

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

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

v.

Case No.: 3:25-cv-1757

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.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Association for Accessible Medicines (“AAM”) brings this complaint for declaratory and injunctive relief against 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. AAM brings this action on behalf of its members, based on personal knowledge as to all AAM-related facts and on information and belief as to all other matters.

INTRODUCTION

1. This lawsuit challenges Connecticut’s new price-control law, sections 345-347 of Public Act No. 25-168, which became effective on July 1, 2025 and begins regulating prices on January 1, 2026. The Act imposes civil penalties on generic and biosimilar manufacturers if their prices for generic drugs, other off-patent prescription

drugs, or interchangeable biosimilars exceed a threshold tied to the Consumer Price Index, and exposes their officers and employees to fines and imprisonment. This action seeks to enjoin the Connecticut Commissioner of Revenue Services and the Attorney General of Connecticut from enforcing the statute against sales by AAM members that occur outside Connecticut.

2. The Act forbids any pharmaceutical manufacturer or wholesale distributor from selling an “identified prescription drug,” including essentially all generic drugs, “in this state” at a price above the statutory “reference price” set by Connecticut, as adjusted by the Consumer Price Index. The “[r]eference price” is the wholesale acquisition cost as of January 1, 2025, or the date the drug is first marketed, if later. § 345(11). In other words, Connecticut has set a permanent price cap that will never increase except at the general rate of inflation—not even if, for example, the cost of producing the particular drug increases for reasons beyond the manufacturer’s control.

3. With two exceptions, the Act directs the Commissioner of Revenue Services to impose a civil penalty on any manufacturer or wholesaler that violates the cap. The civil penalty is 80 percent of the revenue earned above the cap from sales in Connecticut of the identified prescription drug. § 346(b)(1). Officers and employees who “owe[] a duty to the pharmaceutical manufacturer or wholesale distributor to pay the civil penalty” face fines and imprisonment for willfully failing to pay the penalty. § 346(j)(1).

4. Drug manufacturers and wholesale distributors cannot simply remove their products from Connecticut to avoid the price cap because the Act also prohibits them from withdrawing an “identified prescription drug” from Connecticut “for the purpose of avoiding the civil penalty.” § 347(a). And the manufacturer or wholesale distributor must

give 180 days of advance notice in order to withdraw an “identified prescription drug” for a different purpose. § 347(b). A violation of these withdrawal rules incurs a \$500,000 fine. § 347(c).

5. The defendant state officials 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. Indeed, no AAM member is located in Connecticut, and AAM understands that no national wholesaler is located or even has a distribution facility in Connecticut. Yet, testimony regarding the legislation by the Commissioner of the Office of Health Strategy indicates that Connecticut intends to apply the Act to these out-of-state transactions. Deidre S. Gifford, Commissioner, Office of Health Strategy, *Testimony Prepared for the Insurance and Real Estate Committee*, (Feb. 18, 2025) (predicting that “more than 400 generic prescription drugs ... would have had their wholesale price limited by this legislation” and “would have reduced wholesale costs paid for off-patent branded drugs by at least \$9 million”).¹ Despite repeated outreach, the State Attorney General and other officials have declined to disavow the application of the Act to out-of-state manufacturers and distributors whose products are ultimately sold in Connecticut by third parties.

6. By enforcing the Act so as to regulate sales that occur outside Connecticut, Defendants will violate multiple provisions of the U.S. Constitution, as well as limits implicit in constitutional structure and design. Extraterritorial application of the Act not

¹ <https://cga.ct.gov/2025/insdata/TMY/2025HB-06871-R000218-Gifford,%20Deidre,%20Commissioner-Office%20of%20Health%20Strategy-Supports-TMY.PDF>. Commissioner Gifford’s testimony addressed the Act’s price-limiting provisions as presented in an earlier bill introduced by Connecticut Governor Edward M. Lamont.

only will infringe on the sovereignty of other States by regulating conduct beyond Connecticut's borders, in violation of the Constitution's federalism and comity principles, it will violate the Commerce Clause, the Due Process Clause, and the horizontal separation of powers embedded in the U.S. Constitution.

7. First and foremost, out-of-state enforcement of the Act is an unlawful regulation of interstate commerce that violates the "dormant" aspect of the Commerce Clause. The dormant Commerce Clause is "a restriction on permissible state regulation." *Nat'l Shooting Sports Found., Inc. v. James*, 144 F.4th 98, 113 (2d Cir. 2025) (internal quotation marks and citations omitted). It "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders." *Id.* (citation omitted); *see id.* at 116. Connecticut cannot "directly control[] ... commercial pricing and marketing activity that occur[s] outside of Connecticut." *Grand River Enters. Six Nations, Ltd. v. Boughton*, 988 F.3d 114, 124 (2d Cir. 2021).

8. The Supreme Court recently "refined [its] Commerce Clause framework" in some respects, *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 160 (2023) (Alito, J., concurring in part and concurring in the judgment), in its decision in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). But the Court kept intact the bedrock principle prohibiting state laws that directly regulate out-of-state conduct. Indeed, *Ross* went out of its way to confirm the vitality of the constitutional rule that States may not "directly regulate[]" the price term of "out-of-state transactions," and thereby "prevent[] out-of-state firm[s] from undertaking competitive pricing' or 'deprive[] businesses and consumers in other States of whatever competitive advantages they may possess.'" 598 U.S. at 374, 376 n.1 (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 338-39 (1989)). For

exactly that reason, the Eighth Circuit recently affirmed a preliminary injunction against a similar price-control law in Minnesota, in another case brought by AAM. The Eighth Circuit explained that in *Ross* the Court “preserv[ed] its precedent that a state violates the extraterritoriality principle when it enacts “price control or price affirmation statutes that tie[] the price of in-state products to out-of-state-prices.” *Ass’n for Accessible Meds. v. Ellison*, 140 F.4th 957, 960 (8th Cir. 2025) (citation omitted). “So the classic observation 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 remains good law.” *Id.* (internal quotation marks and citations omitted).

9. The defendants’ interpretation and enforcement of the Act will violate the Commerce Clause’s clear command by directly regulating prices in transactions that take place entirely outside Connecticut. Take, for example, a drug manufacturer located in Pennsylvania that sells generic drugs to a wholesale distributor in Ohio. If the Pennsylvania manufacturer increases the price charged to the Ohio wholesaler by more than the Consumer Price Index, and if the drug is later distributed in Connecticut, the defendants will likely impose the Act’s civil penalty against the Pennsylvania manufacturer even though the relevant transaction occurred wholly outside of Connecticut and the Pennsylvania manufacturer has “no connection to the State.” *Ross*, 598 U.S. at 376 n.1. Application of the Act to directly regulate transactions entirely outside Connecticut will violate the Commerce Clause.

10. The extraterritorial enforcement of the Act will separately violate the Commerce Clause because it will impose a burden on interstate commerce that “is clearly excessive in relation to the putative local benefits.” *Pike v. Bruce Church, Inc.*, 397 U.S.

137, 142 (1970). To avoid violating the Act’s price control, manufacturers of generic or other off-patent drugs or biosimilar medicines would either have to try to keep their medicines out of the Connecticut market—which may well be impossible given the nature of the nationwide wholesale market—or treat Connecticut’s price ceiling as the national standard. A decision permitting state-created price ceilings like Connecticut’s would allow all 50 States to apply their own views of what price increases are permissible nationwide, creating an untenable U.S. market and disrupting patients’ access to affordable generic and interchangeable biological products throughout the country. Those cumulative effects on all relevant market actors will impose a substantial burden on interstate commerce, which far outweighs any interest Connecticut may have in regulating the upstream prices charged for drugs that are later resold in Connecticut by third parties.

11. Enforcement of the Act as to out-of-state transactions will independently violate the limitations on state power imposed by the Due Process Clause of the Fourteenth Amendment. That clause restricts States’ authority to “regulate and control activities wholly beyond [their] boundaries,” *Watson v. Empps. Liab. Assurance Corp.*, 348 U.S. 66, 70 (1954), in the absence of “some minimal contact[s]” between both the “regulated party and the state” and “the regulated subject matter and the state,” *Gerling Glob. Reinsurance Corp. of Am. v. Gallagher*, 267 F.3d 1228, 1236 (11th Cir. 2001) (emphasis and citation omitted). AAM’s members are located outside Connecticut and sell to wholesale distributors outside the State. Enforcing the Act as to these entities exceeds Connecticut’s constitutional authority. *McCluney v. Joseph Schlitz Brewing Co.*, 649 F.2d 578, 581 (8th Cir. 1981), *aff’d*, 454 U.S. 1071 (1981); *see Klinghoffer v. S.N.C. Achille Lauro Ed Altri-*

Gestione Motonave Achille Lauro in Amministrazione Straordinaria, 937 F.2d 44, 53 (2d Cir. 1991).

12. Enforcing the Act extraterritorially not only will run afoul of these specific constitutional provisions but will also violate principles implicit in the very structure of our constitutional order. The principle that States may not “reach out and regulate conduct that has little if any connection with the State’s legitimate interests” is “an obvious and necessary result” of the Constitution’s design—one that “is not confined to any one clause or section.” *Mallory*, 600 U.S. at 154 (Alito, J., concurring in part and concurring in the judgment) (alterations, citation, and quotation marks omitted) (collecting cases). Rather, that tenet is embedded “in the very nature of the federal system,” in “numerous provisions that bear on States’ interactions with one another,” *id.*, and in the “historical understandings of the Constitution’s structure and the principles of ‘sovereignty and comity’ it embraces.” *Ross*, 598 U.S. at 376 (citation omitted). By regulating activities that occur wholly outside Connecticut’s borders, the Act would transgress the “horizontal separation of powers” embedded in the constitutional design. *Id.* at 376 n.1.

13. The Act targets extraterritorial transactions, while protecting in-state interests, such as the in-state Connecticut retailers, medical practices, hospitals, and others who sell “identified prescription drugs” to consumers. The prices charged by those entities to the consumer are not regulated by the Act. Instead, only the prices charged by out-of-state entities—the manufacturers and wholesale distributors—are regulated by the Act. Further evidencing the Act’s economic protectionism, the Act exempts brand drugs until two full years after all their market exclusivity has expired, thus protecting Connecticut’s brand manufacturers, like Pfizer, while targeting generic manufacturers, none of whom are

located in Connecticut. As a result, the Act violates yet another “core” concern of the dormant Commerce Clause: “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.’” *Ross*, 598 U.S. at 369.

14. Finally, enforcement of the Act on out-of-state sales will violate the fundamental requirement of due process that a law be written with sufficient clarity to “give [regulated parties] a reasonable opportunity to know what is prohibited, so that [they] may act accordingly,” and to “provide explicit standards for those who apply them” to prevent “arbitrary and discriminatory enforcement.” *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972); *see, e.g., FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). Defendants’ extraterritorial application of the Act fails these basic requirements: it authorizes civil and criminal penalties for “sell[ing] an identified prescription drug in this state” above the statute’s price ceiling. Act § 346. But the statute does not define the term “sell” or indicate its extraterritorial reach. Because the Act—under Defendants’ interpretation—provides no meaningful guidance as to what conduct falls within its sweep, and thus also invites arbitrary enforcement by Defendants, the Act violates the Due Process Clause of the Fourteenth Amendment.

15. AAM’s members, who manufacture, offer, and sell generic and interchangeable biosimilar medicines, are suffering immediate and irreparable injury as the subjects of unconstitutional state enforcement action. Under the new price-control law (as interpreted by Defendants), AAM’s members will be exposed to prohibitive civil and criminal penalties for selling their products at prices deemed by the Act to be unacceptable, even if the sales occur wholly outside Connecticut. AAM’s members will face significant

economic harm as a result of the Act's price control no matter what course of action they take—forced to choose between (a) forgoing reasonable price increases on their generic and interchangeable biological products, including price increases necessary to maintain profitability; (b) raising prices on those products, but in doing so, triggering substantial civil penalties and criminal liability for their officers and employees; or (c) withdrawing the regulated generic products from Connecticut, and thus losing revenues from those products and also facing a significant civil penalty for that withdrawal. Each option results in unrecoverable economic injury.

16. These harms are especially acute given the “severe financial strain” and supply chain vulnerabilities already facing the generic drug industry. Christina Jewett, *Drug Shortages Near an All-Time High, Leading to Rationing*, N.Y. Times (May 17, 2023).² Today, the generic drug market is “defined by a persistent and deepening crisis of scarcity.” DrugPatentWatch, *The Persistent Problem: Why Hospitals Keep Running Out of Generic Drugs* (July 30, 2025).³ The market is already “economically unsustainable for many producers and inherently fragile.” *Id.* The result is that many generics, such as “the workhorses of modern medicine—from chemotherapy agents to anesthetics to simple saline solutions—are frequently and unpredictably out of reach.” *Id.* The Act's penalties and restrictions will exacerbate drug shortages, threaten the quality of generic drugs, and threaten access to affordable medicines for patients in Connecticut and nationwide.

² <https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html>.

³ <https://www.drugpatentwatch.com/blog/the-persistent-problem-why-hospitals-keep-running-out-of-generic-drugs/>.

17. For these reasons, AAM seeks an injunction prohibiting extraterritorial enforcement of the Act, and a declaration that the Act is unconstitutional and unenforceable as applied to AAM members' out-of-state transactions.

PARTIES

18. Plaintiff Association for Accessible Medicines ("AAM") is a nonprofit association representing leading manufacturers and distributors of generic and biosimilar medicines, as well as manufacturers and distributors of bulk active pharmaceutical ingredients and suppliers of goods and services to the generic and biosimilar pharmaceutical industry. A complete list of AAM's current members is attached as Exhibit A.

19. AAM's core mission is to improve the lives of patients by improving timely access to affordable, FDA-approved generic and biosimilar medicines. AAM's members provide safe and effective generic and biosimilar drugs to American patients nationwide at substantially lower cost than brand-name counterparts. AAM is authorized by its Board of Directors to bring this suit on behalf of its members.

20. Mark D. Boughton is the Commissioner of the Connecticut Department of Revenue Services. In that capacity, he is authorized to investigate and enforce the Act. *See Act §§ 346(c)-(i), (l)-(m).*

21. William Tong is the Attorney General of Connecticut. In that capacity, Attorney General Tong is authorized to enforce Connecticut Public Act No. 25-168, including by bringing actions of foreclosure to enforce the Act's civil penalty and enforcing the criminal provisions of the Act. *See Act §§ 346(i)-(j).*

JURISDICTION

22. AAM's causes of action arise under 42 U.S.C. § 1983 and the U.S. Constitution. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3). This case involves civil penalties, not taxes, so this Court's jurisdiction does not depend on whether state law provides a plain, speedy, and efficient remedy.

23. Venue is proper in this district under 28 U.S.C. § 1391(b)(1) and (2).

24. There is a justiciable case or controversy. AAM brings this action on behalf of its members, and neither the claims nor the requested relief require the participation of individual members. AAM fulfills its mission in part by litigating against governmental authorities to protect its members from unconstitutional laws, and has previously brought successful challenges to similar state price-control measures. The Act is already injuring AAM's members, who manufacture and sell generic and biosimilar medicines, by subjecting them to unconstitutional regulation. If not enjoined, the Act will imminently cause AAM's members unrecoverable economic harm. A favorable decision will redress these injuries.

FACTUAL BACKGROUND

I. Generic and Biosimilar Products and the Pharmaceutical Market

25. Generic and biosimilar medicines play a crucial role in reducing healthcare costs for Americans. *See* U.S. Dep't of Health & Hum. Servs., *Analysis of New Generic Markets, Effect of Market Entry on Generic Drug Prices: Medicare Data 2007-2022*, ASPE Issue Brief, 1-2 (January 16, 2025).⁴ Through vigorous competition, generics "are consistently lower than brand-name prices across all market sizes and time periods." *Id.* at

⁴ <https://aspe.hhs.gov/sites/default/files/documents/510e964dc7b7f00763a7f8a1dbc5ae7b/aspe-ib-generic-drugs-competition.pdf>.

1. Generic entry into the market drives significant price decreases, causing prices to decline between 20 percent to 80 percent after three years of entry, depending on the number of generic competitors. *Id.* at 10-11; *see also* U.S. Dep’t of Health & Hum. Servs., *Understanding Recent Trends in Generic Drug Prices*, ASPE Issue Brief, 1 (Jan. 27, 2016) (Generic and biosimilar medicines have “drive[n] prices for generic drugs to be a fraction of that of the corresponding brand name drug.”).⁵ Biosimilars likewise are lower-cost versions of biologics, which are complex medicines with biological origins (such as proteins). As a result, generic and biosimilar medicines account for 90 percent of all prescriptions dispensed in the United States but amount to only 12 percent of the money spent on prescriptions. *See* Ass’n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report 2*, 10 (Sept. 2025).⁶ These medicines have produced nearly \$3.4 trillion in savings to the U.S. healthcare system over the past decade, with \$467 billion in savings in 2024 alone—a \$27 billion increase over the prior year. *Id.* at 10-11.

26. However, generic and biosimilar manufacturers also face significant barriers to bringing their drugs to market and keeping them there, including intense price competition, uncertain revenue streams, high investment requirements, supply chain vulnerabilities, regulatory complexity, and intellectual property challenges, all of which limit potential returns. Sarah Ibrahim, Ph.D., *Unlocking Global Access to Generic Drugs*, FDA, 6 (Sept. 2023)⁷; FDA, *Drug Shortages: Root Causes and Potential Solutions* 22-23 (Feb. 21, 2020).⁸ As a result, generic manufacturers often operate on “[t]hin [p]rofit

⁵ https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//141996/GenericsDrugpaperr.pdf.

⁶ <https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf>.

⁷ <https://www.fda.gov/media/177933/download>.

⁸ <https://www.fda.gov/media/131130/download>.

[m]argins” and are unable to afford to support redundant capacity. Ibrahim, *Unlocking Global Access*, *supra* at 6; FDA, *Drug Shortages*, *supra* at 23, 41.

27. Numerous factors impact manufacturers’ thin profit margins and put upward pressure on generic and biosimilar drug prices. For example, “[m]ost generic drug manufacturers rely on other companies to produce” the raw ingredients “for the drugs they produce,” Mariana P. Socal et al., *Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients*, 42 *Health Affairs* 407, 407 (Mar. 2023)⁹, and the “raw material prices for essential drugs” have risen sharply, by as much as 140 percent in the post-COVID era, *see Active Pharmaceutical Ingredients Market Size*, Precedence Research (Jan. 2023).¹⁰ In addition, prices for biosimilar medicines and for off-patent drugs approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(b)(2),¹¹ face additional upward pressure due to the need to recover substantial costs arising from clinical and other studies needed to obtain FDA approval, as well as increased costs arising from marketing, patient-support services, and other non-production related costs.

28. The high cost of manufacturing generic and biosimilar products, combined with “a complex array of [other] factors,” FDA, *Drug Shortages*, *supra*, at 7—such as “manufacturing problems ..., shortage of raw materials, and just in time inventory,”

⁹ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.01120>.

¹⁰ <https://web.archive.org/web/20230706200401/https://www.precedenceresearch.com/active-pharmaceutical-ingredient-market>.

¹¹ Section 505(b)(2) creates a pathway for approval of a new drug meant to build on FDA’s previous approval of another drug—such as by creating a new dosage form for an existing drug. Because section 505(b)(2) drugs are not identical copies of the brand drug, they do not benefit from state laws that require or allow pharmacists to substitute a generic drug for a prescribed brand name drug. Thus, manufacturers of section 505(b)(2) drugs must invest in marketing these products. Some such drugs are “identified prescription drugs” for which all patents and exclusivities have expired.

Sundus Shukar et al., *Drug Shortage: Causes, Impact, and Mitigation Strategies*, 12 *Frontiers in Pharmacology* 1, 6 (July 9, 2021)¹²; Kirsten Axelsen et al., *Root Causes to Solutions: A Policy Proposal to Address Generic Drug Shortages*, Charles River Assocs., 3-4 (Feb. 2025)¹³—can lead manufacturers to leave the market entirely or otherwise create a shortage in the supply of life-saving and cost-effective treatments to patients. Surges in demand, as occur with treatments for seasonal illnesses, for example, may also lead to shortages. See Jewett, *Drug Shortages, supra*. Such supply shortages in critical medicines have increased substantially in recent years. “Between 2021 and 2022, drug shortages increased by approximately 30 percent,” which has produced “devastating consequences for patients and health care providers.” Comm. on Homeland Sec. & Governmental Affs., U.S. Senate, *Short Supply: The Health and National Security Risks of Drug Shortages* 5 (Mar. 2023).¹⁴

29. Generic and biosimilar manufacturers, including many of AAM’s members, are at the start of the drug-supply chain. Typically, these manufacturers do not sell their medicines directly to patients. Instead, they sell their products to large national wholesale distributors, who then resell those products to retail pharmacies, hospitals, or other healthcare facilities. See Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp., 4-5

¹² <https://www.frontiersin.org/articles/10.3389/fphar.2021.693426/full>.

¹³ <https://media.crai.com/wp-content/uploads/2025/02/05144140/CRA-Pfizer-Report-Policy-Solutions-to-Address-Generic-Drug-Shortages-February-2025.pdf#:~:text=We%20find%20four%20key%20root%20causes%20of%20generic,challenges%2C%20rebate%20policies%2C%20and%20purchasing%20practices%20among%20intermediaries>.

¹⁴ <https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf>.

(2021)¹⁵; Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 1-2 (Mar. 2005).¹⁶

30. Generic and biosimilar manufacturers, including AAM’s members, do not make drug-pricing or drug-distribution decisions on a state-by-state basis. Instead, they sell their products to wholesale distributors in pre-negotiated bulk—and typically long-term—contracts that cover a range of products for resale nationwide. The “Wholesale Acquisition Cost” is a nationwide price. Manufacturers do not control the prices at which wholesale distributors resell their medicines or where those products are ultimately resold.

31. A number of national and regional stakeholders, including wholesale distributors, pharmacy benefit managers, retail pharmacy chains, health insurers, Medicaid and Medicare contractors, hospital networks, and others, play a role in determining the ultimate prices that are paid by end users for generic and biosimilar medications.

32. AAM’s manufacturer members sell their generic and biosimilar products to wholesale distributors outside Connecticut, and wholesale distributors take title to those products outside Connecticut. None of AAM’s manufacturer members is located in Connecticut. None of the three largest wholesale distributors (who collectively control over 90 percent of the wholesale market)—Cencora, Cardinal Health, and McKesson—is incorporated or headquartered in Connecticut.¹⁷ AAM understands that no national wholesaler even has a distribution facility in Connecticut.

¹⁵ <https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf>.

¹⁶ <https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>.

¹⁷ Adam J. Fein, Ph.D., *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, Drug Channels (Oct. 2, 2019), <https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html>; see Cencora, Inc., SEC Form 8-K (Sept. 3, 2025), <https://d18rn0p25nwr6d.cloudfront.net/CIK-0001140859/e5c34d9c-6699-4f34-8286-02db2c313d01.pdf>; Cardinal Health, Inc., SEC Form 8-K (Aug. 27,

II. Connecticut's New Drug Price-Control Law

33. The Governor of Connecticut signed House Bill No. 7287 into law as Public Act No. 25-168 on June 30, 2025. The provisions relevant to this litigation are sections 345 through 347 of that Act. Those provisions became effective on July 1, 2025, and will begin regulating prices as of January 1, 2026. *See* Act § 346(a).

34. The Act regulates the prices charged for “identified prescription drugs,” which include essentially all generic drugs and some interchangeable biosimilar medicines as well, but not most brand-name drugs. Specifically, “[i]dentified prescription drugs” include “a generic drug or interchangeable biological product.” *Id.* § 345(6)(B). A “generic drug” includes any prescription drug product that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 U.S.C. § 355—in other words, any drug approved as a generic through the abbreviated pathway that federal law provides—as well as an authorized generic drug as defined in 42 C.F.R. § 447.502. *Id.* § 345(5). “Identified prescription drug” also includes an “interchangeable biological product.” *Id.* § 345(6)(B). An *interchangeable* biological product is a type of biosimilar that either has been approved under the abbreviated pathway for biosimilars and also determined by the FDA to be “expected to produce the same clinical result as the [brand-name] reference product,” 42 U.S.C. § 262(k)(4)(A), or is therapeutically equivalent to an FDA-approved biological product; *see* Act § 345(7); Conn. Gen. Stat. § 20-619(a)(4) (provision cross-referenced by the Act and in turn cross-referencing the federal statute). Finally, “[i]dentified prescription drug” includes a limited number of

2025), <https://d18rn0p25nwr6d.cloudfront.net/CIK-0000721371/f5decf8a-1599-422b-b661-816e3c075c28.pdf>; McKesson Corp., SEC Form 8-K (Aug. 6, 2025), <https://d18rn0p25nwr6d.cloudfront.net/CIK-0000927653/0a4ed28b-f768-44fa-9a2c-e26b702e70c3.pdf>.

brand-name drugs and biological products: “a brand-name drug or biological product to which all exclusive marketing rights granted under the federal Food, Drug and Cosmetic Act, section 351 of the federal Public Health Service Act and federal patent law have expired for at least twenty-four months.” Act § 345(6)(A). Because most brand-name drugs are covered by at least one patent or exclusivity, most brand-name drugs will be exempted from Connecticut’s cap, even though brand-name drugs are the primary driver of high pharmaceutical prices.

35. The Act prohibits pharmaceutical manufacturers and wholesale distributors from selling identified prescription drugs in Connecticut at prices exceeding “the reference price for the identified prescription drug, adjusted for any increase in the consumer price index.” *Id.* § 346(a)(2).

36. The “[r]eference price” is the wholesale acquisition cost (WAC) on January 1, 2025, with exceptions for circumstances in which January 1, 2025 would not yield a relevant WAC. *Id.* § 345(11). For a generic “drug or interchangeable biological product,” the reference price is the WAC on January 1, 2025, or “if the generic drug or interchangeable biological product is first commercially marketed in the United States after January 1, 2025, on the date such generic drug or interchangeable biological product is first commercially marketed in the United States.” *Id.*

37. The Act delineates certain circumstances in which the price cap does not apply. First, pharmaceutical manufacturers or wholesale distributors may exceed the price cap, “if the federal Secretary of Health and Human Services determines, pursuant to 21 USC 356e, as amended from time to time, that such identified prescription drug is in shortage in the United States.” Act § 346(a)(2). Second, pharmaceutical manufacturers or

wholesale distributors are not liable for exceeding the price cap if they made less than \$250,000 “in total annual sales in this state for the calendar year for which such civil penalty would otherwise be imposed.” *Id.* § 346(b)(2).

38. The Act establishes a civil penalty for violations of the price cap. Any pharmaceutical manufacturer or wholesale distributor that violates the price-control provisions is liable for a civil penalty equal to 80 percent of the difference between the revenue “earned from all sales of the identified prescription drug” in Connecticut during the calendar year and the revenue that would have been earned if the drug had been sold at the reference price, adjusted for Consumer Price Index increases. Act § 346(b)(1).

39. To administer the civil penalty, the Act creates a comprehensive reporting mechanism. Pharmaceutical manufacturers and distributors that violate the price-control provisions must pay the civil penalty and file “a statement” with the Commissioner “containing all information” required by the Commissioner by March 1 of the following calendar year. Act § 346(c)(1)(A).

40. If no statement is filed, the Commissioner “may make such statement” using “the best obtainable information.” *Id.* § 346(c)(2). The Act also authorizes the Commissioner to “examine the records of any pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty,” and may “bill such pharmaceutical manufacturer or wholesale distributor for the full amount of such civil penalty.” *Id.* § 346(d). In addition, the Commissioner “may require” manufacturers and wholesale distributors to keep records and produce “books, papers, documents and other data to provide or secure information pertinent to the enforcement and collection of” the civil

penalty. *Id.* § 346(e). The Commissioner also has subpoena power and may compel testimony under oath. *Id.* § 346(h).

41. The Act further prohibits market withdrawal from Connecticut “for the purpose of avoiding the civil penalty.” Act § 347(a). To withdraw for any other purpose is also restricted by the Act: the manufacturer or wholesale distributor must give 180 days of advance notice. § 347(b). Because the Act was signed into law on June 30, 2025, the length of the advance-notice period made withdrawal from Connecticut before the price cap and civil penalty take effect on January 1, 2026, effectively impossible. A violation of either withdrawal rule incurs a \$500,000 fine. § 347(c).

42. Officers and employees of pharmaceutical manufacturers and wholesale distributors who owe “a duty” to their company to pay the Act’s civil penalty face fines and criminal punishment if they “wilfully fail[]” to comply with the Act. § 346(j).

III. The Act Will Injure AAM’s Members and Substantially Burden Interstate Commerce.

A. Defendants Intend to Regulate AAM’s Members’ Pricing Decisions.

43. Since January 1, 2025, several of AAM’s members—each of which generates over \$250,000 in annual sales within Connecticut—have made competitively reasonable price adjustments to identified prescription drugs that exceed the Act’s price ceiling. For example, in 2025 one such member has already increased the price of a generic drug by 15 percent, which exceeds the increase permitted by the Consumer Price Index. Other AAM members, all similarly above the statutory sales threshold, have planned to raise prices for certain identified prescription drugs in a manner that would exceed Connecticut’s price cap. The increased prices for those medicines will (or would) subject

manufacturers to the civil penalty. Like all AAM members, these manufacturers are located outside Connecticut.

44. In addition, some AAM members above the statutory sales threshold had concrete plans to raise their prices for one or more identified prescription drugs, but are refraining from changing their prices for these medicines as a direct result of the Act and Defendants' likely enforcement of it. These members face economic harm in the form of lost revenues they would otherwise realize but for the Act and Defendants' interpretation and enforcement of it.

45. Some of these AAM members' planned price increases are necessitated, at least in part, by economic or cost factors other than general inflation reflected in the Consumer Price Index.

46. Neither of the Act's exceptions to the price cap applies to these AAM members' relevant price changes.

47. AAM members, who are located outside Connecticut, sell their medicines overwhelmingly to large wholesale distributors, who are also located outside Connecticut. Nevertheless, there is a substantial risk that Defendants will apply the Act to these wholly out-of-state transactions.

48. Enjoining Defendants from applying the Act to AAM's members' out-of-state transactions would avert irreparable harm to these AAM members.

B. The Act Will Cause AAM's Members Significant and Immediate Harm and Substantially Burden the Interstate Market for Generic and Biosimilar Products.

49. The Act's regulations and penalties will cause AAM's members who manufacture generic prescription drugs and interchangeable biological products to suffer

substantial and immediate economic injury and will burden the interstate market for pharmaceutical medicines.

50. As a result of intense competition in the pharmaceutical market, profit margins for many products are often thin. In addition to increased costs in the production of pharmaceutical products, other external factors outside manufacturers' control can reduce or outright erase manufacturers' thin profit margins for their products, thus making it unprofitable to continue producing those medicines at existing prices. In those circumstances, increasing prices may be the only way for manufacturers to profitably market a pharmaceutical product. Moreover, pricing for biosimilars and drugs approved under section 505(b)(2) of the FDCA, 21 U.S.C. § 355(b)(2), relies in part on manufacturers' needs to recoup upfront investment costs and to pay for marketing, patient-support, and other product-related services.

51. The Act's price controls and penalties, as well as the substantial likelihood of Defendants' extraterritorial enforcement of the Act, either prevent AAM's members from making reasonable and necessary price increases on certain of their prescription drugs, or punish those AAM members who do increase the prices of their products through the civil penalty for exceeding the price cap. The Act's restrictions therefore place these manufacturers in a no-win dilemma that will cause significant economic losses no matter their course of action. Specifically, AAM's members will be compelled to choose among: (1) forgoing reasonable price increases on their pharmaceutical products, including price increases necessary to maintain product and overall profitability, and thereby losing the revenue they would otherwise realize; (2) raising prices on those products, but in doing so, triggering substantial civil penalties equal to 80 percent of revenues above the price cap;

or (3) attempting to withdraw the regulated pharmaceutical products from the Connecticut market and losing all revenue from the sale of those medicines while facing additional penalties under section 347 of the Act for market withdrawal. AAM's members will suffer severe and irreparable financial injury as a result of the Act's price control no matter which option they choose.

52. Further, by restricting the prices pharmaceutical manufacturers may charge for products later resold into Connecticut by third parties, the Act will substantially disrupt the contracting and distribution practices between AAM members and wholesale distributors—entities that are located entirely outside Connecticut.

53. To avoid the Act's price control, AAM's members would need to prevent their prescription drug products from being resold in Connecticut or structure their pricing to comply with Connecticut's reference price requirements. But segregating and specially pricing products destined for Connecticut is not feasible. Manufacturers are also bound by existing long-term contracts with wholesale distributors, who do not contemplate state-specific pricing. Renegotiating those contracts would not only be impractical but would also impose significant financial penalties on manufacturers via the Act's withdrawal provision, *see* Act § 347. Moreover, because the Act's coverage depends on Consumer Price Index adjustments that may change over time, manufacturers will have no reliable way to know whether or when a medicine not currently subject to the Act's penalties may become regulated in the future, based on changed circumstances entirely beyond manufacturers' control. Even if manufacturers could restructure their distribution and contracting practices to isolate Connecticut-bound products—which they cannot—their

products could still be resold into Connecticut by downstream entities with whom they have no direct contractual relationship.

54. Pharmaceutical manufacturers, as well as wholesale distributors, will incur substantial costs in connection with efforts (like those described above, which may be impossible) to restructure their contracting and delivery processes, or to comply with the Connecticut law nationwide. Those increased costs will, in turn, place increased upward pressure on the cost of delivering pharmaceutical medications to patients throughout the United States.

55. The substantial disruptions caused by a Connecticut-specific price regime—potentially to be followed by 49 other States, as each adopts its own definition of what qualifies as an unacceptable price increase—will create enormous inefficiencies in the processing of prescription drug products, resulting in significant delays and disruptions in the supply of life-saving medicines throughout the country on top of the existing drug supply shortages that are plaguing the U.S. pharmaceutical market and preventing patients from obtaining critical medications.

56. Accordingly, the Act's price control will place significant burdens on the supply chains for pharmaceutical medications, including manufacturers and wholesale distributors. Because AAM's members and the wholesale distributors they sell to are overwhelmingly located outside Connecticut, the substantial burdens the Act imposes will fall predominantly on out-of-state entities and their interstate commercial activities.

LEGAL BACKGROUND

I. Limits on Extraterritorial State Regulation under the U.S. Constitution

A. Commerce Clause

57. The Framers of the Constitution held “the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.” *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979). Thus, to “create an area of free trade among the several States,” *McLeod v. J. E. Dilworth Co.*, 322 U.S. 327, 330 (1944), the Framers gave Congress the “Power ... [t]o regulate Commerce ... among the several States,” U.S. Const. art. I, § 8, cl. 3. This clause was meant to strike a balance between the “maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and ... the autonomy of the individual States within their respective spheres.” *Healy*, 491 U.S. at 335-36 (footnote omitted). Consistent with that design, the Supreme Court has “long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute.” *United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007).

58. “The absolute constitutional prohibition on state regulation of commerce occurring beyond the state’s borders is clear: ‘...the Commerce Clause ... precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders.’” *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 260 (S.D.N.Y. 2018) (quoting *Healy*, 491 U.S. at 336) (second ellipsis in original), *rev’d in part on other grounds sub nom. Ass’n for Accessible Meds. v. James*, 974 F.3d 216 (2d Cir. 2020). Although “[n]ot every exercise of state power with some impact on interstate commerce is

invalid,” the law is clear that “*direct* regulation is prohibited.” *Edgar v. MITE Corp.*, 457 U.S. 624, 640, 642 (1982) (plurality opinion) (Commerce Clause “precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders”) (emphasis added); accord *Nat’l Shooting Sports Found.*, 144 F.4th at 113. This rule follows from the “inherent limits [on] the State’s power”—“any attempt ‘directly’ to assert extraterritorial jurisdiction over persons or property would offend sister States” and therefore “must be held invalid.” *Edgar*, 457 U.S. at 643 (plurality opinion) (citation omitted); *Ellison*, 140 F.4th at 960 (A state violates the extraterritoriality principle when it enacts “price control or price affirmation statutes that tie[] the price of in-state products to out-of-state-prices.” (citation omitted)). Under Supreme Court precedent, “the classic observation 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 remains good law.” *Id.* (internal quotation marks and citations omitted); *Legato Vapors LLC v. Cook*, 847 F.3d 825, 829, 831 (7th Cir. 2017) (“With almost two hundred years of precedents to consider, our review of prior dormant Commerce Clause decisions has not revealed a single appellate case permitting any direct regulation of out-of-state [commerce]”).

59. Although the Supreme Court recently clarified that the Commerce Clause does not impose any per se barrier to state laws that have indirect extraterritorial *effects*, the Court made clear that it was not disturbing the Commerce Clause’s prohibition of state laws that “*directly* regulate[] out-of-state transactions.” *Ross*, 598 U.S. at 376 n.1; see *Ellison*, 140 F.4th at 960 (In *Ross* “[t]he Court did not overturn ‘the rule that was applied in *Baldwin* and *Healy*,’ preserving its precedent that a state violates the extraterritoriality principle when it enacts ‘price control or price affirmation statutes that tie[] the price of in-

state products to out-of-state-prices.”) (citation omitted); *Interlink Prods. Int’l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. 2023) (“[I]n clarifying that ... laws with extraterritorial effects are not prohibited by the dormant Commerce Clause, the Supreme Court [in *Ross*] distinguished them from those in which ‘a law [] directly regulated out-of-state transactions by those with no connection to the State’” (quoting *Ross*, 598 U.S. at 376 n.1)) (emphasis omitted).

B. Due Process Clause

60. The Due Process Clause of the Fourteenth Amendment provides that “[n]o State shall ... deprive any person of life, liberty, or property, without due process of law.” U.S. Const. amend. XIV, § 1. Like the Commerce Clause, the Due Process Clause restricts States’ authority “to exercise ‘extra territorial jurisdiction,’ that is, to regulate and control activities wholly beyond its boundaries.” *Watson*, 348 U.S. at 70; see also *Home Ins. Co. v. Dick*, 281 U.S. 397, 407-10 (1930) (holding that the application of a Texas law to activities lacking any meaningful connection with Texas violated the Due Process Clause); *Gerling Glob. Reinsurance*, 267 F.3d at 1236-37 (recognizing that the Due Process Clause places “constraints on a state legislature’s ability to regulate subject matters and transactions beyond the state’s boundaries”); *Klinghoffer*, 937 F.2d at 53.

61. Under the Due Process Clause, a state may not “apply its substantive law to factual and legal situations with which it has little or no contact.” *McCluney*, 649 F.2d at 580. For a state to constitutionally impose its law on an out-of-state transaction, there must be “some minimal contact[s]” between both the “regulated party and the state” and also “the regulated subject matter and the state.” *Gerling Glob. Reinsurance*, 267 F.3d at 1236 (emphases and citation omitted); accord *McCluney*, 649 F.2d at 581 (“The basic rule is the state whose law is chosen to control a case must have a substantial factual contact with the

parties or the transaction giving rise to the litigation.”). “When a state’s law is applied to a transaction with which the state has no significant contact, it infringes upon the legitimate interests that other states may have in the transaction.” *McCluney*, 649 F.2d at 582. Importantly, the relevant contacts must be those of the regulated party—“the unilateral act of a third party is not sufficient to create the requisite contacts.” *Am. Charities for Reasonable Fundraising Regul., Inc. v. Pinellas Cnty.*, 221 F.3d 1211, 1216 (11th Cir. 2000) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985)).

C. The Constitution’s Horizontal Separation of Powers

62. In addition to the specific restraints on extraterritorial legislation imposed by the Commerce Clause and the Due Process Clause, the Constitution’s structure and design “restrict[] a State’s power to reach out and regulate conduct that has little if any connection with the State’s legitimate interests.” *Mallory*, 600 U.S. at 154 (Alito, J., concurring in part and concurring in the judgment). That bedrock principle of equal sovereignty among the States is inherent in the plan of the Convention, apparent in several of the Constitution’s structural protections, and deeply rooted in our Nation’s historical tradition. *See Ross*, 598 U.S. at 376 n.1; *id.* at 408-10 (Kavanaugh, J., concurring in part and dissenting in part); *Mallory*, 600 U.S. at 154 (Alito, J., concurring in part and concurring in the judgment) (deeming this principle an “‘obviou[s]’ and ‘necessary result’ of our constitutional order” that “is not confined to any one clause or section, but is expressed in the very nature of the federal system ... and in numerous provisions that bear on States’ interactions with one another”) (citation omitted)).

63. The Supreme Court has emphasized the importance of looking to “original and historical understandings of the Constitution’s structure and the principles of ‘sovereignty and comity’ it embraces” when it comes to cases “testing the territorial limits

of state authority under the Constitution’s horizontal separation of powers.” *Ross*, 598 U.S. at 376 & n.1 (citation omitted). Under those principles, a state may not “*directly regulate*[]” pricing outside its borders. *Id.*

64. At the outset, it is axiomatic that “the States in the Union are coequal sovereigns under the Constitution.” *PPL Mont., LLC v. Montana*, 565 U.S. 576, 591 (2012). Indeed, “the constitutional equality of the states is essential to the harmonious operation of the scheme upon which the Republic was organized.” *Coyle v. Smith*, 221 U.S. 559, 580 (1911). When a state reaches beyond its own borders to “directly regulate[] out-of-state transactions by those with no connection to the State,” *Ross*, 598 U.S. at 376 n.1 (emphasis omitted), it invades the sovereignty and impinges on the equality of other States. Accordingly, the plan of the Convention necessarily restricts one state from directly regulating conduct that neither occurs nor is directed within its borders, as a union of several *equal* States subject to the overarching regulation of only one federal sovereign could not succeed if each state could trump the others’ sovereign powers whenever and however it saw fit. *Cf. State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (“A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction.”).

65. Consistent with that understanding, several provisions of the Constitution—in addition to the Commerce Clause and the Due Process Clause discussed above—impose and/or presuppose limits on the ability of one state to override the regulatory powers of another. For instance, Article I, section 10 of the Constitution deprives States of several

powers that one sovereign might ordinarily exercise against another, including the right to “lay any Imposts or Duties on Imports or Exports,” and to “lay any Duty of Tonnage, keep Troops, or Ships of War in time of Peace, [or] enter into any Agreement or Compact with another State.” U.S. Const. art. I, § 10, cl. 2-3.

66. Conversely, Article IV of the Constitution is devoted entirely to preserving the rights of each state vis-à-vis the others, requiring (among other things) that “Full Faith and Credit shall be given in each State to the public Acts, Records, and judicial Proceedings of every other State,” U.S. Const. art. IV, § 1; that “[t]he Citizens of each State shall be entitled to all Privileges and Immunities of Citizens in the several States,” *id.*, § 2, cl. 1; that “no new State shall be formed or erected within the Jurisdiction of any other State,” *id.*, § 3, cl. 1; and that “[t]he United States shall guarantee to every State in this Union a Republican Form of Government,” *id.*, § 4.

67. Finally, the Tenth Amendment provides that “powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people,” U.S. Const. amend. X, making clear that each state retains its own “integrity, dignity, and residual sovereignty,” *Bond v. United States*, 564 U.S. 211, 221 (2011). It is little surprise, then, that the Supreme Court recently reiterated that “the territorial limits of state authority under the Constitution’s horizontal separation of powers” are grounded not just in any one provision, but in the “original and historical understandings of the Constitution’s structure and the principles of ‘sovereignty and comity’ it embraces.” *Ross*, 598 U.S. at 376 & n.1 (citation omitted); *see also, e.g., id.* at 404, 408-10 (Kavanaugh, J., concurring in part and dissenting in part); *South Dakota v. Wayfair, Inc.*, 585 U.S. 162, 190-191 (2018) (Gorsuch, J., concurring); *Mallory*, 600 U.S.

at 154 (Alito, J., concurring in part and concurring in the judgment). And those understandings distill into the basic principle that a state cannot directly regulate conduct that occurs entirely outside its borders.

II. Limits on State Laws that Substantially Burden Interstate Commerce

68. Separate from its prohibition on state laws that “*directly* regulate[] out-of-state transactions,” *Ross*, 598 U.S. at 376 n.1, the Commerce Clause restricts States from enacting laws that impose undue burdens on interstate commerce. “A state statute violates the dormant Commerce Clause if it ... imposes a burden on interstate commerce incommensurate with the local benefits secured.” *Nat’l Shooting Sports Found.*, 144 F.4th at 113 (internal quotation marks and citation omitted). “Even laws that do not explicitly discriminate against interstate commerce may incidentally, and impermissibly, burden interstate commerce.” *Id.* at 114; *Rest. L. Ctr. v. City of N.Y.*, 90 F.4th 101, 107 (2d Cir. 2024). In assessing whether a state law’s burden is “clearly excessive in relation to the putative local benefits,” *Pike*, 397 U.S. at 142, courts are not limited to “considering the consequences of the statute itself,” but must also “consider[] how the challenged statute may interact with the legitimate regulatory regimes of the other States and what effect would arise if not one, but many or every, jurisdiction adopted similar legislation,” *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 406 (1994) (O’Connor, J., concurring in the judgment) (alterations and citation omitted); *see also U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1069 (8th Cir. 2000). “Requiring a foreign corporation ... to defend itself with reference to all transactions, including those in which it did not have [constitutionally adequate] minimum contacts [with the State], is a significant burden.” *Bendix Autolite Corp. v. Midwesco Enters., Inc.*, 486 U.S. 888, 893 (1988); *see Mallory*, 600 U.S. at 161 (Alito, J., concurring in part and concurring in the judgment). Further, the

availability of a less burdensome alternative is relevant to whether the law's burdens on interstate commerce are clearly excessive. *See Pike*, 397 U.S. at 142 (“[T]he extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.”).

III. Due Process Limits on Vague State Laws

69. Under the Due Process Clause, “laws which regulate persons or entities must give fair notice of conduct that is forbidden or required.” *FCC*, 567 U.S. at 253. This basic requirement of clarity in legislation “is essential to the protections provided by the Due Process Clause,” *id.*, since “[v]ague laws may trap the innocent by not providing fair warning,” *Grayned*, 408 U.S. at 108.

70. There are “two means by which a statute can operate in an unconstitutionally vague manner.” *Karlin v. Foust*, 188 F.3d 446, 458 (7th Cir. 1999). First, a “statute is void for vagueness if it fails to provide ‘fair warning’ as to what conduct will subject a person to liability.” *Id.* A statute violates the Due Process Clause if it “forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application.” *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926); *Copeland v. Vance*, 893 F.3d 101, 114 (2d Cir. 2018). Second, “a statute must contain an explicit and ascertainable standard to prevent those charged with enforcing the statute’s provisions from engaging in ‘arbitrary and discriminatory’ enforcement.” *Karlin*, 188 F.3d at 459. “The Supreme Court has conceived this doctrine as ‘a basic principle of due process,’ as well as ‘a corollary of the separation of powers—requiring that Congress, rather than the executive or judicial branch,

define what conduct is sanctionable and what is not.” *United States v. Concepcion*, 139 F.4th 242, 248 (2d Cir. 2025) (citations omitted).

CLAIMS FOR RELIEF

COUNT ONE

(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Commerce Clause’s Prohibition on State Laws That Regulate Extraterritorially)

71. AAM re-alleges and incorporates herein by reference the allegations of all preceding paragraphs of this Complaint as if fully set forth in this paragraph.

72. Defendants intend to enforce, and are substantially likely to enforce, the Act so as to directly regulate out-of-state commerce by applying the price cap and civil penalty to prices charged in transactions wholly outside Connecticut, as well as the civil penalty for withdrawing drugs from sale in Connecticut.

73. Defendants intend to apply, and are substantially likely to apply, the Act to transactions between pharmaceutical manufacturers and wholesale distributors even when the sale occurs outside the State, so long as the product is ultimately sold in Connecticut.

74. The application of the Act to those transactions violates the Commerce Clause because direct regulation of interstate commerce is invalid under the Commerce Clause.

COUNT TWO

(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Due Process Clause’s Prohibition on State Laws That Regulate Extraterritorially)

75. AAM re-alleges and incorporates herein by reference the allegations of all preceding paragraphs of this Complaint as if fully set forth in this paragraph.

76. The Due Process Clause of the Fourteenth Amendment prohibits a State from regulating activities that occur wholly outside the State’s borders in the absence of

“significant contact[s],” *McCluney*, 649 F.2d at 582, between the “regulated party and the state” and “the regulated subject matter and the state,” *Gerling Glob. Reinsurance*, 267 F.3d at 1236 (emphases omitted).

77. AAM’s members that manufacture generic and biosimilar products or interchangeable biological products are located outside Connecticut and sell to wholesale distributors outside the State.

78. Connecticut lacks any significant contacts with AAM’s out-of-state members or the out-of-state prices they charge to wholesale distributors located outside Connecticut.

79. Accordingly, the application of the Act to transactions between AAM’s members located outside Connecticut and purchasers outside Connecticut violates the Due Process Clause’s restrictions on state power.

COUNT THREE

(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the U.S. Constitution’s Horizontal Separation of Powers)

80. AAM re-alleges and incorporates herein by reference the allegations of all preceding paragraphs of this Complaint as if fully set forth in this paragraph.

81. The “Constitution’s horizontal separation of powers,” *Ross*, 598 U.S. at 376 n.1—reflected in the fundamental principle of coequal sovereignty among the States, the Constitution’s specific provisions restricting States’ ability to control conduct outside their territorial bounds, and the “historical understandings of the Constitution’s structure,” and “the principles of ‘sovereignty and comity’ it embraces,” *id.* at 376 & n.1 (citation omitted)—prohibits States from directly regulating transactions that occur wholly outside their borders.

82. The Act directly regulates prices charged wholly outside Connecticut and therefore violates the Constitution’s “horizontal separation of powers.” *Ross*, 598 U.S. at 376 n.1.

COUNT FOUR

(Declaratory/Injunctive Relief – Unduly Burdening Interstate Commerce)

83. AAM re-alleges and incorporates herein by reference the allegations of all preceding paragraphs of this Complaint as if fully set forth in this paragraph.

84. A state law violates the Commerce Clause if it imposes a substantial burden on interstate commerce that is “clearly excessive in relation to [any] putative local benefits.” *Pike*, 397 U.S. at 142.

85. Defendants’ interpretation and enforcement of the Act’s price and other regulations, such as the reporting and recordkeeping requirements, will impose a substantial burden on interstate commerce, requiring that each manufacturer either make every or a substantial portion of sales nationwide of generic or biosimilar medicines comply with Connecticut’s rules; or attempt to restructure pricing and supply processes to segregate drug products for sale in Connecticut, resulting in significant compliance costs and disruptions to the drug-supply chain; or else “‘defend itself’” in Connecticut “‘with reference to all transactions,’ including those with no forum connection.” *Mallory*, 600 U.S. at 161 (Alito, J., concurring in part and concurring in the judgment) (quoting *Bendix Autolite Corp.*, 486 U.S. at 893).

86. Those burdens will fall overwhelmingly on interstate commerce, as drug manufacturers and the wholesale distributors they sell to are overwhelmingly located outside Connecticut. Those burdens are particularly substantial when considering the effect if “not one, but many or every, jurisdiction adopted similar legislation.” *C & A*

Carbone, Inc., 511 U.S. at 406 (O’Connor, J., concurring in the judgment) (alterations and citation omitted); *Grand River Enters. Six Nations, Ltd. v. Pryor*, 425 F.3d 158, 170 (2d Cir. 2005).

87. Those cumulative effects on interstate commerce far outweigh any interest Connecticut may have in regulating the prices charged outside Connecticut for drugs that are later resold in Connecticut by third parties.

88. There are alternatives to the Act’s extraterritorial price regulation that will have “a lesser impact on interstate activities,” *Pike*, 397 U.S. at 142, including limiting enforcement to in-state transactions.

89. Defendants’ enforcement of the Act as to out-of-state transactions will undermine Connecticut’s interest in making life-saving medications available to Connecticut consumers by making it more difficult for generic and biosimilar manufacturers to preserve their thin profit margins for their products, potentially resulting in those manufacturers withdrawing those products from the market altogether.

90. Accordingly, the Act violates the Commerce Clause because it imposes a substantial burden on interstate commerce that is clearly excessive in relation to any putative local benefits.

COUNT FIVE

(Declaratory/Injunctive Relief – Unconstitutionality of the Act Under the Due Process Clause’s Prohibition on Vague State Laws)

91. AAM re-alleges and incorporates herein by reference the allegations of all preceding paragraphs of this Complaint as if fully set forth in this paragraph.

92. A statute is unconstitutionally vague under the Due Process Clause if (1) “it fails to provide ‘fair warning’ as to what conduct will subject a person to liability”; or (2)

it lacks “an explicit and ascertainable standard to prevent ... ‘arbitrary and discriminatory’ enforcement.” *Karlin*, 188 F.3d at 458-59 (citations omitted).

93. Defendants’ enforcement of the Act as to wholly out-of-state transactions will violate these twin requirements of due process. By interpreting the plain text of the Act in a manner that renders it vague and nebulous as to its scope, Defendants’ interpretation of the Act invalidates any guidance the text of the Act might provide.

94. Moreover, by interpreting the scope of the Act to cover out-of-state transactions, Defendants deprive pharmaceutical manufacturers and wholesale distributors of any standard or guidance for determining which transactions will be subject to the Act’s civil penalty.

95. Accordingly, Defendants’ interpretation and enforcement of the Act fails to provide the minimal fair notice to regulated parties that is required by due process and is therefore unconstitutional.

COUNT SIX

(42 U.S.C. § 1983 and 42 U.S.C. § 1988)

96. AAM re-alleges and incorporates herein by reference the allegations of all preceding paragraphs of this Complaint as if fully set forth in this paragraph.

97. By seeking to implement and enforce the Act as to wholly out-of-state transactions, Defendants, acting under color of state law, will violate and, unless enjoined by this Court, continue to violate the rights of AAM’s members to engage in activities free from unconstitutional state regulation in violation of the Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and/or the Constitution’s horizontal separation of powers.

98. An actual “Case or Controversy” exists because the Act’s unconstitutional provisions create a genuine, credible, and immediate threat that the Defendants—acting in their official capacities under color of state law—will violate AAM’s members’ constitutionally protected rights.

99. AAM seeks a declaration that Defendants’ enforcement of the Act as applied to AAM members’ wholly out-of-state transactions is unconstitutional under the Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and/or the Constitution’s horizontal separation of powers.

100. AAM also seeks reasonable attorney’s fees pursuant to 42 U.S.C. § 1988.

PRAYER FOR RELIEF

WHEREFORE, AAM prays:

A. For a declaration, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that Defendants’ enforcement of the Act as to the wholly out-of-state transactions of AAM’s members, or any of their agents, privies, or licensees, violates the Commerce Clause, the Due Process Clause of the Fourteenth Amendment, and/or the Constitution’s horizontal separation of powers, and is unlawful and void;

B. For a preliminary injunction prohibiting the Defendants from implementing or enforcing the Act against the wholly out-of-state transactions of AAM’s members, or any of their agents, privies, or licensees, in violation of the U.S. Constitution;

C. For a permanent injunction prohibiting the Defendants from implementing or enforcing the Act against the wholly out-of-state transactions of AAM’s members, or any of their agents, privies, or licensees, in violation of the U.S. Constitution;

D. For such costs and reasonable attorney’s fees to which it might be entitled by law, including under 42 U.S.C. § 1988; and

E. For any other relief the Court deems just and proper.

Dated: October 17, 2025

Respectfully submitted,

/s/ Paul Tuchmann

Paul Tuchmann (ct30523)
Tadhg Dooley (ct29364)
WIGGIN AND DANA LLP
265 Church Street
New Haven, CT 06510
Tel.: (203) 498-4336 / 4549
Fax: (203) 782-2889
ptuchmann@wiggin.com
tdooley@wiggin.com

William M. Jay (*pro hac vice* forthcoming)
Isabel M. Marin (*pro hac vice* forthcoming)
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
Tel.: (202) 346-4000
Fax: (202) 346-4444
wjay@goodwinlaw.com
imarin@goodwinlaw.com

*Counsel for Plaintiff Association for
Accessible Medicines*

EXHIBIT A

2025 AAM Regular Members

Accord Healthcare, Inc.

Ajanta Pharma USA Inc.

American Regent

Amneal Pharmaceuticals

Amphastar Pharmaceuticals, Inc.

Apotex Corp.

Aurobindo Pharma USA, Inc.

B. Braun Medical Inc.

Biocon Biologics Limited

Cipla USA

Dr. Reddy's Laboratories, Inc.

Fresenius Kabi USA

Glenmark Pharmaceuticals, Inc. USA

Hikma Pharmaceuticals USA

Jubilant Cadista Pharmaceuticals, Inc.

Lupin Inc.

Meitheal Pharmaceuticals

MSN Pharmaceuticals Inc.

Padagis LLC

PAI Pharma

Sandoz Inc.

Somerset Therapeutics LLC

Strides Pharma Inc.

Sun Pharmaceutical Industries, Inc.

Teva Pharmaceuticals USA, Inc.

Torrent Pharma Inc.

Zydus Pharmaceuticals USA, Inc.

2025 AAM Associate Members

ACIC Pharmaceuticals

Catholic Medical Mission Board, Inc. (CMMB)

ChemWerth Inc.

Direct Relief

Dispensary of Hope

Gedeon Richter USA

Husch Blackwell

Lachman Consultant Services, Inc.

MAP International

Operation Smile