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

Introduction

Plaintiff, the Association for Accessible Medicines ("AAM"), has filed this pre-enforcement suit challenging the constitutionality of Illinois Public Act 103-367 (the "Act"), which prohibits excessive and unduly burdensome price increases for generic prescription drugs sold in Illinois. This Court dismissed AAM's initial complaint for lack of standing for two separate and independent reasons: (1) AAM had not adequately alleged that its members' intended price increases violate the Act; and (2) AAM had not adequately alleged a credible threat of enforcement against its members. Dkt. 32.

AAM's amended complaint fails to cure these deficiencies and, therefore, should also be dismissed for lack of standing. First, although the amended complaint provides some additional detail regarding the intended price increases, it still fails to plausibly show a violation of the Act. Second, AAM still has not alleged a credible threat that the Act will be enforced against any of its members. As to the threat of enforcement requirement for standing, AAM's amended complaint includes no new allegations, so dismissal is warranted for the same reasons that the Court identified in its prior order.

Unable to cure the deficiencies identified in the Court's order, AAM effectively seeks reconsideration of the Court's ruling regarding the threat of enforcement requirement. It suggests that it satisfies the requirement merely because the Act is "on the books" and the Attorney General has not disavowed enforcement; but as discussed below, this is incorrect. Standing requires a more holistic analysis, and AAM is unable to point to *any* case finding pre-enforcement standing under circumstances similar to those present here, where: (a) is not clear that the Act prohibits the intended conduct (indeed, AAM itself argues that the Act's definition of "price gouging" is vague); (b) AAM does not claim that its members are chilled from exercising any fundamental constitutional liberties, such as those protected by the First and Second Amendments; (c) AAM does not allege that any of its members are under investigation for potentially violating the Act, nor does it identify a single instance in which the Act has been enforced against anyone; (d) enforcement authority under the Act is not widely disbursed but rather limited to the Attorney General; (e) the Act does not provide for any criminal penalties; and (f) the Act allows for an interactive process before any enforcement action is brought. AAM lacks standing to bring this pre-enforcement action, and for similar reasons, its claims are not ripe.

Argument

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

"The party invoking federal jurisdiction bears the burden of establishing' standing." *Clapper v. Amnesty Int'l USA*, 568 U.S. 411-12 (2013). In a pre-enforcement action like this one, the plaintiff must sufficiently allege that it or its members intend to take action that is arguably proscribed by the law and plausibly show a substantial threat of enforcement against them. Order, Dkt. 32, at 2. To determine whether standing exists, the factors should not be viewed in a vacuum because "[t]he difference between an abstract question and a 'case or controversy' is one of degree,

of course, and is not discernible by any precise test." *Babbit v. UFW Nat'l Union*, 442 U.S. 289, 297-98 (1978); *see also NSSF v. Attorney General of New Jersey*, 80 F.4th 215, 223 (3d. Cir. 2023), *citing Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 165 (2014) (illustrating the holistic analysis required to determine if a party has standing). Here, when AAM's allegations are viewed as a whole, it is clear that AAM has not satisfied its burden of establishing standing, and its claims should be dismissed for lack of jurisdiction.

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

The first step in a pre-enforcement standing analysis asks if the plaintiff intends to engage in conduct that is proscribed by the challenged statute. Order, Dkt. 32, at 2. Based on the Act's definition of "price gouging," AAM must go beyond alleging that its members intend to raise the prices of the applicable generic prescription drugs by an amount that exceeds the numeric thresholds outlined in the Act. It must *also* show that the anticipated price increases could be deemed "otherwise excessive" and unduly burdensome to consumers. *Id.*

While AAM's amended complaint adds some additional allegations about its members' intended price increases, it still falls short of showing that the intended price increases meet both the quantitative and non-quantitative ("otherwise excessive" and "unduly burdensome") components of price gouging. AAM alleges that some of its members intend to implement increases in the wholesale acquisition costs for essential generic medicines in excess of the Act's numeric threshold for the purpose of increasing profitability and offsetting price reductions in other products. Dkt. 35 ¶ 45. It adds that at least one member anticipates a price increase over the Act's 30% threshold to increase profitability and to cover, in part, regulatory approval costs, inventory loss costs, and inflation, and then asserts that the Attorney General is likely to find that this price increase violates the Act. *Id.* ¶¶ 47-48. But AAM's speculation about how the Attorney General

might perceive a possible future price increase is too speculative and conclusory to meet the required plausibility standard under *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007) (noting that a plaintiff's "factual allegations must be enough to raise a right to relief above the speculative level") and *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009) (explaining that "conclusory" allegations are "not entitled to be assumed true"). AAM has not alleged sufficient facts to establish that its members' intended price increases could be deemed "otherwise excessive" and unduly burdensome to consumers.

When viewed as a whole, AAM's allegations are not materially different from the allegations in the initial complaint. In both its initial and amended complaints, AAM says that some of its members might at some point raise prices above the numeric price thresholds for a variety of reasons, including to account for normal business expenses and growth. Dkt. 35 at ¶¶ 45-47, 50. AAM has not sufficiently alleged a course of conduct proscribed by the Act, and therefore lacks standing to bring this pre-enforcement action.

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

AAM also lacks standing for a second, independent reason: it has failed to establish a "credible threat of prosecution." *See* Dkt. 39 at 12-13. The Supreme Court "ha[s] repeatedly reiterated that threatened injury must be certainly impending to constitute injury in fact, and that allegations of possible future injury are not sufficient." *Clapper*, 568 U.S. at 409. Yet AAM has not alleged that an enforcement action is "certainly impending," nor has it alleged that the Attorney General has "taken even a single step along the path to enforcement." *Sweeney v. Raoul*, 990 F.3d 555, 560 (7th Cir. 2021).

In dismissing AAM's original complaint for lack of standing, this Court emphasized that AAM had not alleged that any of its members had received notice of an investigation or had been the subject of an investigation or enforcement action. Dkt. 32 at 3. And that is still the case. Nothing

has changed. The amended complaint adds *no* new allegations on this front. If the Attorney General has "reason to believe" that a manufacturer or distributor has violated the Act, he may send a notice requesting information relevant to that determination. 410 ILCS 725/10(b). As with its original complaint, AAM's amended complaint does not allege that any of its members have received such a notice, or even that any of its members have any reason to believe they are currently under investigation. AAM's amended complaint also does not identify a single instance in which the Act has been enforced against any manufacturer or distributor, AAM member or otherwise. Because AAM still has not alleged a "credible threat of prosecution," Order, Dkt. 32, at 3, its claims again fail for lack of standing.

AAM does not point to any new allegations that cure this fatal deficiency identified in the Court's dismissal order. Rather, it challenges the legal basis for the Court's prior ruling, arguing primarily that the very *existence* of the Act necessarily establishes a credible threat of enforcement. Dkt. 40 at 11. But if that were the standard, 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. That is not the law.

Contrary to AAM's position, the mere fact that a statute is "on the books" is not sufficient to establish a credible threat of enforcement. The Supreme Court has "never recognized an unqualified right to pre-enforcement review of constitutional claims in federal court." *Whole Woman's Health v. Jackson*, 595 U.S. 30, 49 (2021). "As our cases explain, the 'chilling effect' associated with a potentially unconstitutional law being 'on the books' is insufficient to justify federal intervention in a pre-enforcement suit." *Id*. at 50.

Applying this rule, the Seventh Circuit recently held that a group of parents lacked standing to challenge a school district's gender identity policy (even though it was "on the books"), because they faced no "imminent harm" attributable to the policy. *Parents Protecting Our Child. v. Eau Claire Area Sch. Dist.*, 95 F.4th 501, 506 (7th Cir. 2024). AAM tries to avoid this holding by noting that the parents were not "directly regulated" by the school's policy, Dkt. 40 at 11, but this distinction misses the point: the mere existence of the policy did not establish a credible threat of harm. *See id.*; *see also, e.g.*, *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1139 (9th Cir. 2000) ("[N]either the mere existence of a proscriptive statute nor a generalized threat of prosecution satisfies the 'case or controversy' requirement.").

The Third Circuit's recent decision in *National Shooting Sports Foundation v. Attorney General of New Jersey*, 80 F.4th 215 (3d Cir. 2023), which AAM ignores, also contradicts its position. An association of gun makers, retailers, and other industry members filed a pre-enforcement action challenging the constitutionality of a state gun law. Even though the statute "directly regulated" (to use AAM's phrase) the association's members, they lacked standing to sue. *Id.* at 218, 223. The law had not been enforced against anyone, only the Attorney General had enforcement authority, and only civil penalties were available. *Id.* at 220-223. Applying the "holistic" analysis mandated by Supreme Court precedent, the court concluded that the case should be dismissed for lack of standing. *Id.* at 223 (citing *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 165 (2014)). Again, it was not enough that the statute was "on the books." *Id.* at 223 (citing *Whole Woman's Health*, 595 U.S. at 50).

The case for standing is even weaker here. As in *National Shooting Sports Foundation,* AAM has not alleged that any of its members are under investigation for a potential violation of the Act; it identifies no history of past enforcement against anyone; the Act is not privately

enforceable (only the Attorney General has enforcement authority); and the Act does not provide for criminal liability (only civil penalties are available). On top of that, the Act allows for an interactive process before any enforcement action is brought (410 ILCS 725/10(b)); it is not clear that the potential price increases alleged in the complaint would violate the Act; and AAM does not claim that the Act infringes on any fundamental constitutional liberty.

AAM's response does not cite a single case finding pre-enforcement standing under similar circumstances. In nearly all of AAM's cases, the plaintiffs sought to enjoin enforcement of statutes that chilled—with the threat of criminal sanctions—the exercise of fundamental constitutional liberties such as those protected by the First and Second Amendments. Dkt. 40 at 11-12.[1] Here, however, the Act provides only for civil enforcement, which weighs against standing. *See, e.g.*, *Driehaus*, 573 U.S. at 166 (declining to decide whether a threat of civil enforcement can establish an Article III injury); *Prim v. Raoul*, No. 20-cv-50094, 2021 U.S. Dist. LEXIS 10833, at *8-9 (N.D. Ill. Jan. 21, 2021) (questioning whether civil enforcement can satisfy the "credible threat of prosecution" standard); *National Sports Shooting Foundation*, 80 F. 4th at 222-23 ("civil penalties lower the temperature"). Moreover, AAM does not contend that the Act prevents its members from exercising a core constitutional right, which further weighs against standing. As Judge Johnston recently observed, "[t]he pre-enforcement standing case law in this circuit and others largely invokes First and Second Amendment interests," and the extent to which other claims implicate

[1] *See Virginia v. American Booksellers Ass'n*, 484 U.S. 383, 392-93 (1987) (criminal statute burdened First Amendment rights and resulted in self-censorship); *Babbitt v. UFW Nat'l Union*, 442 U.S. 289, 293-95 (1979) (same); *Brown v. Kemp*, 86 F.4th 745, 752-69 (7th Cir. 2023) (criminal statute caused self-censorship of protected speech, enforcement authority was "widely disbursed," a private right of action existed, and there was a "history of attempted prosecutions"); *ACLU v. Alvarez*, 679 F.3d 583, 590-92 (7th Cir. 2012) (criminal statute implicated First Amendment rights and there were "many recent prosecutions"); *Bell v. Keating*, 697 F.3d 445, 41-54 (7th Cir. 2012) (plaintiff previously arrested under criminal statute that chilled his speech); *Ezell v. City of Chicago*, 651 F.3d 684, 691-92 (7th Cir. 2011) (ordinance implicated Second Amendment rights and threatened criminal penalties); *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003) (criminal statute deterred "constitutionally protected expression").

"constitutional interests" sufficient to support pre-enforcement standing is not at all clear. *Prim*, 2021 U.S. Dist. LEXIS 10833, at *5-6.

AAM cites a case finding that a hotel had pre-enforcement standing to pursue an action challenging a labor law on preemption grounds, *520 South Michigan Avenue Associates, Ltd. v. Devine*, 433 F.3d 961 (7th Cir. 2006). But that decision is inapposite, first because the law at issue threatened criminal penalties, and second because the hotel was under investigation by the Illinois Department of Labor, which gave it reason to believe that it was "in the state's cross-hairs." *Id.* at 962. Here, in contrast, the Act provides for only civil penalties, and AAM has not alleged that any of its members have received notice of an investigation or have ever been the subject of an enforcement action. *See* Order, Dkt. 32, at 3.

AAM also asserts that this Court should presume that a credible threat exists unless the Attorney General disavows enforcement. Dkt. 40 at 12-13. But, again, this is not the law. In *Brown*, for example, 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." 86 F. 4th 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.

The existence or absence of a disavowal of enforcement is not dispositive, as AAM suggests, but rather is just one of many factors that a court may weigh when assessing whether there is a credible threat of enforcement. *See, e.g.*, *Driehaus*, 573 U.S. at 160–61 (considering

government's decision not "to disavow prosecution" as one factor among others); *ACLU of Illinois*, 679 F.3d at 592–93 (assessing credible threat of enforcement by reviewing totality of the circumstances, including recent prosecutions and failure to disavow enforcement against plaintiff); *see also 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). Here, every other factor weighs against standing.

Indeed, AAM's allegation that the Act's definition of "price gouging" is vague does not support standing, as it claims. Dkt. 40 at 13, but provides yet another reason why this lawsuit is premature. AAM cites *Brown* for the proposition that vagueness is "relevant in evaluating plaintiffs' fears of prosecution" (*id.*, citing 86 F.4th at 766), but *Brown* involved a challenge to a criminal statute on First Amendment grounds, and in that specific context, courts are "wary of the chilling effect that unduly vague statues can have." *Ind. Right to Life Victory Fund v. Morales*, 66 F. 4th 625, 630 (7th Cir. 2023). The same considerations do not apply here, where AAM challenges a consumer protection statute that does not chill the exercise of any fundamental constitutional right. If anything, AAM's assertion that the Act is vague confirms that its pre-enforcement suit is premature and should be dismissed so that courts can determine how the statute

applies in specific, concrete factual scenarios. *See, e.g., Babbitt*, 442 U.S. at 307-08 (an authoritative construction of a challenged statute "may significantly alter the constitutional questions requiring resolution"); *Ind. Right to Life Victory Fund v. Morales*, 66 F.4th 625, 633 (7th Cir. 2023) (the "[w]arnings against premature adjudication of constitutional questions" applied in a pre-enforcement challenge to a state statute).

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

Apart from AAM's inability to establish an injury-in-fact, this lawsuit also should be dismissed because AAM's request for the Court to adjudicate the constitutionality of the Act is premature, and its claims are best resolved later, on a case-by-case basis. *See* Dkt. 39 at 13-15. In arguing to the contrary, AAM relies on *Owner-Operator Independent Drivers Association, Inc. v. Federal Motor Carrier Safety Administration*, 656 F. 3d 580 (7th Cir. 2011), where the Seventh Circuit permitted a pre-enforcement challenge to an administrative rule issued by the Federal Motor Carrier Safety Administration based on the principles of *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967).

But AAM's reliance on this line of cases is misplaced and does not support its position here. In *Abbott Laboratories*, the Supreme Court held that prescription drug manufacturers were entitled to pre-enforcement review of federal agency regulations under the Administrative Procedure Act, where the challenge was "purely legal" and the regulations unequivocally required the manufacturers to immediately "change all of their labels, advertisements, and promotional materials…destroy stocks of printed matter…and investing heavily in new printing type and new supplies," or face serious criminal and civil penalties. *Id.* at 693. For multiple reasons, that is not the situation here, and AAM's claims are not ripe:

First, AAM challenges the constitutionality of a state statute, not a federal agency regulation pursuant the Administrative Procedure Act. The distinction matters because "an agency rule, unlike a statute, is typically reviewable without waiting for enforcement." *See Chamber of Commerce v. FEC*, 69 F.3d 600, 603-04 (D.C. Cir. 1995).

Second, contrary to its assertion, AAM's claims are not "purely legal" within the meaning of *Abbott Laboratories*, where the parties agreed that the constitutionality of the challenged regulations "boiled down to a question of congressional intent." *Thomas*, 220 F.3d at 1141-42; *Abbott Laboratories*, 387 U.S. at 149. Here, AAM characterizes its claims as "as applied" and dependent upon on multiple factual allegations. Dkt. 40 at 14-15.

Third, the regulations in *Abbott Laboratories* were "clear-cut," 387 U.S. at 152, and enforcement against the plaintiff "was highly probable." *Brandt v. Village of Winnetka*, 612 F.3d 647, 650-51 (7th Cir. 2010). Here, in contrast, it is not clear that AAM's intended price increases would be deemed "price gouging" under the Act, and AAM itself argues that the Act's definition is price gouging is vague. Where, as here, the plaintiff is bringing a pre-enforcement action challenging "the general applicability of a statutory scheme to its conduct," the need for "more factual development" weighs against a finding of ripeness. *See Ammex v. Cox*, 351 F.3d 697, 707-08 (6th Cir. 2003) (holding that a pre-enforcement challenge to the applicability of Michigan's Consumer Protection Act on federal preemption and commerce clause grounds was not ripe), citing *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158 (1967).

Fourth, unlike the federal regulations at issue in *Abbott Laboratories*, the Act does not affirmatively mandate immediate, extensive, costly, and across-the-board changes to the business practices of AAM's members. *See, e.g., Ammex*, 351 F.3d at 709 ("In *Abbott Laboratories*, the claim was ripe in part because the challenged regulation had a direct and immediate impact on the

day-to-day operations of the plaintiff drug company. The drug companies had to incur the enormous cost of changing all of their labels and promotional materials, or 'risk serious criminal and civil penalties for the unlawful distribution of 'misbranded' drugs."). While AAM claims that its members are "refraining from previously planned price increases," Dkt. 40 at 14, they "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." *Clapper*, 568 U.S. at 416.

Fifth, and finally, unlike the manufacturers in *Abbott Laboratories*, AAM's members do not face criminal penalties under the Act. *See* 410 ILCS 725/10; *see also Prim*, 2021 U.S. Dist. LEXIS 10833, at *8-10 (explaining that it is unclear whether a pre-enforcement action can be brought when the plaintiff not subject to a criminal action). These differences illustrate why a pre-enforcement challenge is neither necessary nor appropriate in this case. AAM's claims are not ripe and should be dismissed.

Conclusion

For these reasons and those set forth in his memorandum in support of his motion to dismiss, the Attorney General requests that AAM's amended complaint be dismissed for lack of subject-matter jurisdiction.

Dated: October 18, 2024

Respectfully submitted,

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