury was likely caused by the defendant; and (3) the injury is likely to be redressed by judicial relief. *TransUnion*, 594 U.S. at 423. Where, as here, a party seeks pre-enforcement review of the constitutionality of a statute, a plaintiff may satisfy the injury-in-fact requirement by alleging “an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (citing *Babbitt v. United Farm Workers Nat. Union*, 442 U.S. 289, 298 (1979)).

A. AAM sufficiently alleges its members' intent to engage in a proscribed course of conduct.

In its Amended Complaint, AAM explains that one of its members, Sandoz, Inc. (“Sandoz”), produces digoxin, a generic medication for treating mild to moderate heart failure in adults, which is a chronic and life-threatening condition. (Dkt. 35 ¶ 46). Digoxin is on the World Health Organization’s most recent list of essential medicines and is manufactured in the United States by only three companies. (*Id.*). Sandoz intends to raise the wholesale acquisition cost of digoxin by [REDACTED], which constitutes a [REDACTED] increase from the product’s price in 2023. (*Id.* at 47). This price increase is driven by various financial goals, including increasing or sustaining the company’s profit margins, “provid[ing] a greater return on investment” for company shareholders, and “offset[ing] price reductions on certain other Sandoz products that have reduced the company’s overall profitability.” (*Id.*). AAM alleges similar motivations for various other members’ intended price increases on other medicines. (*Id.* ¶¶ 45, 50). Because the Act is explicitly concerned with the harm to the public’s health caused by unconscionable price increases on medicines, AAM’s allegations are sufficient to allege conduct that is “arguably affected” by the Act, which is all that is required at this stage. *Driehaus*, 573 U.S. at 159 (citing *Babbitt*, 442 U.S. at 298).

B. AAM sufficiently alleges a credible threat of prosecution.

To allege a credible threat of prosecution, a plaintiff must have a fear of prosecution that is not “imaginary or speculative.” *Babbitt*, 442 U.S. at 298 (quoting *Younger v. Harris*, 401 U.S. 37, 42 (1971)). When plaintiffs “do not claim that they have ever been threatened with prosecution” or “that a prosecution is likely,” they do not allege a dispute susceptible to resolution by a federal court. *Id.* These guidelines follow with the Supreme Court’s repeated instruction that a “threatened injury must be certainly impending to constitute injury in fact” and that “allegations of possible future injury are not sufficient.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013). There is no well-defined formula for evaluating whether a credible threat of enforcement exists. Accordingly, courts look at various factors, including: whether there is a law on the books at all; whether the law has been enforced against others; whether there has been a general showing of active enforcement intentions; whether there has been an express disclaimer of any intent to enforce the challenged law; and whether enforcement authority under the law is widely disbursed. See *Brown v. Kemp*, 86 F.4th 745, 768 (7th Cir. 2023) (collecting cases); *Am. C.L. Union of Illinois v. Alvarez*, 679 F.3d 583, 591 (7th Cir. 2012) (quoting *Bauer v. Shepard*, 620 F.3d 704, 708 (7th Cir.2010)).

Here, AAM does not claim that any of its members have been subject to an investigation or enforcement action, or that its members received notice from the Attorney General initiating an investigation into whether a violation occurred. Nor does AAM identify any instance in which the Act has been enforced against any manufacturer or distributor—AAM member or otherwise. Further, enforcement authority of the Act belongs exclusively to the Attorney General.

The Attorney General insists that a fulsome consideration of facts alleged necessitates a finding that AAM has not alleged a credible threat of prosecution. In rebuttal, AAM rests the weight of its case on the proposition that “[t]he very ‘existence of a statute implies a threat to

prosecute.” (Dkt. 40 at 16). Indeed, the Seventh Circuit has repeatedly reached this conclusion. *See Bell v. Keating*, 697 F.3d 445, 451 (7th Cir. 2012) (“[t]he existence of the statute constitutes the government’s commitment to prosecute in accordance with it and, thus, a concrete prospect of future harm for one who would flout it”); *ACLU of Illinois v. Alvarez*, 679 F.3d 583, 591 (7th Cir. 2012) (same); *Ezell v. City of Chicago*, 651 F.3d 684, 696 (7th Cir. 2011) (“[t]he very ‘existence of a statute implies a threat to prosecute’”) (internal citations omitted); *Bauer v. Shepard*, 620 F.3d 704, 708 (7th Cir. 2010) (same); *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003) (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”). While these cases involve the exercise of fundamental constitutional liberties (such as those protected by the First and Second Amendments), the Seventh Circuit does not provide any limiting language to suggest that only the existence of a statute implicating “fundamental constitutional liberties” can imply a threat to prosecute. Nor does the Seventh Circuit suggest that the mere presence of a potentially unconstitutional law, without more, is necessarily insufficient to find a credible threat of prosecution. Accordingly, the Court finds that a credible threat of prosecution exists in the existence of the Act, especially because the Attorney General has not yet disclaimed his intent to prosecute AAM members’ violations of the Act.

II. AAM’s claims are ripe for adjudication.

“Much like standing, ripeness gives effect to Article III’s Case or Controversy requirement by preventing the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements.” *Sweeney v. Raoul*, 990 F.3d 555, 559 (7th Cir. 2021) (cleaned up). In evaluating ripeness, courts consider “the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.” *Id.* at 560. In the context of a pre-enforcement challenge, like the present case, ripeness and standing often boil down to the same question.

When a plaintiff faces a realistic threat that a law will be enforced against him, “a party may advance a pre-enforcement challenge before suffering an injury—so long as the threatened enforcement is sufficiently imminent.” *Sweeney*, 990 F.3d at 559 (internal quotation marks omitted) (quoting *Driehaus*, 573 U.S. at 159). The plaintiff need not suffer “an actual arrest, prosecution, or other enforcement action,” nor does the plaintiff need “to confess that he will in fact violate the law.” *Driehaus*, 573 U.S. at 163. Rather, a plaintiff may bring a pre-enforcement challenge where (1) he intends to perform conduct that is arguably constitutionally protected, (2) the conduct is prohibited by the rule or statute challenged, and (3) there is a credible threat of enforcement. *Id.* at 159.

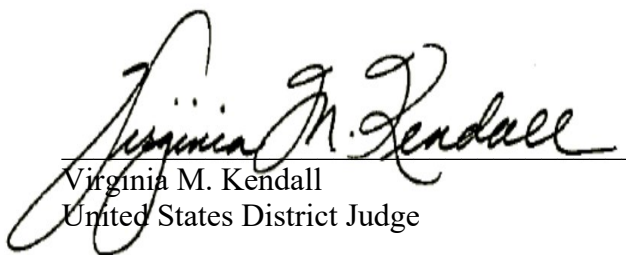
Having concluded that AAM sufficiently alleges its members’ intent to engage in a proscribed course of conduct and that there is a credible threat of enforcement, the Court turns its attention to the constitutional liberty requirement. The Attorney General urges the Court to find that “AAM does not claim that the Act infringes on any fundamental constitutional liberty.” (Dkt. 44 at 7). But AAM very clearly asserts that the Act violates the Due Process Clause and the Commerce Clause. (*See generally* Dkt. 35 ¶¶ 73–86). Nothing more is required of AAM at this stage.

III. AAM presents an as-applied challenge to the Act.

Finally, the Attorney General argues that this case should be dismissed because AAM seeks premature adjudication of fact-intensive theories best reserved for as-applied challenges. But the Attorney General’s argument fails because AAM’s claims are not “inherently fact-bound” and do not “depend on the specific circumstances” of a given sale. (Dkt. 39 at 18). AAM seeks adjudication of a purely legal issue: “whether the Constitution permits Illinois to regulate the prices charged in wholly out-of-state sales.” (Dkt. 40 at 20).

CONCLUSION

For the reasons set forth above, the Attorney General’s motion to dismiss [38] is denied.


Virginia M. Kendall
United States District Judge

Date: December 13, 2024