

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT**

ASSOCIATION FOR ACCESSIBLE, MEDICINES,	:	CIVIL ACTION NO.
	:	3:25-cv-01757-OAW
	:	
<i>Plaintiff,</i>	:	
	:	
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,	:	
	:	
<i>Defendants.</i>	:	November 17, 2025

**DEFENDANTS’ MEMORANDUM IN OPPOSITION TO
PLAINTIFF’S MOTION FOR PRELIMINARY INJUNCTION**

I. INTRODUCTION

Healthcare has long been described as “a calling, not a business.”¹ However, certain members of pharmaceutical industry are putting those words to the test by imposing outrageous and unwarranted price increases on essential, life-saving medications. They do so in markets where there is scant competition for the production and sale of such medications. And they do it for the sake of maximizing profit.

Connecticut residents are now in the crosshairs. They face extraordinary and irreparable harm to their health—physical, mental, and financial—from the Hobson’s choice offered by the pharmaceutical industry: pay our crushing markups or suffer the consequences of not having your vital medications. Connecticut’s General Assembly

¹ See, e.g., <https://med.stanford.edu/stanfordmedicine25/blog/archive/2014/10-Osler-isms-to-Remember-in-Your-Daily-Practice.html> (“The practice of medicine is an art, not a trade; a calling, not a business; a calling in which your heart will be exercised equally with your head.”) (attributed to William Osler, “The Father of Modern Medicine”).

ORAL ARGUMENT REQUESTED

and Governor responded to this cruel predicament by enacting the Public Act 25-168 §§ 345 to 347 (Act), which combats those unconscionable markups by capping the prices at which pharmaceutical manufacturers and wholesale distributors may sell certain prescription drugs in Connecticut. And the Act does so in a nondiscriminatory way that only furthers the goal of safeguarding the well-being of Connecticut residents.

The plaintiff, Association for Accessible Medicines (AAM), nevertheless sued, asking the Court to declare the Act unconstitutional and enjoin its implementation and enforcement. As part of that effort, AAM now moves for a preliminary injunction (PI Motion), Dkt. #20, based on its claim that the Act violates the dormant Commerce Clause. But because the Supreme Court has rejected the dormant Commerce Clause theory that AAM proposes, AAM is unlikely to succeed on the merits. The financial harm that AAM purports its members will suffer is not irreparable. And the equities weigh heavily in favor of the defendants. The Court should deny AAM's PI Motion.

II. BACKGROUND

The parties largely agree on how the pharmaceutical supply chain works for those drugs identified under the Act.² Manufacturers make the identified drugs. Memo. of

² The Act defines “identified prescription drugs,” as (1) generic drugs or interchangeable biological products; or (2) brand-name drugs or biological products to which all exclusive marketing rights granted under the Food, Drug, and Cosmetic Act have expired for at least twenty-four months. PA 25-168 § 345(6). Under the Act, *see* PA § 345(1), a “biological product” has the same meaning that as provided in Section 20-619 of the Connecticut General Statutes, which in turn gives “biological product” the same meaning as that under the 42 U.S.C. § 262, the Public Health Services Act. *See* 42 U.S.C. § 262(i)(1) (“The term ‘biological product’ means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.”); *see also Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 6 (2017) (“A biologic is a type of drug derived from natural, biological

Law in Support of Pl.’s Mot. for a Preliminary Injunction, Dkt. # 20-1 (PI Memo), p. 6. Distributors (e.g., wholesalers) act as middlemen between the manufacturers and dispensers (e.g., pharmacies, hospitals), operating a network of drug distribution centers across the country. *Id.*³ Dispensers provide patients with the identified drugs when prescribed. *Id.*

The manufacturers’ “list price” for drugs is also known as the “Wholesale Acquisition Cost” (WAC). *Id.*; see 42 U.S.C. § 1395w-3a(c)(6)(B) (“The term ‘wholesale acquisition cost’ means . . . the manufacturer’s list price for the drug or biological to wholesalers . . . , not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.”).

Manufacturers set the WAC at a nationwide level. PI Memo, p. 6. Still, manufacturers often sell drugs to distributors at negotiated prices, and distributors often pay less than the WAC by leveraging their market share or sales volume to obtain discounts.⁴ *Id.*; see

sources such as animals or microorganisms. Biologics thus differ from traditional drugs, which are typically synthesized from chemicals.”).

³ AAM is a trade association for generic drug and biosimilar manufacturers and distributors. PI Memo, p. 4; Complaint, ¶ 18.

⁴ *Follow the Pill: Understanding the U.S. Commercial Supply Chain*, The Kaiser Family Foundation (March 2005), p. 18 (“For generic products, the purchase price is highly variable, largely depending upon competition in the class and the ability of the wholesale distributor to drive market share or increase the volume sold. In this case, wholesale distributors play a larger role in the negotiation of the price of the product.”), available at <https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>. The Court may take notice of this information, and other information presented here as background, to provide context because “District Courts may take judicial notice of facts ‘not subject to reasonable dispute’ when they ‘can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.’” *Kravitz v. Tavlarios*, No. 20-2579-cv, 2021 U.S. App. LEXIS 34224, at *8-9 (2d Cir. Nov. 18, 2021) (quoting

Mont. ex rel. Knudsen v. Eli Lilly & Co. (In re Insulin Pricing Litig.), No. 2:23-cv-04214, 2025 U.S. Dist. LEXIS 173773, at *83 (D.N.J. Sep. 5, 2025) (discussing how prescription drugs “move through a complex distribution chain where pharmaceutical manufacturers typically sell their products to wholesalers at a negotiated price.”). When dispensers purchase identified drugs from distributors, they negotiate the price such that individual dispensers may pay different prices when purchasing from the same distributor.⁵

It is undisputed that millions of Americans, including Connecticut residents, rely on prescription drugs to maintain their health and very lives.⁶ And approximately 90% of prescriptions are filled with generic drugs,⁷ which *should* cost 80-85% less than brand-name drugs.⁸

Fed. R. Evid. 201(b)(2)).

⁵ *Flow of Money through the Pharmaceutical Distribution System*, USC Leonard D. Schaeffer Institute for Public Policy & Government Service (June 2017), p. 2 (“Pharmacies in turn negotiate agreements with drug wholesalers, setting the wholesale rates at which they obtain the drugs, and wholesalers negotiate to buy drugs from manufacturers and distribute them to pharmacies.”), available at https://schaeffer.usc.edu/wp-content/uploads/2024/10/The-Flow-of-Money-Through-the-Pharmaceutical-Distribution-System_Final_Spreadsheet.pdf.

⁶ See Cost Growth Benchmark Initiative Report, Connecticut Office of Health Strategy (April 24, 2025) (OHS Report), p. 51 (“Many Americans depend on prescription drugs to maintain or improve their health. According to the National Health and Nutrition Survey, 67% of Americans aged 45-64 have used at least one prescription drug in the last 30 days.”), available at https://portal.ct.gov/ohs/-/media/ohs/cost-growth-benchmark/benchmark-reports-py2023/ohs-hcbi-cost-growth-benchmark-report-py2023-rev-04_24_2025.pdf.

⁷ Andrew W. Mulcahy & Vishnupriya Karedy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp. (Oct. 27, 2021), p. 2, available at https://www.rand.org/pubs/research_reports/RA328-1.html.

⁸ FTC, *How to Get Generic Drugs and Low-Cost Prescriptions*, October 2023 (available at <https://consumer.ftc.gov/articles/generic-drugs-low-cost-prescriptions>).

Unfortunately, despite this potential for lower-cost prescriptions, patients face “skyrocketing drug prices, sometimes by more than 1,000%, and sometimes overnight.” *Ass’n for Accessible Meds. v. Raoul*, No. 24 C 544, 2025 U.S. Dist. LEXIS 190215, at *1-2 (N.D. Ill. Sep. 26, 2025) (*Raoul*). Those skyrocketing prices stem from a variety of causes, including a lack of competition within the industry.⁹ This situation has been well documented across the country.¹⁰ Connecticut residents have not been spared, feeling the pain sharply.¹¹

⁹ See Ellen Andrews, Ph.D., *Connecticut Is a National Leader in Fight to Control Drug Costs*, CT News Junkie (July 3, 2025) (“But price fixing and collusion are not the only way generic drug prices are kept artificially high. Too often, even when drug patents expire, no company comes forward to create a competitor medication.” (discussing Martin Shkreli, who bought the manufacturer of Daraprim and then raised the price by 5,000%, even though the drug was developed in the 1950s)), available at <https://ctnewsjunkie.com/2025/07/03/analysis-connecticut-is-a-national-leader-in-fight-to-control-drug-costs/>.

¹⁰ See, e.g., *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664, 674 (4th Cir. 2018) (*Frosh*) (Wynn, J., dissenting) (“After a series of high-profile incidents in which several generic pharmaceutical manufacturers imposed multiple-thousand-fold price increases for single-source generic drugs that treat rare and life-threatening conditions, the Maryland legislature enacted legislation prohibiting ‘unconscionable’ price increases for certain generic drugs ‘made available for sale’ to Maryland consumers.”); U.S. Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs* (Dec. 2016), available at <https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf>; U.S. Government Accountability Office, Report to Congressional Requesters, *Generic Drugs Under Medicare* (Aug. 2016) (noting the “extraordinary price increase” for some generic drugs), available at <https://www.gao.gov/assets/gao-16-706.pdf>; Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, NY Times (Sept. 20, 2015), available at <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

¹¹ See OHS Report, *supra*, p. 51 (“[H]igh costs continue to impede patient access to pharmaceuticals. A 2022 survey of Connecticut residents found that 23% of respondents had cut pills in half, skipped doses of medicine, or did not fill a prescription due to costs. High and rising prescription drug costs were a significant contributor to Connecticut’s healthcare spending growth in 2023.”); Liese Klein, *New Connecticut laws aim to tame surging prescription drug prices for patients, hospitals*, CT Insider (July 27, 2025) (“Drug costs for hospitals in Connecticut rose at a higher rate in recent

To help alleviate that pain, in 2025, Connecticut entered the fray¹² by enacting, among other things,¹³ a drug price cap. Public Act 25-168 §§ 345 to 347. Starting on January 1, 2026, no manufacturer or distributor shall “sell an identified drug in this state at a price that exceeds the reference price for the identified prescription drug, adjusted for any increase in the consumer price index.” *Id.* § 346(a)(1). The “reference price” is defined as the WAC on a particular date (depending on the status of the drug). *Id.* § 345(11). The “consumer price index” is defined as the consumer price index, annual average, for all urban consumers. *Id.* § 345(4). Put simply, the Act’s drug price cap ties cost of identified drugs to their WAC, adjusted for inflation.¹⁴

years compared to other Northeast states and have outpaced national averages The Connecticut Hospital Association warns that higher drug costs . . . are threatening the survival of the state’s medical safety net.”), *available at* <https://www.ctinsider.com/business/article/new-laws-target-rising-prescription-drug-costs-20786384.php>

¹² *Governor Lamont Announces 2025 Legislative Proposal: Reduce Prescription Drug Costs* (Feb. 2, 2025), *available at* https://portal.ct.gov/governor/news/press-releases/2025/02-2025/governor-lamont-announces-2025-legislative-proposal-reduce-prescription-drug-costs?language=en_US; *New Connecticut laws*, CT Insider, *supra* (“Lamont plans an official ceremony . . . to highlight the newly approved package of a dozen new measures aimed at drug costs, which earned bipartisan support.”); *Connecticut Is a National Leader*, CT News Junkie, *supra* (“This year, Connecticut passed meaningful laws to control stubbornly-high prescription drug prices.”).

¹³ *See also* PA 25-167 § 2 (requiring a pharmacy benefits manager to offer a health plan the option of being charged the same price for a prescription drug that the pharmacy benefits manager pays a pharmacy for that prescription drug); § 6 (authorizing the Commissioner of Economic and Community Development to use certain bond proceeds to support prescription drug production capacity in Connecticut); §§ 9-18 (authorizing a study on the feasibility of establishing a Canadian prescription drug importation program “to reduce prescription drug costs in the state.”).

¹⁴ *See Connecticut Is a National Leader*, CT News Junkie, *supra* (“The Governor’s generic drug price proposal that passed in Connecticut’s big budget bill . . . caps future increases at the level of general inflation.”); Ed Silverman, *Generic drugmakers seek to thwart a Connecticut law that would cap rising prices*, Stat+ (Oct. 27, 2025) (“The law, which goes into effect in January, prohibits drugmakers from raising the prices of their

A manufacturer or distributor that violates the Act then becomes liable to the state for a civil penalty, which is imposed, calculated, and collected by the Commissioner of Revenue Services. *Id.* § 346(b)(1). However, the Act exempts from its requirements prescription drugs that the federal government has identified as being “in shortage” in the United States. *Id.* § 346(a)(2). It also provides manufacturers and distributors with administrative and judicial relief with respect to such penalties. *Id.* § 346(f) & (g). There is nothing in the Act that discriminates against out-of-state persons or entities or furthers any protectionist goals. *See generally id.* §§ 345 to 347.

AAM filed suit on October 17, 2025, seeking to invalidate Connecticut’s efforts to protect its residents by alleging that the Act violates the dormant Commerce Clause, the Due Process Clause, Separation of Powers, the Supremacy Clause, and 42 U.S.C. § 1983. Complaint, Dkt. # 1. AAM brings this action on behalf of its members, claiming “[i]f not enjoined, the Act will imminently cause AAM’s members unrecoverable economic harm,” which essentially boils down to making less money if they comply with the Act (or facing the Act’s penalties if they do not). *Id.* ¶¶ 49-56 (discussing members’ purported “economic injury” and how their “profit margins . . . are often thin”); *see* PI Memo, pp. 29-32.

AAM now asks this Court to preliminarily enjoin the defendants from implementing or enforcing the Act against any of AAM’s members. *See generally* PI Memo. It does so based on the contention that the Act violates the dormant Commerce Clause.

medicines above the inflation rate.”), *available at* [Generic drugmakers seek to thwart a Connecticut law that would cap rising prices | STAT](#).

III. LEGAL STANDARD

A preliminary injunction “is an extraordinary and drastic remedy and should not be granted unless the movant, by a clear showing, carries the burden of persuasion.” *St. Joseph’s Hosp. Health Ctr. v. Am. Anesthesiology of Syracuse, P.C.*, 131 F.4th 102, 106 (2d Cir. 2025) (internal quotation marks omitted). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Gazzola v. Hochul*, 88 F.4th 186, 194 (2d Cir. 2023) (internal quotation marks omitted). These requirements are “demanding” because a preliminary injunction is never awarded as of right and should not be routinely granted. *Daileader v. Certain Underwriters at Lloyds London Syndicate 1861*, 96 F.4th 351, 356 (2d Cir. 2024); *We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 279 (2d Cir. 2021). An allegation of constitutional harm does not conclusively determine balance-of-the-equities inquiry. *Nat’l Ass’n for Gun Rights v. Lamont*, 153 F.4th 213, 2025 U.S. App. LEXIS 21570 at *65 (2d Cir. 2025) (*Lamont*). Rather, when the government is a party to the suit, the inquiries into the public interest and the balance of the equities merge, and “courts should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.” *We the Patriots USA*, 17 F.4th at 279 & 295 (internal quotation marks omitted).

IV. ARGUMENT

In its PI Memo, AAM raises Commerce Clause arguments and theories are unsupported by the most relevant Supreme Court decision on this issue, see *Nat’l Pork Producers Council v. Ross*, 598 U.S. 356 (2023) (*Pork*), and/or are simply inapplicable

here. Because AAM is unlikely to succeed on the merits, the Court should deny the PI Motion on that basis alone.

AAM also has failed to demonstrate irreparable harm. AAM argues that its allegation of a violation of a constitutional right triggers an automatic finding of irreparable injury. PI Memo, pp. 29. But because AAM is unlikely to succeed on the merits, its irreparable harm argument necessarily fails. Also, AAM's delay in suing indicates that its members are not facing the kind of irreparable harm that requires the urgent relief of a preliminary injunction. In any event, in this Circuit, there is no automatic presumption of irreparable harm based only on a claim of the abridgement of a constitutional right. Such a presumption arises only when the violations involve personal constitutional rights and injuries that are not compensable by money damages. The Commerce Clause enshrines structural, not personal, rights. And even if that were not the case, the other alleged harm here is a loss of money, *see* PI Memo pp. 29-32, for which AAM's members would have statutory avenues to seek compensation.

Finally, the public interest and balance of equities strongly favor the defendants. The purpose of the Act is to protect the health and lives of the Connecticut people. The purpose of requested injunction is to keep money flowing into the pockets of AAM's members, so that cash rules at the expense of the health of the Connecticut people. Therefore, there is no real "public interest" that supports enjoining the Act, and the equities are extremely unbalanced. The Court should deny the AAM's Motion.

A. AAM Is Unlikely to Succeed on the Merits of Its Claim that the Act Is Unconstitutional.

"Companies that choose to sell products in various States must normally comply with the laws of those various States." *Pork*, 598 U.S. at 364. And state laws are

presumed to be constitutional. *Conn. ex rel. Blumenthal v. Crotty*, 346 F.3d 84, 102 (2d Cir. 2003); see *Lemon v. Kurtzman*, 411 U.S. 192, 208 (1973) (“[O]ne of the first principles of constitutional adjudication [is] the basic presumption of the constitutional validity of a duly enacted state or federal law.”). That is the starting point of the analysis here.

1. The Act does not violate the dormant Commerce Clause because it is nondiscriminatory and not driven by economic protectionism.

Congress is vested with the power to regulate commerce among the states. U.S. Const. art. I, § 8, cl. 3. In doing so, it may directly regulate interstate trade of products, and such congressional enactments may preempt conflicting state laws. *Pork*, 598 U.S. at 368. Beyond direct congressional legislation, the Supreme Court “has held that the Commerce Clause . . . also contain[s] a further, negative command, one effectively forbidding the enforcement of certain state [economic regulations] even when Congress has failed to legislate on the subject.” *Id.* (internal quotation marks omitted). This is the so-called dormant Commerce Clause. *Id.*

Under the dormant Commerce Clause, “no State may use its laws to discriminate purposefully against out-of-state economic interests.” *Pork*, 598 U.S. at 364. But in *Pork*, the Supreme Court made it clear that the dormant Commerce Clause does not invalidate a state law just because it has extraterritorial effect. Rather, it is a principle that developed over time in circumstances where state laws attempted to “build up . . . domestic commerce through burdens upon the industry and business of other States, regardless of whether Congress has spoken.” *Id.* at 369 (internal quotation marks omitted). “[T]his antidiscrimination principle lies at the “very core” of our dormant Commerce Clause jurisprudence,” which “prohibits the enforcement of state laws driven

by . . . economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.” *Id.* (internal quotation marks omitted). “[A]bsent discrimination, a State may exclude from its territory, or prohibit the sale therein of any articles which, in its judgment, fairly exercised, are prejudicial to the interests of its citizens.” *Id.* (internal quotation marks omitted).

Thus, in *Pork*, the Court ultimately upheld a California law that *completely banned* the sale of pork products derived from pigs subjected to cruel breeding and living conditions, notwithstanding that the law affected out-of-state pork producers’ business practices and financial interests. *See id.* at 364-67. The Court specified that the plaintiffs “begin in a tough spot” because there was no allegation that the California law “seeks to advantage in-state firms or disadvantage out-of-state rivals.” *Id.* at 370-71. That lack of discrimination was fatal to the plaintiffs’ “normal” dormant Commerce Clause challenge. *See id.*

Moreover, *Pork* expressly rejected the “more ambitious” theory that the dormant Commerce Clause embodies an “extraterritoriality doctrine” in which an “almost *per se*” rule forbids enforcement of state laws that “have the practical effect of controlling commerce outside the State, even when those laws do not purposely discriminate against out-of-state economic interests.” *Id.* at 371 (internal quotation marks omitted). In doing so, the Court stated that “[t]his argument falters out of the gate” because the line of cases upon which the plaintiffs’ relied for their theory “typifie[d] the familiar concern with preventing purposeful discrimination against out-of-state economic interests.” *Id.* at 371.

Indeed, the Court observed that the plaintiffs “read too much into too little” with respect to the cases they used to support their theory. *Id.* at 373. And throughout its

discussion, the Court emphasized that the decisions upon which the plaintiffs had relied for their extraterritoriality argument all involved discriminatory or protectionist state statutes. *See id.* at 373-74; *see also Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511 (1935) (New York laws that barred out-of-state dairy farmers from selling milk in New York unless the price paid to them matched the minimum price New York law guaranteed to in-state producers); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573 (1986) (New York law required liquor distillers to affirm that their in-state prices were no higher than their out-of-state prices); *Healy v. Beer Inst.*, 491 U.S. 324 (1989) (Connecticut law required out-of-state beer merchants to affirm that their in-state prices were no higher than those they charged in neighboring states). That is, in those cases, the states had enacted laws to “erect[] an economic barrier protecting a . . . local industry against competition from without the State” (*Baldwin*), “force out-of-state [producers] to ‘surrender’ whatever cost advantages they enjoyed against their in-state rivals” (*Brown-Forman*), or “hoard commerce for the benefit of in-state merchants and discourage consumers from crossing state lines to make their purchases from nearby out-of-state vendors.” (*Healy*). *Pork*, 598 U.S. at 372-73 (internal quotation marks omitted). In all those situations, “protectionism took center stage.” *Id.* at 372. The Court thus concluded that the language from its earlier cases “appeared in a particular context and did particular work[] [t]hroughout . . . explain[ing] that the challenged statutes had a *specific* impermissible extraterritorial effect—they deliberately prevent[ed out-of-state firms] from undertaking competitive pricing or deprive[d] businesses and consumers in other States of whatever competitive advantages they may possess.” *Id.* at 374 (internal quotation marks omitted).

These *Pork* principles defeat AAM’s dormant Commerce Clause arguments. Connecticut has passed a law prohibiting manufacturers and distributors from selling identified drugs in this state at a price that exceeds their reference price (i.e., WAC on a certain date), adjusted for inflation. The Act does not contain any facially discriminatory language, as it makes no distinction between in-state and out-of-state interests. It applies equally to all identified drug manufacturers and distributors that do business in Connecticut, imposing the same burdens on in-state and out-of-state interests. In short, the Act does not insulate in-state interests from the consequences of interstate commerce or further any economic protectionist goals with respect to similarly situated out-of-state interests, and therefore does not run afoul of the dormant Commerce Clause. *See Nat’l Shooting Sports Found., Inc. v. James*, 144 F.4th 98, 113 (2d Cir. 2025) (*James*) (“[T]he dormant Commerce Clause’s scope is not absolute. . . . Rather, states retain broad power to legislate and regulate, even in ways that may bear adversely upon interstate commerce. . . . And courts are not to wield the dormant Commerce Clause as a roving license . . . to decide what activities are appropriate for state and local government to undertake.”) (internal citations and quotation marks omitted).

2. AAM’s assertion that the Act is unconstitutionally discriminatory is without basis and meritless because AAM has not shown discrimination with respect to substantially similar entities.

Notwithstanding this facial neutrality, AAM asserts that the Act has “obvious protectionist purposes” because the price cap applies only to identified drugs “while protecting brand-drugs” and “thus protect[ing] Connecticut’s in-state brand manufacturers while prejudicing generic manufacturers.” PI Memo, p. 26. This

argument stumbles from the start because AAM has not presented evidence regarding the status of any purported in-state manufacturers. In its complaint, AAM alleges that “no AAM member is located in Connecticut, and AAM understands that no national wholesaler is located or even has a distribution facility in Connecticut.” Complaint, ¶ 5; *see* PI Memo, p. 13. But in the PI Memo, AAM makes the assertion, without supporting evidence, that “no *generic manufacturer* and no national drug wholesale distributor is located in Connecticut.” PI Memo, p. 24 (emphasis added)¹⁵; *see id.*, p. 26 (“The Act thus protects Connecticut’s in-state brand manufacturers while prejudicing generic manufacturers, *all of which are out-of-state.*”) (emphasis added). That is, AAM has pronounced what it “understands,” but presented no evidence showing whether Connecticut has in-state brand drug manufacturers, generic drug manufacturers, or any drug manufacturers at all. This is far from the “clear showing” necessary for the issuance of a preliminary injunction because Connecticut is somehow discriminating against out-of-state interests in violation of the dormant Commerce Clause.

Regardless, AAM’s argument fails anyway because AAM is not comparing like-to-like. For the purposes the Commerce Clause, “any notion of discrimination assumes a comparison of substantially similar entities.” *GMC v. Tracy*, 519 U.S. 278, 298 (1997). So “[w]hen the allegedly competing entities provide different products, . . . there is a threshold question whether the companies are indeed similarly situated for

¹⁵ AAM cites to paragraph 5 of its own complaint to support this assertion. Of course, “allegations in a complaint are not evidence.” *Welch-Rubin v. Sandals Corp.*, No. 3:03CV481 (MRK), 2004 U.S. Dist. LEXIS 22112, at *4 (D. Conn. Oct. 20, 2004); *see Gomez v. 4 Runners, Inc.*, 769 F. App’x 1, 3 (2d Cir. 2019). But beyond that, paragraph 5 of the complaint does not reference “generic manufacturers” at all, and so the naked assertion in the complaint does not even support AAM’s naked assertion here.

constitutional purposes.” *Id.* at 299. “This is so for the simple reason that the difference in products may mean that the different entities *serve different markets*, and would continue to do so even if the supposedly discriminatory burden were removed.” *Id.* (emphasis added); *see id.* at 297-312 (holding that two allegedly similar products were, nonetheless, substantially different for the purposes of the dormant Commerce Clause because they served two different markets.); *see also Allco Fin., Ltd. v. Klee*, 861 F.3d 82, 102-08 (2d Cir. 2017).

There is no question that “[t]he approval processes for brand-name drugs and generic drugs differ significantly.” *Bennett v. Teva Pharms. USA Inc.*, Nos. 21-1642, 21-2304, 2022 U.S. App. LEXIS 25168, at *2-3 (3d Cir. Sep. 7, 2022); *see Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476-77 (2013) (detailing the different approval processes for brand and generic drugs). “Moreover, given other economic factors, even functionally identical products—like brand-name and generic versions of the same drug—can sort into different product markets.” *United States v. Visa, Inc.*, 788 F. Supp. 3d 585, 2025 U.S. Dist. LEXIS 119414, at *37 (S.D.N.Y. 2025); *see Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496-500 (2d Cir. 2004) (analyzing how Coumadin and generic warfarin operate in separate markets based on, inter alia, price differentials, customer demand, and different distribution chains); *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 82 (D.D.C. 2006) (discussing trial evidence that generic industry does not consider the brand price in setting their own prices; industry participants view generic manufacturers as competing in a different market than the branded manufacturers; and brand and generic drugs have different consumer bases and are promoted and marketed very differently).

Further, AAM alleges that the Act discriminates against generic manufacturers because brand-name drugs may be “exempted from Connecticut’s cap indefinitely” by obtaining “multiple rounds of patents.” PI memo, p. 26. But brand-name drugs subject to patents or other exclusivities do not have comparable generics.¹⁶ So, even if a brand-name drug and its generic alternative(s) are considered like-to-like, a brand-name drug cannot have a comparable generic to give rise to a discrimination claim. “[I]n the absence of actual or prospective competition between the supposedly favored and disfavored entities in a single market there can be no local preference, whether by express discrimination against interstate commerce or undue burden upon it, to which the dormant Commerce Clause may apply.” *Tracy*, 519 U.S. at 300.

All of which is to say, treating brand and generic manufacturers differently does not implicate the dormant Commerce Clause because those entities serve different markets and are not substantially similar from a constitutional perspective. The same holds true with respect to AAM’s throwaway line that “the Act protects in-state retailers and resellers by exempting them from the price cap altogether.” PI Memo, p. 26.¹⁷ Retailers are not “similarly situated” with manufacturers and distributors; they are not in the same market at all. Therefore, AAM’s challenge under the dormant Commerce Clause is unlikely to prevail.

¹⁶ *Generic Drugs: Questions and Answers*, U.S. Food & Drug Administration (Mar. 16, 2021) (“It is only after both patent and other periods of exclusivity are resolved that FDA can approve a generic of the brand-name medicine.”), *available at* <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers>.

¹⁷ AAM uses the term “exempt,” although the Act does not contain an exemption for retailers and resellers; it simply does not mention them. In any event, the Act does not “protect in-state retailers and resellers” because the so-called exemption applies to all retailers and resellers, regardless of location.

3. AAM’s argument that the Act is unconstitutional because it “directly” regulates “wholly” out-of-state transactions is unsupported, conflicts with the language of *Pork*, and raises immaterial distinctions between the circumstances presented here and those in *Pork*.

AAM’s primary argument is that the Commerce Clause prohibits a state from “directly” regulating transactions that occur “wholly” outside that state. PI Memo, pp. 15-25. Leaving aside for a moment which legal principles apply in light of *Pork*, the question to AAM should be: if Connecticut is not telling AAM’s members what their WACs should be, not dictating what the negotiated prices between manufacturers and distributors should be, and capping prices based on manufacturer-established WACs only for drugs sold *in Connecticut*, then how is Connecticut “directly” regulating transaction that are “wholly” unconnected to Connecticut? The answer: “it’s not.” See *James*, 144 F.4th at 116 (rejecting argument that state law regulated extraterritorial transactions that took place “wholly outside of the State’s borders” and gave “carte blanche to impose their regulatory preferences on other states” when that law contained a state nexus requirement, *i.e.*, “plainly focused on regulating conduct that occurs in or has a connection to” that state.); *cf. Watson v. Emp’rs Liab. Assurance Corp.*, 348 U.S. 66 (1954) (upholding a state law permitting direct lawsuits against insurance companies that issued policies to persons who inflicted injury when those policies were negotiated, issued, and delivered out-of-state and contained language under out-of-state law prohibiting direct actions against the insurance companies).¹⁸

¹⁸See *Watson*, 348 U.S. at 71-73 (“[A]s this case illustrates, a vast part of the business affairs of this Nation does not present . . . simple local situations. . . . As a consequence of the modern practice of conducting widespread business activities throughout the entire United States, this Court has in a series of cases held that more states than one may seize hold of local activities which are part of multistate transactions and may regulate to protect interests of its own people, even though other phases of the same

In any case, *Pork* could not have been clearer: absent discrimination or protectionism, a state may enact laws applicable within the state’s jurisdiction that otherwise have an extraterritorial effect, even if it burdens out-of-state business practices and financial interests. That is exactly what the Court blessed in *Pork*, namely, a state law that required all pork producers that sold their products in the state to comply with certain requirements, even though those requirements affected the practices and finances of out-of-state businesses.

Yet AAM’s first argument glides over *Pork* completely, relying largely on a reversed, pre-*Pork* district court decision for the proposition an injunction should issue because the Commerce Clause prohibits “direct regulations of transactions outside the State, which Connecticut’s law violates by targeting out-of-state transactions while exempting in-state transactions.” PI Memo, pp. 15; see *Healthcare Distribution All. v. Zucker*, 353 F. Supp. 3d 235 (S.D.N.Y. 2018) (*Zucker*), *rev’d sub nom. Ass’n for Accessible Meds. v. James*, 974 F.3d 216 (2d Cir. 2020).

The defects in AAM’s argument are many. Of course, reliance on any pre-*Pork* Commerce Clause decisions here is problematic, as *Pork* is the most recent, relevant Supreme Court case applicable the circumstances presented here, and those earlier decisions did not have the benefit of the Supreme Court’s guidance.

Still, AAM asserts that “direct ‘state regulation of commerce occurring beyond the state’s borders’ is prohibited.” PI Motion, p. 16 (quoting *Zucker*, 353 F. Supp. 3d at 260). This appears to be a standard that AAM has proffered for the purpose of creating

transactions might justify regulatory legislation in other states. Louisiana's direct action statute is not a mere intermeddling in affairs beyond her boundaries which are no concern of hers. . . . Louisiana[] [has a] legitimate interest in safeguarding the rights of persons injured there.”).

an alternative dormant Commerce Clause claim that *Pork* did not recognize. However, even *Zucker* itself did not say that “direct” state regulation is prohibited. Rather, the actual quote from *Zucker* is: “The *absolute constitutional prohibition* on state regulation of commerce occurring beyond the state’s borders is clear: ‘Taken together, . . . cases concerning the extraterritorial effects of state economic regulation stand ... for the following proposition[]: . . . the “Commerce Clause” . . . precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders[.]’” *Zucker*, 353 F. Supp. 3d at 260 (emphasis added) (quoting *Healy*, 491 U.S. at 336). But *Pork* rejected any such absolute, unconditional prohibition, effectively nullifying that language from *Zucker*.¹⁹ And likely realizing this, AAM has now altered the standard to distinguish “direct” regulation from other types of regulation, a distinction that *Zucker* did not make (because it was relying on a more absolute prohibition that *Pork* repudiated) and *Pork* does not recognize.

This leaves AAM to rely on the language from *Edgar*’s plurality opinion that “any attempt ‘directly’ to assert extraterritorial jurisdiction over persons or property would offend sister States and exceed the inherent limits of the State’s power.” *Edgar v. MITE Corp.*, 457 U.S. 624, at 643 (1982) (internal quotation marks omitted). Of course,

¹⁹ The end of *Zucker*’s quote from *Healy* omitted an important clause, “whether or not the commerce has effects within the State,” *Healy*, 491 U.S. at 336, which itself is a quote from a plurality opinion from *Edgar v. MITE Corp.*, 457 U.S. 624, 642-643 (1982). And *Pork* (1) discussed at length how *Healy* did not stand for the absolute rule that AAM proposes, but rather was a case protectionism took center stage, see *Pork*, 598 U.S. at 372-73; and (2) cast serious doubt on the validity of that language from the *Edgar*’s plurality opinion, see *id.* at 376 n.1.

because that language comes from a plurality opinion, its reasoning is not binding here unless later accepted by the Supreme Court or the Second Circuit. *See CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 81 (1987) (“As the plurality opinion in [*Edgar*] did not represent the views of a majority of the Court, we are not bound by its reasoning.”) (internal quotation marks omitted). While a plurality opinion still could be deemed persuasive, *cf. United States v. Leonard*, 844 F.3d 102, 109 (2d Cir. 2016), *Pork* found the *Edgar* plurality opinion to be otherwise in this context, noting (1) it was unclear whether *Edgar* presented a dormant Commerce Clause issue at all; and (2) to the extent that *Edgar* language could apply, “[t]hat decision spoke to a law that *directly* regulated out-of-state transactions by those with *no* connection to the State.” *Pork*, 598 U.S. 356, 376 n.1. And as discussed above, it would be absurd for AAM to claim that the transactions have *no* connection to Connecticut. AAM challenges the Act because it imposes a prices cap on certain prescription drugs sold *in Connecticut*. If there really were no connection between Connecticut and the transactions at issue, that would mean that AAM’s members are not selling their goods in Connecticut (in which case, the Act would not apply, and AAM would not have standing to challenge it).

Additionally, AAM raises a distinction between state action that “directly” regulates out-of-state conduct and state action that has the “effect” of regulating out-of-state conduct. As discussed at length above, Connecticut is not “directly” regulating any out-of-state transaction, but has enacted a law applying to in-state conduct, which could affect out-of-state conduct. AAM provides no persuasive reason for how that is different from the situation in *Pork*, where California required pork producers to comply with California’s standards to the extent that those pork producers wished to conduct business in California. California was not directly regulating out-of-state conduct with

no in-state connection. Rather, it set the ground rules for operating *in California*. And *Pork* held that that did not violate the dormant Commerce Clause even though there were substantial out-of-state effects (that would presumably require out-of-state actors to alter their business practices and contracts).²⁰

4. AAM’s argument that the Act penalizes AAM’s members for drug prices charged in other states a meritless attempt to reap the benefits of dormant Commerce Clause principles that do not apply here.

AAM’s additional claim that the Act penalizes AAM’s members for “prices they charge *in other states*,” PI Memo, p. 16, is also wrong.²¹ Connecticut is not directing that a prescription drug sold in Connecticut must conform to the price of a sister state, nor does it penalize AAM’s members for whatever prices they impose in any other state. Instead, the Act requires a manufacturer or distributor to fix the price to the WAC—an amount that the manufacturers themselves establish *nationwide*. There are no

²⁰ This argument is similar to HDA’s argument that *Pork*’s principles are inapplicable here because *Pork* did not involve a price regulation statute, but rather a law barring sales of an entire product in the state unless certain conditions were satisfied. But *Pork* did not say that its holding applies to some types of dormant Commerce Claims and not others, nor did it say that the antidiscrimination principles that lie at the “very core” of its dormant Commerce Clause jurisprudence becomes irrelevant when the issue concerns the regulation of prices. And for good reason, as that would make no sense. Indeed, it would be absurd to hold that a state may ban an entire product from its borders in a nondiscriminatory way yet be powerless to set nondiscriminatory prices for products that come into its jurisdiction.

²¹ AAM asserts that the basis for its PI Motion differ from those raised in preliminary injunction motion that Healthcare Distribution Alliance (HDA) filed in the related case *Healthcare Distribution Alliance v. Boughton*, No. 3:25-cv-1724-OAW. See PI Memo, p. 15. But AAM’s motion and HDA’s motion are just two sides to the same “pay no attention to *Pork*” coin. Indeed, it is difficult to tell where AAM’s argument (the Act is unconstitutional because AAM’s members face consequences “based on prices they charge in other states,” PI Memo, p. 16) ends, and HDA’s argument (the Act is unconstitutional because it “seeks to tie Connecticut prices to prices outside the state[,]” HDA’s PI Memo, p. 9) begins.

“Connecticut prices” vs. “out-of-state” prices in the first place. Or put another way, the WAC is the Connecticut price, as well as that for all the states.

AAM’s argument about prices charged “in other states” is thus a red herring. When *Baldwin*, *Brown-Forman*, and *Healy* discussed the relationship of in-state product prices to out-of-state prices, they were talking about the prices of products produced in state in relation to those same products produced out of state (in an effort to eliminate any disadvantage the in-state products might face from out-of-state prices), or the prices merchants could charge in relation to prices in other states (in an effort to eliminate any disadvantage local merchants might face from out-of-state merchants and/or to eliminate any advantage out-of-state merchants might have over local merchants). But that is not the situation here. AAM’s contention notwithstanding, the Act provides no similar benefit solely to local manufacturers or distributors. It simply sets a price cap that applies to all such entities who do business in Connecticut.

This very issue was recognized in *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001) (*Concannon*), *aff’d sub nom.*, *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003) (*Walsh*), to which AAM references. *Concannon* concerned Maine’s drug price law that tied the state’s rebate amount to that calculated under the Federal Medicaid Rebate Program, *i.e.*, at a national level. *Concannon*, 249 F.3d at 71. The First Circuit ultimately rejected the plaintiff’s “per se” extraterritorial reach argument under the dormant Commerce Clause, concluding that “Maine is not tying the price of its in-state products to out-of-state prices. There is nothing within the Act that requires the rebate to be a certain amount dependent on the price of

prescription drugs *in other states*.” *Id.* at 82 (emphasis added).²² And the Supreme Court upheld that conclusion. *See Walsh*, 538 U.S. at 669.²³

As HDA did in its motion for preliminary injunction, AAM is attempting to have its cake and eat it too by (1) insisting that it should get the benefit of Supreme Court decisions where state laws were invalidated for being protectionist, i.e., favoring distinct in-state interests at the expense of distinct out-of-state interests, and yet (2) maintaining that all the relevant pricing decisions are done on a nationwide, not state-by-state, level. That way, it gets the best of both worlds, where no individual state would ever be able to enact legislation that affects those drug prices. But such a result does not flow from, and is not required by, our dormant Commerce Clause principles.

5. AAM’s contentions about the disruption to the business model that it created are insufficient to bar a state from enacting nondiscriminatory legislation to protect its people.

AAM’s parade of horrors about the Act’s effects fares no better. Boiled down, AAM urges the Court to invalidate the Act because it would disrupt the business model

²² *See also id.* at 81-82 (“Unlike the[] price affirmation and price control statutes [in *Baldwin*, *Brown-Forman*, and *Healy*], the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price. . . . Furthermore, unlike *Brown-Forman* and [*Healy*], the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state. . . . [And] [s]imply because the manufacturers’ profits might be negatively affected by the Maine Act . . . does not necessarily mean that the Maine Act is regulating those profits. The Act does not regulate the transaction between manufacturers and wholesalers.”)

²³ AAM asserts that a state “directly regulating prices charged in transactions wholly outside” that state is so obviously a dormant Commerce Clause violation that the defendants in *Zucker* and *Concannon* did not bother to appeal that portion of the district courts’ decisions. *See* PI Memo, pp. 15 & 20-21. But again, decisions issued before *Pork* clarified the dormant Commerce Clause analysis should give AAM little to crow about.

that its members established. *See, e.g.*, PI Memo, p. 8. Undoubtedly, the manufacturers and distributors have created a business model that is advantageous to their financial interests. But a state is not prevented from acting just because it might disrupt a particular method of doing business, nor may a business that operates in a particular state insulate itself from those state’s laws based on how the business set up its market. To the contrary, there is a myriad of businesses that both have a nationwide (or worldwide) presence yet still must comply with state law. Again, *Pork* shows the way:

In our interconnected national marketplace, many (maybe most) state laws have the practical effect of controlling extraterritorial behavior. State income tax laws lead some individuals and companies to relocate to other jurisdictions. . . . Environmental laws often prove decisive when businesses choose where to manufacture their goods. . . . Add to the extraterritorial-effects list all manner of libel laws, securities requirements, charitable registration requirements, franchise laws, tort laws, and plenty else besides. Nor . . . is this a recent development. Since the founding, States have enacted an immense mass of [i]nspection laws, quarantine laws, [and] health laws of every description that have a considerable influence on commerce outside their borders. . . . Petitioners’ “almost *per se*” rule against laws that have the practical effect of controlling extraterritorial commerce would cast a shadow over laws long understood to represent valid exercises of the States’ constitutionally reserved powers.

Pork, 598 U.S. at 374-75 (internal citations and quotation marks omitted).

To summarize, AAM asks this court to conclude that Connecticut is powerless to act with respect to the prices of identified drugs sold within its borders because the distributors and manufacturers have established a pricing system where they make the decisions for Connecticut’s people outside of Connecticut. But *Pork* does not require Connecticut to sit on the sidelines, and the Court should decline to accept AAM’s argument.²⁴

²⁴Page 22 of the PI Memo contains a citation to *Pike v. Bruce Church*, 397 U.S. 137 (1970), which stood for the principle that a facially neutral state law that serves a

6. Based on the clear holdings of *Pork*, the most recent case to consider a state’s drug price cap has denied the request for a preliminary injunction blocking the state law.

The defendants acknowledge that the cases considering state drug prices caps have not been uniformly decided. However, the most recent relevant case the defendants are aware of is *Raoul*, where Chief Judge Kendall concluded that, in a challenge to Illinois’ drug price cap, AAM had failed to make the required showing of its likelihood of success on the merits based on a thorough reading and comprehensive application of *Pork*. *See Raoul*, 2025 U.S. Dist. LEXIS 190215, at *6-17. And *Raoul* concerned essentially the same claims and arguments raised here. *See id.* at *4-5 (“While [the] Complaint alleges six independent causes of action, the throughline is whether the Constitution permits Illinois to regulate the prices of wholly out-of-state sales. . . . [The plaintiff] asks the Court to enjoin the Act based on Count One of its Complaint, which alleges the Act violates the dormant Commerce Clause’s prohibition against extraterritorial state legislation.”).

Chief Judge Kendall stated that the plaintiff was relying on the “extraterritoriality principle” that the Supreme Court addressed in *Pork*. *Id.* at *7-8. She noted that the

legitimate local interest might violate the dormant Commerce Clause if the burden it imposes on out-of-state commerce is clearly excessive in relation to the local benefit. The PI Memo does not, however, contain a substantive argument regarding *Pike*, which is unsurprising, given the uncertain status of *Pike* and its application in a post- *Pork* world. *See Pork*, 598 U.S. at 377-89 (*Pike* discussion in Part IV-A is the Court’s opinion, while *Pike* discussion in Parts IV-B, IV-C, and IV-D is Justice Gorsuch’s opinion in which some other justices joined); *id.* at 391-94 (Sotomayor, J., concurring in part) (discussing *Pike*); *id.* at 393-94 (Barrett, J., concurring in part) (discussing *Pike*); *id.* at 394-403 (Roberts, C.J., concurring in part and dissenting in part) (discussing *Pike*); *id.* at 403 (Kavanaugh, J., concurring in part and dissenting in part (noting the Court’s “fractured decision” with respect to *Pike*)). In any event, because AAM does not analyze *Pike* in the PI Motion, the defendants do not address it here.

case before her presented “an inverse” of the facts in *Pork*, because “[w]here the California law . . . regulated in-state commerce based on upstream conduct, the [Illinois] Act regulates upstream commerce based on downstream effects.” *Id.* at *8. She then stated that, while *Pork* did not squarely address that issue, “it offered a robust discussion on three cases that have long been linked to the extraterritoriality principle,” clarifying that those cases “did not prohibit extraterritorial legislation writ large, but only legislation with a ‘specific impermissible extraterritorial effect’ tracing directly back to the antidiscrimination principle.” *Id.* at *9-10 (quoting *Pork*, 598 U.S. at 374); *see id.* at *10 (“[A] closer examination of [*Baldwin*, *Brown-Forman*, and *Healy*] reveals three laws that were plainly designed either to protect an in-state industry . . . or to hoard commerce for in-state merchants[.]”).

Chief Judge Kendall further observed that the Illinois law did not discriminate against out-of-state interests but rather regulated the price of drugs sold in Illinois without regard for their place of manufacture, and thus in no way favored local manufacturers or discouraged consumers from engaging across state lines. *Id.* at *10-11. As a result, she found the plaintiff’s extraterritoriality argument under the dormant Commerce Clause to be unpersuasive in light of *Pork* and concluded that the plaintiff had failed to show a likelihood of success on the merits. *Id.* at *17.

The defendants recognize that there are other decisions that have come out the other way, as referenced in AAM’s PI Memo. *See Ass’n for Accessible Meds. v. Ellison*, 140 F.4th 957 (8th Cir. 2025) (*Ellison*); *Frosh*, 887 F.3d 664; *Zucker*, 353 F. Supp. 3d 235; *Pharm. Research v. DC*, 406 F. Supp. 2d 56 (D.D.C. 2005); *Pharm. Research & Mfrs. of Am. v. Comm’r, Me. Dep’t of Human Serv.*, Civil No. 00-157-B-H, 2000 U.S. Dist. LEXIS 17363 (D. Me. Oct. 26, 2000) (*Pharm. Research v. Maine*). The problem

with most of those cases, however, is that all but one are pre-*Pork*. Therefore, they did not have the benefit of the Supreme Court’s analysis instructing that antidiscrimination and non-protectionism lie at the very core of the dormant Commerce Clause analysis, even when there are extraterritorial consequences. And even in those pre-*Pork* cases, there was disagreement with the extraterritorial argument, which *Pork* later rejected and AAM pursues now. See *Frosh*, 887 F.3d at 674-93 (Wynn, J., dissenting); see also *Pharm. Research v. Maine*, 2000 U.S. Dist. LEXIS 17363, at *8-16, *rev’d sub nom. Concannon*, 249 F.3d at 80-83, *aff’d sub nom. Walsh*, 538 U.S. 668-670.

That leaves *Ellison*, where the Eighth Circuit upheld, on dormant Commerce Clause grounds, a preliminary injunction against Minnesota’s drug price law that prohibited manufacturers from imposing excessive price increases on the sale of generic drugs sold in Minnesota. *Ellison*, 140 F.4th at 958-59. In doing so, the Eighth Circuit concluded that because the Minnesota law had “the specific impermissible extraterritorial effect of controlling the price of wholly out-of-state transactions,” under the Supreme Court’s precedents (such as *Pork*, *Baldwin*, and *Healy*), no showing of discrimination or protectionism was required. *Id.* at 961.

“This is a misreading of [*Pork*].” *Raoul*, 2025 U.S. Dist. LEXIS 190215, at *13. Instead, “[t]he ‘specific impermissible extraterritorial effect’ [*Pork*] observed of the state laws at issue in the *Baldwin-Healy* cases was that each ‘deliberately prevented out-of-state firms from undertaking competitive pricing or deprived businesses and consumers in other States of whatever competitive advantages they may possess.’” *Id.* (quoting *Pork*, 598 U.S. at 374). “In other words, they were discriminatory and protectionist. Thus, the *Ellison* court’s conclusion that the Minnesota law was unconstitutional simply because it impacted the price of out-of-state transactions again ‘reads too much’ into the

Baldwin-Healy cases.” *Id.* (quoting *Pork*, 598 U.S. at 373). That is, as Chief Judge Kendall correctly concluded, *Ellison* got *Pork* wrong. The defendants respectfully urge this court, after considering the language of *Pork*, to conclude the same.

B. AAM Has Failed to Establish that Its Members Are Likely to Suffer Irreparable Harm Absent a Preliminary Injunction.

For AAM to establish irreparable harm, it must demonstrate that, absent a preliminary injunction, its members will suffer an actual and imminent injury that cannot be remedied if a court waits until the end of trial to resolve the harm. *Lamont*, 2025 U.S. App. LEXIS 21570 at *62. AAM argues that its members face two forms of irreparable harm sufficient to justify a preliminary injunction, one based on its allegation of a violation of a constitutional right and the other based monetary loss.

At the outset, though, AAM’s delay in bringing this case undercuts their argument. A district court should consider delay in assessing irreparable harm. *Beyond Gravity Sweden AB v. Ensign-Bickford Aero. & Def. Co.*, No. 3:24-CV-2021 (OAW), 2025 U.S. Dist. LEXIS 29227, at *11 (D. Conn. Feb. 19, 2025); *see Tom Doherty Associates, Inc. v. Saban Entertainment Inc.*, 60 F.3d 27, 39 (2d Cir. 1995). “That is because a preliminary injunction implies an ‘urgent need for speedy action to protect the plaintiff[’s] rights.’” *Beyond Gravity*, 2025 U.S. Dist. LEXIS 29227, at *11 (quoting *Citibank, N.A. v. Citytrust*, 756 F.2d 273, 276 (2d Cir. 1985)). “[D]elay ‘indicates an absence of the kind of irreparable harm required to support a preliminary injunction.’” *Id.* at *11-12 (quoting *Citibank*, 756 F.2d at 276). Here, the Act was signed by Governor Lamont on June 30, 2025. AAM filed suit on October 17, 2025—approximately three and a half months later. *See* Complaint, Dkt. # 1. While “[t]here is no bright-line rule for how much delay is too much, . . . courts in this Circuit ‘typically decline to grant

preliminary injunctions in the face of unexplained delays of more than two months.” *Beyond Gravity*, 2025 U.S. Dist. LEXIS 29227, at *12 (quoting *Monowise Ltd. Corp. v. Ozy Media, Inc.*, 17-cv-8028 (JMF), 2018 U.S. Dist. LEXIS 75312, 2018 WL 2089342, at *2 (S.D.N.Y. May 3, 2018) (collecting cases)); see *Weight Watchers Int’l v. Luigino’s, Inc.*, 423 F.3d 137, 144 (2d Cir. 2005) (“We have found delays of as little as ten weeks sufficient to defeat the presumption of irreparable harm that is essential to the issuance of a preliminary injunction.”).

Even without that delay, AAM’s irreparable harm arguments fail. AAM first claims that, in the Second Circuit, an alleged violation of a constitutional right automatically triggers a finding of irreparable injury. PI Memo, p. 29. But as discussed above, AAM has failed to establish a likelihood of success on its constitutional claims, so there necessarily cannot be a presumption of irreparable harm on that basis. Regardless, AAM paints an incomplete picture because “the Second Circuit ‘has not consistently presumed irreparable harm in cases involving allegations of the abridgement of’ constitutional rights.” *Chan v. United States DOT*, No. 23-cv-10365 (LJL), 2024 U.S. Dist. LEXIS 231658, at *153 (S.D.N.Y. Dec. 23, 2024) (quoting *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 349 (2d Cir. 2003)) (collecting cases); see *Lamont*, 2025 U.S. App. LEXIS 21570 at *62-63 (“To be sure, we have presumed irreparable harm for alleged deprivations of certain constitutional rights. . . . But the Supreme Court has never applied this presumption outside the First Amendment context. And even in that context, our Court has not axiomatically applied the presumption[.]”) (internal citations omitted).

Instead, courts in the Second Circuit “have identified two primary exceptions in which alleged violations of constitutional rights are not presumed to be irreparably

injurious: violations of non-personal constitutional rights and constitutional injuries that are compensable by money damages.” *Chan*, 2024 U.S. Dist. LEXIS 231658, at *154 (collecting cases). Cases where courts have held that a constitutional deprivation equals an irreparable harm are almost entirely restricted to infringement of personal rights that cannot be remedied by any subsequent relief. *Id.* at *155 (collecting cases). In contrast, a violation of “structural rights,” such as those that allocate power to the states, does not necessarily injure at all, let alone cause irreparable injury. *Id.* at *155-56 (collecting cases). “The Commerce Clause . . . concern[s] the division of power between the states and the federal government and therefore enshrine[s] structural, rather than personal, rights.” *Id.* at *156 (collecting cases). Therefore, contrary to AAM’s contention, irreparable harm “cannot be presumed” with respect to its dormant Commerce Clause claim. *See id.* at *157; *see also USA Recycling v. Town of Babylon*, 66 F.3d 1272, 1295 (2d Cir. 1995) (in a preliminary injunction matter challenging a state law under the dormant Commerce Clause, concluding that “[b]ecause the record supports the district court’s determination that plaintiffs’ alleged injuries would be entirely financial—and therefore remediable by an award of money damages—we cannot say that the district court clearly erred when it found that the plaintiffs had not demonstrated irreparable harm.”).

Additionally, “even when ‘personal’ constitutional rights are violated and the harm that accompanies the violation is remediable or compensable, the damage is not irreparable.” *Id.* (internal quotation marks omitted) (collecting cases). This addresses the second form of harm AAM alleges—a loss of money. *See* PI Memo, pp. 29-32.²⁵ But

²⁵ Although AAM mentions the Act’s criminal penalties, *see* PI Memo, p. 13 & 30, it does not rely on those penalties for its “irreparable harm” argument, but instead has focused

in the Second Circuit, it “has always been true that irreparable injury means injury for which a monetary award cannot be adequate compensation and that where money damages is adequate compensation a preliminary injunction will not issue.” *Jackson Dairy, Inc. v. H. P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979).

AAM’s answer to that is that Connecticut’s sovereign immunity and/or the Eleventh Amendment are an obstacle to any compensation. *See* PI Memo, p. 18-19 & n. 5. Of course, the defendants do not waive Connecticut’s Eleventh Amendment immunity and cannot waive Connecticut’s sovereign immunity, *see State v. Lombardo Bros. Mason Contractors, Inc.*, 307 Conn. 412, 462 (2012). That being said, Connecticut’s legislature has established a process for potential resolution of money claims against the state via the Office of the Claims Commissioner. *See generally* Chapter 53 of the Connecticut General Statutes (“Claims Against the State”). So again, AAM’s claim of monetary loss is insufficient to support a preliminary injunction.

C. The Balance of Equities and Public Interest Weigh Strongly in Favor of the Act and Against a Preliminary Injunction.

Finally, the court “must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.” *Winter v. NRDC, Inc.*, 555 U.S. 7, 24 (2008) (internal quotation marks omitted). In exercising its discretion, the court “should pay particular regard for the public

on economic harm, *see id.*, pp. 29-32. And for good reason. Those criminal penalties arise when individual officers or employees of AAM’s members “wilfully” fail to comply with certain provisions of the Act. AAM does not claim to have standing to assert claims on behalf of the individual officers or employees of its members, and at this point, the imposition of such a penalty would be based on potential facts and circumstances that are too remote or speculative to necessitate the issuance of a preliminary injunction. *See Lamont*, 2025 U.S. App. LEXIS 21570 at *62.

consequences in employing the extraordinary remedy of injunction.” *Id.* (internal quotation marks omitted); see *United States SEC v. Citigroup Glob. Mkts., Inc.*, 673 F.3d 158, 163 n.1 (2d Cir. 2012) (“[W]hen a court orders injunctive relief, it should ensure that injunction does not cause harm to the public interest.”). These two factors merge when the state is a party to the suit. *Lamont*, 2025 U.S. App. LEXIS 21570 at *64.

AAM’s interests are vastly outweighed by Connecticut’s. The Second Circuit has recognized the harm governments suffer when enjoined from effectuating statutes enacted by the people’s representatives. See *id.*; see also *Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025) (“[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury”) (quoting *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers)). In this scenario, AAM’s purported interest is not just outweighed by the public’s interest, it conflicts with the public’s interest. That is, AAM is focused on the financial burdens its members may face if they are required to alter their current business practices. But as discussed above, those business practices have created a world in which people now face “skyrocketing” drug prices that put critical medications out of reach. The state’s interest in the Act, on the other hand, is to improve the health and lives of Connecticut’s residents by protecting them from oppressive drug price increases that have no purpose other than the amassing of wealth at the expense of those residents. This is not a close call: the balance of equities and public interest weigh strongly in favor of the Act.

V. CONCLUSION

For the foregoing reasons, the defendants respectfully request that the court deny AAM's motion for a preliminary injunction.

DEFENDANTS
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CERTIFICATION

I hereby certify that on November 17, 2025, a copy of the foregoing was filed electronically. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the court's CM/ECF System.

/s/ Patrick T. Ring
Assistant Attorney General