UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

ASSOCIATION FOR ACCESSIBLE MEDICINES, *Plaintiff*, v. MARK D. BOUGHTON, in his official capacity as Commissioner of the Connecticut Department of Revenue Services; and WILLIAM M. TONG, in his official capacity as Attorney General of the State of Connecticut, *Defendants*.	Case No.: 3:25-cv-1757-OAW

PLAINTIFF'S REPLY IN SUPPORT OF
MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Defendants' Opposition, ECF No. 29, makes a number of bold (but baseless) claims about constitutional law, but it is what Defendants do *not* say that is most telling: Defendants do not deny that they will apply the Act to impose severe penalties on out-of-state transactions, between out-of-state manufacturers and out-of-state wholesalers, if the product in question is later re-sold in Connecticut *by someone else*. That is plainly unconstitutional, and this Court should enjoin enforcement of the Act as to such wholly out-of-state transactions.

In arguing to the contrary, Defendants insist that the Supreme Court recently revolutionized the law and gave states free rein to directly regulate wholly out-of-state conduct. That is incorrect. *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), held that state laws that regulate *in-state* conduct are not per se invalid just because they may have indirect *effects* on out-of-state commerce. But *Ross* expressly preserved existing case law invalidating state laws that "directly regulate[]" out-of-state commerce, without requiring proof of discrimination. *Id.* at 376 n.1. Here, unlike in *Ross*, the law at issue is just such a direct regulation. Under binding precedent, the Act is unconstitutional as applied to out-of-state transactions, as almost every court that has considered the constitutionality of similar laws has held. This Court should do the same.

Defendants' cursory arguments on the remaining factors fail. Defendants do not deny the irreparable economic injuries AAM's members face due to the Act. And they cannot deny that deprivation of constitutional rights—including, as the Second Circuit recently reiterated, under the Commerce Clause—constitutes irreparable harm. Finally, the public interest weighs in AAM's favor, as the Act threatens patients' access to generic drugs. The Court should enter an injunction.

ARGUMENT

I. Defendants Do Not Deny Their Plan To Enforce The Act Against Out-Of-State Sales.

Defendants fill their Opposition with ever-more-elliptical verbal formulations as they seek

to avoid admitting that they plan to enforce the Act against generic manufacturers' out-of-state transactions. Thus, Defendants repeatedly assert that the Act applies "only for drugs sold *in Connecticut*." Opp. 17, 20; *see also* Opp. 24 ("drugs sold within its borders"). Sold in Connecticut *by whom*? Defendants do not rely on any in-state sale by AAM's members. While Defendants repeatedly seek to portray the Act as just a regulation of in-state sales, that is not what AAM is challenging. Defendants intend to apply the Act's price cap to *out-of-state* sales between out-of-state parties, just because the drug in question is later *re*-sold in Connecticut—by someone else.

If Defendants do not intend to apply the Act to those out-of-state sales, they could have said so. Indeed, it was incumbent upon them to do so, as AAM clearly alleged that Defendants "intend to apply Connecticut's price cap to prices charged in transactions between manufacturers and wholesalers *outside* Connecticut: generic drug manufacturers (like AAM's members) sell their products to wholesalers, and these sales take place outside Connecticut." Compl. ¶ 5. AAM backed that allegation with legislative history, and before filing, invited the Attorney General to disavow any such intent. He did not. *Id.*

Given Defendants' failure to disavow the application of the Act that AAM challenges, not to mention the Opposition's hints that out-of-state sales are "phases of the same transaction[]" as a later in-state sale (Opp. 17 n.18, 20), this Court should simply proceed to decide AAM's as-applied challenge.[1] *Cf. Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 165 (2014) (pre-enforcement challenge ripe where enforcer refused to disavow challenged interpretation).

[1] If any doubt remains, this Court has two options: (1) If, at the hearing, Defendants represent that the Act does not apply to out-of-state transactions, then the Court can dismiss this action, and Defendants will be judicially estopped from changing position. (2) If this Court determines for itself that the Act does not apply to out-of-state transactions—which is arguably the best reading, *see* Mot. 11 n.15—then it can enter a judgment binding Defendants accordingly.

II. AAM Is Likely To Succeed On Its Claim That Enforcement Of The Act Against Its Members' Out-Of-State Transactions Will Violate The Constitution.

A. The prohibition on direct regulation of out-of-state sales is alive and well.

Ross resolved just one question: whether the Commerce Clause establishes an "'almost *per se*' rule forbidding enforcement of state laws" that directly regulate only *in-state* conduct but nonetheless "have the 'practical effect of controlling commerce outside the State.'" 598 U.S. at 371. The Supreme Court answered no. But, in doing so, the Court took pains to clarify that it was not disturbing the constitutional prohibition on state laws that "*directly* regulate[] out-of-state transactions by those with *no* connection to the State." *Id.* at 376 n.1.

That makes sense. The California law in *Ross* did not attempt to impose liability on out-of-state actors for engaging in out-of-state conduct; Iowa pork producers could *not* be held liable for conduct in Iowa. Instead, the law regulated only the *in-state* sale of pork, *id.* ("Proposition 12 regulates only products that companies choose to sell 'within' California"); the challengers argued that the law had an indirect "practical effect" elsewhere that made it impermissible. *Id.* at 371. That is not the challenge AAM brings here. AAM does not seek to enjoin the Act as to *in-state* sales; nor does AAM rely on an indirect "practical effect" out-of-state. Rather, because the Act *directly regulates* (*i.e.*, imposes liability based upon) out-of-state sales, AAM relies on the settled rule that states may not "*directly* regulate[] out-of-state transactions"—a rule expressly distinguished in *Ross*. *See id.* at 376 n.1. Laws in the latter camp are unconstitutional.

Indeed, *Ross* approvingly cited (*id.* at 374) *AAM v. Frosh*, 887 F.3d 664 (4th Cir. 2018), which struck down a Maryland law just like this one under that doctrine. *Frosh* held that Maryland's "price gouging" law was invalid under the Commerce Clause because it directly "regulate[d] the price of any out-of-state transaction" involving a drug later re-sold in Maryland by someone else. *Id.* at 666, 670 (citation omitted). If *Ross* meant to disturb cases like *Frosh*, it

would have said so.[2] Nor did *Ross* call into question cases such as *Shafer v. Farmers' Grain Co. of Embden*, 268 U.S. 189, 199 (1925), and *Shaffer v. Heitner*, 433 U.S. 186, 197 (1977), which (the *Edgar* plurality explained) stand for the proposition that the Commerce Clause "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion).[3]

Ross thus provides no basis to question longstanding precedent holding that state laws are unconstitutional to the extent they directly regulate out-of-state transactions. *See* Mot. 15-17. Accordingly both the Second and Eighth Circuits have recently recognized the continued validity of AAM's position. *See, e.g.*, *Nat'l Shooting Sports Found., Inc. v. James*, 144 F.4th 98, 116 (2d Cir. 2025) (State statute violates the Commerce Clause if it "regulates 'commerce that takes place wholly outside of the State's borders.'" (citation omitted)); *AAM v. Ellison*, 140 F.4th 957, 960 (8th Cir. 2025) (explaining that *Ross* preserved the rule that "'[a state] has no power to project its legislation into [another state] by regulating the price to be paid in that state' for drugs sold there" (citation omitted)). The Second Circuit's precedent is binding, and the Eighth Circuit's analysis is persuasive. By contrast, the only case Defendants cite that reads *Ross* their way is unpersuasive on its face: it acknowledges *both* that AAM would prevail under pre-*Ross* precedent *and* that *Ross* "does not squarely address whether the dormant Commerce Clause itself prohibits a state from

[2] *HDA. v. Zucker* applied the same rule as *Frosh*, correctly identifying that "absolute constitutional prohibition" on a state law that "directly controls commerce occurring wholly outside the boundaries of a State." 353 F. Supp. 3d 235, 260 (S.D.N.Y. 2018), *rev'd in part on other grounds sub nom. AAM v. James*, 974 F.3d 216 (2d Cir. 2020). Nothing about that clear legal rule depends upon the practical-effects test that the Supreme Court rejected in *Ross*.

[3] The *Edgar* plurality confirms that some nebulous *connection* to the regulating state is not enough. Illinois violated the Commerce Clause by seeking to "directly regulate[] transactions … wholly outside" Illinois. 457 U.S. at 641 (plurality opinion); *see also id.* at 643. The shareholders in *Edgar* plainly had a connection to Illinois—they owned shares in "a publicly held Illinois corporation"—yet that connection was insufficient to uphold the statute. *Id.* at 642. The Act here reaches manufacturer-to-wholesaler transactions that have no Connecticut connection whatsoever.

regulating out-of-state transactions based on their downstream consequences." *AAM v. Raoul*, 2025 WL 2764558, at *3, *4 (N.D. Ill. Sept. 26, 2025), *appeal docketed*, No. 25-2960 (7th Cir. Oct. 31, 2025); *see id.* at *4 ("*Ross* did not answer the precise question this case presents"). Defendants echo that court's view that discrimination is now required for any Commerce Clause claim and that *Ross* somehow overturned all contrary precedent. *See id.* at *4; Opp. 10-11. But as *every* other post-*Ross* decision holds, and *Ross* itself shows,[4] that is incorrect. Mot. 22-23.

B. Defendants' planned enforcement will directly regulate out-of-state sales.

Unlike in *Ross*, Defendants here intend to directly regulate out-of-state transactions between out-of-state manufacturers and out-of-state wholesalers. To be sure, the Act's price cap is not triggered until a drug is (re-)sold in Connecticut. But Defendants' position is that if a drug is sold in Connecticut, even if by an unrelated third party, they may impose liability on parties to upstream transactions *outside of* Connecticut, punishing them for the price charged in those out-of-state transactions—*not* the price charged in Connecticut. That is textbook direct regulation. *See, e.g.*, *Ellison*, 140 F.4th at 960. And if generic manufacturers try to ensure that their product *does not* end up in Connecticut, the Act imposes a separate half-million-dollar penalty. Act § 347.

Defendants assert that a manufacturer's out-of-state sales should count as in-state conduct if a product from that sale is later re-sold in Connecticut. *See* Opp. 17. That is the same argument Minnesota made in *Ellison* and Maryland made in *Frosh*. But the Eighth and Fourth Circuits squarely rejected that argument, and for good reason: The fact that a product is later *re*-sold in a state (giving *the product* a "connection" or "nexus" to the state) does not allow that state to regulate the manufacturer's original sale. The manufacturer's original sale is not in-state conduct; a

[4] *Ross* itself made clear that a so-called *Pike* claim—which balances the benefits and burdens of a *non-discriminatory* state law—remains viable. Defendants recognize that their argument fails unless the Court overruled *Pike*, too, so they question *Pike*'s continued viability, Opp. 24 n.24. But the *Ross* majority (and the two Justices on whose votes it depended) expressly left the "courtroom door … open" for challenges to nondiscriminatory laws. Mot. 22.

subsequent, downstream sale in Connecticut by a third party does not change that.

In *Frosh*, the challenged statute applied to *medications* "made available for sale in [Maryland]" but was not limited to "sales that actually occur within Maryland." 887 F.3d at 671. The State acknowledged "that the Act [wa]s intended to reach sales upstream from consumer retail sales," and those "upstream" sales occurred "almost exclusively outside Maryland." *Id.* The court thus concluded "the Act targets conduct that occurs entirely outside Maryland's borders." *Id.*

What is more, just as in this case, the state laws in *Frosh* and *Ellison* did not actually regulate the prices the states' own consumers paid. In *Frosh,* "the lawfulness of a price increase [wa]s measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*." *Id.* That made it abundantly clear that Maryland's law "directly regulate[d] transactions that take place *outside Maryland*" and was "unconstitutional under the dormant commerce clause." *Id.* at 674. While Defendants claim "Connecticut is not telling AAM's members what their WACs should be," Opp. 17, it is telling out-of-state manufacturers exactly what their prices may be[5]—while leaving in-state retailers free to charge whatever they want.

Similarly, in *Ellison*, Minnesota's law "prohibit[ed] manufacturers from imposing (or causing to be imposed) 'an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the *sale* of any generic or off-patent drug *sold, dispensed, or delivered* to any consumer in the state.'" *AAM v. Ellison*, 704 F. Supp. 3d 947, 953 (D. Minn. 2023), *aff'd,* 140 F.4th 957 (8th Cir. 2025) (citation omitted). Thus, the Act "subject[ed] manufacturers to liability as a result of sales that take place wholly outside of Minnesota—say, the sale of a drug by a manufacturer in Colorado to a national distributor in New Jersey—so long as

[5] The Act caps the price that may be charged for identified drugs at the WAC in effect on January 1, 2025, adjusted for inflation (or a later date for later-introduced drugs). In some recent years, this would have precluded even a 1% price increase—giving the lie to Defendants' claim that the Act regulates only price gouging. This is more draconian than any similar state law: Minnesota's (enjoined) law permitted annual price increases up to 15% *plus* inflation.

the drug in question is eventually 'sold, dispensed, or delivered' by *anyone* to any consumer in Minnesota." *Id.* Minnesota there, like Connecticut here, argued that the "manufacturer's initial sale outside of Minnesota (such as the Colorado manufacturer's sale to the New Jersey distributor)—even though it has no connection whatsoever to Minnesota at the time it occurs—will *acquire* a sufficient connection to Minnesota when someone else (even someone far down the supply chain, acting outside of the control or knowledge of the manufacturer or the distributor to whom the manufacturer sold the drug) sells, dispenses, or delivers the drug to any consumer in Minnesota." *Id*. at 954. The District Court and Eighth Circuit squarely rejected that argument and held the law unconstitutional, since it directly regulated wholly out-of-state transactions. *Id.*; *Ellison*, 140 F.4th at 960-61. This Court should do the same.

In an effort to justify the Act's nationwide reach, Defendants point (at 21 n.20) to Connecticut's power to ban an entire product from its borders. That power could not be more different because it regulates *in-state* sales (a power AAM does not challenge). By contrast, here, the effectiveness of the Act *depends* on its $500,000 penalty *prohibiting* withdrawal from the State. Generic manufacturers are not allowed to take steps to ensure that their product does not end up in Connecticut. That is "fundamentally at odds with dormant Commerce Clause jurisprudence," as it makes the Act's extraterritorial reach "unavoidable." *Ellison*, 704 F. Supp. 3d at 956-57.

Because Connecticut "insist[s] that manufacturers sell their drugs to a wholesaler for a certain price" in "out-of-state transaction[s]," "[t]he rule that was applied in *Baldwin*" applies here. *Ellison*, 140 F.4th at 961 (citation omitted). Enforcing the Act in that manner is unconstitutional.

C. The Act independently violates the Commerce Clause because it is protectionist.

While direct regulation is the Act's most obvious constitutional defect, it is not the only one. The Act was also "enacted at the instance of, and primarily benefit[s], in-state interests."

Ross, 598 U.S. at 379 n.2 (internal quotation marks and citation omitted); *see also id.* at 370. Defendants do not dispute the prominence or in-state influence of Connecticut's brand-name drug industry, or of its retail pharmacies. Instead, they suggest that perhaps Connecticut also contains some generic manufacturer unknown to AAM, *the generic industry's trade association*—but they conspicuously do not identify any such company. Against Defendants' bare speculation, AAM's knowledge is more than sufficient to establish a likelihood of success at this preliminary stage.

Defendants' fallback fares no better. Defendants argue that even if the Act disfavors the out-of-state generic drug industry while favoring in-state interests, that is not "discrimination" against interstate commerce. Opp. 15-16. But their attempts to argue that generic and brand-name drugs are differently situated are simply wrong. Consider *Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263 (1984). There, the Supreme Court held that a Hawaii tax exemption favoring pineapple wine over all other alcohol was discriminatory, rejecting the State's argument that pineapple wine did not really compete with the taxed products. *Id.* at 268-69. Brand-name and generic drugs—which are so therapeutically equivalent that pharmacists may substitute one for the other—are considerably more similar than pineapple wine and Budweiser. As *Bacchus* shows, discrimination under the Commerce Clause does not turn on fine distinctions between submarkets like those made in the antitrust cases Defendants cite (Opp. 15). And Defendants are demonstrably wrong when they claim that "brand-name drugs subject to patents or other exclusivities"—and thus exempt from the price cap, *see* Mot. 9-10—"do not have comparable generics." Opp. 16. Hundreds of brand-name drugs have both patents (or exclusivities) and generic competitors. Indeed, a generic can be approved during a period of patent protection if its label "carve[s] out" the specific use covered by "live patents," *Novartis Pharms. Corp. v. Kennedy*, 156 F.4th 626, 627, 630 (D.C. Cir. 2025); if the generic is found not to infringe the patent, *Caraco Pharm. Lab'ys v. Novo Nordisk*

A/S, 566 U.S. 399, 405-06 (2012); or if the brand and the generic reach a settlement.

Thus, Connecticut imposes an extraordinarily tight cap on generic drugs but *none* on patent-protected brand equivalents or on in-state retail sales. Connecticut's brand-name companies and pharmacies may raise prices to recoup costs. The out-of-state generic industry cannot—and if they discontinue products as a result, the brand industry will benefit, not consumers.

III. AAM Members Will Suffer Irreparable Harm Absent An Injunction

The Act subjects AAM members to unconstitutional regulation and imposes unrecoverable economic harms. Both are irreparable injuries. First, and *contra* Opp. 29-30, Commerce Clause violations are no less irreparable than other constitutional violations. The Second Circuit just reiterated as much in a Commerce Clause case that AAM cited and Defendants simply ignore. *See Variscite NY Four, LLC v. N.Y. State Cannabis Control Bd.*, 152 F.4th 47, 60 (2d Cir. 2025) (irreparable harm follows from the merits "[w]hen, as here, a plaintiff alleges constitutional injury"). Second, Defendants do not (and cannot) deny that, because of the State's constitutional immunity from damages suits, AAM members could not be made whole—either for their forgone revenue (if they comply with the Act) or for the Act's unlawful civil penalties. *See* Opp. 31.[6]

Unable to dispute irreparable injury, Defendants claim AAM delayed seeking an injunction. That is wrong at every turn. The Act's price control applies only to sales on or after January 1, 2026. Act § 346. AAM brought suit months *before* that date, once its members could provide the concrete declarations about their *2026* pricing plans needed to show their injury—and after AAM had attempted to determine whether Defendants would take the enforcement position

[6] While Defendants gesture toward "potential" recovery through Connecticut's Office of the Claims Commissioner, that is an illusory option. The Claims Commissioner cannot pay claims exceeding $35,000, *see* Conn. Gen. Stat. Ann. § 4-158; any favorable ruling by the Commissioner may be vacated by the General Assembly—the very entity that adopted the Act, *id.* § 4-159(b)(2); and there is no indication that the Commissioner (who generally pays garden-variety tort claims) can or would provide relief for the harm caused by an unconstitutional law, *see id.* § 4-160.

that makes this action necessary, Compl. ¶ 5. That is not the type of "unexplained" delay (Opp. 29) that could defeat irreparable harm. *See Tom Doherty Assocs., Inc. v. Saban Ent., Inc.*, 60 F.3d 27, 39-40 (2d Cir. 1995) (four-month, good-faith investigation of claims did not rebut presumption of irreparable harm); *accord Marks Org., Inc. v. Joles*, 784 F. Supp. 2d 322, 332-33 (S.D.N.Y. 2011) (16-month delay for good-faith investigation). Defendants have no example of a constitutional challenge to a law being deemed too late months *before* the law takes effect.

IV. The Balance Of Hardships And Public Interest Support An Injunction

The balance of hardships and the public interest likewise support an injunction. The Act threatens the availability of generic drugs by preventing price adjustments that are driven by higher input costs and necessary to keep the products commercially viable. Mot. 33-34; Rockwell Decl. ¶ 14. An injunction preventing that harm to patients and to competition serves the public interest. And as the Second Circuit recognizes, "[n]o public interest is served by maintaining an unconstitutional policy when constitutional alternatives are available to achieve the same goal." *Variscite*, 152 F.4th at 60 (citation omitted) (applying rule to alleged Commerce Clause violation).

Defendants invoke the inapposite principle that a State "suffers a form of irreparable injury" if a court enjoins its duly enacted law. Opp. 32 (citation omitted). That principle does not immunize state laws from being enjoined; it just means the State has some equities to weigh. Here, the public's interest, and AAM's, in preserving an effective market for generic drugs far outweighs the State's interest in imposing unconstitutional penalties that it will not collect until 2027.

CONCLUSION

The Court should grant AAM's motion for a preliminary injunction.

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Respectfully submitted,

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