

25-3216

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

HEALTHCARE DISTRIBUTION ALLIANCE,
Plaintiff-Appellant,

v.

MARK D. BOUGHTON, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE
CONNECTICUT DEPARTMENT OF REVENUE SERVICES, WILLIAM TONG, ATTORNEY
GENERAL, IN HIS OFFICIAL CAPACITY AT ATTORNEY GENERAL FOR THE STATE OF
CONNECTICUT,
Defendants-Appellees.

On Appeal from the United States District Court
for the District Court of Connecticut

BRIEF OF APPELLANT
HEALTHCARE DISTRIBUTION ALLIANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, Plaintiff-Appellant Healthcare Distribution Alliance states that it is a 501(c)(6) nonprofit, voluntary association. It does not have a parent corporation, and no publicly held company has a 10% or greater ownership interest in it.

By: /s/ Jonathan S. Massey
Jonathan S. Massey

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INTRODUCTION

This appeal presents a federal constitutional challenge to the Connecticut Drug Price Cap of Public Act No. 25-168 §§ 345–47 (“the Drug Price Cap” or “Cap”) (A009–021), which became effective January 1, 2026. The Cap freezes the prices for Connecticut sales of covered products (off-patent branded drugs, generic drugs, and interchangeable biologic products) at a specific “reference price,” defined as the Wholesale Acquisition Cost (“WAC”) (*i.e.*, the manufacturer’s list price) as of January 1, 2025, adjusted by the Consumer Price Index (“CPI”). *Id.* § 345(11) (A012). Regardless of how much WAC increases in the rest of the United States, the Cap freezes the Connecticut price at the reference price, adjusted for inflation.

On December 24, 2025, the U.S. District Court for the District of Connecticut (Williams, J.) denied a motion for preliminary injunction against the Drug Price Cap brought by Plaintiff-Appellant the Healthcare Distribution Alliance (“HDA”) (A126–44). HDA is the trade association for wholesale distributors of pharmaceutical and other healthcare products. Distributors ensure the safe, efficient, and reliable delivery of 10.5 million products every day. Distributors operate on an interstate basis, purchasing from manufacturers and serving their downstream customers (*i.e.*, retail pharmacies, medical practices, hospitals, and other patient-facing entities) through a network of distribution centers geographically dispersed throughout the nation.

The District Court ruled that HDA had failed to demonstrate a likelihood of success on the merits of its argument that the Cap is unconstitutional under the dormant Commerce Clause and Fourteenth Amendment. That decision was incorrect. This Court should reverse the District Court's order and direct the entry of a preliminary injunction against the Drug Price Cap with respect to HDA and its members.

The Drug Price Cap violates the Commerce Clause's prohibition on extraterritorial state price controls. It is undisputed that drug manufacturers (not distributors) set WAC, and they do so on a national, not state-by-state, basis. Distributors are subject to the Cap even though they do not set or control WAC for drug products. By targeting prices set at the national level, Connecticut's law impermissibly regulates beyond the boundaries of the state. In fact, it is undisputed that no member of HDA even has a distribution facility in Connecticut.

Thus, although cast as a local economic regulation, the Cap targets pricing decisions that occur wholly outside Connecticut. Indeed, the Cap does not apply at all to the in-state retail pharmacies and other patient-facing entities that actually sell drug products to Connecticut consumers. The Cap does not prevent those entities from charging whatever prices they wish. Rather, the Cap targets only *out-of-state* pricing decisions.

The Drug Price Cap independently violates the Commerce Clause because it displays impermissible in-state favoritism and protectionism. It mandates a lower reference price for Connecticut than the prevailing WAC price in other states and thus ensures that the prices of covered products will be artificially lower in Connecticut than in New York, Massachusetts, and every other state where WAC is the prevailing price. The price differential between Connecticut and other states will only grow over time. Either consumers in other states will be forced to absorb the costs pushed onto them by the Connecticut Drug Price Cap, or other states will respond by adopting their own price control statutes, unleashing the kind of interstate retaliation that the Commerce Clause was meant to preclude. Distributors would be forced to navigate different sets of rules, and the fragmentation of the market would hinder supply chain efficiencies, establish inconsistent pricing for patients across state lines, and ultimately reduce reliable access to affordable medications for patients nationwide.

No federal appellate court has sustained the constitutionality of a similar state price control law. Similar state-level drug price caps have been invalidated by the Fourth and Eighth Circuits, and by district courts in Maine and the District of Columbia. *See Ass'n for Accessible Meds. v. Ellison*, 140 F.4th 957 (8th Cir. 2025); *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018), cited with approval in *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 374 (2023); *Pharm.*

Rsch. & Mfrs. of Am. v. Dist. of Columbia (PhRMA), 406 F. Supp. 2d 56 (D.D.C. 2005), *aff'd sub nom., Biotech. Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007); *Pharm. Rsch. & Mfrs. of Am. v. Comm'r, Maine Dep't of Hum. Servs.*, No. Civ. 00-157-B-H, 2000 WL 34290605 (D. Me. Oct. 26, 2000), *rev'd on other grounds sub nom., Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001).

Moreover, the State has reinterpreted the Cap during the course of this litigation in a way that creates additional constitutional infirmities. By its terms, the Cap applies to both “pharmaceutical manufacturer[s]” and “wholesale distributor[s].” § 346(a)(1) (A012). But at the December 9, 2025 preliminary injunction hearing in the District Court, the State “for the first time” (A131) announced a new interpretation of the statute under which the Cap applies only to sales where title is transferred in Connecticut. (A73:2–6, A105:3–8, A131). This construction effectively reads out of the statute transactions where manufacturers sell to HDA-member distributors (none of whom has a Connecticut distribution center) because in such cases, title is transferred outside Connecticut.

The State invoked the doctrine of “constitutional avoidance” in support of this new interpretation (A117:14–15), evidently recognizing the grave constitutional

questions raised by the Cap.¹ But the new interpretation creates the bizarre situation in which the Cap will *not* apply to the important transactions in the drug pricing context. The journey of drug products from manufacturers to patients generally consists of three transactions: (i) a sale from manufacturer to distributor, then (ii) from distributor to retail pharmacy (or other patient-facing entity, like a hospital), and finally (iii) from retailer to consumer. Under the State's new interpretation, the Cap covers only the second transaction, not the one where a manufacturer sells to a distributor at WAC or the transaction where the drug product is actually sold to a consumer. Instead, the Cap will target only the entities stuck in the middle (distributors) that have no control over either WAC or the prices ultimately charged to consumers. Such a Kafkaesque construction puts distributors in the untenable position where they face potentially endless increases in WAC from manufacturers without recourse (absent injunctive relief). A price control law that does not cover the entities that actually control prices is unconstitutionally arbitrary.

Distributors already face irreparable harm. Since January 1, 2025, manufacturers have already raised the WAC of *over 650* covered products by more than the rate of inflation. Thus, as of January 1, 2026, HDA members purchasing covered products at WAC face a Hobson's choice: (1) buy the product at the

¹ “[T]hose who invoke the doctrine [of constitutional avoidance] must believe that the alternative is a serious likelihood that the statute will be held unconstitutional.” *Almendarez-Torres v. United States*, 523 U.S. 224, 238 (1998).

manufacturer's *higher* WAC price and sell to Connecticut customers at the *lower* reference price, or (2) violate the Drug Price Cap and face severe civil penalties. The Drug Price Cap discourages wholesale distributors from doing business in Connecticut and risks isolating the state from the national drug market. The public interest thus weighs decidedly in HDA's favor, and the State has no valid interest in enforcing this unconstitutional scheme.

The District Court's order should be reversed, and this Court should direct the entry of a preliminary injunction against the Drug Price Cap with respect to HDA and its members.

JURISDICTION

HDA's causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The District Court thus had subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1343.

The District Court denied HDA's motion for preliminary injunction on December 24, 2025. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

QUESTIONS PRESENTED FOR REVIEW

(1) Has Plaintiff-Appellant Healthcare Distribution Alliance demonstrated a likelihood of success on the merits of its argument that the Connecticut Drug Price Cap violates the dormant Commerce Clause and Fourteenth Amendment, where the

Drug Price Cap is impermissibly extraterritorial, protectionist, and arbitrary, and punishes distributors for pricing decisions outside their control?

(2) Should this Court direct the entry of a preliminary injunction against the Connecticut Drug Price Cap in favor of HDA and its members?

STATEMENT

A. The Connecticut Drug Price Cap

The Drug Price Cap establishes a “reference price” for branded drug products that have been off patent for at least 24 months, generic drug products, and interchangeable biologic products. Conn. Pub. Act No. 25-168 § 345(6), (11) (A011–12). The “reference price” is defined as the WAC on January 1, 2025 for branded drug products whose patent has expired, the WAC on the date a branded drug’s existing patent expires, or for generic drugs, the WAC on January 1, 2025 or the WAC when the product is first commercially available. *Id.* § 345(11) (A012).

The text of the law provides that, beginning on January 1, 2026, a manufacturer or wholesaler is prohibited from selling a covered drug product in Connecticut at a price that exceeds the reference price adjusted for any increase in the CPI unless the drug has been identified by the U.S. Department of Health & Human Services as being in shortage.² *Id.* § 346(a) (A012–13). Violations of this

² Currently, only 74 drugs are designated by HHS as being in shortage. FDA Drug Shortages, U.S. Food & Drug Admin.,

provision are subject to a civil penalty equal to 80% of the difference between (i) the revenue the seller would have earned from all sales of the identified drug in the state in the calendar year, and (ii) the revenue that the seller would have earned from all sales of the drug in the state during the calendar year if the seller had sold the product at a price that did not exceed the reference price. *Id.* § 346(b)(1) (A013).

Penalties extend to officers and employees of the seller who owe a duty to pay the civil penalty imposed, or who are to deliver or disclose information to the commissioner of the Connecticut Department of Revenue Services. These penalties include a fine of up to \$1,000/day, one year imprisonment, or imposition of a Class D felony. *Id.* § 346(j) (A019–20). The law also prohibits distributors from withdrawing covered drug products from Connecticut without 180 days' notice and from withdrawing drugs for the purpose of avoiding the civil penalties prescribed by the Act, subject to a separate \$500,000 civil penalty. *Id.* § 347 (A021).

The Drug Price Cap does not apply to the in-state Connecticut retailers and other entities (such as medical practices, hospitals, and other licensed healthcare providers) that actually sell covered drugs and products to consumers. Those retailers and other entities are free to charge whatever they wish under the Drug Price Cap. *Id.* § 346 (A012–20).

<https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm> (last visited Jan. 12, 2026). In contrast, the Drug Price Cap applies to thousands of drug products.

B. The Role of Distributors in the Pharmaceutical Supply Chain

The U.S. pharmaceutical supply chain is a complex system. It comprises multiple entities working together to ensure the safe, secure, and efficient delivery of essential medicines and other healthcare products. (A028–29, A039, A042, A045). Wholesale distributors move products from manufacturers to healthcare institutions, providers, and pharmacies. (A028–29, A039, A042, A045). HDA members efficiently deliver approximately 10.5 million diverse medical products across the nation every day.³

Distributors do not set WAC. (A030, A040, A043, A046). Rather, manufacturers set WAC for drug products, and they do so on a national basis, outside Connecticut. (A030, A040, A043, A046). Distributors do not manufacture, produce, or prescribe pharmaceutical products, nor do they engage in pharmaceutical research and development. (A029).

Distributors operate on an interstate basis. (A030, A040, A043, A046). They efficiently and securely serve more than 200,000 U.S.-based pharmacies, hospitals, and other patient-facing entities. (A029). They accomplish this task through a network of distribution centers geographically dispersed across the nation (A029, A039–40, A042–43, A045–46), each of which processes 4,100 orders daily on

³ HDA Rsch. Found., HDA Factbook 4 (96th ed. 2025), available at <https://hda.org/publications/96th-edition-hda-factbook-the-facts,-figures-and-trends-in-healthcare/>.

average.⁴ These distribution centers and the systems they support provide consistent just-in-time delivery to their service areas so that providers can reliably deliver high quality care to patients. (A029).

In the interest of efficiency, distributors work closely with manufacturers, providers, and other supply-chain partners to accurately forecast demand and ensure timely and secure delivery to pharmacies and other licensed providers. (*Id.*). Distributors also manage inventory, provide financial credit, maintain pharmacy management systems, and support retail operations. (*Id.*).

Distributors invest significant time, energy, and resources to ensure that pharmaceutical products are shipped under the right conditions to the right customers at the right time. (*Id.*). They ensure safe supply chains by maintaining drugs' proper temperatures, providing manufacturers data on where their products are used, verifying that customers are eligible to purchase products, and complying with federal and state regulations. (*Id.*).

These services are critical. Without distributors, each medical provider would have to order, receive, and store products directly from manufacturers. (A030). Without distributors' just-in-time delivery, medical providers would have to maintain large inventories of expensive products. (*Id.*). Inventories at local distribution facilities prevent critical medical products from going out of stock. (*Id.*).

⁴ HDA Rsch. Found., HDA Factbook 4, *supra* note 3.

These functions make the supply chain more efficient, reliable, and secure, and they ensure that patients can get medicines when they need them. (*Id.*).

No HDA member has a distribution center in Connecticut. (A030, A040, A043, A046). Instead, drugs and other healthcare products are delivered to licensed Connecticut retailers, hospitals, and other patient-facing entities from distribution centers in other states. (A030, A040, A043, A046). Distributors ship drugs and products to their customers “Free On Board (‘F.O.B.’) Destination,” meaning that title does not pass until the drug product is delivered to the customer inside Connecticut. (A057, A061–62, A065). The F.O.B. Destination term is consistent with a long course of dealing between distributors and their sell-side customers, as well as the reasonable commercial expectations of customers. (A057–58, A062, A065). By delivering F.O.B. Destination, distributors bear the risk of loss or damage until physical delivery. (A057–58, A062, A065). Distributors pay for insurance to mitigate that risk, while their customers do not. (A057–58, A062, A065). Additionally, distributors are subject to regulatory and compliance obligations under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, and the Drug Supply Chain Security Act, 21 U.S.C. § 360eee *et seq.*, both of which prescribe detailed rules for the distribution of pharmaceutical products. (A057–58, A062, A065–66). Distributors’ Connecticut customers would strongly resist assuming these added costs and responsibilities. (A058–59, A062–63, A065–66).

Further, changing the existing F.O.B. Destination arrangement would be impractical. (A059, A063, A066–67). Many contracts between distributors and their customers cover multiple years and multiple states at a time. (A059, A063, A066–67). A single customer may have multiple locations in different states. (A059, A063, A066–67). Distributors would face very substantial administrative burdens if they sought to deliver products under a special arrangement to Connecticut customers and deliver F.O.B. Destination to all other customers. (A059, A063, A066–67). Their distribution facilities outside Connecticut would have to operate under a special exception every time they fulfilled an order for a covered product through delivery to a customer’s location in Connecticut. (A066). To make matters worse, the Drug Price Cap applies to only a subset of healthcare products: off-patent brand-name prescription and generic drugs, and interchangeable biological products. Conn. Pub. Act No. 25-168 § 345(6). Keeping track of which products could be shipped F.O.B. Destination to Connecticut (and which could not) would be an expensive administrative nightmare for any distributor. (A066). The multi-year nature of customer contracts means that, even if renegotiation of customer contracts were feasible, it would take years before distributors would even be in a realistic position to propose new agreements with Connecticut customers departing from the F.O.B. Destination term. (A059, A063, A066–67).

C. Procedural History.

HDA filed an action in the U.S. District Court for the District of Connecticut on October 14, 2025, raising Commerce Clause, Fourteenth Amendment, and other claims. The complaint alleged (in part) that the Cap violates the Fourteenth Amendment because it “exposes wholesale distributors to penalties for activities beyond their control. Wholesale distributors operate under contract with manufacturers and do not set or control the WAC for drug products.” (A034).

On October 23, 2025, HDA filed a motion for a preliminary injunction against enforcement of the Drug Price Cap, arguing that (1) HDA is likely to succeed on its claim that the Drug Price Cap violates the Commerce Clause and the Fourteenth Amendment of the United States Constitution; (2) HDA’s members will suffer irreparable harm absent an injunction; and (3) the balance of hardships and public interest militate in favor of an injunction. ECF No. 27. On October 29, HDA filed an unopposed motion for expedited briefing and consideration of its Motion for Preliminary Injunction, which the district court granted. ECF Nos. 31, 32.

The State opposed the motion for preliminary injunction but told the District Court that “[t]he parties largely agree on how the pharmaceutical supply chain works,” and acknowledged that “[m]anufacturers, not distributors, set the WAC.” ECF No. 34, at 2, 3. The State did not controvert any of the declarations filed by HDA in support of its motion for preliminary injunction, nor did it file any

declarations of its own or introduce any evidence to dispute HDA’s showing that none of its members has a distribution center in Connecticut.

The District Court held a preliminary injunction hearing on December 9, at which the State announced its new statutory interpretation exempting out-of-state manufacturers from the Cap. (A073:2–6). HDA responded at the hearing that the State’s new position aggravated the constitutional flaws in the Cap with respect to distributors. (A077:9–79:18, A106:8–17, A109:23–110:6, A115:24–117:1, A120:5–19, A123:11–24). The District Court requested supplemental briefing on the State’s new interpretation, and both HDA and the State filed supplemental briefs. ECF Nos. 43, 44.⁵

On December 24, the District Court denied HDA’s motion for preliminary injunction, ruling that HDA had failed to establish a likelihood of success on the merits but not reaching the other preliminary injunction factors. (A126–144). On December 26, HDA filed a notice of appeal to this Court (A145) and a motion for injunction pending appeal in the District Court, which the District Court denied on December 28. ECF Nos. 46–48.

⁵ The Association for Accessible Medicines (“AAM”), representing generic drug manufacturers, also filed an action in the District of Connecticut and a motion for preliminary injunction. No. 25-cv-01757 (D. Conn.), ECF Nos. 1, 20. On December 15, AAM and the State stipulated to dismissal of AAM’s action based on the State’s new interpretation of the Cap. *Id.*, ECF No. 39.

On December 29, HDA filed a motion for injunction pending appeal and for expedited appeal in this Court. Dkt. 6. On December 31, this Court denied the motion for injunction pending appeal but granted the request for expedition. Dkt. 15.

STANDARD OF REVIEW

To obtain a preliminary injunction that “will affect government action taken in the public interest pursuant to a statute or regulatory scheme, the moving party must demonstrate (1) irreparable harm absent injunctive relief, (2) a likelihood of success on the merits, and (3) public interest weighing in favor of granting the injunction.” *Agudath Isr. of Am. v. Cuomo*, 983 F.3d 620, 631 (2d Cir. 2020) (citation omitted).

This Court “reviews a district court’s legal rulings de novo and its ultimate denial of a preliminary injunction for abuse of discretion.” *N. Am. Soccer League, LLC v. U.S. Soccer Fed’n, Inc.*, 883 F.3d 32, 36 (2d Cir. 2018). *See also A.H. ex rel. Hester v. French*, 985 F.3d 165, 175 (2d Cir. 2021) (“The Supreme Court has generally favored de novo review in ‘the constitutional realm’” (quoting *U.S. Bank Nat’l Ass’n ex rel. CWCapital Asset Mgmt. LLC v. Vill. at Lakeridge, LLC*, 583 U.S. 387, 396 n.4 (2018))).

This Court has plenary authority to direct the entry of a preliminary injunction in favor of HDA and its members under 28 U.S.C. § 2106 and related principles. *See*

Poor ex rel. NLRB v. Parking Sys. Plus, Inc., --- F.4th ---, No. 24-3324-cv, 2025 WL 3684245, at *6 (2d Cir. Dec. 19, 2025) (recognizing this Court’s authority to direct the district court to enter an injunction (citing *Patton v. Dole*, 806 F.2d 24, 31 (2d Cir. 1986))).

ARGUMENT

I. THE DRUG PRICE CAP IS UNCONSTITUTIONAL.

The Drug Price Cap is unconstitutional for multiple reasons.

A. The Drug Price Cap Is Impermissibly Extraterritorial.

1. *The Drug Price Cap Regulates Out-of-State Pricing Decisions.*

The Drug Price Cap takes aim at pricing decisions that occur entirely outside Connecticut and therefore violates the constitutional prohibition on extraterritorial state legislation embodied in the Commerce Clause. There is no dispute in this case that manufacturers set WAC, and they do so outside Connecticut on a national basis. The Drug Price Cap challenges those out-of-state pricing decisions and requires that Connecticut prices be instead set at the “reference price,” an ever-growing discount to the WAC price prevailing nationally. That is the epitome of extraterritorial price regulation.

Even the Drug Price Cap itself acknowledges the extraterritorial nature of its drug price determination by referring to *national* pricing benchmarks in connection with its own requirements. Under § 345(11) of the Connecticut statute, the term

“wholesale acquisition cost,” commonly known as WAC, is given the same meaning as in Title 42 of the U.S. Code. (A012). *See* 42 U.S.C. § 1395w-3a(c)(6)(B) (defining “wholesale acquisition cost” to mean “the manufacturer’s list price for the drug . . . to wholesalers or direct purchasers in the United States . . . as reported in wholesale price guides or other publications of drug or biological pricing data”).

Moreover, the Drug Price Cap, by its own terms, is not focused on the in-state price that Connecticut consumers ultimately pay for a drug. The Cap does not apply to the in-state Connecticut retailers and other entities (such as medical practices, hospitals, and other licensed healthcare providers) that actually sell covered products to consumers. Those retailers and other entities are free to charge whatever they wish. The Cap targets only pricing decisions made outside Connecticut.

Section 347 is another extraterritorial feature of the Drug Price Cap. It prohibits distributors from “withdraw[ing] [an] identified prescription drug from sale” in Connecticut “for purpose of avoiding the civil penalty established in” Section 346(b), subject to a \$500,000 civil penalty applied per every “identified prescription drug” sold. Conn. Pub. Act No. 25-168 § 347 (A021). This provision effectively requires distributors to perform an extraterritorial act. It compels them to send drug products from out-of-state distribution centers into Connecticut, subject to a severe penalty if they refuse. Yet the Commerce Clause “precludes the application of a state statute to commerce that takes place wholly outside of the

State's borders, whether or not the commerce has effects within the State." *Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982) (plurality opinion). This prohibition 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." *Id.* at 643 (plurality opinion) (citation omitted). Section 347 violates this fundamental limit on Connecticut's power.

These extraterritorial features doom the Drug Price Cap. In *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (1989), the Supreme Court invalidated a Connecticut price-regulation statute (which required beer producers to affirm that their Connecticut prices were no higher than those in bordering states) because it "control[led] commercial activity occurring wholly outside the boundary of the State." *Id.* at 337. The Court emphasized that the result "of th[e] affirmation law, in conjunction with the many other beer-pricing and affirmation laws that have been or might be enacted throughout the country, [was] to create just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Id.*

It is immaterial that the Drug Price Cap purports to regulate only in-state Connecticut sales. "[W]hether a state law 'is addressed only to [in-state] sales is irrelevant if the "practical effect" of the law is to control' out-of-state prices." *Pork Producers*, 598 U.S. at 373 (quoting *Brown-Forman Distillers Corp. v. N.Y. State*

Liquor Auth., 476 U.S. 573, 583 (1986)). Thus, in *Brown-Forman*, the Supreme Court invalidated a New York price regulation statute requiring distillers to affirm that the prices at which they sold to wholesalers in New York were no higher than the lowest prices they charged wholesalers anywhere else in the United States. The Court opined that, “[w]hen a state statute” seeks to regulate pricing decisions made outside the state, the statute must be “struck down” even if by its statutory language it “is addressed only to sales . . . in [that state].” 476 U.S. at 579, 583.

This Court has similarly recognized that “price-regulation statutes” are impermissible if they “require[] out-of-state commerce to be conducted according to in-state terms.” *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 110 (2d Cir. 2001) (internal quotation marks and citation omitted); *see also Nat'l Shooting Sports Found., Inc. v. James*, 144 F.4th 98, 116 (2d Cir. 2025) (state statute violates the Commerce Clause if it “regulates ‘commerce that takes place wholly outside of the State’s borders.’” (citation omitted)); *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 193 (2d Cir. 2007) (state law invalid if it “require[es] out-of-state commerce to be conducted at the regulating state’s direction”) (quoting *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 102 (2d Cir. 2003)).

2. *Every Other Appellate Court to Consider the Issue Has Held Similar State Drug Price Controls Invalid.*

The District Court’s order in this case conflicts with every federal appellate decision to have considered similar state drug price controls. In *Frosh*, for example,

the Fourth Circuit invalidated a state drug price cap that applied to sales by distributors, “*none of which are based in Maryland.*” 887 F.3d at 667 (emphasis in original). Here, no HDA member has a distribution facility in Connecticut. The Fourth Circuit also explained that “[e]ven if the Act did require a nexus to an actual sale in Maryland, it is nonetheless invalid because it still controls the price of transactions that occur wholly outside the state.” *Id.* at 671. Similarly, Connecticut Drug Price Cap’s application to in-state sales does not save it, because the Cap controls pricing decisions made out-of-state to create an artificially low in-state price. The Fourth Circuit continued: “Significantly, the retailers that sell the drug directly to the consumer cannot be held liable under the Act; only ‘[a] manufacturer or wholesale distributor’ is prohibited from ‘engag[ing] in price gouging.’” *Id.* (alterations in original). The Connecticut Cap likewise does not apply to the in-state retailers that actually sell covered drug products to consumers. Finally, the Fourth Circuit observed that “[b]ecause the Act targets wholesale rather than retail pricing, an analogous restriction imposed by a state other than Maryland” had the potential to create “conflicting state requirements.” *Id.* at 673. Again, the same is true here.

The Supreme Court cited *Frosh* with approval in *Pork Producers*, commenting that *Frosh* read prior cases⁶ condemning state price controls “in exactly

⁶ *Healy*, 491 U.S. 324; *Brown-Forman*, 476 U.S. 573; *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935).

the same way” as the Supreme Court did. *Pork Producers*, 598 U.S. at 374 (citing *Frosh*, 887 F.3d at 669). And in a recent opinion applying *Pork Producers*, the Eighth Circuit invalidated a Minnesota drug price statute because it had “the specific impermissible extraterritorial effect of controlling prices outside of Minnesota.” *Ellison*, 140 F.4th at 960. The reasoning of *Pork Producers* and *Ellison* is squarely applicable here.

District courts encountering similar price-control laws have determined that those schemes were impermissibly extraterritorial and thus unconstitutional. In *Pharmaceutical Research and Manufacturers of America v. District of Columbia (PhRMA)*, 406 F. Supp. 2d 56 (D.D.C. 2005) , the district court invalidated a District of Columbia drug price cap under the dormant Commerce Clause, noting that the relevant distributors were “found out of state,” even though the law’s application was “triggered by an in-state sale.” *Id.* at 69–70.⁷ And in *Pharm. Rsch. & Mfrs. of Am. v. Comm’r, Maine Dep’t of Hum. Servs.*, Civ. No. 00-157-B-H, 2000 WL 34290605 (D. Me. Oct. 26, 2000) , the district court struck down a Maine drug price control targeting drug manufacturers on extraterritoriality grounds, noting that “all the drug manufacturers represented by the plaintiff are located outside the State of

⁷ The Federal Circuit affirmed on preemption grounds. *See Biotech. Indus. Org.*, 496 F.3d at 1374.

Maine.”⁸ *Id.*, at *2. Likewise, all of HDA’s members are located outside Connecticut, and the Cap’s applicability to sales in Connecticut does not cure its impermissible extraterritorial effect.

3. *The District Court’s Reasoning Was Incorrect.*

The District Court described the extraterritoriality principle as a “dead letter” after *Pork Producers*. (A135 (internal quotation marks and citation omitted)). This was error. *Pork Producers* explained that it was saying “nothing new” about the treatment of state price-control laws under the Commerce Clause. 598 U.S. at 374. *Pork Producers* reaffirmed that state “price control or price affirmation statutes” are invalid if they tie “the price of . . . in-state products to out-of-state prices.” *Id.* (quoting *Pharm. Rsch. and Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003)). The Drug Price Cap operates in precisely that forbidden way. It ties Connecticut prices to a discounted version of out-of-state prices. The Cap imposes an in-state reference price defined according to a nationwide metric (January 1, 2025 WAC, adjusted for inflation), which will ensure that Connecticut prices remain below manufacturer list prices prevailing nationally.

⁸ Maine did not appeal the district court’s preliminary injunction against the price control provision, and the First Circuit acknowledged that “price control” schemes have been held invalid where they sought “to benefit the buyers and sellers in the home state,” *Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 81 (1st Cir. 2001), which is exactly what the Drug Price Cap seeks to do in Connecticut.

Although *Pork Producers* distinguished the prior price regulation cases, it did not overrule or reject them. *See id.* It simply found them inapplicable to a California hog-slaughtering law having nothing to do with price (and carrying no risk of a race-to-the-bottom among states). *Pork Producers* did not involve a price-control law, nor does it provide a basis for upholding the Connecticut Cap. *See Nat'l Pork Producers Council v. Ross*, 6 F.4th 1021, 1028 (9th Cir. 2021) (“Proposition 12 is neither a price-control nor price-affirmation statute, as it neither dictates the price of pork products nor ties the price of pork products sold in California to out-of-state prices.”), *aff'd*, 598 U.S. 356 (2023). Indeed, the author of *Pork Producers* has recognized the special concerns raised by price control laws. *See Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1172–73 (10th Cir. 2015) (Gorsuch, J.) (explaining that the “three essential characteristics” that mark *Healy*, *Brown-Forman*, and *Baldwin* are that the state law at issue (1) was a price-control statute, (2) linked prices paid in-state with those paid out-of-state, or (3) discriminated against interstate commerce, and noting that “price control and price affirmation laws that control ‘extraterritorial’ conduct,” “that is, conduct outside the state’s borders,” “are deemed almost *per se* invalid”).

The District Court’s holding creates a sharp conflict with *Pork Producers* and with the Eighth Circuit’s recent application of that case, which correctly observed that *Pork Producers* “[said] nothing new” about *Healy*, *Brown-Forman*, and

Baldwin, and applied those cases to strike down Minnesota’s drug price cap due to its “specific impermissible extraterritorial effect of controlling prices outside of Minnesota.” *Ellison*, 140 F.4th at 960–61.

Other cases cited by the District Court below recognized the key distinction (for Commerce Clause purposes) between state price control laws and other forms of state legislation. For example, the District Court cited *New Jersey Staffing Alliance v. Fais*, 749 F. Supp. 3d 511, 525 (D.N.J. 2023), *aff’d*, 110 F.4th 201 (3d Cir. 2024), as “describing *Pork Producers* as a ‘revolution.’” (A134). In fact, the district court in *Fais* noted that the price control cases of *Healy*, *Brown-Forman*, and *Baldwin* “clearly survived the *National Pork* revolution.” 749 F. Supp. 3d at 525. The Third Circuit also recognized those cases’ focus on the impermissible extraterritorial effects of price-control laws. *See Fais*, 110 F.4th at 206 (noting the “price-control laws” in those cases that “‘operated like a tariff or customs duty’” (citation omitted)).

The District Court also cited *GenBioPro, Inc. v. Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *11 (S.D.W. Va. Aug. 24, 2023), *aff’d sub nom.*, *GenBioPro, Inc. v. Raynes*, 144 F.4th 258 (4th Cir. 2025), as stating that *Pork Producers* “abrogated” the “principle against extraterritoriality.” (A135). In fact, *GenBioPro* opined that *Pork Producers* “appeared to limit dormant Commerce Clause extraterritoriality claims to statutes that discriminate against interstate commerce by

tying in-state prices to out-of-state prices.” 2023 WL 5490179, at *11 n.15. The Connecticut Drug Price Cap violates that principle.⁹

The District Court also rejected HDA’s extraterritoriality challenge on the ground that “the dormant Commerce Clause does not ‘protect[] the particular structure’ or methods ‘of operation’ of a given industry.” (A137–38 (citing *Flynt v. Bonta*, 131 F.4th 918, 928 (9th Cir. 2025) (in turn quoting *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978)))). But that language has no application here. It reflects the principle that “[l]egislation that causes certain out-of-state companies to cease selling in a particular state will not violate the dormant Commerce Clause as long as other out-of-state suppliers ‘will . . . promptly replace[]’ the goods that would have been sold by the companies that cease selling in state.” *Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200, 208 (2d Cir. 2003) (alterations in original) (quoting *Exxon*, 437 U.S. at 127). But the vice of the Drug Price Cap is not that it falls on some distributors and not others. Indeed, it applies to *all* distributors, and that is why HDA, as the trade association of distributors, is the plaintiff here. This is not a situation like *Exxon*.

⁹ *Ass’n for Accessible Meds. v. Raoul*, No. 24 C 544, 2025 WL 2764558 (N.D. Ill. Sept. 26, 2025), appeal docketed, No. 25-2960 (7th Cir. Oct. 31, 2025), upheld an Illinois drug price control law but acknowledged that *Pork Producers* “did not answer the precise question this case presents,” *id.* at *4, thereby effectively conceding that *Pork Producers* could not have overturned the Court’s precedents striking down impermissibly extraterritorial price-control laws.

Rather, the vice of the Drug Price Cap is that it is impermissibly extraterritorial for the undisputed fact that manufacturers set WAC on a national basis—a feature of the industry that the Cap does not change—and that the Cap impermissibly ties Connecticut prices to a discounted version of out-of-state prices for all distributors.

Immediately after its reference to *Flynt*, the District Court aptly noted that *Pork Producers* found “that ‘each’ of *Baldwin*, *Brown-Forman*, and *Healy* ‘typifies the familiar concern with preventing purposeful discrimination against out-of-state economic interests.’” (A140 (quoting *Pork Producers*, 589 U.S. at 371)). This case mirrors the manner in which the states in those cases forced the plaintiffs to choose between valid, competitive pricing decisions and an unconstitutionally mandated price. In *Healy* and *Brown-Forman*, for example, the plaintiffs could have complied with the challenged state laws by ending their promotional pricing efforts. But the Supreme Court held that putting beer brewers and liquor distillers to a choice between (i) continuing the promotional pricing efforts or (ii) complying with state price control statutes amounted to an unconstitutional interference with commerce. *See Healy*, 491 U.S. at 339 (statute impermissibly “deter[ed] volume discounts” and “promotional discounts”); *Brown-Forman*, 476 U.S. at 578 (“Appellant contended that the only way to avoid this dilemma was to stop offering promotional allowances”). Offering an out-of-state company “the Hobson’s choice . . . of

discontinuing the promotional allowances altogether” would amount to “extraterritorial regulation of interstate commerce in violation of the Commerce Clause.” *Healy*, 491 U.S. at 332 (noting the “Court agreed” with this argument by plaintiffs). The Cap’s impact on distributors is even more severe. Rather than banning discretionary discounts, the Cap mandates a steep, ever-growing discount by establishing a reference price that is artificially lower than the prevailing WAC established in the national market.

B. The Drug Price Cap Is Protectionist.

I. The Cap is Protectionist on the Consumer Level.

The Drug Price Cap violates the Commerce Clause for the independent reason that it is impermissibly protectionist. The Cap mandates an artificially lower price for Connecticut than the prevailing WAC price in other states and thus “attempts to give local consumers an advantage over consumers in other States.” *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 577–78 (1997) (quoting *Brown-Forman*, 476 U.S. at 580)). Either consumers in other states will absorb the costs not borne by those in Connecticut, or other states will respond by enacting their own price caps mandating even lower prices with even more burdensome reference price formulas, setting off an “artificial race between legislatures to set the lowest” reference price for drugs. *PhRMA*, 406 F. Supp. 2d at 70 (striking down D.C. drug price regulation under Commerce Clause).

The Supreme Court has consistently instructed that “[a]voiding this sort of ‘economic Balkanization,’ and the retaliatory acts of other States that may follow, is one of the central purposes of our negative Commerce Clause jurisprudence,” *Camps Newfound/Owatonna*, 520 U.S. at 577 (quoting *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979)); *see also C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 390 (1994) (Commerce Clause “prohibit[s] . . . laws that would excite those jealousies and retaliatory measures the Constitution was designed to prevent”).

The Supreme Court in *Pork Producers* also recognized the risk of economic retaliation inherent in state price-control laws, explaining (in its discussion of *Healy*) that, “if the Connecticut law stood, ‘each of the border States’ could ‘enac[t] statutes essentially identical to Connecticut’s’ in retaliation—a result often associated with avowedly protectionist economic policies.” 598 U.S. at 373 (alteration in original) (quoting *Healy*, 491 U.S. at 339–40). *Pork Producers* condemned state price-control laws for depriving “consumers in other States of whatever competitive advantages they may possess.” *Id.* at 374 (internal citations and quotation marks omitted). The Drug Price Cap similarly deprives consumers in other states of the competitive advantages they would otherwise enjoy; indeed, it forces them to absorb the costs not borne by Connecticut consumers.

In a related case, the State of New York did not *even challenge* a district court order striking down under the dormant Commerce Clause a prohibition on the pass-

through of opioid taxes to New York consumers. *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 262 (S.D.N.Y. 2018), *rev'd in part on other grounds sub nom.*, *Ass'n for Accessible Meds. v. James*, 974 F.3d 216 (2d Cir. 2020). The Southern District of New York reasoned that “New York opioid customers would be protected from any price increases in their purchases,” and “out-of-state drug purchasers, with no representation in New York’s legislature or executive, would bear the cost of New York’s policy program.” *Id.* The Drug Price Cap similarly shields distributors’ Connecticut customers from price increases based on manufacturers’ increases in WAC and forces consumers in other states to bear the costs. The Southern District opined that “[t]his shifting of burdens and benefits is antithetical to the idea of intra-national free trade and demonstrates why the Dormant Commerce Cause exists.” *Id.* On appeal, this Court noted that New York did not challenge the invalidation of the opioid tax cost-pass-through prohibition, *James*, 974 F.3d at 228, and on remand the district court noted that the prohibition remained “constitutionally invalid.” *Healthcare Distrib. All. v. Zucker*, Nos. 18 Civ. 6168 (KPF), 18 Civ. 8180 (KPF), 18 Civ. 9830 (KPF), 2021 WL 12103902, at *2 (S.D.N.Y. Oct. 20, 2021); *see also Brown & Williamson*, 320 F.3d at 208 (“Discrimination against commerce itself occurs when a statute . . . shifts the costs of regulation onto other states, permitting in-state lawmakers to avoid the costs of their political decisions.”); *Sorrell*, 272 F.3d

at 108 (Commerce Clause meant to preclude laws whose “costs will fall in some measure on the residents of other political jurisdictions”).

The District Court below did not deny that the Drug Price Cap risks forcing consumers in other states to absorb costs not borne by Connecticut consumers. Indeed, the District Court acknowledged that distributors could respond to the Drug Price Cap by selling covered drugs in other states at prices “higher than the Reference Price.” (A141). Rather than contend with the Cap’s impermissible cost-shifting impact, the District Court reasoned that the Cap “does not mandate that HDA’s members sell identified drugs in Connecticut at prices lower than anywhere else.” (*Id.*). But the Drug Price Cap mandates exactly that. It requires distributors to sell covered drugs in Connecticut at a discount to the WAC price prevailing nationally. And simple economics dictate that the mandate will burden consumers outside Connecticut. Distributors purchasing drugs at WAC and selling them in Connecticut at the artificially low reference price will lose revenue on every Connecticut transaction. The Cap will necessarily require consumers in other states to bear a greater burden, just as the New York prohibition on the pass-through of opioid taxes did. *See Zucker*, 353 F. Supp. 3d at 262.

2. *The Cap Is Protectionist on the Commercial Level.*

Although this Court need not go further to conclude that the Drug Price Cap is protectionist, it is clear that the Cap also discriminates against out-of-state entities

(distributors, none of whom has a distribution center in Connecticut) by forcing them alone to bear the cost of Connecticut’s program and exempting in-state retailers (and other in-state patient-facing entities) from any price restriction. In rejecting HDA’s objection on these grounds, the District Court’s decision conflicts with the Fourth Circuit’s decision in *Frosh*, which expressly noted that Maryland’s price-control law rule applied to out-of-state distributors but not in-state retailers. 887 F.3d at 671. *Frosh* proceeded to strike down Maryland’s law under the dormant Commerce Clause. *Id.* at 674. And as previously noted, *Pork Producers* cited *Frosh* with approval. *Pork Producers*, 598 U.S. at 374.

Nevertheless, the District Court brushed aside the Connecticut Cap’s discrimination against out-of-state entities on the ground that retailers and distributors are not “competitors,” citing *General Motors Corp. v. Tracy*, 519 U.S. 278 (1997). (A136 n.6). But the District Court’s approach misreads Supreme Court precedent. As this Court has observed, *Tracy* involved a unique regulatory setting where Ohio had created two distinct natural gas markets. *Allco Fin. Ltd. v. Klee*, 861 F.3d 82, 104–05 (2d Cir. 2017). *Tracy* considered a claim that an Ohio tax scheme favored natural gas utilities located in Ohio and discriminated against other natural gas producers or “independent marketers,” 519 U.S. at 282, 285, and asked merely whether the entities at issue were “*substantially similar*.” *Id.* at 298 (emphasis added). In determining whether those entities were “similarly situated for

constitutional purposes,” the Court explained that a “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.* at 299. *Tracy* ultimately held that the Ohio tax at issue did not violate the dormant Commerce Clause because “Ohio’s regulatory response to the needs of the local natural gas market ha[d] resulted in a . . . product that distinguishe[d] its regulated [local utilities] from independent marketers to the point that the enterprises could not be considered ‘similarly situated’ for purposes of a claim of facial discrimination under the Commerce Clause.” *Id.* at 310.

This case does not involve anything like the unique regulatory program created by Ohio. Here, in-state retailers and out-of-state distributors hardly serve different markets involving different products. Rather, they are “similarly situated” for constitutional purposes. Both are links in the chain of moving important medicines from manufacturer to patient. Forcing one link but not the other to shoulder the costs of Connecticut’s program is plainly an attempt to favor local economic interests in violation of what the Supreme Court has described as one of the dormant Commerce Clause’s fundamental objectives: “preventing purposeful discrimination against out-of-state economic interests.” *Pork Producers*, 598 U.S. at 371; *see also* *Ore. Waste Sys., Inc. v. Dep’t of Env’t Quality*, 511 U.S. 93, 99 (1994) (discrimination “simply means differential treatment of in-state and out-of-state

economic interests that benefits the former and burdens the latter”); *United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 261 F.3d 245, 260 (2d Cir. 2001) (Commerce Clause reflects an “intent to prevent state or local governments from favoring in-state business or investment at the expense of out-of-state businesses”).

The District Court was also wrong in ruling that the Cap does not “prevent or discourage competition among distributors.” (A142). A distributor that does a disproportionate amount of business in Connecticut will be put at a competitive disadvantage in other states vis-à-vis other distributors because it will be saddled with extra costs that Connecticut has forced it to absorb. Thus, the Cap hinders distributors from undertaking competitive pricing outside Connecticut, which is precisely the kind of “impermissible ‘extraterritorial effect’” that the Supreme Court specifically condemned in *Pork Producers*, 598 U.S. at 374 (condemning price control laws that “prevent[] [out-of-state firms] from undertaking competitive pricing’ or ‘deprive[] businesses . . . in other States of ‘whatever competitive advantages they may possess’”) (citations omitted). The Drug Price Cap impairs competitive pricing outside Connecticut and deprives distributors in other states of the competitive advantages they would otherwise enjoy. These interferences with interstate commerce are yet another reason that the Cap is invalid.

3. ***The State's Position Has No Limiting Principle.***

The consumer protection rationale offered by the State in this case knows no bounds. It would open a Pandora's box permitting any jurisdiction to set its own unilateral price caps on any and all goods traded on an interstate basis—whether gasoline, grocery items, cars, or anything else—in the name of consumer protection. Such a move would fragment national markets and force interstate businesses to navigate different sets of rules, interfering with the national free market that the Commerce Clause safeguards. Unilateral action by one state would incentivize every other state to adopt its own price control law, provoking the kind of destructive cycle that prompted the adoption of the Constitution in the first place: “[T]he 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.” *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 588 U.S. 504, 517 (2019) (citation omitted). “The Constitution was framed . . . upon the theory that the peoples of the several states must sink or swim together, and that in the long run prosperity and salvation are in union and not division.” *Baldwin*, 294 U.S. at 523.

C. **The State's New Interpretation of the Cap Creates Additional Constitutional Defects.**

The State's eleventh-hour reinterpretation of the Drug Price Cap to exempt manufacturers makes it even *more* unconstitutional, in two respects. First, the State's

new approach based on the situs of title transfer (A131–32) renders the Cap *more* extraterritorial. The State now tells distributors they can avoid the Cap only by changing the fundamental nature of their business and arranging for title to transfer at distribution centers outside Connecticut—in other words, to take additional out-of-state actions to avoid the irreparable harm the Cap would otherwise impose. However, the undisputed evidence shows that transferring title outside Connecticut does not work for distributors, because Connecticut retailers and other customers demand that distributors bear the risk of loss, insurance requirements, and regulatory burdens until the products are delivered in-state. (A057–59, A062–63, A065–67). Moreover, if other states could adopt the same “situs” test as Connecticut, it would up-end distributors’ businesses. For example, if New York adopted a similar statute, a distributor (having moved the situs of title transfer to its New York facility in response to Connecticut’s new interpretation) would now find that sales to Connecticut retailers were governed by the New York statute—unless the distributor moved its operations out of New York as well. And so on. In sum, the State is merely piling one extraterritorial feature upon another.

In addition, the Drug Price Cap as reinterpreted by the State is wholly arbitrary. It is a form of price control that does not apply to the entities that actually control prices—manufacturers and downstream entities like retailers. Instead, the Cap targets distributors, even though it is undisputed that they do not set or control

WAC. Such an arbitrary classification is unconstitutional. *See, e.g., Allegheny Pittsburgh Coal Co. v. Cnty. Comm'n of Webster Cnty.*, 488 U.S. 336, 345–46 (1989) (arbitrary tax treatment); *Metro. Life Ins. Co. v. Ward*, 470 U.S. 869, 874–83 (1985) (arbitrary classification may violate the Equal Protection Clause even if it passes muster under the Commerce Clause); *Saint Joseph Abbey v. Castille*, 712 F.3d 215, 225 (5th Cir. 2013) (noting fatal “disconnect” between law and rationale); *Merrifield v. Lockyer*, 547 F.3d 978, 991 (9th Cir. 2008) (“[A] rationale so weak . . . fails to meet the relatively easy standard of rational basis review”).

The State’s new interpretation also penalizes distributors for manufacturer-driven pricing decisions beyond their control. It is undisputed that distributors do not set or control WAC. (A030, A040, A043, A046). This Court has opined that “due process is not satisfied” where liability is imposed on a person for actions taken by a third party. *Viking Indus. Sec., Inc. v. NLRB*, 225 F.3d 131, 135 (2d Cir. 2000). Indeed, “personal guilt is a fundamental element in the American scheme of liberty.” *St. Ann v. Palisi*, 495 F.2d 423, 426 (5th Cir. 1974) (child may not be penalized for actions of parent). Yet the Cap penalizes distributors for price increases adopted by manufacturers.

The District Court “appreciate[d]” HDA’s argument that the reinterpreted law was “Kafkaesque” but deferred to the findings of a “bipartisan, bicameral” task force. (A138–39). But the task force report, while discussing manufacturers’ role

in drug pricing, said nothing about distributors' role.¹⁰ In fact, there is not a shred of legislative history indicating that the Governor and legislature intended an arbitrary measure that would target distributors but not manufacturers. Indeed, the Governor's press statement focused only on manufacturers, explaining that the Cap would "levy a civil penalty on manufacturers that raise prices above that threshold."¹¹ Additionally, one of the secondary sources cited by the State in defense of the Cap explains that "[m]anufacturers have the most influence over pharmaceutical prices."¹² In short, there is no support in the legislative record, or in common sense, for the State's new interpretation of the Drug Price Cap.

II. THIS COURT SHOULD DIRECT THE ENTRY OF AN INJUNCTION IN FAVOR OF HDA AND ITS MEMBERS.

"[A]n appellate court, on a finding of merit in plaintiff's case," may "direct the district court to issue [an] injunction" on remand. *Patton*, 806 F.2d at 31. That

¹⁰ See Prescription Drug Task Force, Final Report and Recommendations (Feb. 26, 2025), https://www.cga.ct.gov/hs/tfs/20241204_Prescription%20Drug%20Task%20Force/Final%20Report/CT%20Prescription%20Drug%20Task%20Force%20Final%20Report_20250226.pdf.

¹¹ Press Release, Governor Lamont Announces 2025 Legislative Proposal: Reduce Prescription Drug Costs (Feb. 6, 2025), https://portal.ct.gov/governor/news/press-releases/2025/02-2025/governor-lamont-announces-2025-legislative-proposal-reduce-prescription-drug-costs?language=en_US.

¹² Kaiser Family Foundation, Follow the Pill: Understanding the U.S. Commercial Supply Chain 17 (Mar. 2005), <https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>.

course is appropriate here. Although the District Court did not make findings on the remaining preliminary injunction factors, the undisputed record amply demonstrates that HDA’s case is meritorious and that HDA has made more than a sufficient showing under each factor to warrant injunctive relief. HDA’s members face ongoing irreparable harm from the Drug Price Cap, and this Court granted HDA’s motion for expedition. Given the need for prompt relief, this Court should follow its frequent approach and direct the District Court to enter the requested injunction.

See, e.g., Poor, 2025 WL 3684245, at *6, *13 (reversing denial of preliminary injunction and ordering remand for entry of requested injunction); *Mid Vt. Christian Sch. v. Saunders*, 151 F.4th 86, 89, 96 (2d Cir. 2025) (reversing denial of preliminary injunction and remanding with instructions to grant plaintiffs’ motion for preliminary injunction); *Agudath*, 983 F.3d at 625, 637 (remanding in part for district court to enter injunction); *N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 489 (2d Cir. 2013) (remanding with instructions to enter preliminary injunction); *Hoffman ex rel. NLRB v. Inn Credible Caterers, Ltd.*, 247 F.3d 360, 363, 370 (2d Cir. 2001) (reversing denial of injunction and remanding for entry of the requested injunction); *Hsu ex rel. Hsu v. Roslyn Union Free Sch. Dist. No. 3*, 85 F.3d 839, 873 (2d Cir. 1996) (remanding for issuance of injunction and “additional proceedings (if necessary)’’); *see also* 28 U.S.C. § 2106.

A. HDA’s Members Will Suffer Imminent Irreparable Harm Without an Injunction.

HDA’s members face at least two forms of irreparable harm sufficient to justify injunctive relief. First, “the alleged violation of a constitutional right triggers a finding of irreparable injury.” *Conn. Dep’t of Env’t Prot. v. OSHA*, 356 F.3d 226, 231 (2d Cir. 2004) (internal quotation marks and citations omitted); *see also Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996) (“[I]t is the *alleged* violation of a constitutional right that triggers a finding of irreparable harm.”). This Court has applied this rule in the dormant Commerce Clause context. *See Variscite NY Four, LLC v. N.Y. State Cannabis Control Bd.*, 152 F.4th 47, 60 (2d Cir. 2025).

Second, HDA’s members face irreparable harm because WAC prices for hundreds of covered drug products have already increased faster than inflation during calendar year 2025. According to a database that reports only WAC increases greater than 16%, manufacturers have already raised the WAC of *over 650* covered products by far more than the rate of inflation since January 1, 2025. (A048–54); *see also* ECF No. 44, at 2 n.3.¹³ Moreover, in the future manufacturers will

¹³ Although the 16% figure within this dataset includes cumulative increases within the two previous calendar years, the CPI increased less than 3% in 2025 and only about 8% between January 2023 and December 2025. *See* Consumer Price Index for All Urban Consumers, Fed. Rsrv. Bank of St. Louis (FRED) (Dec. 18, 2025), <https://fred.stlouisfed.org/series/CPIAUCSL>. Manufacturers’ 2025 increases in WAC range as high as 40.73%, 56.4%, 93.72%, and even 98.8%. *See* January 2026 Monthly Update (Q1-Q4 2025 data) – Prescription Drug WAC Increases (Excel), CalHHS (Jan. 12, 2026) (respectively, Nystatin (row 1249), silver

inevitably increase prices for additional covered drug products above the January 1, 2025 WAC (adjusted by the CPI). (A051, A055). The legislative history that ultimately led to the Drug Price Cap shows that the legislature understood these economic impacts.¹⁴

Thus, distributors purchasing at WAC already face the Hobson's choice of (1) buying covered product at WAC and selling at the lower reference price, or (2) facing draconian civil penalties and even potential criminal liability under the Cap. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (finding irreparable injury where plaintiffs faced "choice" to either "continually violate the [challenged] law and expose themselves to potentially huge liability, or violate the law once as a test case and suffer the injury of obeying the law during the pendency of the proceedings and any further review"); *Am. 's Health Ins. Plans v. Hudgens*, 742 F.3d 1319, 1334 (11th Cir. 2014) (finding irreparable harm when plaintiffs "will be forced

sulfadiazine cream (row 128), Flotrex (row 1049), and Lidotral (row 1052) (NDC Numbers 00904727670, 67877012420, 59088001554, 59088020407)), <https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases/resource/b4554543-fec7-46c7-a518-b7d07bd1c1f3>.

¹⁴ See Deidre S. Gifford, Commissioner, Office of Health Strategy, Testimony Prepared for the Insurance and Real Estate Committee (Feb. 18, 2025) ("[M]ore than 400 generic prescription drugs . . . would have had their wholesale price limited by this legislation," which "would have reduced wholesale costs paid for off-patent branded drugs by at least \$9 million."), available at <https://cga.ct.gov/2025/insdata/TMY/2025HB-06871-R000218-Gifford,%20Deidre,%20Commissioner-Office%20of%20Health%20Strategy-Supports-TMY.PDF>.

either to incur the costs of compliance with a preempted state law or face the possibility of penalties”).

Any suggestion that distributors could shift the situs of title transfer outside Connecticut is a non-starter. (A057–59, A062–63, A065–67). To do so would require changing the F.O.B. Destination term of delivery in distributors’ customer contracts. (A057–59, A062–63, A065–67). This would entail a “[m]ajor disruption of [distributors’] business” that constitutes further irreparable harm warranting injunctive relief. *Nemer Jeep-Eagle, Inc. v. Jeep-Eagle Sales Corp.*, 992 F.2d 430, 435 (2d Cir. 1993). Moreover, the State has declined to respond to HDA’s inquiry whether arranging for title to transfer outside Connecticut—even if it were feasible, which it is not—would be construed as “withdraw[ing]” a covered product “from sale in this state” and subject the distributor to a \$500,000 civil penalty per drug under Section 347. ECF No. 44, at 5 n.4. In short, irreparable harm is clear.

In light of Connecticut’s sovereign immunity, which it asserted in the District Court (ECF No. 34, at 29), an after-the-fact monetary award would not be available to compensate HDA members for their losses. *See Am. Trucking Ass’ns, Inc. v. Gray*, 483 U.S. 1306, 1309 (1987) (granting stay in Commerce Clause case in light of sovereign immunity obstacles to after-the-fact compensation); *United States v. New York*, 708 F.2d 92, 93 (2d Cir. 1983) (harm irreparable in light of Eleventh Amendment).

B. The Balance of Hardships and Public Interest Militate in Favor of an Injunction.

Both the balance of hardships and the public interest favor a preliminary injunction. HDA members face clear irreparable harm. “The purpose of a preliminary injunction is . . . to preserve the relative positions of the parties.” *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). That purpose favors HDA.

In contrast, “the Government does not have an interest in the enforcement of an unconstitutional law.” *N.Y. Progress & Prot. PAC*, 733 F.3d at 488 (citation and internal quotation marks omitted). Nor can consumer protection justify a Commerce Clause violation. *See Hunt v. Wash. State Apple Advertising Comm’n*, 432 U.S. 333, 353 (1977) (state law invalid “even if enacted for the declared purpose of protecting consumers”).

“No public interest is served by maintaining an unconstitutional policy when constitutional alternatives are available to achieve the same goal.” *Agudath*, 983 F.3d at 637. Multiple provisions of federal law already address drug prices. For example, Medicare, which covers over 69 million Americans,¹⁵ includes two major prescription drug programs addressing drug prices. *See* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A), 1395w-3a (Part B); 42 U.S.C. §§ 1395w-102, 1395w-111(i)(1) (Part D). Other federal drug price initiatives include the Inflation Reduction Act’s Drug

¹⁵ Medicare Enrollment Dashboard, Data.CMS.gov (Sept. 2025), <https://data.cms.gov/tools/medicare-enrollment-dashboard>.

Price Negotiation Program, 42 U.S.C. § 1320f, which creates a procedure by which pharmaceutical manufacturers sell certain drugs at steeply discounted prices negotiated by HHS, *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 494 (5th Cir. 2024), and Section 340B of the Public Health Service Act, 42 U.S.C. § 256(b), which requires pharmaceutical manufacturers participating in Medicaid to provide significant discounts on outpatient drugs to qualified safety-net healthcare providers.

Moreover, given the State's reinterpretation of the Drug Price Cap to exclude out-of-state manufacturers, it cannot rely on the legislative record that was assembled to justify a completely different statute. Rather than furthering the public interest, the Cap threatens to disturb the essential logistical function performed by distributors and ultimately imperil patient access to important medicines. In fact, the Cap creates a perverse incentive for distributors not to sell drug products in Connecticut and instead to focus their business on other jurisdictions where they can earn a fair return. Thus, this case is not simply about harm to interstate markets and out-of-state distributors; it is also about protecting patients' access to medicine. The public interest weighs decidedly in HDA's favor.

CONCLUSION

This Court should reverse the District Court's order and direct the entry of a preliminary injunction against the Drug Price Cap with respect to HDA and its members.

Dated: January 14, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2026, a copy of the foregoing document was filed electronically through the Court's CM/ECF System. 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 below. Parties may access this filing through the Court's CM/ECF System.

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CERTIFICATE OF COMPLIANCE

1. This document complies with the word limit of Fed. R. App. P. 32(a)(4)(A) and Local Rule 32.1(4) because it contains 10,054 words, excluding the exempted portions of this document.
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By: /s/ Jonathan S. Massey
Jonathan S. Massey

25-3216

IN THE
UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

HEALTHCARE DISTRIBUTION ALLIANCE,
Plaintiff-Appellant,

v.

MARK D. BOUGHTON, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE
CONNECTICUT DEPARTMENT OF REVENUE SERVICES, WILLIAM TONG,
ATTORNEY GENERAL, IN HIS OFFICIAL CAPACITY AT ATTORNEY GENERAL FOR
THE STATE OF CONNECTICUT,
Defendant-Appellee.

On Appeal from the United States District Court
for the District Court of Connecticut

**APPENDIX TO BRIEF OF APPELLANT
HEALTHCARE DISTRIBUTION ALLIANCE**

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**U.S. District Court
District of Connecticut (New Haven)
CIVIL DOCKET FOR CASE #: 3:25-cv-01724-OAW**

Healthcare Distribution Alliance v. Boughton et al
Assigned to: Judge Omar A. Williams
Cause: 42:1983 Civil Rights Act

Date Filed: 10/14/2025
Jury Demand: None
Nature of Suit: 950 Constitutional - State
Statute
Jurisdiction: Federal Question

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Date Filed	#	Docket Text
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10/14/2025	1	COMPLAINT against All Defendants (Filing fee \$405 receipt number ACTDC-8367721.), filed by Healthcare Distribution Alliance. (Attachments: # 1 Civil Cover Sheet) (Finn, Thomas) (Entered: 10/14/2025)
10/14/2025		Request for Clerk to issue summons as to All Defendants. (Finn, Thomas) (Entered: 10/14/2025)
10/14/2025	2	Disclosure Statement <i>Corporate Rule 7.1</i> by Healthcare Distribution Alliance. (Finn, Thomas) (Entered: 10/14/2025)
10/14/2025		CASE ASSIGNMENT: District Judge Omar A. Williams assigned to the case. If the District Judge issues an Order of Referral to a Magistrate Judge for any matter other than settlement, the matter will be referred to Magistrate Judge Robert A. Richardson. (Oliver, T.) (Entered: 10/14/2025)
10/14/2025	3	Notice: Pursuant to Federal Rule of Civil Procedure 7.1(b), a disclosure statement required under Rule 7.1(a) must be filed with a party's first appearance, pleading, petition, motion, response, or other request addressed to the Court and must be supplemented if any required information changes during the case. Signed by Clerk on 10/14/25.(Hushin, Z.) (Entered: 10/14/2025)
10/14/2025	4	Order on Pretrial Deadlines: Amended Pleadings due by 12/15/2025; Discovery due by 4/15/2026; Dispositive Motions due by 5/20/2026 Signed by Clerk on 10/14/2025. (Kelsey, N) (Entered: 10/15/2025)
10/14/2025	5	ELECTRONIC FILING ORDER FOR COUNSEL - PLEASE ENSURE COMPLIANCE WITH COURTESY COPY REQUIREMENTS IN THIS ORDER Signed by Judge Omar A. Williams on 10/14/2025. (Kelsey, N) (Entered: 10/15/2025)
10/14/2025	6	Standing Protective Order Signed by Judge Omar A. Williams on 10/14/2025. (Kelsey, N) (Entered: 10/15/2025)
10/14/2025	7	Notice to Counsel and Litigants Regarding AI-Assisted Research: Attorneys and <i>pro se</i> litigants alike should exercise <u>great</u> caution in submitting any AI-generated language in filings before the Court. Use of AI without verification of the accuracy of the information it generates like any other shoddy research method from other sources or tools implicates Federal Rule of Civil Procedure 11, the central purpose of which is to deter baseless filings in district court and thus to streamline the administration and procedure of the federal courts. Rule 11 applies fully to actions filed by <i>pro se</i> litigants. Therefore, all parties are on notice that the Court has a no-tolerance policy for any briefing (AI-assisted or not) that hallucinates legal propositions or otherwise severely misstates the law. Such filings will often result in sanctions absent reasonable excuse. <i>See generally Willis v. U.S. Bank Nat'l Ass'n et al</i> , No. 3:25-CV-516-BN, 2025 WL 1408897 (N.D. Tex. May 15, 2025). Signed by Clerk on 10/14/2025. (Kelsey, N) (Entered: 10/15/2025)
10/14/2025	8	Notice of Option to Consent to Magistrate Judge Jurisdiction. (Kelsey, N) (Entered: 10/15/2025)
10/14/2025	9	Standing Order re: Letters. Signed by Judge Omar A. Williams on 10/14/2025. (Kelsey, N) (Entered: 10/15/2025)
10/15/2025	10	NOTICE TO COUNSEL/SELF-REPRESENTED PARTIES : Counsel or self-represented parties initiating or removing this action are responsible for serving all parties with attached documents and copies of 8 Notice of Option to Consent to Magistrate Judge Jurisdiction, 6 Standing Protective Order, 4 Order on Pretrial Deadlines, 5 Electronic Filing Order, 2 Disclosure Statement filed by Healthcare Distribution Alliance, 7 Notice re: AI-

		Assisted Research, 9 Standing Order re: Letters, 3 Notice re: Disclosure Statement, 1 Complaint filed by Healthcare Distribution Alliance Signed by Clerk on 10/15/2025. (Kelsey, N) (Entered: 10/15/2025)
10/15/2025	11	ELECTRONIC SUMMONS ISSUED in accordance with Fed. R. Civ. P. 4 and LR 4 as to *Mark D. Boughton, William Tong* with answer to complaint due within *21* days. Attorney *Thomas J. Finn* *McCarter & English, LLP* *CityPlace 1, 185 Asylum Street* *Hartford, CT 06103*. (Kelsey, N) (Entered: 10/15/2025)
10/15/2025	12	NOTICE of Appearance by Snigdha Mamillapalli on behalf of Healthcare Distribution Alliance (Mamillapalli, Snigdha) (Entered: 10/15/2025)
10/16/2025	13	MOTION for Attorney(s) Jonathan S. Massey to be Admitted Pro Hac Vice (paid \$200 PHV fee; receipt number ACTDC-8371075) by Healthcare Distribution Alliance. (Attachments: # 1 Affidavit of Jonathan S. Massey, # 2 Certificate of Good Standing)(Finn, Thomas) (Entered: 10/16/2025)
10/16/2025	14	MOTION for Attorney(s) Bret R. Vallacher to be Admitted Pro Hac Vice (paid \$200 PHV fee; receipt number ACTDC-8371106) by Healthcare Distribution Alliance. (Attachments: # 1 Affidavit of Bret R. Vallacher, # 2 Certificate of Good Standing)(Finn, Thomas) (Entered: 10/16/2025)
10/16/2025	15	MOTION for Attorney(s) Austin S. Martin to be Admitted Pro Hac Vice (paid \$200 PHV fee; receipt number ACTDC-8371121) by Healthcare Distribution Alliance. (Attachments: # 1 Affidavit of Austin S. Martin, # 2 Certificate of Good Standing)(Finn, Thomas) (Entered: 10/16/2025)
10/17/2025	16	ORDER denying without prejudice 13 Motion to appear pro hac vice; denying 14 Motion to appear pro hac vice; denying 15 Motion to appear pro hac vice for Attorneys Jonathan S. Massey, Bret R. Vallacher, and Austin S. Martin. Movant has cited to the wrong subparagraph of the local rules, and therefore the motions cannot be granted as filed, but movant may refile the motions with the error corrected. It is so ordered.Signed by Judge Omar A. Williams on 10/17/2025. (Kelsey, N) (Entered: 10/17/2025)
10/17/2025	17	MOTION for Attorney(s) Jonathan S. Massey to be Admitted Pro Hac Vice (paid \$200 PHV fee; receipt number ACTDC-8372596) by Healthcare Distribution Alliance. (Attachments: # 1 Affidavit of Jonathan S. Massey, # 2 Exhibit Certificate of Good Standing - Jonthan S. Massey)(Finn, Thomas) (Entered: 10/17/2025)
10/17/2025	18	MOTION for Attorney(s) Bret R. Vallacher to be Admitted Pro Hac Vice (paid \$200 PHV fee; receipt number ACTDC-8372625) by Healthcare Distribution Alliance. (Attachments: # 1 Affidavit of Bret R. Vallacher, # 2 Certificate of Good Standing - Bret R. Vallacher) (Finn, Thomas) (Entered: 10/17/2025)
10/17/2025	19	MOTION for Attorney(s) Austin S. Martin to be Admitted Pro Hac Vice (paid \$200 PHV fee; receipt number ACTDC-8372644) by Healthcare Distribution Alliance. (Attachments: # 1 Affidavit of Austin S. Martin, # 2 Certificate of Good Standing - Austin S. Martin) (Finn, Thomas) (Entered: 10/17/2025)
10/20/2025	20	ORDER granting 17 Motion to Appear Pro Hac Vice for Attorney Jonathan S. Massey. Signed by Clerk on 10/20/2025. (Kelsey, N) (Entered: 10/20/2025)
10/20/2025	21	ORDER granting 18 Motion to Appear Pro Hac Vice for Attorney Bret R. Vallacher. Signed by Clerk on 10/20/2025. (Kelsey, N) (Entered: 10/20/2025)
10/20/2025	22	ORDER granting 19 Motion to Appear Pro Hac Vice for Attorney Austin S. Martin. Signed by Clerk on 10/20/2025. (Kelsey, N) (Entered: 10/20/2025)

10/21/2025	23	NOTICE of Related Case by Healthcare Distribution Alliance (Finn, Thomas) (Entered: 10/21/2025)
10/21/2025	24	NOTICE of Appearance by Jonathan S. Massey on behalf of Healthcare Distribution Alliance (Massey, Jonathan) (Entered: 10/21/2025)
10/21/2025	25	NOTICE of Appearance by Bret Vallacher on behalf of Healthcare Distribution Alliance (Vallacher, Bret) (Entered: 10/21/2025)
10/21/2025	26	NOTICE of Appearance by Austin Scott Martin on behalf of Healthcare Distribution Alliance (Martin, Austin) (Entered: 10/21/2025)
10/23/2025	27	MOTION for Preliminary Injunction by Healthcare Distribution Alliance. Responses due by 11/13/2025 (Attachments: # 1 Memorandum in Support, # 2 Affidavit of Martin Igel, # 3 Affidavit of Christopher Reed, # 4 Affidavit of Chris Van Norman, # 5 Affidavit of Nicolette Louissaint)(Finn, Thomas) (Entered: 10/23/2025)
10/23/2025	28	SUMMONS Returned Executed by Healthcare Distribution Alliance. Mark D. Boughton served on 10/15/2025, answer due 11/5/2025. (Finn, Thomas) (Entered: 10/23/2025)
10/23/2025	29	SUMMONS Returned Executed by Healthcare Distribution Alliance. William Tong served on 10/15/2025, answer due 11/5/2025. (Finn, Thomas) (Entered: 10/23/2025)
10/23/2025	30	NOTICE of Appearance by Patrick Thomas Ring on behalf of Mark D. Boughton, William Tong (Ring, Patrick) (Entered: 10/23/2025)
10/29/2025	31	Emergency MOTION to Expedite re 27 MOTION for Preliminary Injunction by Healthcare Distribution Alliance. (Finn, Thomas) (Entered: 10/29/2025)
10/30/2025	32	<p>ORDER. The court GRANTS the unopposed 31 Emergency Motion to Expedite and hereby ADOPTS the briefing schedule proposed therein.</p> <p>Defendants shall file a response to the 27 Motion for Preliminary Injunction by November 17, 2025.</p> <p>Plaintiff shall file a reply, if it so chooses, by November 25, 2025.</p> <p>A consolidated hearing on the Motion and a similar Motion for Preliminary Injunction in the related case <i>Association for Accessible Medicines v. Boughton et al</i>, Civil No. 3:25-cv-01757 (OAW), is set for December 9, 2025, at 10:00 a.m., before United States District Judge Omar A. Williams.</p> <p>Defendants shall respond to the 1 Complaint within twenty-one days of the court's decision on the Motion.</p> <p>It is so ordered. Signed by Judge Omar A. Williams on 10/30/2025. (Karamanakis, K) (Entered: 10/30/2025)</p>
10/30/2025	33	<p>Set/Reset Deadlines as to 27 MOTION for Preliminary Injunction. Responses due by 11/17/2025, Plaintiff's reply, if it so chooses, by November 25, 2025.</p> <p>NOTICE OF E-FILED CALENDAR: THIS IS THE ONLY NOTICE COUNSEL/THE PARTIES WILL RECEIVE. ALL PERSONS ENTERING THE COURTHOUSE MUST PRESENT PHOTO IDENTIFICATION.</p> <p>A Consolidated Hearing on the Motion and a similar Motion for Preliminary Injunction set for 12/9/2025 at 10:00 AM in Courtroom Two, 450 Main St., Hartford, CT before Judge Omar A. Williams (Peterson, M) (Entered: 11/04/2025)</p>
11/17/2025	34	Memorandum in Opposition re 27 MOTION for Preliminary Injunction filed by Mark D. Boughton, William Tong. (Ring, Patrick) (Entered: 11/17/2025)

11/25/2025	35	REPLY to Response to 27 MOTION for Preliminary Injunction filed by Healthcare Distribution Alliance. (Finn, Thomas) (Entered: 11/25/2025)
12/04/2025	36	Consent MOTION for Permission to Use Courtroom Technology <i>at Consolidated Hearing on 12/9/2025</i> by Healthcare Distribution Alliance. Responses due by 12/26/2025 (Finn, Thomas) (Entered: 12/04/2025)
12/05/2025	37	ORDER granting 36 Consent Motion for Permission to Use Courtroom Technology. Signed by Judge Omar A. Williams on 12/5/2025. (Karamanakis, K) (Entered: 12/05/2025)
12/05/2025	38	NOTICE. Should any party wish to test any necessary courtroom technology prior to the consolidated hearing on December 9, 2025, they may schedule a time to do so by directly contacting the Courtroom Deputy, at 860-240-3495. Signed by Judge Omar A. Williams on 12/5/2025. (Karamanakis, K) (Entered: 12/05/2025)
12/09/2025	39	NOTICE of Appearance by Victoria Field on behalf of Mark D. Boughton, William Tong (Denault, S) (Entered: 12/09/2025)
12/09/2025	40	Minute Entry. Proceedings held before Judge Omar A. Williams: taking under advisement 27 Motion for Preliminary Injunction; Motion Hearing held on 12/9/2025, re 27 MOTION for Preliminary Injunction filed by Healthcare Distribution Alliance. Total Time: 1 hour and 29 minutes(Court Reporter C. Cullen.) (Wood, R.) (Entered: 12/09/2025)
12/09/2025	41	<p>ORDER requiring Supplemental Briefing.</p> <p>At today's consolidated hearing on the pending Motions for Preliminary Injunction in this case and the related case <i>Association for Accessible Medicines v. Boughton et al</i>, Civil No. 3:25-cv-01757 (OAW), Defendants clarified, <i>for the first time</i>, that it is their position that Sections 345 through 347 of Connecticut Public Act No. 25-168 (hereinafter, the "Act") do <i>not</i> apply to non-Connecticut manufacturers transacting with non-Connecticut distributors outside of Connecticut; <i>nor</i> to non-Connecticut distributors transacting with Connecticut retailers outside of Connecticut. Specifically, Plaintiff Healthcare Distribution Alliance (hereinafter, "HDA") received assurances from Defendants that, when a Connecticut hospital purchases <i>and takes title</i> of a covered product from a non-Connecticut distributor <i>outside of Connecticut</i>, such transaction is <i>not</i> considered a sale "in this state" under the Act, and thus does not expose the distributor to liability under the Act.</p> <p>While HDA and Plaintiff Association for Accessible Medicines (hereinafter, "AAM") appeared relieved by Defendants' assurances at the hearing, they understandably expressed a preference for written confirmation of the same, if even by way of a court ruling which could have the effect of judicial estoppel. Plaintiffs' concern is even more reasonable given that the Act's price cap goes into effect on January 1, 2026, which is quickly approaching.</p> <p>Further, AAM reiterated at the hearing that it previously asked Defendants for such assurances, but had not received a response this helpful prior to initiating litigation. <i>See also</i> Civil No. 3:25-cv-01757 (OAW), ECF No. 20-1, at 12-13.</p> <p>Because the parties' memoranda of law contemplated a more broad application of the Act than Defendants represented at the hearing, <i>see</i> ECF Nos. 27-1, 34, 35, the court hereby ORDERS limited supplemental briefing.</p> <p>The court acknowledges that Plaintiffs carry the burden of demonstrating that they are entitled to injunctive relief; nevertheless, based on their representations at the hearing, the court believes that it would be most efficient for Defendants to submit their brief first, on or before Friday, December 12, 2025. Defendants' brief should explain how their position on the Act's applicability to Plaintiffs' members, as articulated at the hearing, affects the</p>

		<p>merits of the 27 Motion for Preliminary Injunction. Plaintiffs shall file their respective briefs, doing the same, on or before Tuesday, December 16, 2025.</p> <p>No brief shall exceed ten double-spaced pages.</p> <p>To the extent that there now may be areas of agreement regarding any issues in this case, the parties are <i>strongly encouraged</i> to meet, confer, and inform the court by filing a notice on or before Friday, December 12, 2025.</p> <p>The court believes these deadlines to be reasonable based on the record before it, the significance of the January 1 date, and the fact that the parties requested an expedited briefing schedule. <i>See</i> ECF Nos. 31, 32.</p> <p>It is so ordered. Signed by Judge Omar A. Williams on 12/9/2025. (Karamanakis, K) (Entered: 12/09/2025)</p>
12/12/2025	42	TRANSCRIPT of Proceedings: Type of Hearing: Consolidation Hearing. Held on 12/09/2025 before Judge OAW. Court Reporter: Catherine Cullen. IMPORTANT NOTICE - REDACTION OF TRANSCRIPTS: To remove personal identifier information from the transcript, a party must electronically file a Notice of Intent to Request Redaction with the Clerk's Office within seven (7) calendar days of this date. If no such Notice is filed, the court will assume redaction of personal identifiers is not necessary and the transcript will be made available through PACER without redaction 90 days from today's date. The transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. The policy governing the redaction of personal information is located on the court website at www.ctd.uscourts.gov . Redaction Request due 1/2/2026. Redacted Transcript Deadline set for 1/12/2026. Release of Transcript Restriction set for 3/12/2026. (Cullen, Catherine) (Entered: 12/12/2025)
12/12/2025	43	Supplemental Memorandum in Opposition re 27 MOTION for Preliminary Injunction filed by Mark D. Boughton, William Tong. (Ring, Patrick) (Entered: 12/12/2025)
12/16/2025	44	Supplemental RESPONSE re 41 Order,,,,,,,,,, filed by Healthcare Distribution Alliance. (Attachments: # 1 Supplemental Declaration of Michelle Britt, # 2 Supplemental Declaration of Christopher Reed, # 3 Supplemental Declaration of Christopher Van Norman)(Finn, Thomas) (Entered: 12/16/2025)
12/24/2025	45	<p>ORDER. For the reasons articulated in the attached order, Plaintiff's 27 Motion for Preliminary Injunction is DENIED.</p> <p>The parties shall comply with the deadlines therein.</p> <p>It is so ordered. Signed by Judge Omar A. Williams on 12/24/2025. (Karamanakis, K) (Entered: 12/24/2025)</p>
12/26/2025	46	NOTICE OF APPEAL as to 45 Order on Motion for Preliminary Injunction, by Healthcare Distribution Alliance. Filing fee \$ 605, receipt number ACTDC-8446516. (Finn, Thomas) (Entered: 12/26/2025)
12/26/2025	47	MOTION for Injunction Pending Appeal by Healthcare Distribution Alliance. Responses due by 1/16/2026 (Finn, Thomas) (Entered: 12/26/2025)
12/28/2025	48	ORDER. Plaintiff has appealed the court's 45 Order denying its Motion for a Preliminary Injunction, <i>see</i> ECF No. 46, and seeks to enjoin Defendants from enforcing against its members Sections 345 through 347 of Public Act No. 25-168 pending such appeal before the United States Court of Appeals for the Second Circuit, <i>see</i> ECF No. 47, at 1 (citing

Fed. R. Civ. P. 62(d); Fed. R. App. P. 8(a)(1)(C)).

Because granting the instant Motion for an Injunction Pending Appeal would "affect government action taken in the public interest pursuant to a statutory or regulatory scheme," *see Cnty. of Nassau, N.Y. v. Leavitt*, 524 F.3d 408, 414 (2d Cir. 2008) (quoting *Wright v. Giuliani*, 230 F.3d 543, 547 (2d Cir. 2000)), the court cannot do so absent a showing that (i) Plaintiff is "likely to succeed on the merits" of its claims, (ii) its members are "likely to suffer irreparable harm" absent an injunction, (iii) the "balance of equities tips" in its favor, and (iv) a preliminary injunction "would be in the public interest," *see Mahmoud v. Taylor*, 606 U.S. 522, 546 (2025); *see also Salinger v. Colting*, 607 F.3d 68, 79-80 (2d Cir. 2010).

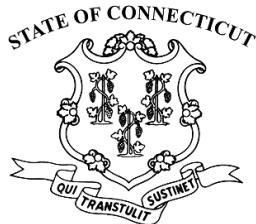
In support of its Motion, Plaintiff points the court to its "prior submissions" and its "arguments" at the hearing on December 9, 2025. ECF No. 47, at 2. The court "carefully has reviewed" such submissions and arguments already, and found them to be insufficient grounds for granting injunctive relief. ECF No. 45, at 1; *see also id.* at 11-18 (explaining that Plaintiff failed to show that it is likely to succeed on the merits of its claims).

Accordingly, the court **DENIES** the [47](#) Motion for an Injunction Pending Appeal for the reasons articulated in the [45](#) Order.

It is so ordered. Signed by Judge Omar A. Williams on 12/28/2025. (Karamanakis, K) (Entered: 12/28/2025)

12/29/2025	49	CLERK'S CERTIFICATE RE: INDEX AND RECORD ON APPEAL re: 46 Notice of Appeal. The attached docket sheet is hereby certified as the entire Index/Record on Appeal in this matter and electronically sent to the Court of Appeals, with the exception of any manually filed documents as noted below. Dinah Milton Kinney, Clerk. Documents manually filed not included in this transmission: none (Denault, S) (Entered: 12/29/2025)
12/31/2025	50	ORDER of USCA as to 46 Notice of Appeal filed by Healthcare Distribution Alliance USCA Case Number 25-3216 (Denault, S) (Entered: 01/05/2026)

PACER Service Center			
Transaction Receipt			
01/05/2026 12:07:43			
PACER Login:	austinmartin	Client Code:	
Description:	Docket Report	Search Criteria:	3:25-cv-01724-OAW
Billable Pages:	7	Cost:	0.70



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Public Act No. 25-168

**AN ACT CONCERNING THE STATE BUDGET FOR THE BIENNIUM
ENDING JUNE 30, 2027, AND MAKING APPROPRIATIONS
THEREFOR, AND PROVISIONS RELATED TO REVENUE AND
OTHER ITEMS IMPLEMENTING THE STATE BUDGET.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (*Effective July 1, 2025*) The following sums are appropriated from the GENERAL FUND for the annual periods indicated for the purposes described.

	2025-2026	2026-2027
LEGISLATIVE		
LEGISLATIVE MANAGEMENT		
Personal Services	60,694,802	64,296,079
Other Expenses	22,660,836	24,954,131
Equipment	3,295,000	3,295,000
Flag Restoration	65,000	65,000
Minor Capital Improvements	4,000,000	4,000,000
Interim Salary/Caucus Offices	750,556	591,748
Connecticut Academy of Science and Engineering	219,000	226,000
Old State House	850,000	900,000
Translators	150,000	150,000
Wall of Fame	10,000	10,000

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Section 501(c)(3) of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as amended from time to time. Such disregard shall be applied for the length of time the family member participates in such program, not to exceed thirty-six cumulative months.

Sec. 343. (NEW) (*Effective July 1, 2025*) To the extent permissible under federal and state law, the Commissioner of Social Services shall disregard from income eligibility determinations any direct rental assistance received under a pilot program by an applicant for state and federal assistance programs administered by the Department of Social Services, including, but not limited to, the temporary family assistance program established pursuant to section 17b-112 of the general statutes. The Commissioner of Social Services may seek any waiver from federal law deemed necessary or amend the Medicaid state plan to implement the provisions of this section.

Sec. 344. (*Effective from passage*) Not later than September 1, 2026, the Transforming Children's Behavioral Health Policy and Planning Committee, in collaboration with the Departments of Education and Social Services, shall develop a framework and operational guidelines to streamline Medicaid billing by municipalities for Medicaid-eligible school-based behavioral health services. Not later than October 1, 2026, the committee shall file a report, in accordance with the provisions of section 11-4a of the general statutes, on the framework and operational guidelines with the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, education and human services.

Sec. 345. (NEW) (*Effective July 1, 2025*) For the purposes of this section and sections 346 and 347 of this act:

(1) "Biological product" has the same meaning as provided in section 20-619 of the general statutes;

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(2) "Brand-name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 USC 355, as amended from time to time, but does not include an authorized generic drug as defined in 42 CFR 447.502, as amended from time to time;

(3) "Commissioner" means the Commissioner of Revenue Services;

(4) "Consumer price index" means the consumer price index, annual average, for all urban consumers: United States city average, all items, published by the United States Department of Labor, Bureau of Labor Statistics, or its successor, or, if the index is discontinued, an equivalent index published by a federal authority, or, if no such index is published, a comparable index published by the United States Department of Labor, Bureau of Labor Statistics;

(5) "Generic drug" means (A) a prescription drug product that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 USC 355, as amended from time to time, (B) an authorized generic drug as defined in 42 CFR 447.502, as amended from time to time, or (C) a drug that entered the market before calendar year 1962 that was not originally marketed under a new prescription drug product application;

(6) "Identified prescription drug" means (A) 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, including any drug-device combination product for the delivery of the brand-name drug or biological product, or (B) a generic drug or interchangeable biological product;

(7) "Interchangeable biological product" has the same meaning as provided in section 20-619 of the general statutes;

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(8) "Person" has the same meaning as provided in section 12-1 of the general statutes;

(9) "Pharmaceutical manufacturer" means a person that manufactures a prescription drug and sells, directly or through another person, the prescription drug for distribution in this state;

(10) "Prescription drug" means a legend drug, as defined in section 20-571 of the general statutes, approved by the federal Food and Drug Administration, or any successor agency, and prescribed by a health care provider to an individual in this state;

(11) "Reference price" means the wholesale acquisition cost, as defined in 42 USC 1395w-3a, as amended from time to time, of (A) a brand-name drug or biological product (i) on January 1, 2025, if the patent for the brand-name drug or biological product expired on or before said date, or (ii) if the patent for the brand-name drug or biological product expires after January 1, 2025, on the date the patent for such brand-name drug or biological product expires, or (B) a generic drug or interchangeable biological product (i) on January 1, 2025, or (ii) 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; and

(12) "Wholesale distributor" means a person, including, but not limited to, a repacker, own-label distributor, private-label distributor or independent wholesale drug trader, engaged in the wholesale distribution of prescription drugs.

Sec. 346. (NEW) (*Effective July 1, 2025*) (a) (1) Notwithstanding any provision of the general statutes and except as provided in subdivision (2) of this subsection, no pharmaceutical manufacturer or wholesale distributor shall, on or after January 1, 2026, sell an identified

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prescription 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.

(2) A pharmaceutical manufacturer or wholesale distributor may, on or after January 1, 2026, sell an identified prescription 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, 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.

(b) (1) Except as provided in subdivision (2) of this subsection, any pharmaceutical manufacturer or wholesale distributor that violates the provisions of subsection (a) of this section shall be liable to this state for a civil penalty. Such civil penalty shall be imposed, calculated and collected on a calendar year basis by the Commissioner of Revenue Services, and the amount of such civil penalty for a calendar year shall be equal to eighty per cent of the difference between:

(A) The revenue that the pharmaceutical manufacturer or wholesale distributor earned from all sales of the identified prescription drug in this state during the calendar year; and

(B) The revenue that the pharmaceutical manufacturer or wholesale distributor would have earned from all sales of the identified prescription drug in this state during the calendar year if the pharmaceutical manufacturer or wholesale distributor had sold such identified prescription drug at a price that did not exceed the reference price for such identified prescription drug, as such reference price is adjusted for any increase in the consumer price index.

(2) No pharmaceutical manufacturer or wholesale distributor of an identified prescription drug shall be liable to this state for the civil

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penalty imposed under subdivision (1) of this subsection unless the pharmaceutical manufacturer or wholesale distributor made at least two hundred fifty thousand dollars in total annual sales in this state for the calendar year for which such civil penalty would otherwise be imposed.

(c) (1) (A) For calendar years commencing on or after January 1, 2026, each pharmaceutical manufacturer or wholesale distributor that violated the provisions of subsection (a) of this section during any calendar year shall, not later than the first day of March immediately following the end of such calendar year:

(i) Pay to the commissioner the civil penalty imposed under subsection (b) of this section for such calendar year; and

(ii) File with the commissioner a statement for such calendar year in a form and manner, and containing all information, prescribed by the commissioner.

(B) A pharmaceutical manufacturer or wholesale distributor that is required to file the statement and pay the civil penalty pursuant to subparagraph (A) of this subdivision shall electronically file such statement and make such payment by electronic funds transfer in the manner provided by chapter 228g of the general statutes, irrespective of whether the pharmaceutical manufacturer or wholesale distributor would have otherwise been required to electronically file such statement or make such payment by electronic funds transfer under chapter 228g of the general statutes.

(2) If no statement is filed pursuant to subdivision (1) of this subsection, the commissioner may make such statement at any time thereafter, according to the best obtainable information and the prescribed form.

(d) The commissioner may examine the records of any

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pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty imposed under subsection (b) of this section as the commissioner deems necessary. If the commissioner determines from such examination that the pharmaceutical manufacturer or wholesale distributor failed to pay the full amount of such civil penalty, the commissioner shall bill such pharmaceutical manufacturer or wholesale distributor for the full amount of such civil penalty.

(e) (1) The commissioner may require each pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty imposed under subsection (b) of this section to keep such records as the commissioner may prescribe, and produce books, papers, documents and other data to provide or secure information pertinent to the enforcement and collection of such civil penalty.

(2) The commissioner, or the commissioner's authorized representative, may examine the books, papers, records and equipment of any person who is subject to the provisions of this section and may investigate the character of the business of such person to verify the accuracy of any statement made or, if no statement is made by such person, to ascertain and determine the amount of the civil penalty due under subsection (b) of this section.

(f) Any pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty imposed under subsection (b) of this section and aggrieved by any action of the commissioner under subdivision (2) of subsection (c) of this section or subsection (d) of this section may apply to the commissioner, in writing and not later than sixty days after the notice of such action is delivered or mailed to such pharmaceutical manufacturer or wholesale distributor, for a hearing, setting forth the reasons why such hearing should be granted and if such pharmaceutical manufacturer or wholesale distributor believes that such pharmaceutical manufacturer or wholesale distributor is not liable for such civil penalty or the full amount of such civil penalty, the grounds

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for such belief and the amount by which such pharmaceutical manufacturer or wholesale distributor believes such civil penalty should be reduced. The commissioner shall promptly consider each such application and may grant or deny the hearing requested. If the hearing request is denied, the commissioner shall immediately notify the pharmaceutical manufacturer or wholesale distributor. If the hearing request is granted, the commissioner shall notify the pharmaceutical manufacturer or wholesale distributor of the date, time and place for such hearing. After such hearing, the commissioner may make such order as appears just and lawful to the commissioner and shall furnish a copy of such order to the pharmaceutical manufacturer or wholesale distributor. The commissioner may, by notice in writing, order a hearing on the commissioner's own initiative and require a pharmaceutical manufacturer or wholesale distributor, or any other person who the commissioner believes to be in possession of relevant information concerning such pharmaceutical manufacturer or wholesale distributor, to appear before the commissioner or the commissioner's authorized agent with any specified books of account, papers or other documents for examination under oath.

(g) Any pharmaceutical manufacturer or wholesale distributor that is aggrieved by any order, decision, determination or disallowance of the commissioner made under subsection (f) of this section may, not later than thirty days after service of notice of such order, decision, determination or disallowance, take an appeal therefrom to the superior court for the judicial district of New Britain, which appeal shall be accompanied by a citation to the commissioner to appear before said court. Such citation shall be signed by the same authority and such appeal shall be returnable at the same time and served and returned in the same manner as is required in case of a summons in a civil action. The authority issuing the citation shall take from the appellant a bond or recognizance to this state, with surety, to prosecute the appeal to effect and to comply with the orders and decrees of the court. Such

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appeals shall be preferred cases, to be heard, unless cause appears to the contrary, at the first session, by the court or by a committee appointed by the court. Said court may grant such relief as may be equitable and, if the civil penalty was paid prior to the granting of such relief, may order the Treasurer to pay the amount of such relief. If the appeal was taken without probable cause, the court may tax double or triple costs, as the case demands and, upon all such appeals that are denied, costs may be taxed against such pharmaceutical manufacturer or wholesale distributor at the discretion of the court but no costs shall be taxed against this state.

(h) The commissioner, and any agent of the commissioner duly authorized to conduct any inquiry, investigation or hearing pursuant to this section, shall have power to administer oaths and take testimony under oath relative to the matter of inquiry or investigation. At any hearing ordered by the commissioner, the commissioner, or the commissioner's agent authorized to conduct such hearing and having authority by law to issue such process, may subpoena witnesses and require the production of books, papers and documents pertinent to such inquiry or investigation. No witness under any subpoena authorized to be issued under the provisions of this section shall be excused from testifying or from producing books, papers or documentary evidence on the ground that such testimony or the production of such books, papers or documentary evidence would tend to incriminate such witness, but such books, papers or documentary evidence so produced shall not be used in any criminal proceeding against such witness. If any person disobeys such process or, having appeared in obedience thereto, refuses to answer any pertinent question put to such person by the commissioner, or the commissioner's authorized agent, or to produce any books, papers or other documentary evidence pursuant thereto, the commissioner, or such agent, may apply to the superior court of the judicial district wherein the pharmaceutical manufacturer or wholesale distributor resides or

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wherein the business was conducted, or to any judge of such court if the same is not in session, setting forth such disobedience to process or refusal to answer, and such court or such judge shall cite such person to appear before such court or such judge to answer such question or to produce such books, papers or other documentary evidence and, upon such person's refusal to do so, shall commit such person to a community correctional center until such person testifies, but not for a period longer than sixty days. Notwithstanding the serving of the term of such commitment by any person, the commissioner may proceed in all respects with such inquiry and examination as if the witness had not previously been called upon to testify. Officers who serve subpoenas issued by the commissioner or under the commissioner's authority and witnesses attending hearings conducted by the commissioner pursuant to this section shall receive fees and compensation at the same rates as officers and witnesses in the courts of this state, to be paid on vouchers of the commissioner on order of the Comptroller from the proper appropriation for the administration of this section.

(i) The amount of any civil penalty unpaid under the provisions of this section may be collected under the provisions of section 12-35 of the general statutes. The warrant provided under section 12-35 of the general statutes shall be signed by the commissioner or the commissioner's authorized agent. The amount of any such civil penalty shall be a lien on the real property of the pharmaceutical manufacturer or wholesale distributor from the last day of the month next preceding the due date of such civil penalty until such civil penalty is paid. The commissioner may record such lien in the records of any town in which the real property of such pharmaceutical manufacturer or wholesale distributor is situated, but no such lien shall be enforceable against a bona fide purchaser or qualified encumbrancer of such real property. When any civil penalty with respect to which a lien was recorded under the provisions of this subsection is satisfied, the commissioner shall, upon request of any interested party, issue a certificate discharging such

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lien, which certificate shall be recorded in the same office in which such lien was recorded. Any action for the foreclosure of such lien shall be brought by the Attorney General in the name of this state in the superior court for the judicial district in which the real property subject to such lien is situated, or, if such property is located in two or more judicial districts, in the superior court for any one such judicial district, and the court may limit the time for redemption or order the sale of such real property or make such other or further decree as the court judges equitable. The provisions of section 12-39g of the general statutes shall apply to all civil penalties imposed under this section.

(j) (1) Any officer or employee of a pharmaceutical manufacturer or wholesale distributor, who owes a duty to the pharmaceutical manufacturer or wholesale distributor to pay the civil penalty imposed under subsection (b) of this section on behalf of such pharmaceutical manufacturer or wholesale distributor, shall file a statement with the commissioner pursuant to subsection (c) of this section on behalf of such pharmaceutical manufacturer or wholesale distributor and keep records or supply information to the commissioner on behalf of such pharmaceutical manufacturer or wholesale distributor pursuant to this section. Any such officer or employee who wilfully fails, at the time required under this section, to pay such civil penalty, file such statement, keep such records or supply such information on behalf of such pharmaceutical manufacturer or wholesale distributor shall, in addition to any other penalty provided by law, be fined not more than one thousand dollars or imprisoned not more than one year, or both. Notwithstanding the provisions of section 54-193 of the general statutes, no such officer or employee shall be prosecuted for a violation of the provisions of this subdivision committed on or after January 1, 2026, except within three years next after such violation is committed.

(2) Any officer or employee of a pharmaceutical manufacturer or wholesale distributor, who owes a duty to the pharmaceutical

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manufacturer or wholesale distributor to deliver or disclose to the commissioner, or the commissioner's authorized agent, any list, statement, return, account statement or other document on behalf of such pharmaceutical manufacturer or wholesale distributor, and who wilfully delivers or discloses to the commissioner, or the commissioner's authorized agent, any such list, statement, return, account statement or other document that such officer or employee knows to be fraudulent or false in any material matter shall, in addition to any other penalty provided by law, be guilty of a class D felony.

(3) No officer or employee of a pharmaceutical manufacturer or wholesale distributor shall be charged with an offense under both subdivisions (1) and (2) of this subsection in relation to the same civil penalty, but such officer or employee may be charged and prosecuted for both such offenses upon the same information.

(k) Each civil penalty imposed under subsection (b) of this section shall be deemed to constitute a civil fine or penalty within the meaning of 42 USC 1396b(w), as amended from time to time. No portion of any civil penalty imposed under subsection (b) of this section shall be waived under section 12-3a of the general statutes or any other applicable law. No tax credit shall be allowable against any civil penalty imposed under subsection (b) of this section.

(l) Not later than July 1, 2027, and annually thereafter, the commissioner shall prepare a list containing the name of each pharmaceutical manufacturer or wholesale distributor that violated subsection (a) of this section during the preceding calendar year. The commissioner shall make each such list publicly available.

(m) The commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section.

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Sec. 347. (NEW) (*Effective July 1, 2025*) (a) No pharmaceutical manufacturer or wholesale distributor of an identified prescription drug shall withdraw the identified prescription drug from sale in this state for the purpose of avoiding the civil penalty established in subsection (b) of section 346 of this act.

(b) Any pharmaceutical manufacturer or wholesale distributor that intends to withdraw an identified prescription drug from sale in this state shall, at least one hundred eighty days before such withdrawal, send advance written notice to the Office of Health Strategy disclosing such pharmaceutical manufacturer's or wholesale distributor's intention.

(c) Any pharmaceutical manufacturer or wholesale distributor that violates the provisions of subsection (a) or (b) of this section shall be liable to this state for a civil penalty in the amount of five hundred thousand dollars.

Sec. 348. Subsection (b) of section 17b-238 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2027*):

(b) Any institution or agency to which payments are to be made under sections 17b-239 to 17b-246, inclusive, and sections 17b-340 and 17b-343 which is aggrieved by any decision of said commissioner may, within ten days after written notice thereof from the commissioner, obtain, by written request to the commissioner, a rehearing on all items of aggrievement. On and after July 1, 1996, a rehearing shall be held by the commissioner or his designee, provided a detailed written description of all such items is filed within ninety days of written notice of the commissioner's decision. The rehearing shall be held within thirty days of the filing of the detailed written description of each specific item of aggrievement. The commissioner shall issue a final decision within sixty days of the close of evidence or the date on which final briefs are

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

HEALTHCARE DISTRIBUTION ALLIANCE, : CIVIL ACTION NO. : 3:25-cv-1724

Plaintiff,

v.

MARK D. BOUGHTON, in his official capacity as Commissioner of the Connecticut Department of Revenue Services, and WILLIAM TONG, in his official capacity as Attorney General for the State of Connecticut,

Defendants.

: OCTOBER 14, 2025

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Healthcare Distribution Alliance (“HDA”) brings this complaint against Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services (“Commissioner”), and William Tong, in his official capacity as Attorney General for the State of Connecticut (“Attorney General” and collectively, “Defendants”). HDA brings this complaint on behalf of its members, based on personal knowledge as to HDA facts and upon information and belief as to all other matters:

NATURE OF THE ACTION

1. In this action, HDA challenges an extraordinary Connecticut law, the Drug Price Cap of Public Act No. 25-168 (“the Drug Price Cap”), which seeks to cap the prices charged by manufacturers and wholesale distributors for off-patent branded drugs, generic drugs, and interchangeable biologic products (the “covered products”). The Drug Price Cap threatens to disrupt the essential logistical function performed by wholesale distributors: ensuring the safe, efficient, and reliable delivery of 10.5 million healthcare products every day from manufacturers to pharmacies, hospitals, and other healthcare providers.

2. The Drug Price Cap freezes the price of a covered product at the Wholesale Acquisition Cost (“WAC”) (*i.e.*, the manufacturer’s list price) as of January 1, 2025, adjusted by the Consumer Price Index (“CPI”), unless the drug or biological product has been identified by the federal Department of Health and Human Services (“HHS”) as being in shortage. Wholesale distributors do not set or control the WAC for drug products, and they do not introduce or withdraw drugs from the national market. Yet the Drug Price Cap imposes massive penalties on wholesale distributors if covered products are sold in Connecticut at prices exceeding the WAC. These draconian penalties include imprisonment for officers or employees of wholesaler distributors for the conduct of third-party manufacturers outside their control.

3. First and foremost, the Drug Price Cap violates the Commerce Clause’s per se prohibition on extraterritorial state legislation. Though cast as a local economic regulation, the Drug Price Cap targets commerce and pricing decisions that occur wholly outside Connecticut. Drug manufacturers (not wholesale distributors) set the WAC, and they do so on a national, not state-by-state, basis. Wholesale distributors also operate on an interstate basis under contracts with manufacturers that are not tailored to individual states. Indeed, no member of HDA has any distribution facility inside Connecticut. By capping prices set at the national level, Connecticut’s law effectively governs out-of-state commerce.

4. If permitted to stand, the Drug Price Cap would encourage other states to apply their own views of what price increases are permissible nationwide, resulting in a patchwork of inconsistent and conflicting pricing regimes. Wholesale distributors would be forced to navigate different sets of rules, and fragmentation of the market would increase drug costs, hinder supply chain efficiencies, establish inconsistent pricing for patients across state lines, and ultimately reduce reliable access to affordable medications for patients nationwide.

5 Separate from its impermissible direct regulation of wholly out-of-state transactions, the Drug Price Cap further violates the Commerce Clause by imposing an excessive burden on interstate commerce. The Drug Price Cap would discourage wholesale distributors from participating in the Connecticut market and risk isolating the state from the national drug market. Those negative effects impose a substantial burden on interstate commerce, which far outweighs any interest Connecticut may have in controlling drug prices.

6. The Drug Price Cap also violates the fundamental requirement of due process by imposing massive financial penalties on wholesale distributors for third-party conduct beyond their control. Given that wholesale distributors play no role in setting the WAC, the law's imposition of liability on distributors for manufacturer-driven pricing decisions is both inequitable and unsustainable as a matter of due process.

7. HDA members face imminent and irreparable injury from the Drug Price Cap. Indeed, WAC prices for numerous covered products have *already* increased during calendar year 2025 or are set to increase before the end of 2025. Because the Drug Price Cap uses the January 1, 2025 WAC (adjusted by the CPI) as its reference price, wholesale distributors *already* face a Hobson's choice: either (1) buy the covered product at the manufacturer's price *above* the January 1, 2025 WAC and sell to Connecticut customers at the January 1, 2025 WAC (*i.e.*, a *lower* price), or (2) sell to Connecticut customers at a price above the January 1, 2025 WAC and face severe civil penalties under the Drug Price Cap. Moreover, history indicates that in the future manufacturers will inevitably increase prices for additional covered products above the January 1, 2025 WAC (adjusted by the CPI). And if wholesale distributors attempt to avoid the Drug Price Cap by withdrawing a covered product from Connecticut, they will face a separate \$500,000 civil

penalty. In any scenario, both HDA members and the public at large will suffer irreparable harm if the Drug Price Cap is implemented or enforced.

8. No federal appellate court has sustained the constitutionality of a similar law. State-level drug price caps have been invalidated in Maryland, Minnesota, and the District of Columbia. *See Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 668 (4th Cir. 2018) (“A state law violates the extraterritoriality principle if it . . . expressly applies to out-of-state commerce.”); *id.* at 672 (“[T]he Act is effectively a price control statute that instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland.”); *Ass'n for Accessible Meds. v. Ellison*, 140 F.4th 957, 959–60 (8th Cir. 2025) (holding that a similar statute, which prohibited manufacturers of prescription drugs from “impos[ing], or caus[ing] to be imposed, an excessive price increase . . . on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state,” had “the specific impermissible extraterritorial effect of controlling prices outside of Minnesota”) (alterations in original); *Pharm. Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 69–70 (D.D.C. 2005) (holding that the law “effect[ed] an impermissible extraterritorial reach” even though its application was “triggered by an in-state sale”), *aff'd sub nom. Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007); *see also Pharm. Rsch. & Mfrs. of Am. v. Comm'r, Maine Dep't of Hum. Servs.*, Civ. 00-157-B-H, 2000 WL 34290605, at *2 (D. Me. Oct. 26, 2000) (striking down Maine drug price cap on extraterritoriality grounds), *rev'd on other grounds sub nom. Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001).¹

¹ A federal court recently denied a preliminary injunction motion against an Illinois drug price regulation on the basis of a Commerce Clause challenge, Memorandum Opinion and Order, *Ass'n for Accessible Meds. v. Raoul*, Case No. 1:24-cv-00544, 2025 WL 2764558 (N.D. Ill. Sept. 26, 2025), but its reasoning is unconvincing.

9. For these reasons, and as explained below, HDA seeks an injunction against the implementation and enforcement of the Drug Price Cap, a declaration that the Drug Price Cap is unconstitutional, preempted, and invalid on its face, and any other relief this Court deems appropriate.

JURISDICTION AND VENUE

10. HDA's causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court thus has subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1333(a)(3).

11. The Drug Price Cap is effective July 1, 2025. That it does not purport to govern transactions until January 1, 2026 does not render this action unripe. *See, e.g., Pierce v. Soc'y of Sisters of the Holy Names of Jesus & Mary*, 268 U.S. 510, 536 (1925).

12. This Court has personal jurisdiction over Defendants because Defendants reside within this judicial district.

13. Venue is appropriate in this district pursuant to 28 U.S.C. § 1333(b), because a substantial part of the events giving rise to these claims have occurred or will occur in this district and because Defendants reside in this District.

THE PARTIES

14. HDA is a national trade association representing pharmaceutical wholesale distributors. Its core mission is to promote the safe, efficient and secure distribution of pharmaceutical products to licensed healthcare providers and patients across the United States. HDA members ship approximately 10.5 million diverse medical products across the nation every day. A substantial part of HDA's mission is to advocate for its members' interests, including

through lobbying and litigation, and this lawsuit is germane to its purpose. HDA is authorized by its Board of Directors to bring this suit on its members' behalf.

15. Mark D. Boughton is Commissioner of the Connecticut Department of Revenue Services, and charged with implementation and enforcement of the Drug Price Cap. Public Act No. 25-168, § 345(3).

16. William Tong is Attorney General for the State of Connecticut and responsible for the enforcement of the statutes of Connecticut.

17. Defendants and those subject to Defendants' supervision, direction, or control are responsible for the enforcement of the Act. In enforcing, administering, and adhering to the Act, Defendants and those subject to Defendants' supervision, direction, or control will act under color of state law.

BACKGROUND

I. Connecticut's Drug Price Cap

18. The Drug Price Cap establishes a "reference price" for branded drug products that have been off patent for at least 24 months, generic drug products, and interchangeable biologic products. Public Act No. 25-168, § 345. The "reference price" is defined as the WAC on January 1, 2025 for branded drug products when the patent has expired, the WAC on the date a patent expires, or for generic drugs, the WAC on January 1, 2025 or when the product is first commercially available. *Id.* § 345(11).

19. Beginning on January 1, 2026, a manufacturer or wholesaler is prohibited from selling a covered product in Connecticut at a price that exceeds the reference price adjusted for any increase in the CPI unless the drug has been identified by HHS as being in shortage. *Id.* § 346(a).

20. Any manufacturer or wholesaler that violates this provision is subject to civil penalty equal to 80% of the difference between: (i) revenue the manufacturer or wholesaler would have earned from all sales of the identified drug in the state in the calendar year, and (ii) revenue that the manufacturer or wholesale distributor would have earned from all sales of the drug in the state during the calendar year if the manufacturer or wholesaler had sold the product at a price that did not exceed the reference price. *Id.* § 346(b)(1). Entities are not held liable if sales in Connecticut are under \$250,000. *Id.* § 346(b)(2).

21. Penalties extend to officers and employees of the manufacturer or wholesaler who owe a duty to pay the civil penalty imposed, or who are to deliver or disclose information to the Commissioner. These penalties can include a fine of up to \$1,000/day, one year imprisonment, or imposition of a Class D felony. *Id.* § 346(j).

22. The law also prohibits wholesalers from withdrawing prescription drugs from Connecticut without 180 days' notice and also prohibits them from withdrawing drugs for the purpose of avoiding the civil penalties prescribed by the Act, subject to a \$500,000 civil penalty. *Id.* § 347.

23. The Drug Price Cap does not apply to the in-state Connecticut retailers and other entities (such as medical practices, hospitals, and other licensed healthcare providers) that actually sell covered products to consumers. Those retailers and other entities are free to charge whatever they wish under the Drug Price Cap, which applies only to out-of-state manufacturers and wholesale distributors. *Id.* § 346.

II. The Role of Wholesale Distributors in the Pharmaceutical Supply Chain

24. The U.S. pharmaceutical supply chain is a complex system. It comprises several kinds of entities that work to ensure products' safe, secure, and efficient delivery. Wholesale

distributors move products from manufacturers to healthcare institutions, providers, and pharmacies. These distributors do not manufacture, produce, or prescribe pharmaceutical products, nor do they engage in pharmaceutical research and development. Rather, they coordinate receipt and delivery of pharmaceutical products from the manufacturers who make them and who, in many cases, market them to pharmacies, hospitals, and other licensed dispensers, who provide them to patients when prescribed.

25. By serving as intermediaries, distributors reduce the number of transactions that would occur if providers and retailers had to order products directly from manufacturers. Distributors efficiently and securely serve more than 200,000 U.S.-based pharmacies, hospitals, clinics, long-term care facilities, and other patient-facing organizations. They do this through a network of distribution centers geographically dispersed across the nation, each of which processes 4,100 orders daily on average. These distribution centers and the systems they support provide consistent just-in-time delivery to their service areas so that providers can reliably deliver high quality care to patients.

26. In the interest of efficiency, distributors work closely with manufacturers, providers, and other supply-chain partners to accurately forecast demand and ensure timely and secure delivery to pharmacies and other licensed providers. Distributors also manage inventory, provide financial credit, maintain pharmacy management systems, and support retail operations.

27. Distributors invest significant time, energy, and resources to ensure that pharmaceutical products are shipped under the right conditions to the right customers at the right time. They ensure safe supply chains by maintaining drugs' proper temperatures, providing manufacturers data on where their products are used, verifying that customers are eligible to purchase products, and complying with federal and state regulations.

28. These services are critical. Without distributors, each medical provider would have to order, receive, and store products directly from manufacturers. Without distributors' just-in-time delivery, medical providers would have to maintain large inventories of expensive products. Inventories at local distribution facilities prevent critical medical products from going out of stock. These functions make the supply chain more efficient, reliable, and secure, and they ensure that patients can get medicines when they need them.

III. The Drug Price Cap Seeks to Regulate Extraterritorial Drug Pricing Decisions.

29. Manufacturers set the WAC for drug products on a national basis, outside Connecticut. Even the Drug Price Cap itself acknowledges the nationwide nature of drug price determinations, by referring to *national* pricing benchmarks in connection with its own price provisions. Under § 345(11), the term “wholesale acquisition cost,” commonly known as WAC, is given the same meaning as in Title 42 of the U.S. Code. *See* 42 U.S.C. § 1395w-3A(c)(6)(B) (defining “wholesale acquisition cost” to mean “the manufacturer’s list price for the drug . . . to wholesalers or direct purchasers in the United States . . . as reported in wholesale price guides or other publications of drug or biological pricing data”).

30. Wholesale distributors also operate on an interstate, rather than state-by-state, basis. Given the integrated nature of the pharmaceutical supply chain, wholesale distributors structure their contractual relationships with manufacturers and with downstream customers with multistate operations through interstate agreements that apply uniformly across states. Further, many customers of wholesale distributors typically maintain operations across numerous states and expect pricing to be consistent, rather than subject to variation based on individual state markets.

31. No member of HDA has any distribution facility inside Connecticut. Products distributed in Connecticut are shipped from distribution centers located outside the state.

32. In short, the relevant pricing decisions are made outside Connecticut. By imposing state-specific pricing controls, the Drug Price Cap governs out-of-state commerce and threatens to disrupt the uniformity of the national pharmaceutical market. The law's extraterritorial scope could hardly be clearer.

PLAINTIFF'S CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

**(Declaratory/Injunctive Relief against All Defendants—
Unconstitutional Extraterritorial Regulation)**

33. Plaintiff re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

34. The Commerce Clause not only vests Congress with "Power . . . [t]o regulate Commerce with foreign Nations, and among the several States," U.S. Const. art. I, § 8, cl. 3, but also prohibits states from interfering with interstate commerce. "The critical inquiry" under this "dormant" aspect of the Commerce Clause "is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Healy v. Beer Institute, Inc.*, 491 U.S. 324, 336 (1989).

35. In addition, the "Constitution's horizontal separation of powers"—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, the "historical understandings of the Constitution's structure," and "the principles of 'sovereignty and comity' it embraces"—prohibits states from directly regulating transactions that occur wholly outside their borders. *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 376 & n.1 (2023) (citation omitted).

36. The Drug Price Cap violates the Commerce Clause because it directly regulates interstate commerce and prices beyond the boundaries of the State of Connecticut and expressly targets pricing determinations and conduct occurring exclusively outside of the state. Indeed, the Drug Price Cap itself acknowledges and refers to *national* pricing benchmarks (WAC) in connection with its own price provisions.

37. Because the Drug Price Cap regulates conduct occurring entirely outside of the State of Connecticut and “has the practical effect of establishing ‘a scale of prices for use in other states,’” *Healy*, 491 U.S. at 336 (quoting *Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511, 528 (1935)), it violates the Commerce Clause, and is void.

38. The Drug Price Cap further interferes with interstate commerce because it prohibits wholesalers from withdrawing prescription drugs from Connecticut without 180 days’ notice and from withdrawing drugs for the purpose of avoiding the civil penalties prescribed by the Act, subject to a \$500,000 civil penalty. In fact, the requirement not to “withdraw” drugs from the state is nonsensical because wholesale distributors have no distribution centers in Connecticut in the first place.

SECOND CAUSE OF ACTION

(Declaratory/Injunctive Relief against All Defendants— Excessive Burden on Interstate Commerce)

39. Plaintiff re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

40. Even if Connecticut’s attempt to directly regulate out-of-state transactions were not per se invalid, it would still violate the Commerce Clause because the burden imposed on interstate commerce by such extraterritorial regulation “is clearly excessive in relation to the putative local benefits.” *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

41. The substantial disruptions caused by Connecticut's pricing regime, which could potentially be followed by other states, will create enormous inefficiencies in the supply chain and result in significant delays in the supply and delivery of, and reliable patient access to, life-saving medicines throughout the United States. The law will also force wholesale distributors to incur substantial costs to alter their contracting and delivery processes, or to comply with the law nationwide. HDA members will suffer financial injury as a result of the Drug Price Cap regardless of the option they choose. Those cumulative effects on all relevant market actors impose a substantial burden on interstate commerce, which far outweighs any interest Connecticut may have. Accordingly, the Drug Price Cap is unconstitutional.

THIRD CAUSE OF ACTION

(Declaratory/Injunctive Relief against All Defendants— Arbitrary and Confiscatory Rates of Return)

42. Plaintiff re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

43. The Drug Price Cap denies wholesale distributors a fair and reasonable return by freezing prices at the January 1, 2025 WAC, adjusted by the CPI, unless the drug has been identified by HHS as being in shortage. This ignores the substantial contribution made by wholesale distributors to the healthcare system and will produce arbitrary, unreasonable, and confiscatory rates of return for wholesale distributors.

44. The Due Process Clause of the Fourteenth Amendment provides that no state may deprive a person "of life, liberty, or property, without due process of law." The Equal Protection Clause protects Plaintiff and its members against arbitrary action. And the Fifth Amendment provides that "private property" shall not "be taken for public use[] without just compensation." The Drug Price Cap violates each of these constitutional guarantees.

FOURTH CAUSE OF ACTION**(Declaratory/Injunctive Relief against All Defendants—Due Process)**

45. Plaintiff re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

46. The Drug Price Cap exposes wholesale distributors to penalties for activities beyond their control. Wholesale distributors operate under contract with manufacturers and do not set or control the WAC for drug products.

47. Imposing penalties on wholesale distributors (and their officers and employees) for activities beyond their control violates the Due Process Clause of the Fourteenth Amendment, which provides that no state may deprive a person “of life, liberty, or property, without due process of law.” The Due Process Clause restricts states’ authority to “regulate and control activities wholly beyond [their] boundaries,” *Watson v. Emps. 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 omitted) (citation omitted).

FIFTH CAUSE OF ACTION**(Declaratory/Injunctive Relief Against all Defendants—Impairment of Contracts)**

48. The Drug Price Cap imposes a severe and unexpected liability on wholesale distributors simply for carrying out their obligations under their contracts with manufacturers and with customers such as pharmacies, medical practices, and hospitals.

49. The impairment is not a necessary and reasonable exercise of the state’s police power to serve a significant public purpose.

50. Accordingly, the Drug Price Cap violates the Impairment of Contracts Clause of Article I, § 10, cl. 1. *See Allied Structural Steel v. Spannaus*, 438 U.S. 234 (1978).

SIXTH CAUSE OF ACTION

(Declaratory/Injunctive Relief Against all Defendants— Preemption Under the Supremacy Clause)

51. Plaintiff re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

52. The Drug Price Cap is preempted insofar as it purports to dictate the prices that federal healthcare programs—such as Medicare, TRICARE, the Veterans Health Administration, and the Federal Employees Health Benefits Program—are required to pay for prescription drugs on behalf of beneficiaries of those programs. In doing so, the Drug Price Cap directly regulates federal activities and interferes with the operation of federal healthcare programs. It is well settled that “the activities of the Federal Government are free from regulation by any state.” *Mayo v. United States*, 319 U.S. 441, 445 (1943).

53. In addition, the Drug Price Cap is preempted by federal statutes, including the Inflation Reduction Act (42 U.S.C. § 1320f), Medicare drug pricing provisions, and the 340B Drug Pricing Program, which together establish comprehensive federal oversight of pharmaceutical pricing and access. For example, federal Medicare programs contain “sweeping” preemption provisions that displace the Drug Price Cap. *Pharm. Care Mgmt. Ass’n v. Mulready (PCMA)*, 78 F.4th 1183, 1206 (10th Cir. 2023). Medicare Parts C and D are public-private partnerships between the federal Centers for Medicare & Medicaid Services and private insurers (called plan sponsors). Plan sponsors may offer prescription-drug coverage to Medicare recipients and must abide by federal statutes and regulations in doing so. Against that “backdrop of extensive federal regulation,” Medicare Parts C and D have “broad preemption clause[s].” *Id.* at 1205. Those

clauses provide, in relevant part, that “[t]he standards established under [Part C or D] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Part C or D plans] which are offered by [plan sponsors] under [Part C or D].” 42 U.S.C. § 1395w-26(b)(3) (Part C); *see id.* § 1395w-112(g) (incorporating same preemption clause into Part D). The Tenth Circuit has held that this “sweeping” preemption language “is ‘akin to field preemption’ and precludes States from regulating Part [C or] D plans except for licensing and plan solvency.” *PCMA*, 78 F.4th at 1206 (citation omitted).

54. These principles make clear that Connecticut’s Drug Price Cap is preempted insofar as it purports to dictate the prices that Medicare and other federal healthcare programs must pay for prescription drugs on behalf of beneficiaries of those programs.

SEVENTH CAUSE OF ACTION

(All Defendants—42 U.S.C. § 1983 and 42 U.S.C. § 1988)

55. Plaintiff re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

56. By seeking to implement and threatening to enforce the Drug Price Cap, Defendants, acting under color of state law, have violated and, unless enjoined by this Court, will continue to violate the rights of HDA members to engage in interstate commerce free from unconstitutional state interference as well as their rights under other constitutional provisions.

57. An actual “Case or Controversy” exists because the Drug Price Cap’s constitutional infirmities create a genuine, credible, and immediate threat that Defendants—acting in their official capacities under color of state law—will violate Plaintiff’s constitutionally protected rights. HDA’s members have no adequate remedy at law available against Defendants for the infringement of their constitutional rights.

58. Plaintiff accordingly seeks a declaration that Defendants' implementation or enforcement of the Drug Price Cap would violate 42 U.S.C. § 1983. Plaintiff also seeks reasonable attorneys' fees pursuant to 42 U.S.C. § 1988.

RELIEF REQUESTED

WHEREFORE, HDA prays:

- A. For a declaration, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that the Drug Price Cap violates the United States Constitution, including but not limited to the dormant Commerce Clause, the Supremacy Clause, the Impairment of Contracts Clause, and the Fifth and Fourteenth Amendments, and is therefore void on its face and unenforceable;
- B. For a preliminary injunction prohibiting Defendants and their agents, servants, employees, and all persons in active concert or participation with them from implementing or enforcing the Drug Price Cap;
- C. For a permanent injunction prohibiting Defendants and their agents, servants, employees, and all persons in active concert or participation with them from implementing or enforcing the Drug Price Cap;
- D. For such costs and reasonable attorneys' fees to which it might be entitled by law; and
- E. For any other relief that the Court deems just and proper.

Dated: October 14, 2025
Hartford, Connecticut

Respectfully submitted,

/s/ Thomas J. Finn
Thomas J. Finn (ct20929)
Snigdha Mamillapalli (ct31142)
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*Attorneys for Healthcare Distribution
Alliance*

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

Healthcare Distribution Alliance,

Plaintiff,

v.

Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services, and William Tong, in his official capacity as Attorney General for the State of Connecticut,

Defendants.

Case No. 3:25-cv-1724 (OAW)

**DECLARATION OF MARTIN IGEL IN SUPPORT OF PLAINTIFF'S MOTION FOR
PRELIMINARY INJUNCTION**

I, Martin Igel, am over 18 years of age and hereby declare as follows:

1. I am the Vice President of Strategic Sourcing and Manufacturer Services at Cardinal Health, Inc. (“Cardinal Health”) and provide this declaration based on my own personal knowledge.
2. Wholesale distributors in the pharmaceutical industry play a critical role in ensuring the safe, efficient, and reliable delivery of healthcare products every day from manufacturers to pharmacies, hospitals, and other healthcare providers. Distributors provide sophisticated services, including thermally controlled packaging and transport, electronic data reporting, advanced analytics, administrative third-party contract management, exception management systems, quality controls, and inventory logistics.
3. Distributors efficiently and securely serve pharmacies, hospitals, clinics, long-term care facilities, and other patient-facing organizations. They do this through a network of

distribution centers geographically dispersed across the nation. These distribution centers and the systems they support provide consistent just-in-time delivery to their service areas so that providers can reliably deliver high quality care to patients.

4. Cardinal Health serves pharmacies, hospitals, and other healthcare providers in Connecticut. But Cardinal Health does not have a distribution center in Connecticut. Instead, products we distribute in Connecticut are shipped from distribution centers outside Connecticut.
5. Wholesale distributors do not set or control the Wholesale Acquisition Cost (“WAC”) for drug products. Instead, manufacturers set the WAC for drug products on a national basis, and those decisions occur outside Connecticut. Wholesale distributors also operate on a national (rather than a state-by-state) basis, under contracts with manufacturers that are not tailored to individual states. Given the integrated nature of the pharmaceutical supply chain, wholesale distributors structure their contractual relationships with manufacturers and downstream customers with multistate operations through national agreements that apply uniformly across states.
6. Cardinal Health faces imminent and irreparable injury from the Drug Price Cap. When manufacturers inevitably increase prices for one or more covered products above the 2025 WAC (adjusted by the CPI), wholesale distributors (and their officers and employees) will face severe potential liability (including criminal sanctions) under the statute even though they do not set or control the WAC.

I declare under penalty of perjury that the foregoing is true and correct.

Date: October 17, 2025

Martin Igel
Martin Igel (Oct 17, 2025 14:03:12 EDT)

Martin Igel
Vice President
Strategic Sourcing and Manufacturer Services
Cardinal Health, Inc.

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

Healthcare Distribution Alliance,

Plaintiff,

v.

Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services, and William Tong, in his official capacity as Attorney General for the State of Connecticut,

Defendants.

DECLARATION

Case No. 3:25-cv-1724 (OAW)

**DECLARATION OF CHRISTOPHER REED IN SUPPORT OF PLAINTIFF'S MOTION
FOR PRELIMINARY INJUNCTION**

I, Christopher Reed, am over 18 years of age and hereby declare as follows:

1. I oversee distribution operations at Cencora, Inc. and provide this declaration based on my own personal knowledge.
2. Wholesale distributors in the pharmaceutical industry play a critical role in ensuring the safe, efficient, and reliable delivery of millions of healthcare products every day from manufacturers to pharmacies, hospitals, and other healthcare providers. Distributors provide sophisticated services, including thermally controlled packaging and transport, electronic data reporting, advanced analytics, administrative third-party contract management, exception management systems, quality controls, and inventory logistics.
3. Distributors efficiently and securely serve tens of thousands of U.S.-based pharmacies, hospitals, clinics, long-term care facilities, and other patient-facing organizations. They do this through a network of distribution centers

geographically dispersed across the nation. These distribution centers and the systems they support provide consistent just-in-time delivery to their service areas so that providers can reliably deliver high quality care to patients.

4. My company serves pharmacies, hospitals, and other healthcare providers in Connecticut. But my company has no distribution center in Connecticut. Instead, medical products we distribute in Connecticut are shipped from distribution centers outside Connecticut.
5. Wholesale distributors do not set or control the Wholesale Acquisition Cost (“WAC”) for drug products. Instead, manufacturers set the WAC for drug products on a national basis. Wholesale distributors also operate on a national (rather than a state-by-state) basis, under contracts with manufacturers that are not tailored to individual states. Given the integrated nature of the pharmaceutical supply chain, wholesale distributors structure their contractual relationships with manufacturers and with downstream customers through national agreements that apply uniformly across states.
6. My company faces imminent and irreparable injury from the Drug Price Cap. When manufacturers inevitably increase prices for one or more covered drugs or products above the 2025 WAC (adjusted by the CPI), wholesale distributors (and their officers and employees) will face severe potential liability (including criminal sanctions) under the statute even though they do not set or control the WAC.

Further affiant sayeth not.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on October 19, 2025.

Reed, Christopher
(a107264)

 Digitally signed by Reed,
Christopher (a107264)
Date: 2025.10.19 13:59:24 -04'00'

Christopher Reed, Vice President

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

Healthcare Distribution Alliance,

Plaintiff,

v.

Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services, and William Tong, in his official capacity as Attorney General for the State of Connecticut,

Defendants.

DECLARATION

Case No. 3:25-cv-1724 (OAW)

**DECLARATION OF CHRIS VAN NORMAN IN SUPPORT OF PLAINTIFF'S MOTION
FOR PRELIMINARY INJUNCTION**

I, Chris Van Norman, am over 18 years of age and hereby declare as follows:

1. I am the Senior Vice President, Supply Chain Operations at McKesson Corp. and provide this declaration based on my own personal knowledge.
2. Wholesale distributors in the pharmaceutical industry play a critical role in ensuring the safe, efficient, and reliable delivery of healthcare products from manufacturers to pharmacies, hospitals, and other healthcare providers. Distributors provide sophisticated services, including thermally controlled packaging and transport, electronic data reporting, advanced analytics, administrative third-party contract management, exception management systems, quality controls, and inventory logistics.
3. Distributors serve pharmacies, hospitals, clinics, long-term care facilities, and other patient-facing organizations through a network of distribution centers geographically dispersed across the nation. These distribution centers and the

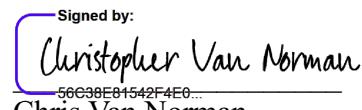
systems they support provide consistent just-in-time delivery to their service areas so that providers can reliably deliver high quality care to patients.

4. McKesson serves pharmacies, hospitals, and other healthcare providers in Connecticut. But my company has no distribution center in Connecticut. Instead, medical products we distribute in Connecticut are shipped from distribution centers outside Connecticut.
5. Wholesale distributors do not set or control the Wholesale Acquisition Cost (“WAC”) for drug products. Instead, manufacturers set the WAC for drug products on a national basis, and those decisions occur outside Connecticut. Wholesale distributors also operate on a national (rather than a state-by-state) basis, under contracts with manufacturers that are not tailored to individual states. Given the integrated nature of the pharmaceutical supply chain, wholesale distributors structure their contractual relationships with manufacturers and with downstream customers through national agreements that apply uniformly across states.
6. McKesson faces imminent and irreparable injury from the Drug Price Cap. When manufacturers inevitably increase prices for one or more covered drugs or products above the January 1, 2025 WAC (adjusted by the CPI), we will face the choice of whether (1) to buy the covered product at the manufacturer’s price **above** the January 1, 2025 WAC and sell to Connecticut customers at the statutory reference price (i.e., the **lower** price of January 1, 2025 WAC), or (2) to sell to Connecticut customers at a price above the January 1, 2025 WAC and face severe

civil penalties under the Drug Price Cap. We will face this dilemma even though we do not set or control the WAC.

Further affiant sayeth not.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on 10/20/2025.

Signed by:

Christopher Van Norman
56C38E01542F4E0...
Chris Van Norman

Date: 10/20/2025

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

Healthcare Distribution Alliance,

Plaintiff,

v.

Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services, and William Tong, in his official capacity as Attorney General for the State of Connecticut,

Defendants.

DECLARATION

Case No. 3:25-cv-1724 (OAW)

**DECLARATION OF NICOLETTE LOUSSAINT IN SUPPORT OF PLAINTIFF'S
MOTION FOR PRELIMINARY INJUNCTION**

I, Nicolette Louissaint, PhD, am over 18 years of age and hereby declare as follows:

1. I am the Chief Policy Officer at Healthcare Distribution Alliance and provide this declaration based on my own personal knowledge.
2. I understand that Connecticut's Drug Price Cap of Public Act No. 25-168 ("the Drug Price Cap") applies to branded drugs that have been off-patent for at least 24 months, generic drugs, and interchangeable biologic products (the "covered products").
3. Wholesale distributors do not set or control the WAC for drug products. Instead, manufacturers set the WAC for drug products on a national basis.
4. Several states require manufacturers to report when they increase the WAC of their products, subject to specific conditions or limitations, and this data is often made publicly available. For example, the State of California requires pharmaceutical manufacturers to report when they increase the WAC on a given

product by more than 16%—including the immediate increase and cumulative increases within the two previous calendar years—where the course of therapy costs more than \$40. *See Cal. Health & Safety Code § 127677; 22 Cal. Code Regs. § 96065*, available at <https://hcai.ca.gov/wp-content/uploads/2024/03/CTRx-Regulations-Text.pdf>. The California Health and Human Services Agency (“CalHHS”) currently makes reporting data from 2019 through October 8, 2025 publicly available. *See Prescription Drug Wholesale Acquisition Cost (WAC) Increases*, CalHHS, <https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases> (Oct. 8, 2025);¹ *October Monthly Update – Prescription Drug WAC Increases (Excel)*, CalHHS, <https://data.chhs.ca.gov/dataset/prescription-drug>

¹ I analyzed CalHHS’s data on WAC increases from 2019 through 2024 using the following datasets:

- *Q1-Q4 2024 Prescription Drug WAC Increases*, CalHHS (Sept. 11, 2025), <https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases/resource/882bb30d-44ed-48c9-b722-beb5aedc2c1b>;
- *Q1-Q4 2023 Prescription Drug WAC Increases*, CalHHS (Sept. 11, 2025), <https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases/resource/aca55cd5-a1a7-49cb-a490-997df1e27480>;
- *Q1-Q4 2022 Prescription Drug WAC Increases*, CalHHS (Sept. 11, 2025), <https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases/resource/dbed46b3-e823-487a-8a96-c0b2381af2c9>;
- *Q1-Q4 2021 Prescription Drug WAC Increases*, CalHHS (Sept. 11, 2025), <https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases/resource/34c373bb-cf9a-463e-93bf-6ae4ff3afad8>;
- *Q1-Q4 2020 Prescription Drug WAC Increases*, CalHHS (Sept. 11, 2025), <https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases/resource/f3e4ba62-3df4-40dd-9876-f7aea7384c1b>;
- *Q1-Q4 2019 Prescription Drug WAC Increases*, CalHHS (Sept. 11, 2025), <https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases/resource/9b8e12dc-1b3c-4c36-9ba9-adba6b921a6c>;

(collectively, “CalHHS 2019–2024 Data”).

wholesale-acquisition-cost-wac-increases/resource/b4554543-fec7-46c7-a518-b7d07bd1c1f3 (Oct. 8, 2025) (“CalHHS Oct. 2025 Update”).

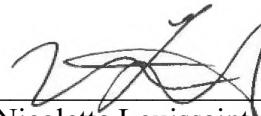
5. Although the limitations on California’s reporting requirements mean that not every WAC increase is reported, CalHHS’s data demonstrates that manufacturers frequently and consistently raise the WAC on a variety of products covered under the Drug Price Cap. After filtering CalHHS’s data to exclude drugs that are reported to be off-patent for less than 24 months, the data shows manufacturer-reported WAC increases on thousands of covered products, primarily consisting of branded and generic drugs. *See generally* CalHHS 2019–2024 Data (reporting “Patent Expiration Date” in column G);² CalHHS Oct. 2025 Update (reporting “Drug Category” in column G as either “Brand” or “Generic,” and reporting “Patent Expiration Date” in column K).
6. WAC prices for numerous covered products have *already* increased during calendar year 2025 or are set to increase before the end of 2025. California’s reporting data shows that, since January 1, 2025, manufacturers have raised the WAC of over 500 covered products. *See generally* CalHHS Oct. 2025 Update. Appendix A to this Declaration provides a representative sample of just some of the covered products that have experienced a WAC increase—or sometimes two WAC increases—so far in 2025.

² Unlike the CalHHS Oct. 2025 Update, the CalHHS 2019–2024 Data does not report “Brand” or “Generic” categorization, *see generally* CalHHS 2019–2024 Data, but it does report “Drug Source Type” as “single source,” “innovator multiple source,” or “noninnovator multiple source,” *see generally id.* (column H). Branded drugs are often classified in the CalHHS 2019–2024 Data as “single source,” but there are some instances of single source generic or biosimilar products. Generic or biosimilar products are often classified as “innovator multiple source” or “noninnovator multiple source” in the CalHHS 2019–2024 data.

7. Historical data on WAC increases further indicates that, in the future, manufacturers will inevitably increase prices for additional covered drug products above the January 1, 2025 WAC (adjusted by the CPI). As summarized in Appendix B to this Declaration, California's reporting data shows that manufacturers increased the WAC on an average of about 1,300 covered products each year between 2019 and 2024. *See generally* CalHHS 2019–2024 Data; Appendix B. In other words, manufacturers consistently raise WAC on a variety of covered products and have increased the WAC on many of the same products every year.

Further affiant sayeth not.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on 10/22/2025.


Nicolette Louissaint, PhD

APPENDIX A:**Representative Sample of Reported WAC Increases on Covered Products in 2025**

1. “BSS Plus Intraocular Solution 500ml per package”
 - Manufacturer: Alcon Labs
 - WAC Increase Reported on: 04/29/2025
 - WAC Increase Effective Date: 02/08/2025
 - Source: CalHHS Oct. 2025 Update, Row 18
2. “ACETYLCYSTEINE SOLUTION 10%, 100MG/ML, 4ML Vial, PKG OF 25”
 - Manufacturer: American Regent
 - WAC Increase Reported on: 04/28/2025
 - WAC Increase Effective Date: 02/01/2025
 - Source: CalHHS Oct. 2025 Update, Row 35
3. “HYDROXYZINE HCL, 25MG/ML, 1ML SDV, PKG. OF 25”
 - Manufacturer: American Regent
 - WAC Increase Reported on: 4/29/2025
 - WAC Increase Effective Date: 02/01/2025
 - Source: CalHHS Oct. 2025 Update, Row 38
4. “Opicapone 25 MG Capsule 30 EA”
 - Manufacturer: Amneal Pharmaceuticals
 - WAC Increase Reported on: 4/11/2025
 - WAC Increase Effective Date: 01/20/2025
 - Source: CalHHS Oct. 2025 Update, Row 46
5. “Silver sulfadiazine cream 1% 20gm tube”
 - Manufacturer: Ascend Laboratories, LLC
 - WAC Increase Reported on: 04/23/2025
 - WAC Increase Effective Date: 03/24/2025
 - Source: CalHHS Oct. 2025 Update, Row 71
6. “NAGLAZYME 1MG/ML INJ, (5 mL vial)”
 - Manufacturer: BioMarin Pharmaceutical Inc
 - WAC Increase Reported on: 04/25/2025, 07/28/2025 (respectively)
 - WAC Increase Effective Date: 01/01/2025, 06/01/2025
 - Source: CalHHS Oct. 2025 Update, Rows 150–51

7. "VOXZOGO .56MG/VIAL, Ten .56mg vial"
 - Manufacturer: BioMarin Pharmaceutical Inc
 - WAC Increase Reported on: 04/25/2025, 07/28/2025 (respectively)
 - WAC Increase Effective Date: 01/01/2025, 06/01/2025
 - Source: CalHHS Oct. 2025 Update, Rows 162–63
8. "CALDOLOR 800MG RTU BAGS/CASE OF 20"
 - Manufacturer: Cumberland Pharmaceuticals
 - WAC Increase Reported on: 07/23/2025
 - WAC Increase Effective Date: 07/01/2025
 - Source: CalHHS Oct. 2025 Update, Row 259
9. "Acetylcysteine Solution, USP 10% 100mg/mL 10mL Package Quantity 3"
 - Manufacturer: Fresenius Kabi USA LLC
 - WAC Increase Reported on: 04/24/2025
 - WAC Increase Effective Date: 02/19/2025
 - Source: CalHHS Oct. 2025 Update, Row 332
10. "Glucagon HCl (Diagnostic) Injection Solution Reconstituted 1 MG Package Quantity 10"
 - Manufacturer: Fresenius Kabi USA LLC
 - WAC Increase Reported on: 04/24/2025
 - WAC Increase Effective Date: 02/19/2025
 - Source: CalHHS Oct. 2025 Update, Row 339
11. "HydrOXYzine HCl, 10 mg/5 mL Solution, 473 mL bottle"
 - Manufacturer: Lannett Company, Inc.
 - WAC Increase Reported on: 4/25/25
 - WAC Increase Effective Date: 1/21/25
 - Source: CalHHS Oct. 2025 Update, Row 416
12. "Ketorolac Tromethamine Ophthalmic Solution 0.4% 5mL"
 - Manufacturer: Mylan Pharmaceuticals Inc.
 - WAC Increase Reported on: 07/31/2025
 - WAC Increase Effective Date: 06/17/2025
 - Source: CalHHS Oct. 2025 Update, Row 460
13. "AFINITOR DISPERZ TABLET FOR SUSPENSION 2 mg 28"
 - Manufacturer: Novartis
 - WAC Increase Reported on: 04/29/2025
 - WAC Increase Effective Date: 01/14/2025
 - Source: CalHHS Oct. 2025 Update, Row 491

14. "Erythrocin™ (lactobionate) IV Rx, 500 mg, Single Dose Glass Fliptop Vial, 10"

- Manufacturer: Pfizer
- WAC Increase Reported on: 4/30/2025, 7/31/2025 (respectively)
- WAC Increase Effective Date: 1/01/2025, 5/15/2025
- Source: CalHHS Oct. 2025 Update, Rows 672–73

15. "MAGNESIUM SULFATE (magnesium sulfate), 4 mEq/mL (50 %), SYRINGE (ML), 1"

- Manufacturer: Pfizer
- Type: generic
- WAC Increase Reported on: 4/30/2025, 7/31/2025 (respectively)
- WAC Increase Effective Date: 1/1/2025, 5/15/2025
- Source: CalHHS Oct. 2025 Update, Rows 720–21

16. "AMANTADINE HYDROCHLORIDE (AMANTADINE HYDROCHLORIDE)

50mg/5mL Oral Solution, 10mL Cup [Qty: 100]"

- Manufacturer: Pharmaceutical Associates, Inc.
- WAC Increase Reported on: 01/06/2025
- WAC Increase Effective Date: 01/02/2025
- Source: CalHHS Oct. 2025 Update, Row 804

17. "Flotrex 0.5mg, Vitamin A, Vitamin C, Vitamin D3, Vitamin E, Thiamin, Vitamin E, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Fluoride, chewable tablets (30ct)"

- Manufacturer: PureTek Corporation
- WAC Increase Reported on: 04/02/2025
- WAC Increase Effective Date: 04/01/2025
- Source: CalHHS Oct. 2025 Update, Row 858

18. "Lidotral 5% Gel, Lidocaine HCl 5%, (3oz)"

- Manf: PureTek Corporation
- WAC Increase Reported on: 04/02/2025
- WAC Increase Effective Date: 04/01/2025
- Source: CalHHS Oct. 2025 Update, Row 860

19. "MORPHINE SULFATE ER 100MG TAB 100 tablet in 1 blister pack"

- Manufacturer: SpecGx
- WAC Increase Reported on: 06/18/2025
- WAC Increase Effective Date: 06/02/2025
- Source: CalHHS Oct. 2025 Update, Row 929

20. "NYSTATIN 100MU/ML SUSP UD -100x5mL"

- Manufacturer: The Harvard Drug Group, L.L.C. dba Major Pharmaceuticals
- WAC Increase Reported on: 07/23/2025
- WAC Increase Effective Date: 05/12/2025
- Source: CalHHS Oct. 2025 Update, Row 1019

APPENDIX B:

<u>Year</u>	<u>Reported WAC Increases on Covered Products</u>
2019	1,369
2020	1,189
2021	979
2022	1,223
2023	1,484
2024	1,584
AVERAGE	1,304.7

Source: CalHHS 2019–2024 Data

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

Healthcare Distribution Alliance,

Plaintiff,

v.

Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services, and William Tong, in his official capacity as Attorney General for the State of Connecticut,

Defendants.

Case No. 3:25-cv-1724 (OAW)

**SUPPLEMENTAL DECLARATION OF MICHELLE BRITT IN
SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

I, Michell Britt, am over 18 years of age and hereby declare as follows:

1. I am the Senior Vice President, Retail Independent Sales in Pharmaceutical & Specialty Distribution at Cardinal Health, Inc. (“Cardinal Health”) and provide this declaration based on my own personal knowledge.
2. Cardinal Health distributes pharmaceutical products to licensed pharmacies, hospitals, clinics, long-term care facilities, and other healthcare providers in Connecticut. But Cardinal Health does not have a distribution center in Connecticut. Instead, products we distribute in Connecticut are shipped from distribution centers outside Connecticut.

3. Per Cardinal Health's customer contracts, Cardinal Health sells pharmaceutical products "Free On Board (FOB) Destination,"¹ meaning that title to the products transfers from Cardinal Health to its customer at the time and place of delivery to the customer. Therefore, Cardinal Health bears the risk of any damage, loss and theft until the goods reach Cardinal Health's customer.² To my knowledge, none of Cardinal Health's customer contracts provide for a transfer of title at a different time and place.
4. The FOB Destination term in Cardinal Health's customer contracts is a fundamental part of our relationship with our customers. Because Cardinal Health bears the risk of loss, damage and theft until physical delivery, Cardinal Health (and not the customer) pays for insurance to mitigate those risks. Additionally, Cardinal Health is subject to record maintenance and reporting obligations to the U.S. Drug Enforcement

¹ "Free on Board (insert named port of loading)" is a common "incoterm" associated with shipping contracts. *Know Your Incoterms*, Int'l Trade Admin., <https://www.trade.gov/know-your-incoterms> (last visited Dec. 11, 2025). "Incoterms" are "widely-used terms of sale . . . which define the responsibilities of sellers and buyers. Incoterms specify who is responsible for paying for and managing the shipment, insurance, documentation, customs clearance, and other logistical activities." *Id.*

² See also *Free on Board (FOB) Explained: Who's Liable for What in Shipping?*, Investopedia (Sept. 17, 2025) ("FOB Destination means the seller retains the risk of loss until the goods reach the buyer."), [https://www.investopedia.com/terms/f/fob.asp#:~:text=Free%20on%20Board%20\(FOB\)%20indicates,the%20seller%20ships%20the%20product](https://www.investopedia.com/terms/f/fob.asp#:~:text=Free%20on%20Board%20(FOB)%20indicates,the%20seller%20ships%20the%20product).

Administration (“DEA”) for certain drug products (such as controlled substances) before and through delivery to the customer.³

5. Cardinal Health’s customers would almost certainly be unwilling to change the FOB Destination term in their contracts, which would result in them taking title to covered products outside of Connecticut and before physical delivery. Such a change would require in-state Connecticut retailers, hospitals, clinics, long-term care facilities, medical practices, and other healthcare providers to assume the risk of loss or damage to, or theft of, pharmaceutical products before they physically receive them. Each of those customers would likely need to obtain insurance on their own to mitigate those risks. The collective cost for our customers would likely be greater (and in some cases, substantially greater) than what Cardinal Health itself currently bears with respect to its insurance and risk-mitigation measures, because Cardinal Health is able to achieve efficiencies that individual customers are not. Therefore, changing the FOB Destination term would increase business costs for Connecticut retailers, hospitals, and medical practices, likely resulting in greater passed-down costs to Connecticut patients.

³ See 21 U.S.C. § 822, 827; 21 C.F.R. §§ 1304.04, 1304.33; see also 21 C.F.R. §§ 1304.33(d) u7j(covering Schedule I–V controlled substances) and 1301.74(c) (covering theft and loss of controlled substances).

6. Changing the FOB Destination term would also likely require Cardinal Health and its Connecticut retailers, hospitals, and medical practice customers to incur additional costs in assessing any potential changes to their documentation and reporting obligations under DEA regulations.⁴
7. Cardinal Health's customer contracts are typically multi-year, and many of our contracts are multi-state rather than state-specific. For our customers with multi-state operations, we structure our contractual relationships through national agreements that apply uniformly across states. Accordingly, renegotiating existing contracts to provide that Cardinal Health's customers take title to covered products outside of Connecticut and before physical delivery to retailers, hospitals, and medical practices in Connecticut, would be commercially unreasonable, severely disrupting national agreements and imposing substantial time and cost burdens to Cardinal Health as well as its customers in and outside of the state. Certainly, no contractual changes to change the situs of title transfer could take place before January 1, 2026.

⁴ E.g., 21 C.F.R. § 1304.33 (requiring “[a]cquisition/distribution reports [to] provide data on each acquisition to inventory . . . and each reduction from inventory”).

Case 3:25-cv-01724-OAW Document 44-1 Filed 12/16/25 Page 5 of 6

I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 15, 2025.



Michelle Britt (Dec 15, 2025 14:42:56 EST)

Michelle Britt
Senior Vice President, Retail Independent Sales
Pharmaceutical & Specialty Distribution
Cardinal Health, Inc.

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

Healthcare Distribution Alliance,

Plaintiff,

v.

Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services, and William Tong, in his official capacity as Attorney General for the State of Connecticut,

Defendants.

DECLARATION

Case No. 3:25-cv-1724 (OAW)

**SUPPLEMENTAL DECLARATION OF CHRISTOPHER REED IN SUPPORT OF
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

I, Christopher Reed, am over 18 years of age and hereby declare as follows:

1. I oversee distribution operations at Cencora, Inc. and provide this declaration based on my own personal knowledge.
2. As I explained in my declaration in this case dated October 19, 2025,¹ Cencora distributes pharmaceutical products to licensed pharmacies, hospitals, and other healthcare providers in Connecticut. But Cencora does not have a distribution center in Connecticut; rather, products we distribute in Connecticut are shipped from distribution centers outside the state.
3. Our contracts with our Connecticut customers do not provide that title is taken outside of Connecticut. Rather, our customer contracts provide that Cencora sells pharmaceutical products “FOB Destination,” meaning that title does not pass until

¹ See ECF No. 27-3.

the customer receives it. Until delivery occurs, Cencora retains title, bears all risk of damage or loss (against which Cencora generally carries insurance), and is subject to record maintenance and reporting obligations to the U.S. Drug Enforcement Administration (“DEA”) for certain drug products (including controlled substances) before and through delivery to the customer. I am not aware of any contracts with Connecticut customers that are not FOB Destination.

4. FOB Destination provides our customers with important benefits. Because Cencora bears the risk of loss or damage until physical delivery, we pay for insurance to mitigate that risk. We also handle the DEA recordkeeping and reporting requirements.
5. Cencora would likely face immense resistance from our Connecticut retailer, hospital, and other healthcare provider customers if we attempted to amend or renegotiate the FOB Destination term in their contracts. Such a change would require the customers to assume the risk of damage or loss prior to delivery and would likely force them to arrange their own insurance, which would increase their costs. Changing the FOB Destination term would also impose greater DEA record-retention and reporting burdens on Connecticut retailers, hospitals, and medical practices, which will further increase their business costs.²
6. For these reasons, I do not believe that many of our customers would be willing to agree to change the FOB Destination term voluntarily. Cencora would need to

² See e.g., 21 C.F.R. § 1304.33 (requiring “[a]cquisition/distribution reports [to] provide data on each acquisition to inventory . . . and each reduction from inventory”).

make significant concessions in the negotiation process to persuade our customers to accept that change, causing Cencora financial harm.

7. Moreover, our customer contracts are typically multi-year, and many of our contracts apply to customers spanning several states. Accordingly, it would take at least a few years to amend our contracts to change the FOB Destination term (even if agreement could be reached), given the number of Connecticut customers we have and the length of time remaining on many of their existing contracts. Certainly, no contractual changes regarding the situs of title transfer could occur before the Drug Price Cap takes effect on January 1, 2026.

I declare under penalty of perjury that the foregoing is true and correct. Executed on December 11, 2025.

Reed, Christopher
(a107264)

 Digitally signed by Reed,
Christopher (a107264)
Date: 2025.12.11
16:06:05 -04'00'

Christopher Reed, Vice President

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

Healthcare Distribution Alliance,

Plaintiff,

v.

Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services, and William Tong, in his official capacity as Attorney General for the State of Connecticut,

Defendants.

DECLARATION

Case No. 3:25-cv-1724 (OAW)

**SUPPLEMENTAL DECLARATION OF CHRISTOPHER VAN NORMAN IN SUPPORT
OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

I, Christopher Van Norman, am over 18 years of age and hereby declare as follows:

1. I am the Senior Vice President, Supply Chain Operations at McKesson Corporation (“McKesson”) and provide this declaration based on my own personal knowledge.
2. As I explained in my declaration in this case dated October 20, 2025,¹ McKesson distributes pharmaceutical products to licensed pharmacies, hospitals, clinics, long-term care facilities, and other patient-facing organizations in Connecticut. But McKesson does not have a distribution center in Connecticut. Instead, products we distribute in Connecticut are shipped from distribution centers outside Connecticut.

¹ See ECF No. 27-4.

3. Under its agreements with sell-side customers (such as licensed pharmacies, hospitals, clinics, long-term care facilities, and other patient-facing organizations), McKesson generally delivers pharmaceutical products “F.O.B. Destination,” meaning that title and risk of loss stay with McKesson until the products are delivered to the customer, even if the customer pays shipping and handling charges. To my knowledge, McKesson has no customer agreements with any sell-side Connecticut customers specifying a different delivery term or otherwise providing for a transfer of title at a different time and place.
4. F.O.B. Destination is consistent with a long course of dealing between McKesson and its sell-side customers, as well as the reasonable commercial expectations of customers. By delivering F.O.B. Destination, McKesson bears the risk of loss or damage until physical delivery. McKesson pays for insurance to mitigate that risk, while its sell-side customers do not. Additionally, McKesson is subject to regulatory and compliance obligations under the Controlled Substances Act and the Drug Supply Chain Security Act. These laws, and extensive regulations promulgated under them, prescribe detailed rules for the distribution of pharmaceutical products.
5. McKesson would likely face immense resistance from its Connecticut sell-side customers if it attempted to persuade them to change the F.O.B. Destination term in their contracts with McKesson. Such a change would require McKesson’s Connecticut customers to assume the risk of damage or loss prior to delivery and would likely force them to purchase insurance to mitigate that newfound risk. It could also increase the regulatory burden to them under the Controlled Substances

Act and the Drug Supply Chain Security Act. All of these changes would increase burdens and costs for McKesson's sell-side customers.

6. Further, it would be extremely difficult as a practical matter to change the existing F.O.B. Destination arrangement. Many of McKesson's customer contracts cover multiple years and multiple states at a time. A single customer may have multiple locations in different states. McKesson does not have a distribution facility in Connecticut and thus would face very substantial administrative burdens if it sought to deliver products under a special arrangement to Connecticut sell-side customers and deliver F.O.B. Destination to everyone else. McKesson's various facilities outside Connecticut would have to operate under a special exception every time they fulfilled an order for a covered product through delivery to a customer's location in Connecticut.
7. To make matters worse, the Connecticut Drug Price Cap applies to only a small subset of the healthcare products that McKesson distributes: off-patent brand-name prescription and generic drugs, and interchangeable biological products. An on-patent brand-name prescription drug or biological product is currently exempt from the Drug Price Cap, but it would become subject to the Cap once its patent expires. A generic drug that becomes commercially available after January 1, 2025, would also become subject to the Cap. Keeping track of which products could be shipped F.O.B. Destination to Connecticut (and which could not) would be a major administrative challenge for any distributor.
8. The multi-year nature of many sell-side customer contracts would also limit the ability of McKesson to effect prompt changes in the F.O.B. Destination term. While McKesson could in theory seek renegotiation of the F.O.B. Destination term before the contractual

term expired, customers otherwise in compliance with the contracts would be within their contractual rights to refuse. Hence, there would likely be substantial delay before McKesson would even be in a realistic negotiating position to seek departures from the F.O.B. Destination term in multi-year contracts. Certainly, no contractual changes would be feasible before January 1, 2026.

I declare under penalty of perjury that the foregoing is true and correct. Executed on
12/15/2025.

Signed by:



Christopher Van Norman

Christopher Van Norman

CC08473C37F840F

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF CONNECTICUT

3 - - - - - x
4 HEALTHCARE DISTRIBUTION ALLIANCE : Case No. 3:25cv01724
5 -and- :
6 ASSOCIATION FOR ACCESSIBLE : Case No. 3:25cv01757
7 MEDICINES :
8 v. : (OAW)
9 BOUGHTON et al :
10 : December 9, 2025
11 :
12 : CONSOLIDATION HEARING
13 - - - - - x

14 CONSOLIDATION HEARING

15 450 Main Street
16 Hartford, CT 06103

17 BEFORE: THE HONORABLE OMAR A. WILLIAMS

18
19
20
21
22 COURT REPORTER: Catherine Cullen
23 (914) 552-3201

24 Proceedings recorded by mechanical stenography; transcript
25 produced by computer.

1 APPEARANCES:

2

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6

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BY: JONATHAN S. MASSEY

10

11

12 FOR THE DEFENDANTS:

13 CONNECTICUT ATTORNEY GENERAL
165 Capital Avenue
14 Hartford, Connecticut 06106
BY: VICTORIA FIELD

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1 COURTROOM DEPUTY: (Opens the courtroom).

2 THE COURT: Thank you so much, Mr. Courtroom
3 Deputy. Thank you. Good morning. You may all have a
4 seat.

5 Thank you so much. Thank you, Madam Court
6 Reporter. Good morning, everybody. And good morning
7 again, I should say.

8 We are here for a consolidated hearing on
9 applications for a preliminary injunction and temporary
10 restraining order in the cases of Healthcare Distribution
11 Alliance, or HDA, and Association for Accessible
12 Medicines, or AAM, versus Boughton, et al, with
13 corresponding Docket numbers 25cv1724 and 25cv1757
14 respectively.

15 Attorney Konstantinos Karamanakis is my law
16 clerk today. I want to sincerely thank Robert Wood for
17 being here as courtroom deputy standing in for us. There
18 was a sudden loss in the Clerk's Office and Mr. Wood has
19 covered on zero notice. So that's to ensure we didn't
20 have to reschedule, so I thank you for that.

21 And I'll make sure I do my part to make sure the
22 parties have very thoroughly briefed these issues. I have
23 some questions and that's why I scheduled the hearing, but
24 I'll be mindful of that time under these circumstances.
25 So thank you so much.

1 And Catherine Cullen is our court reporter. I
2 always tell them, and I certainly tell the parties, please
3 speak up if you ever need anything repeated, or if Madam
4 Court Reporter needs it to be repeated, or you need
5 anything corrected or if anything is misstated by the
6 Court or otherwise.

7 The Court, again, does thank the parties for
8 your thorough briefing. The Court has reviewed all of it
9 and does have a few follow-up questions. But I'm also
10 realizing I have not yet taken your appearances, so if you
11 would please, for anyone who is going to be speaking
12 today, perhaps we can start with HDA, please.

13 MR. MASSEY: Good morning. John Massey on
14 behalf of HDA. We would thank the Court for scheduling
15 this on an expedited basis and we appreciate the staff's
16 commitment as well.

17 THE COURT: I really mean it when I say, the
18 parties briefing made it a lot easier to narrow the focus
19 of the Court, so thank you, to all of you, for that.

20 MR. JAY: Good morning, Your Honor. For AAM,
21 William Jay.

22 THE COURT: Thank you so much. Good morning,
23 Attorney Jay.

24 MS. FIELD: Good morning, Your Honor. For the
25 defendants, Victoria Field.

1 THE COURT: Thank you, Attorney Field. All
2 right. Very well. Thank you so much.

3 Now, I mean as I say, I did have some questions
4 for the parties, and so if I may start with that. First,
5 for the defense, if I may, would the defense please
6 explain the scope of Public Act 25168, which I'll refer to
7 as the act or as the law.

8 When it applies to sales of generic prescription
9 drugs in this state, what does the State of Connecticut
10 mean by talking about sales in the state when we are
11 talking about a manufacturer, for instance? And just for
12 context, you know, in an era of electronic transactions
13 where pretty much everything happens everywhere, and you
14 know, when we look at wire fraud cases where data is
15 passing through servers in other states, in a broad sense,
16 what does the State of Connecticut think constitutes a
17 sale in this state for the purposes of this statute,
18 please?

19 MS. FIELD: Thank you, Your Honor. Just
20 returning to the text of the statute very quickly to set
21 the stage.

22 THE COURT: Sure.

23 MS. FIELD: It says, no pharmaceutical
24 manufacturer or wholesale distributor shall on or after
25 January 1st, 2026, sell an identified prescription drug in

1 this state at a price that exceeds the reference price.

2 Your Honor, this refers to sales by wholesalers
3 and manufacturers for which the situs of sale is in
4 Connecticut. This does not refer to sales through which a
5 manufacturer or wholesaler is selling to a third party
6 which is then resold in Connecticut.

7 THE COURT: Okay. Through the briefing, is that
8 how the plaintiffs all understood it?

9 MS. FIELD: It doesn't appear to be the case,
10 Your Honor.

11 MR. JAY: Good morning, Your Honor. Speaking
12 for AAM, which is the manufacturer's trade association, we
13 asked the state this question before filing suit and
14 sought what I take to be the interpretation that Mr. Field
15 has just given, that a sale by a manufacturer to someone
16 else, presumably a wholesaler because that's who
17 manufacturers sell to, if the manufacturer is in
18 Pennsylvania and the distributor is in Ohio, their
19 contract may specify what the situs of sale is, because
20 that matter is for when the risk of the shipment transfers
21 from the seller to the buyer that such a sale is not
22 covered by the reference in the statute to in this state.

23 We didn't get that assurance and we do think
24 there's a good basis in the statute to read it that way.
25 But we wouldn't have brought the action if not for the

1 threat that the state would apply in this state to
2 transactions outside the state on the theory that the
3 state, I took to be referring to in its briefs, that if
4 it, if the drugs make their way to this state that the
5 whole chain is regulated by the state.

6 I took Ms. Field to be saying that's not the
7 state's interpretation now. And if we were understanding
8 that correctly, then I think that that reads the statute
9 in a way that would give AAM's member the relief it's
10 seeking.

11 THE COURT: On the statute as written?

12 MR. JAY: On the statute as written. We
13 recognized that the statute has not yet taken effect and
14 there's not yet a history of implementation. There are no
15 regulations and so on. But the whole question is, what is
16 the meaning of the prohibition in Subsection A1 of 346 in
17 sell and identify prescription drug in this state at a
18 price exceeding the reference price. And if a sale
19 between a manufacturer in Pennsylvania and a wholesaler in
20 Ohio is not a sale in this state, even if the wholesaler
21 then resells to someone else, who resells to someone else,
22 who sells to a pharmacy in Hartford, Connecticut, even if
23 that, the state will agree that's not a transaction in
24 this state. That's in substance what our proposed
25 injunction asks the Court to prevent this law from

1 applying to.

2 THE COURT: I agree. Okay. So that does
3 resolve a lot of the Court's questions. I'll say that.
4 But that also seems to involve a good amount of trust.

5 I'm thinking also of the 11th Amendment
6 concerns, the sovereign immunity concerns, where the state
7 has not waived sovereign immunity. So do you want to
8 speak to that; that I'm not sure that everyone would read
9 the statute to interpret it in that way? And do you want
10 to be heard?

11 MR. JAY: I would like to make three points.
12 There's a footnote in our reply briefs that addresses this
13 point somewhat, but I want to elaborate on that.

14 So if the Court were to say there's no
15 controversy between AAM and of the state because of the
16 representations the state made at this hearing, and AAM's
17 suit is therefore dismissed, I think the state would be
18 judicially estopped from taking a different position in
19 whether the administrative proceedings, or anywhere else,
20 and I think we would be able to come back to this Court to
21 make that clear or I think we would be able to assert the
22 judicially estopping force of this Court's decision in
23 other proceedings as well. That's the first point.

24 The second point, I agree with Your Honor that
25 it's possible to read the act both ways. I think that the

1 thing that is most compelling to us, at least in deciding
2 what the right reading is, is the definition of
3 pharmaceutical manufacturer in 345 Subsection 9. And a
4 pharmaceutical manufacturer is defined as a person that
5 manufactures a prescription drug and sells directly, or
6 through another person, the prescription drug for
7 distribution in this state. And you will see that the
8 substantive prohibition which says don't sell in this
9 state for a price exceeding the reference price is worded
10 differently.

11 So, in other words, if the general assembly
12 wanted to pick up indirect sales and call them sales in
13 this state, it likely would have used wording like what it
14 used in the definition of pharmaceutical manufacturer.
15 Instead it just said, sells an identified prescription
16 drug in this state. And we think that contrast is the
17 most compelling textual evidence of the best reading of
18 the statute. I think that covers the point that I want to
19 make, if I answered Your Honor's questions.

20 THE COURT: Yes. Thank you.

21 MR. MASSEY: Your Honor, if I may. John Massey
22 on behalf of HDA, the distributors. We have a couple of
23 issues with the state's interpretation.

24 First, the notion of situs is a little unclear
25 in how Ms. Field articulated it. In particular, if title

1 to the drugs is taken outside the state, say a wholesaler,
2 none of whom have facilities, distribution facilities in
3 Connecticut, if a wholesaler sells to a hospital or a
4 retailer or medical practice inside Connecticut and the
5 contract stipulates that title is taken outside
6 Connecticut, would that qualify as a sale outside
7 Connecticut under the state's interpretation? So we would
8 need, at minimum, clarity on that.

9 Second, I think the state's position this
10 morning highlights the whole constitutional problem with
11 the statute because distributors are caught in the middle.
12 The distributors don't set or control WAC, the wholesale
13 acquisition cost. They provide a valuable service in
14 distributing drugs, 10.5 million healthcare products every
15 day brought across the country under very compelling
16 situations, life-saving drugs that have to be refrigerated
17 or delivered on the day of within hours from one place to
18 another, but they don't set or control WAC.

19 So the notion that the wholesalers could be sort
20 of whipsawed here, that they would buy at current WAC from
21 the manufacturers for brand of drugs and then have to sell
22 at the reference price inside Connecticut when they don't
23 have control over WAC, seems to be, essentially,
24 unconstitutional.

25 And of course in other cases that we have cited

1 in the briefs, the Supreme Court has held the fact that a
2 sale occurs inside the state does not allow the state to
3 regulate the price of the interstate good under the
4 commerce clause.

5 The law in Brown-Forman, for example, was
6 triggered only by liquor sales in New York, but the
7 Supreme Court said that fact was irrelevant. That's at
8 476 U.S. at 583. The price control on Healy, which is a
9 Connecticut statute, governed only prices posted in
10 Connecticut. But that didn't save the law.

11 In the Fourth Circuit's Froch's case, which is
12 the case that the pork producers, the Supreme Court cited
13 Froch with approval, in the Froch decision the Fourth
14 Circuit said that even if there were a nexus, even if the
15 state did require a nexus to an actual sale in Maryland,
16 it is nonetheless invalid because it still controls the
17 price of transactions that occur wholly outside of this
18 state. And that's at page 671 of the Froch decision.

19 So I want to make clear, the state's position in
20 no way eliminates the Dormant Commerce Clause problem with
21 this statute. If it did, it would open the whole
22 pandora's box, because there's lots of interstate goods
23 which are sold into Connecticut.

24 And we have an affordability crisis in this
25 country. People are worried about grocery prices, car

1 prices are too high. If states could unilaterally adopt
2 price caps and price control laws whenever there was a
3 sale inside that state, the country would have a patchwork
4 of 50 different price control laws. And, frankly, the
5 next state after Connecticut is going to try to do better
6 and reduce prices even lower. And that's what the
7 district court in the striking down the D.C. drug control
8 law said would produce a race to the bottom. And as a
9 country, we rejected that approach.

10 It's kind of telling, that even today when
11 people are concerned about high prices for lots of things,
12 you don't see states adopting price caps for groceries and
13 for goods that people care about; because we understand
14 that one of the reasons we moved from the articles of
15 confederation to the constitution was the desire to have
16 an interstate market, and the federal government is the
17 appropriate regulator of products and prices in the
18 national market.

19 THE COURT: Thank you very much. Do defendants
20 want to respond to that?

21 MS. FIELD: Thank you, Your Honor. If I may
22 first address plaintiffs' concern about the transfer of
23 liability through the supply chain. If I understand
24 correctly, they are reading the definition of
25 manufacturer, which again, is a person that manufactures a

1 prescription drug and sells directly or through another
2 person the prescription drug for distribution in this
3 state.

4 There are two clues in the text that point to
5 this not being a transfer of liability through resellers,
6 but rather an implication of agency. So the
7 pharmaceutical manufacturer cannot create a shell
8 corporation that is under its control in order to dodge
9 liability of the statute.

10 If it was applying to any reseller, then there
11 would be no need for the statute to include a separate
12 definition for wholesalers, because they would by default
13 be included in the sales through another person. So this
14 is not referring to supply chain, but rather to issues of
15 agency.

16 Second, plaintiffs have raised concerns about
17 the extraterritoriality of application of the law. And
18 for that, I would point to the laws in Maryland and
19 Minnesota which were struck down as unconstitutional and I
20 would distinguish them from this case.

21 The Maryland law applied to drugs made available
22 for sale in Maryland; not just sales made in Maryland.
23 And the Minnesota law applied to drugs dispensed or
24 delivered to any consumer in this state. In both of those
25 cases, liability applied to sales that made their way to

1 the state in which the law was passed; not sales that were
2 made directly in the state.

3 Furthermore, plaintiffs have alleged a concern
4 about this being a pandora's box whereupon this law would
5 allow the state to regulate the price of any goods sold
6 here. For that, I would refer plaintiffs to the Pike
7 case, which contains a balancing test for any laws that
8 have a discriminatory result coming from a facially
9 neutral application of the law.

10 In *Pike*, the Court found that as long as the law
11 was applied neutrally and it effectuates a legitimate
12 public interest, then as long as the public interest that
13 was being effectuated did not overcome the burden on
14 interstate commerce - that was not directly being forced,
15 so there's no direct discrimination - then the law could
16 be allowed. And in this case, the legit public interest
17 being enforced is affordable healthcare. This is in
18 contrast to the *Pike* case itself where the legitimate
19 public interest was simply the reputation of fruit and
20 vegetable growers in this state. So here we have a much
21 more legitimate interest.

22 THE COURT: Definitely true. We are not talking
23 about luxury cars or stocks. The public interest is clear
24 here.

25 Did the defendant's wish to speak to - I brought

1 it up, I think with respect to Attorney Jay from AAM, but
2 the sovereign immunity aspect, do the defendants wish to
3 speak to that with respect to irreparable harm and its
4 impact?

5 MS. FIELD: Your Honor, every single law, or
6 virtually every law, has an impact on somebody's pockets,
7 and in all cases in Connecticut such people are able to go
8 through the claim's commissioner, which is an action in
9 state court, and that is available to them here.

10 There's no reason why plaintiffs in this case
11 should have any other cause of action or cause for
12 restitution than any other person has been for as long as
13 the law has been in place. This is the system that the
14 legislature put in place as representatives of the state
15 and of the industries that exist within this state.

16 THE COURT: I've given all three parties a
17 chance to address. Does anyone else want to address the
18 sovereign immunity part?

19 MR. MASSEY: Yes, Your Honor. Thank you.

20 THE COURT: Sure.

21 MR. MASSEY: The Second Circuit has already held
22 in a case called New York Progress that the only remedies
23 that can be considered on the irreparable harm point are
24 federal remedies. And that therefore, the state's attempt
25 to use our Chapter 53 of the general Connecticut statutes

1 doesn't get them to first base.

2 In other words, in considering an irreparable
3 harm, the only thing this Court can consider is the
4 federal remedies that would be available to the plaintiff.
5 And so the possibility of Chapter 53 doesn't save the law;
6 it doesn't save the irreparable harm point for the state.

7 And, obviously, the way Chapter 53 works is,
8 this claim's commissioner has to grant a waiver and has
9 authority if and only if the state would be liable if the
10 state were a private person. That's the test under
11 Chapter 53 for the commissioner to grant a waiver. That
12 can't happen here.

13 If the state were a private person, it wouldn't
14 be violating the commerce laws. I don't think Chapter 53
15 applies in this case, but if it does, it's so ephemeral
16 that the Second Circuit says you shouldn't even consider
17 it.

18 Finally, the argument that the state makes would
19 be available in any preliminary injunction case. Even at
20 the federal level, the Court of Federal Claims, or
21 congress, could pass an act. That is another option under
22 the Chapter 53, is the general assembly could grant
23 compensation after the fact. That's true in every
24 jurisdiction. That just means there would never be
25 preliminary injunctions against the government, except in

1 extraordinary cases, but in the normal course there would
2 not be a preliminary injunction because the government
3 could hint it might compensate after the fact, and that's
4 clearly not the law in this country.

5 And Your Honor has granted preliminary
6 injunction in cases where the government has violated the
7 law without the hint of possible after-the-fact money
8 damages that would just be a promise to the ear to be
9 broken to the hope.

10 THE COURT: Response?

11 MS. FIELD: Your Honor, a preliminary injunction
12 is an extraordinary remedy for an extraordinary situation.
13 If every time a law was passed that had a potential impact
14 on someone's pockets and they could obtain a preliminary
15 injunction, then our ability to pass laws would be
16 completely hamstrung.

17 On the other hand, plaintiffs have alleged two
18 different kinds of harm here. The first being
19 constitutional harm and the second being financial harm.
20 As to their constitutional harm, I would be happy to
21 address their concerns about the extraterritoriality and
22 the Dormant Commerce Clause and demonstrate they would not
23 likely win on the merits.

24 As for their financial harm, my statement
25 remains, that they could go through the claim's

1 commissioner.

2 THE COURT: I guess turning back to Attorney
3 Massey, HDA, do we even get there with the available
4 exception for shortages? Would that kick in and allow
5 sales above the WAC?

6 MR. MASSEY: That's what the text says, Your
7 Honor, but it has to be certified as being in shortage by
8 HHS. And there isn't any - there's no showing this would
9 happen. And most drugs are not in shortage, thankfully.
10 That's reserved for emergency situations. In the mind run
11 of cases, the wholesaler would be trapped in this bind
12 where it's buying at the current WAC and selling at the
13 January 2025 WAC.

14 So I don't think that exception is a safety
15 valve for the most extraordinary cases where there's
16 actual shortage that's been satisfied. But the state has
17 failed to show that that would apply to eliminate the
18 constitutional defects. And I don't believe that there's,
19 right now - the percentage of drugs certified as being in
20 shortage is extremely low right now, thankfully.

21 And so the law will, in the mind run of cases,
22 in the vast majority of cases, the law would put
23 wholesalers in a bind where they can't sell at the price
24 which they are buying brand name drugs. And that's an
25 extraterritorial and protectionist violation of the

1 commerce clause.

2 The state referred to the Pike balancing test,
3 which comes in only if a state does not have impermissible
4 extraterritorial effect or is a protectionist. In this
5 case, I think we have shown the state has an impermissible
6 extraterritorial effect under both pork producers, Froch,
7 LSN, all of those cases, even the Maine case which
8 throughout the price control law in Maine, the First
9 Circuit, the state didn't even appeal that aspect of the
10 district court's ruling.

11 So the reason it's extraterritorial, as the
12 Court said and the Supreme Court said, in pork producers
13 it would tie the instate price to an out-of-state price.
14 And the out-of-state price is the WAC that is prevailing
15 in all other states. That's also a reason the law is
16 protectionist. Because what Connecticut is trying to do
17 is say the price for these covered products in Connecticut
18 will be lower than the prevailing price in all the
19 surrounding states. And that will cause one of two things
20 to happen. Either Connecticut is pushing costs onto other
21 states, because the wholesalers are forced to eat some of
22 that cost that is borne by Connecticut, or if the other
23 states see the costs being passed to them, those states
24 will enact similar statutes, or even lower statutes, as I
25 mentioned before, and that precipitates the race to the

1 bottom that the commerce clause is meant to prevent.

2 The statute is also protectionist on the
3 commercial level, because the Connecticut statute does not
4 govern the cost charged by retailers, medical practices,
5 and hospitals. Under the cap, they are allowed to charge
6 whatever they want. It's only the upstream distributors
7 and wholesalers that are governed by the cap. And that
8 was one of the protectionist flaws that the Fourth Circuit
9 identified in Froch.

10 And just to repeat, Froch is the case the
11 Supreme Court in pork producers said was reading the
12 Supreme Court precedence in exactly the same way as the
13 Supreme Court was, so it was endorsing Froch. And Froch
14 said, when you are regulating only the out-of-state
15 upstream parts of the supply chain and not regulating the
16 people who are actually selling drugs to consumers, that
17 proves the extraterritorial and protectionist nature of
18 the statute and it also undermines the state's interest.

19 We can all agree drugs prices, it would benefit
20 consumers if prices were lower. Of course the federal
21 government is trying to do that through Medicare and
22 Medicaid, the Inflation Reduction Act, Section 340B. But
23 the jarring thing about the Connecticut law is it doesn't
24 regulate the prices that consumers pay. The consumers,
25 the cap doesn't regulate what CVS can charge consumers for

1 its prices, and that's the mismatch which demonstrates the
2 benefit to instate interests, the mismatched to the
3 state's articulated objective.

4 So Pike, we don't get to the Pike balancing test
5 in this case because the law is invalid on its face, both
6 as an extraterritorial impermissible regulation and as a
7 protectionist law that is protectionist on two levels,
8 both the consumer and commercial level.

9 The other thing this law does on the commercial
10 level that is protectionist, it puts distributors at a
11 competitive disadvantage in other states. If you are a
12 distributor who has a disproportionate amount of business
13 in Connecticut, then you will be hurt when you are
14 competing in other states, because you will not be able to
15 cover all of your Connecticut costs in Connecticut;
16 Connecticut will be pushing its costs onto you.

17 And so if you have to compete in New York or
18 Massachusetts as a distributor, you're handicapped. And
19 that was the same defect that the Supreme Court identified
20 in Healy and Brown-Forman, where it said the people who
21 are selling beer and liquor in New York and Connecticut in
22 those two cases are going to be, they were going to be
23 robbed of their promotional and rebate programs. That was
24 what was going to happen to the distillers and the beer
25 sellers. So they were placed at a competitive

1 disadvantage in other states.

2 The same thing will happen here to distributors
3 that have a disproportionate amount of business in
4 Connecticut compared to other distributors, and that's a
5 further disruption and a further kind of protectionist
6 interference with interstate commerce.

7 And the last thing I would say is, I would
8 still, if the state's position is that the act does not
9 apply where the situs of the sale is not in Connecticut,
10 then the wholesalers need to know: Does that mean if
11 their contract says we are selling to a Connecticut
12 hospital, but title to the drugs will be taken in New York
13 where our distribution facility is, is that transaction
14 subject to the law or not?

15 MS. FIELD: Your Honor, plaintiffs have alleged
16 two forms of violation of the Dormant Commerce Clause,
17 extraterritorial and protectionism, and neither are
18 present here.

19 The law does not have extraterritorial
20 application because it only applies to sales occurring
21 within the state. As AAM mentioned in its reply brief on
22 page seven, it does not intend to challenge the state's
23 power to regulate instate sales. The argument should stop
24 there, because there are only instate sales occurring
25 here.

1 Regarding any idea of protectionism, economic
2 discrimination requires a showing of an instate entity
3 that is being preferenced over a substantially similar
4 out-of-state agency. This is coming from GMC v. TRACY
5 which says that any notion of discrimination assumes a
6 comparison of substantially similar entities.

7 The entities in question here as alleged by the
8 plaintiffs are three sets of potential pairings, none of
9 which are substantially similar for the purpose of a
10 discrimination analysis.

11 The first is instate brand manufacturers which
12 are not substantially similar to out-of-state generic
13 manufacturers. The role of a brand manufacturer is to
14 research new drug products and obtain FDA approval to
15 bring those to market, a process that can cost billions of
16 dollars and take several years.

17 The role of a generic manufacturer in addition
18 to manufacturing drugs is to copy existing brand drugs, a
19 process that can be obtained in an abbreviated application
20 to the FDA and doesn't take as long as new drug
21 development.

22 If a brand drug manufacturer were to go out of
23 business, no generic drug manufacturer is a kind of
24 competitor that could take over their functions.

25 The second pairing that plaintiffs have

1 suggested is instate manufactured brand drugs being
2 protected from out-of-state manufactured generic drugs.
3 And again, we see that brand drugs and generic drugs are
4 not necessarily substantially similar. Even brand drugs
5 for which all patents and exclusivity have expired and
6 which have a generic alternative that is perfectly
7 comparable from a treatment perspective is treated in
8 antitrust cases as potentially being in a separate market
9 due to the market structure and the way that brand and
10 generics are viewed differently by consumers.

11 We see that in Lorazepam and Clorazepate
12 antitrust litigation. Although this is not an anti-trust
13 case, anti-trust law is similar to the Dormant Commerce
14 Clause analysis; a branch of law that uses the unique
15 characters of the product and the market, and the
16 consumers in the market, in order to identify competing
17 products and is therefore a useful analogy here.

18 There's also brand name drugs for which there
19 are still patents or exclusivity applied. Those drugs, as
20 plaintiffs note, may have generic alternatives, but those
21 alternatives will need to have the indications that are
22 still patented, carved out; meaning that there are
23 patients who can only be treated by the brand version of
24 the drug and cannot be treated by the generic. This means
25 that the market that is consuming the brand product is

1 going to be fundamentally different from the market that
2 is consuming the generic drug. Therefore, under each of
3 these situations, brand drugs and generic drugs are not
4 necessarily substantially similar under the Dormant
5 Commerce Clause for purposes of discrimination.

6 The final potential pairing that plaintiffs have
7 alleged is that instate distributors, meaning hospitals
8 and retail pharmacies, are being protected from
9 out-of-state manufacturers and wholesalers. Once again,
10 there is no substantial similarity between an instate
11 hospital or CVS as to an out-of-state manufacturer or
12 wholesaler. If a hospital went out of business, a
13 manufacturer could not move in and continue to provide
14 those same services.

15 Furthermore, it would not make sense for this
16 law to apply to retail pharmacies because the cost
17 structure of sales at retail are incredibly complicated.
18 Payments are shared by consumers and their insurers and
19 costs can change on a person-to-person basis. Pharmacies
20 themselves are reimbursed for the cost of drugs by a
21 pharmacy benefit manager and that payment is not
22 necessarily made public. A lot of the payments, in fact
23 at that level of the pharmaceutical distribution chain,
24 are protected by trade secret.

25 So this law, which is very straightforward and

1 tries to identify one point in the pharmaceutical
2 distribution chain where there's a simple pricing
3 mechanism that can be regulated, would simply not be
4 applicable at the retail level and might even be preempted
5 by several federal laws such as the 340B Drug Discount
6 Program which establishes drug prices for certain
7 hospitals for generic drugs.

8 THE COURT: May I ask, I did see where the act
9 can be read as part of a larger legislative attempt to
10 manage prescription drug prices, specifically in that
11 there's another public act that was aimed at the pharmacy
12 benefit managers, right? So is there any other
13 legislative tool to go after retailers? Or is it because
14 of the complexity that you mentioned or because of
15 legislative realities that the legislature has not gone
16 after the retailers in the same way? And, if not, then
17 why should it not be viewed as a form of discrimination in
18 that instate Connecticut retailers, even though they are
19 substantially different than the distributors, and
20 certainly than the manufacturers, if the goal is to cap,
21 to make sure we have affordable generic drugs for
22 Connecticut residents, this would seem to be a potential
23 gaping hole preventing that. So do you wish to speak to
24 any of that? Is there a law aimed at the retailers and
25 does it matter?

1 MS. FIELD: I would first say that the
2 complexity of the market at the retail level is a
3 challenge to directly regulating price there. There are,
4 as you mentioned, Your Honor, laws targeting pharmacy
5 benefit managers and the commissioner of insurance would
6 be addressing drug pricing from the insurance perspective.

7 There are various angles that would need to be
8 taken to address drug pricing from a big picture
9 perspective, and I would ask Your Honor to focus on this
10 one discrete law on the constitutionality thereof, and
11 know that I cannot speak for the legislature about their
12 intentions to regulate the other pieces of the market.

13 THE COURT: Thank you, counsel. Does either
14 plaintiff want to be heard?

15 MR. JAY: I would like to respond specifically
16 to the point about whether instate brand manufacturers and
17 favoring instate brand manufacturers, as I think our
18 friends on the other side don't seem to deny, is the type
19 of discrimination that matters for purposes of the Dormant
20 Commerce Clause. I want to disagree with the notion that
21 a brand product and a generic product are sufficiently
22 different, that this isn't the kind of discrimination the
23 Dormant Commerce Clause aims at, because if a brand
24 product and a generic product are chemically the same,
25 they are bioequivalent to each other - to the use the FDA

1 lingo - they can be used the same way by the same patients
2 usually for the same indications.

3 So one example which there is a brand with a
4 patent and a generic without a patent, so a brand covered
5 by the law and a generic not covered by the law, is the
6 pretty straightforward circumstance where the brand has at
7 least one patent. So it has exempted itself from the law,
8 but the generic doesn't infringe that patent.

9 So you have a brand and generic product that are
10 chemically the same, bioequivalent, can be used by the
11 same patient population. One of them is subject to a
12 price control; the other is not.

13 There's no generic manufacturer in Connecticut.
14 There's a substantial brand industry in Connecticut. I
15 think this is really no different than the circumstances
16 in the Bacchus Imports case that we cited in our papers
17 from the Supreme Court from 1984 which involved pineapple
18 wine in Hawaii. That was not a big slice of the market or
19 substitutable for other types of liquor and beer that the
20 tipplers of Hawaii might have chosen to drink. But
21 favoring one slice of Hawaiian industry is discrimination,
22 and the Supreme Court had no trouble saying so without
23 going through a complicated economic analysis of whether
24 pineapple wine could be a substitute for the beer and
25 liquor needs of people in Hawaii.

1 THE COURT: Is it meaningfully different that we
2 are talking about access to prescription medication here
3 and not pineapple wine?

4 MR. JAY: I think the point I made first
5 underscores that doesn't help the state here, because we
6 are talking about medications bioequivalent to each other.
7 So in a circumstance where there's no difference, or the
8 only difference is in the label, in other words, which
9 indications each medication is labeled for which doesn't
10 affect what substitutions a pharmacy can make; in other
11 words, Connecticut law allows a pharmacy to take a
12 prescription written for the brand product and substitute
13 the generic product.

14 So if it is substitutable at the pharmacy by
15 law, that's a pretty good indication they are usable by
16 the same population and that they are similar enough to be
17 comparators in the Dormant Commerce Clause, which I don't
18 think is as tight of a type of connection that might
19 happen in antitrust cases where you have expert evidence
20 that goes to establishing a relevant market. That's not
21 the kind of proof that the Supreme Court is required in
22 discrimination cases here.

23 Before handing off to Mr. Massey, I want to
24 underscore one thing Ms. Field said. Several of her
25 remarks were if a hospital or if a brand company were to

1 go out of business, which I took to be a statement that
2 the state does not care if out-of-state generic
3 manufacturers go out of business; whereas it is trying to
4 protect the brand companies and retailers to make enough
5 money on these products to go out of business. And both,
6 on the harm to our clients and on the public interest
7 point, I would point the state back to their own footnote
8 nine in their opposition, which is that if there are not
9 generic companies willing to market generic alternatives,
10 then there's a lack of competition for those brand
11 products and there's no way to bring those high prices of
12 brand products down.

13 THE COURT: Does defense want to be heard on
14 that issue before I turn to HDA, on any of that, including
15 the bioequivalence and why that might be an indicator of
16 discrimination?

17 MS. FIELD: Thank you. The issue of
18 bioequivalence is a little more nuanced than the
19 plaintiffs have alleged. If there's a brand name product
20 for which even a single patent remains, and if that patent
21 is related to an indication, meaning a particular illness,
22 then even if there's a bioequivalent generic alternative
23 for that drug, the patented indication can only be treated
24 by the brand product. This is quite different from any
25 other product, such as pineapple wine or any other alcohol

1 where the consumer is the one who is choosing which
2 variety of the products to purchase.

3 When it comes to pharmaceuticals, the physician
4 is the one writing the prescription and the laws are the
5 ones determining which prescriptions can be used to treat
6 different illnesses. And so if the patient is somebody
7 who has an illness that is a patented indication for the
8 brand name drug, then they are not choosing to take the
9 patented drug; they can't seek substitution at the
10 pharmacy counter. They have one drug and they are not the
11 one choosing it.

12 MR. MASSEY: Thank you, Your Honor. I'm sorry,
13 Mr. Jay.

14 MR. JAY: What Ms. Field said is not correct
15 about how substitution works, but this is a side issue
16 that I don't want to take the Court's time with. I just
17 want to note that we fundamentally disagree how
18 substitution works at the pharmacy in a carve-out case,
19 but I'll sit down and let Mr. Massey speak.

20 MR. MASSEY: Thank you, Mr. Jay. From the
21 distributor's standpoint, there are three types of
22 discrimination that makes this law protectionist and I
23 hear the state responding to only one, so if I could recap
24 briefly.

25 First is, there's protectionism on the consumer

1 level because Connecticut is making or seeking to make
2 drugs cheaper in Connecticut than in other states. And
3 the problem with that is, that as the Supreme Court said
4 in the Camps Newfound case that we cite in our reply
5 brief, quote, attempts to give local consumers an
6 advantage over consumers in other states is protectionist.

7 And that was the defect in the opioid tax case
8 in New York that the State of New York conceded that the
9 passthrough prohibition, which operated basically to have
10 distributors in New York push costs of the opioid tax onto
11 consumers in Connecticut and in Massachusetts; was
12 unconstitutional for that very feature because it
13 externalized the cost of the tax in New York.

14 This is just the flip side. Instead of New York
15 doing it to Connecticut, Connecticut is trying to do it to
16 New York.

17 THE COURT: Other than the liquor related cases,
18 this isn't the state saying you can't sell it cheaper than
19 you are selling it in Connecticut. They are saying
20 there's a cap, right? Is that a material difference?
21 Those lines of cases?

22 MR. MASSEY: We don't believe so, Your Honor.
23 Because what is happening is Connecticut is setting - it's
24 true these are not minimum prices, but maximum/minimum,
25 although the Court in Baldwin said it didn't matter if it

1 was higher or lower. But the point here is, if the
2 prevailing WAC is higher than the reference price, then
3 the consumers in other states are going to be bearing the
4 costs of Connecticut purchases, or distributors and
5 manufacturers in other states, and those in turn get
6 passed along, ultimately absorbed through the supply chain
7 by consumers.

8 So it's an externalization of Connecticut's
9 costs when it imposes a price cap that is set below WAC.
10 In a world where the distributors, like I said before, are
11 in the middle; we are not able to set or control WAC. And
12 so to force the distributors to buy at current WAC and
13 sell at lower reference price WAC for brand name drugs is
14 a protection of Connect--

15 THE COURT: Well, does the law say it has to be
16 lower or just not higher than?

17 MR. MASSEY: It has to be at the reference
18 price. It can't be higher than the reference price. But
19 we know in 2025, WAC has increased for 500 products. And
20 so as of January 1, 2026, distributors that have purchased
21 drugs throughout 2025 at higher than the reference price
22 WAC, because the WAC went up in 2025, they are sitting
23 with inventory they will have to sell January 1, 2026, at
24 reference price, which is lower. So that is an imminent,
25 immediate injury. That's why we are here in December as

1 opposed to waiting and suing later, because this injury
2 will happen now, and that is the reason for the
3 preliminary injunction.

4 But the second kind of discrimination that the
5 state has not responded to is a discrimination among
6 distributors based on how much business they have in
7 Connecticut. If you're a distributor with a lot of
8 business in Connecticut, a disproportionate amount in
9 Connecticut, you are handicapped outside of Connecticut in
10 competing with other distributors, which is the defect in
11 Healy and Brown-Forman which had a desperate impact on
12 distillers and beer sellers whether they had promotional
13 or rebate schemes.

14 Now, the last commercial level protectionism
15 that the state addressed is the notion that distributors
16 are not similarly situated to the instate retailers,
17 hospitals, and medical practices that operate at the
18 retail level. Now that, of course, was the very defect I
19 mentioned that Froch identified in the Fourth Circuit
20 case. And I hate to repeat myself, but Froch was cited by
21 approval by the Supreme Court for pork producers, so Froch
22 is pretty good authority.

23 And the state relies on a tax case called GMC
24 versus Tracy. That's not the way the Supreme Court has
25 approached discrimination in the commerce clause cases

1 involving interstate regulations beside taxes. For
2 example, in the Oregon Waste Systems case, the Supreme
3 Court said discrimination, quote, means differential
4 treatment of instate and out-of-state economic interests
5 that benefit the former and burdens the latter. That's
6 all it is. It doesn't have to necessarily line up on an
7 apples-to-apples basis. And pork producers itself
8 describe protectionism as laws seeking to benefit, quote,
9 instate interests. And the Eighth Circuit in Ellison held
10 the Minnesota law unconstitutional even though there were
11 no instate Minnesota manufacturers. So I think the
12 state's standard for when discrimination occurs at the
13 commercial level is artificially constricted.

14 THE COURT: Just pausing you there, counsel,
15 when you refer to Ellison and Froch, those are cases,
16 those were AAM cases, those were manufacturer cases,
17 right? So where does that leave distributors like your
18 members; should they be treated similarly or get the same
19 protections or not?

20 MR. MASSEY: We were not in the caption in those
21 cases. But the Maryland law, in particular, did govern
22 both manufacturers and distributors and it was invalidated
23 for both. And the Fourth Circuit even said, noted in
24 striking down the law, that distributors had no facilities
25 in Maryland; and that was one of the reasons why the law

1 was extraterritorial and impermissible. And of course we
2 have, HDA members have, no distribution facilities in
3 Connecticut. So we line up, really on all fours, with
4 Froch. Even though we were not the plaintiffs, we
5 basically obtained relief.

6 The other thing I would say when Your Honor
7 asked what could the state do, the main litigation is very
8 instructive. Because the main litigation, like
9 Connecticut, Your Honor noted that the Connecticut package
10 was originally a bunch of things besides the price. I
11 mean, what is a bunch of things besides the price?

12 The main litigation involved several different
13 provisions, as did the Connecticut legislation. The main
14 legislation involved an anti-profiteering provision that
15 barred unconscionable pricing. It also allowed the Maine
16 Health Commissioner to buy drugs in bulk and ask for
17 rebates equivalent to the Medicaid level of rebates.

18 And the first provision, the price control
19 provision, was struck down by the District Court in Maine
20 and the state gave up. The state conceded that that
21 provision was unconstitutional under the commerce laws.

22 The second provision, the price negotiation and
23 rebate provision, was upheld by the First Circuit. That's
24 the only part the state appealed. The state won in the
25 First Circuit and the First Circuit eventually got

1 affirmed.

2 So that part of the judgment still contains a
3 prohibition on the price control provision, but allows
4 Maine to do other things to solve, to address the drug
5 price issues in Maine. And I think that is a good lesson,
6 that just as New York did not appeal or question the
7 invalidation of the cost passthrough prohibition - because
8 New York recognized it was impermissibly pushing costs
9 onto consumers in other states, just as Maine did not
10 appeal the invalidation of the anti-profiteering provision
11 because it recognized that it was unconstitutional under
12 commerce clause grounds - the law here, just as those
13 states made those decisions, Connecticut should scale back
14 and not target distributors who will be stuck in the
15 middle if transactions - since they don't set a control
16 lack - if the state is allowed to adopt, to follow its
17 interpretation that Ms. Field articulated, I would still
18 like an answer.

19 THE COURT: I was going to ask if we got an
20 answer to that one. Specifically back to your question
21 about, you mentioned if a distributor contracts with - I
22 think you said a hospital in Connecticut - but title is
23 taken in New York where the distribution center is, your
24 question is would that constitute a sale in Connecticut?

25 MR. MASSEY: Exactly, Your Honor.

1 THE COURT: Sorry if I missed it too, but does
2 defense have a response to that?

3 MS. FIELD: So the situs of a transaction will
4 be where the title is taken. So if a wholesaler sells a
5 product to a buyer, if the wholesaler is California and
6 the buyer is in Arkansas and then that product is
7 distributed to a facility in Connecticut, the transaction
8 has occurred outside of the state.

9 THE COURT: Do you want to be heard on that?

10 MR. MASSEY: I mean, that is kind of news to us,
11 so it would be important for HDA to have that
12 representation memorialized somehow. It's an issue that I
13 have not had a chance to discuss with my client, so I
14 don't have a position on how that affects our case. But I
15 do think, as I said before, even under cases like
16 Brown-Forman and even when there's a sale into a state,
17 cases like Brown-Forman say it doesn't allow the state to
18 regulate it in violation of the commerce clause. And
19 because in this - I don't think the state's position
20 necessarily moots our commerce cause challenge, because
21 the relevant transactions are occurring out of state. So
22 I do need to - I can't offer Your Honor a position beyond
23 that.

24 THE COURT: To the extent you are saying that
25 your hypothetical - sorry. You are saying in your

1 hypothetical the act still would implicate the commerce
2 clause even though - go ahead.

3 MR. MASSEY: For example, it would force our
4 members to renegotiate all the contracts to say now the
5 situs is going to be someplace else.

6 THE COURT: To perform an end run around the
7 law?

8 MR. MASSEY: Essentially. We didn't know this
9 existed until this morning, Your Honor. And whether
10 that's feasible, I don't know. And, obviously, the burden
11 to renegotiate a contract is itself an injury and an
12 interference with commerce.

13 So if the state is inviting the members of HDA
14 to redo all of our contracts, I don't know whether that
15 can happen between now and January 1st. There are a lot
16 of practical, logistical complications that make it very
17 difficult.

18 THE COURT: I do want to go back to that,
19 because you raised another point. But I'll pause to ask
20 the defense, Attorney Field, if that's the case, that
21 there's this potential end run around the law, is it
22 effective at all? Or is it enough that it would be
23 effective for a year before everyone adjusts how they do
24 business? Or does that matter?

25 MS. FIELD: The law will affect as many

1 transactions as it can cover. And for all of those
2 transactions that it applies to, it will save consumers
3 money on life-saving drugs.

4 THE COURT: Fair enough. Going back to HDA -
5 maybe this is a question for AAM - but don't manufacturers
6 often, I'll say sometimes, don't they sometimes sell
7 medication to distributors below WAC, sometimes even well
8 below it? And, if so, can you explain why that is? Why
9 that doesn't undercut some of your argument here?

10 Because the point I'm making is, can't bulk
11 sales, can't discounted bulk sales, still be lucrative?
12 Their whole business model is based on that concept.
13 There are very successful companies built on that type of
14 model. So do you wish to speak to that? Isn't it true
15 that there are below WAC sales, why is that, and why does
16 that matter, if you would, please.

17 MR. MASSEY: I can speak first.

18 THE COURT: Sure.

19 MR. MASSEY: That issue on the record that comes
20 before the Court, that issue has not been developed. The
21 state didn't controvert any of the facts. It comes on,
22 the PI motion, comes on the record that we submitted.

23 For brand drugs, WAC is generally both the
24 purchase price from the manufacturer and the sales price
25 to the retailer. There are exceptions. There are, in

1 some cases, Your Honor pointed out, for the discounts.
2 But in general, WAC is the metric that drives all the
3 pricing decisions. Generics are a different matter.
4 Generics are often below WAC, that is true; but the same
5 is true in lots of other cases.

6 In other words, the law in Froch banned price
7 gauging. The law in Minnesota banned increases of WAC in
8 excessive certain percentages. So there were a lot of
9 sales that existed that those laws didn't touch, but that
10 didn't mean that the laws were constitutional. In fact,
11 it meant that every time the law did have application,
12 every time the law did have an impact on transactions, it
13 was unconstitutional.

14 So I would say to Your Honor, that the fact
15 there might be some situations in this case where the law,
16 the Connecticut drug price cap doesn't affect the price,
17 because in some transaction or another it was not set
18 exactly at WAC. That does not allow the law to survive
19 constitutional scrutiny any more than the laws in
20 Minnesota or Maryland did, because basically any time the
21 law has bite, it is regulating commerce in an
22 extraterritorial and protectionist way.

23 So that's really true, I think, for all laws
24 when people challenge the constitutionality. In some
25 sense, sometimes laws have a permissible application. But

1 in this case, every time it actually has an impact on a
2 transaction, it will be unconstitutional.

3 So I don't think - I think that the issue Your
4 Honor posed, which reflects a sophisticated understanding
5 of the pharmaceutical pricing situation, is a valid
6 question, but it doesn't affect the outcome of this case.

7 THE COURT: Also talking about - and I
8 understand that Attorney Jay may want to respond as well -
9 but putting a pin in that for a moment. You did talk
10 about ways in which your members might adjust their
11 contract structure going forward with this new
12 understanding of the act as interpreted by the state.

13 Similarly, won't manufacturers - well, can
14 manufacturers just adjust up the WAC in future years if
15 Connecticut and other states pass laws like this? Can't
16 manufacturers just inflate the WAC and protect themselves
17 that way without a higher starting price at the beginning
18 of the year? Or is that unlikely because of the
19 nationwide nature of the WAC in general?

20 MR. MASSEY: Well, Your Honor, we read the law
21 as creating a reference price of January 1, 2025--

22 THE COURT: Yep.

23 MR. MASSEY: -- that's adjusted by the CPI. In
24 2026, it's that same price. So if the manufacturers
25 increase WAC, the distributors are stuck in a bigger bind.

1 We are stuck at the reference price which is going to be
2 capped at the January 1, 2025 WAC, adjusted by the CPI.
3 If WAC goes up fast, then we are just bleeding. And
4 that's why we fear, as distributors, that we are stuck in
5 the middle. And we don't set or control WAC, and would be
6 at the mercy of manufacturers in that situation.

7 THE COURT: Thank you. Attorney Jay.

8 MR. JAY: I'll add two quick points. One is a
9 principal and the other practicality. On the point of
10 principal, the problem with the extraterritorial
11 application of laws like this is not exactly what cap they
12 set but the fact that every one of the 50 states could in
13 theory set its own conflicting cap.

14 You can see by the different formulas used in
15 Maryland, in Minnesota, in Connecticut, and a proposed
16 legislation in other states, that not only do they adopt
17 different numbers, but they even cover different and
18 overlapping drugs in different ways. So it would make it
19 fundamentally impossible to try to comply with individual
20 state caps.

21 On your question, could the manufacturers
22 increase the WAC, my understanding is the same as
23 Mr. Massey's. And this is the practical point, that this
24 law caps, imposes the cap, at the January 21st, 2025 WAC
25 forever. The only adjustment is the general consumer

1 price index. That doesn't take account of the costs, the
2 increased cost of producing a particular drug. It doesn't
3 take account of price increases in the pharmaceutical
4 sector, generally. It's the general consumer price index,
5 the general basket of goods, the most general measure of
6 inflation there is.

7 So our declarants have explained why it's more
8 expensive to make certain products and they need to
9 increase prices to make money on those products and not
10 have to take them off the market as money losers. And
11 this legislation doesn't take account of that at all.
12 It's the January 21st, 2025 price forever.

13 So even if the discounts made it possible to
14 stay beneath that cap now for some products, because the
15 cap stays there forever as the cost increases, like more
16 and more products bump up against that cap, and
17 discounting isn't going to solve that.

18 THE COURT: Does defense want to be heard on
19 that, on the impact of setting the cap at the 2025 WAC?

20 MS. FIELD: The goal of the legislation is to
21 cap the rise of drug prices for covered purchases at
22 inflation. So setting the WAC at the January 1st, 2025
23 price and capping it at inflation would, for covered
24 transactions, keep that price potentially lower than
25 future WAC prices being set.

1 However, I am curious as to what transactions
2 plaintiffs think would be covered by this. It almost
3 feels like there's a Schrödinger's transaction where there
4 is something that is sufficiently connected to a nexus in
5 Connecticut where we would have some ability to enforce
6 against the transaction while also not being connected to
7 Connecticut such that it is unconstitutional for us to
8 enforce against it. And I think it is likely that
9 plaintiffs are considering more transactions to be covered
10 by this law than are in actuality covered by it.

11 THE COURT: Do plaintiffs want to be heard on
12 that?

13 MR. JAY: I'll repeat my earlier answer, that if
14 Ms. Field's position today is that, for example, the two
15 products described in our declarations, which our members
16 sell outside of Connecticut to wholesalers outside of
17 Connecticut - the concept of situs doesn't appear in their
18 papers - but it's consistent with how we would naturally
19 read in this state.

20 So if the state's position is that those
21 transactions are not covered by the law, then as I said
22 before, I agree that that concession, if memorialized by a
23 ruling from Your Honor, would give us the same relief we
24 are seeking. But unless and until that happens, I've
25 tried to answer the Court's questions based on the

1 positions we have taken in this and other litigation, why
2 it's unconstitutional to reach beyond the state's borders
3 to set prices or to cap prices in transactions charged out
4 of state.

5 So our client, at least, is content with a
6 ruling that prevents this law from applying to those
7 out-of-state transactions. And if that's the state's
8 position and if Your Honor memorializes it, then to your
9 question earlier about trust, we wouldn't just be going on
10 trust; we would be protected by this Court's ruling.

11 THE COURT: Going back to your previous argument
12 on extraterritoriality and if Connecticut is allowed to do
13 this every state can come up with their own similar law
14 creating chaos for the manufacturers; but isn't that what
15 the Supreme Court allowed in California with respect to
16 pork? Couldn't other states come up with similar health
17 based or ethics based laws that then farmers have to
18 adjust to and they just had to do it?

19 MR. JAY: The reason that's not the analogy to
20 what is going on here, I think, is that the state doesn't
21 preclude any product from coming - I should say
22 Connecticut doesn't preclude any product from coming into
23 Connecticut or being resold in Connecticut. So
24 California's law said, you may not resell in California
25 pork that was not produced in compliance with California's

1 standards.

2 And so Connecticut has no problem with a
3 retailer in Connecticut selling to a consumer a product
4 that was sold to the retailer at a price Connecticut
5 doesn't like. It's just punishing whoever sold the
6 product to that retailer.

7 Now this is, of course, subject to the question
8 about what does it mean to be sold in this state. And so
9 if the state, if the legislation does mean what Attorney
10 Field says it means, that would carve out the set of
11 transactions that AAM at least is challenging, which are
12 transactions that occurred outside of the state.

13 THE COURT: And plaintiffs would not be able to
14 share the costs with consumers down the road because of
15 the law.

16 MR. JAY: I want to make sure I understand the
17 Court's question. That manufacturers--

18 THE COURT: In California, when we talk about
19 pork production and how the increased costs of complying
20 with California's law, those increased costs could be
21 shifted to the consumer, to some degree, whereas this law
22 may prevent plaintiffs from doing the same because of the
23 cap.

24 MR. JAY: That is exactly right. A pork
25 producer in Iowa who finds it more expensive to raise hogs

1 in a way that will produce California compliant pork, can
2 charge more for California compliant pork. And if that
3 raises prices in the entire pork market, that's the kind
4 of downstream effect that California was not regulating.
5 It was just regulating the ability to sell noncompliant
6 pork in California, period, full stop. It didn't regulate
7 the price.

8 When you try to regulate a manufacturer or
9 wholesaler's ability to pass on a fee, that is exactly
10 what the HDA versus Zucker litigation that both of us
11 cited in our papers was about. It was about the opioid
12 fee in New York in which the state said we are going to
13 impose a fee on you and bar you from passing it onto
14 consumers. And because that regulated the prices charged
15 by manufacturers outside the state, the Southern District
16 of New York enjoined that aspect of the law.

17 And as with the Maine law to which Mr. Massey
18 alluded, New York didn't even appeal that aspect of the
19 injunction because it was so clearly extraterritorial.
20 And it really gets to the same point Your Honor was
21 making, that a health and safety regulation that costs
22 money to comply with allows that cost to be passed onto
23 the ultimate consumer.

24 MR. MASSEY: Your Honor, if I could just address
25 the question you posed earlier about whether the state's

1 position as to situs affects our constitutional claim, the
2 notion that the distributors could redo their contracts to
3 establish that title was taken outside of Connecticut. I
4 do think that it doesn't solve the problem completely. As
5 I said, the renegotiation or the duty or obligation, the
6 burden of renegotiating the contracts, is itself an
7 injury. It's an extraterritorial interference with
8 interstate commerce.

9 I think it lines up with the burden in Healy and
10 Brown-Forman, which was the discontinuance of rebate and
11 promotional programs, which itself seems in some ways like
12 not such a big deal. So the liquor distillers and the
13 beer sellers couldn't run the rebate programs they wanted,
14 but the Supreme Court said - and they had the choice, they
15 could have complied with the state laws by giving up those
16 programs - the Supreme Court said that's a Hobson's choice
17 and that required that the laws in those cases be
18 invalidated.

19 And so here, the obligation to do so something
20 you don't want to do, because obviously we structured our
21 contracts a certain way for a reason, if we go back to
22 renegotiate, we probably have to give something up;
23 there's no free lunch. And so the reason the contracts
24 are structured the way they are is for a business purpose,
25 and the obligation to redo them in derogation of that

1 business purpose is itself the constitutional injury.

2 MS. FIELD: Plaintiffs have had time to
3 renegotiate contracts in accordance with the plain meaning
4 of this law. Instead, they have interpreted an
5 implausible interpretation that is contrary to the plain
6 meaning. They have cited Commissioner Gifford's
7 testimony, and the relevant portion of this testimony
8 reads and I quote, the prices in the whole chain of
9 transactions through the system where multiple entities
10 touched on the sale of a drug, end quote.

11 This is referring to trickledown sales from a
12 reduced fee upstream, not to liability that is being
13 passed upstream.

14 Furthermore, the canon of constitutional
15 avoidance provides that a plausible reading of a statute
16 that would render the statute unconstitutional should lead
17 to a reasonable alternative reading that would not render
18 it unconstitutional.

19 So between the plain meaning and the lack of
20 legislative history that would imply that this would have
21 the alleged enforcement mechanism, as well as the canons
22 of constitution, canons of statutory interpretation all
23 point to the fact that this law regulates interstate
24 transactions where the manufacturer or wholesaler is
25 selling in this state.

1 To decide now that it is too late to renegotiate
2 contracts and that there would be some kind of injury for
3 failure to renegotiate contracts when this law and its
4 plain meaning have been available for months is
5 inappropriate.

6 THE COURT: On that point of how much notice
7 plaintiffs have had, I imagine their response would be
8 similar to their explanation as to why they filed suit in
9 the time they did, which is that - Well, I guess the
10 Court's question would be, did the state clarify its
11 interpretation of the statute through its briefing or
12 otherwise before the clarity that was provided today on
13 the record?

14 MS. FIELD: The statute is quite clear on its
15 face. Plaintiffs have said that they--

16 THE COURT: But plaintiffs asked for clarity
17 from defendants, right? And was today's clarity given to
18 them prior to today?

19 MS. FIELD: Plaintiffs have said they had some
20 conversation or sought clarity from the state and I don't
21 know which conversations or with whom they were had. If
22 plaintiffs would like to provide that information or the
23 contents of those conversations, I would be better
24 situated to answer this.

25 THE COURT: Fair enough. Okay. All right.

1 This has shifted, some of the analysis that I had
2 undertaken in preparing for today, so I appreciate the
3 parties entertaining the Court's questions and some of the
4 representations made today from each of the three parties.
5 It was very helpful in clarifying some of these issues for
6 the Court.

7 Is there anything else? I'll be respectful of
8 our courtroom deputy's time as well.

9 Does anyone have anything else they feel beyond
10 their briefing that they would like to put on the record
11 for the Court's consideration before we conclude?

12 MR. MASSEY: For HDA, I can represent we did not
13 have prior notice of the state's interpretation of the
14 situs issue. That is something that we have learned today
15 for the first time.

16 Also, for the Court's convenience, I have a
17 proposed order I could hand up, if that's of interest.

18 THE COURT: You can do that or docket it. Does
19 each other party have it?

20 MR. MASSEY: Yes. The state has it.

21 THE COURT: You can approach. Do you have this
22 in Microsoft Word form?

23 MR. MASSEY: We do.

24 THE COURT: So that can be emailed through the
25 courtroom deputy or whomever. That would be fine--

1 MR. MASSEY: Thank you, Your Honor.

2 THE COURT: -- for consideration. Thank you
3 very much, counsel. The Court is in receipt of that.

4 Anything else?

5 MR. MASSEY: Sorry. A little more context on
6 the contract renegotiation process, since that's on the
7 table. They are often multiyear contracts and they are
8 not done by locality. So the burden of negotiating where
9 situs is taken in Connecticut can't be done, can't be
10 changed immediately, and the contracts are not state
11 specific.

12 So the wholesalers, effectively, the only seller
13 into the state, and that bears on the burden of the cap
14 targeted to the manufacturer, while they don't, the
15 distributors do not set the price which occurs out of
16 state. But my point is, the contract renegotiation
17 process is much more complicated than the state's
18 suggestion and it's a sizable, substantial burden on
19 commerce.

20 THE COURT: Attorney Jay.

21 MR. JAY: Just to respond to Attorney Field's
22 question. The allegation in our complaint about meeting
23 with the state, it was a meeting with two senior people in
24 the Attorney General's Office.

25 The only other thing I'll say is that we also

1 have a proposed order which memorializes what we said, in
2 ECF-20, which is our cover motion asking for a PI against
3 extraterritorial impact.

4 In light of what the state has said today, it
5 may be that the appropriate disposition in our case is
6 something different. So I guess I'll refrain from handing
7 that up to the Court at this time, but if the Court would
8 like that from us, we are happy to submit it.

9 THE COURT: Fair enough. Thank you, Attorney
10 Jay. Attorney Field.

11 MS. FIELD: If I may add two things. The first
12 is, if there are existing nationwide contracts, it is the
13 role of the State of Connecticut to govern sales that are
14 occurring within Connecticut; not to get out of the way of
15 nationwide contracts that are being made regardless of
16 Connecticut law.

17 The pharmaceutical industry is already governed
18 by a regulatory patchwork, and the participants in the
19 industry are already skilled at navigating that patchwork
20 and adapting to it as it changes.

21 The second thing that I would add is that the
22 case cited by plaintiffs stating that since the Attorney
23 General has allegedly failed to disavow an alleged
24 enforcement mechanism, the case they cited is Susan B.
25 Anthony List versus Dreihaus, has as very key distinction

1 from the situation at hand. In that case, the plaintiff
2 had to be faced with a credible threat of enforcement, and
3 that case was told that if his conduct continued that he
4 would be prosecuted. The prosecution then failed to
5 disavow that threat. But it was a credible and direct
6 threat of enforcement. Here, we have a statute whose
7 plain meaning does not imply the alleged enforcement
8 mechanism. Thank you.

9 THE COURT: Anything else from anyone? All
10 right. For HDA, one follow-up question. Are you aware of
11 any current contracts where the situs - well, where title
12 is to be taken in Connecticut?

13 MR. MASSEY: Your Honor, as I stand here today,
14 no. But I also don't know the details of the contrary. I
15 do know, all I know is, that we have multiyear, complex
16 contracts that are not specific to Connecticut. And in
17 some instances the contracts might say that title is taken
18 at the distribution facility. In other instances it may
19 say title was taken at the place of delivery. Neither
20 would be specific to Connecticut. The contracts don't
21 really have Connecticut specific provisions. But I'm
22 speaking on behalf of a lot of members.

23 THE COURT: I get it. With a lot of contracts,
24 sure.

25 MR. MASSEY: With a lot of contracts, and I

1 don't want to overstate my ability to answer that
2 question. But I believe it would be a large task to even
3 answer that question, frankly, even to understand exactly,
4 to analyze each contract and determine where title would
5 be taken. I raise the issue today because of the state's
6 comment about situs.

7 THE COURT: Right.

8 MR. MASSEY: It raised a new question for us,
9 how the state is doing it.

10 THE COURT: I appreciate that.

11 MR. MASSEY: And I do need to know that for my
12 members. But at the end of the day, I think they are
13 going to say that is a very large undertaking for us and
14 that is not something that can happen between now and
15 January 1st, 2026.

16 And so if the law goes into effect on
17 January 1st, 2026, we will have to comply with it at great
18 expense, and we believe the constitutional injury itself
19 is a form of irreparable harm.

20 Aside from that, there's also the financial
21 cost. And both of those are forms of irreparable harm.
22 And we don't think, with all respect, that the law was
23 very clear on its face if that's really what the
24 Connecticut General Assembly meant.

25 THE COURT: I thank you all for, again, a very

1 helpful briefing, citations to helpful case law, and your
2 arguments today. I thank you so much for all of that.

3 Anything further before the Court takes a
4 recess? Thank you all. The Court stands in recess.

5 MR. MASSEY: Thank you, Your Honor.

6 MS. FIELD: Thank you, Your Honor.

7 COURTROOM DEPUTY: The United States District
8 Court is now in recess.

9 (Adjourned at 11:33 a.m.)

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2 C E R T I F I C A T E

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5 I, Catherine Cullen, Official Court Reporter for
6 the United States District Court for the District of
7 Connecticut, do hereby certify that the foregoing pages
8 are a true and accurate transcription of my shorthand
9 notes taken in the aforementioned matter to the best of my
10 skill and ability.

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/S/ CATHERINE CULLEN

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UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

HEALTHCARE DISTRIBUTION)
ALLIANCE,)
Plaintiff,) Civil No. 3:25-cv-1724-OAW
)
v.)
)
MARK D. BOUGHTON (in his official)
capacity as Commissioner of the)
Connecticut Department of Revenue)
Services) and WILLIAM TONG (in his)
official capacity as Attorney General for)
the State of Connecticut),)
Defendants.

ORDER

THIS ACTION is before the court upon the Motion for a Preliminary Injunction filed by Plaintiff Healthcare Distribution Alliance (hereinafter, “HDA”). ECF No. 27.

HDA is a national trade association representing wholesale distributors of prescription drugs. ECF No. 27-1, at 1. It seeks to enjoin the Attorney General of Connecticut, Defendant William Tong, and the Commissioner of Connecticut’s Department of Revenue Services, Defendant Mark D. Boughton, from enforcing against its members Sections 345 through 347 of Public Act No. 25-168 (hereinafter, the “Act”), which will “cap” the prices of certain prescription drugs sold by certain manufacturers and distributors in Connecticut beginning on January 1, 2026. *Id.*

The court held a hearing on the Motion on December 9, 2025, see ECF No. 40, and carefully has reviewed the parties’ initial and supplemental memoranda of law, as well as the broader record before it, see ECF Nos. 27, 27-1–27-5, 34, 35, 41, 42, 43, 44, 44-1–44-3. For the reasons that follow, the Motion is **DENIED**.

I. BACKGROUND

A. Rising Prescription Drug Costs

The “rising cost of prescription drugs presents a significant challenge” to maintaining and improving people’s health. Conn. Gen. Assembly’s Prescription Drug Task Force, Final Rep. and Recommendations, at 2 (Feb. 26, 2025) (available at https://www.cga.ct.gov/hs/taskforce.asp?TF=20241204_Prescription%20Drug%20Task%20Force); *see also Ass’n for Accessible Medicines v. Raoul*, No. 24-C-544, 2025 WL 2764558, at *1 (N.D. Ill. Sept. 26, 2025) (acknowledging “skyrocketing drug prices, sometimes by more than 1,000%, and sometimes overnight,” in 2025); *Ass’n for Accessible Medicines v. Frosh*, 887 F.3d 664, 674 (4th Cir. 2018) (Wynn, J., dissenting) (noting, in 2018, “a series of high-profile incidents” of “multiple-thousand-fold price increases for single-source generic drugs that treat rare and life-threatening conditions”); *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 649 n.1 (2003) (acknowledging, in 2003, that prescription drug costs “increased at an average annual rate . . . [higher] than any other component of the healthcare sector”) (internal citation and quotation marks omitted).

A “significant portion” of Connecticut residents “delay filling prescriptions, cut pills in half, and take extreme measures because of these costs.” Liese Klein, *New Connecticut laws aim to tame surging prescription drug prices for patients, hospitals*, CT Insider (Jul. 27, 2025), <https://www.ctinsider.com/business/article/new-laws-target-rising-prescription-drug-costs-20786384.php> (quoting Alex Reger, Director of the Connecticut Office of Health Strategy’s HealthCare Benchmarks Initiative); *see also* Conn. Off. of Health Strategy, Cost Growth Benchmark Initiative Rep., at 51 (Apr. 24,

2025) (available at https://portal.ct.gov/ohs/services/cost-growth-quality-benchmarks-primary-care-target/reports-and-updates?language=en_US). Indeed, in a recent statewide survey, nearly one quarter of respondents—and, notably, nearly one third of respondents whose annual household incomes were under \$50,000—admitted to “rationing” prescription drugs “due to cost concerns.” Healthcare Value Hub, Connecticut Survey Respondents Struggle to Afford High Health Care Costs; Worry about Affording Health Care in the Future; Express Bipartisan Support for Policy Solutions, at 1–2 (September 2025) (available at <https://healthcarevaluehub.org/wp-content/uploads/2025-Affordability-Brief.pdf>); see also Healthcare Value Hub, Connecticut Residents Struggle to Afford High Healthcare Costs; Worry about Affording Healthcare in the Future; Support Government Action across Party Lines, (Oct. 18, 2022) (available at <https://healthcarevaluehub.org/chess-state-survey/connecticut/2022/connecticut-residents-struggle-to-afford-high-healthcare-costs-worry-about-affording-healthcare-in-the-future-support-government-action-across-party-lines/>).¹

In response, Connecticut’s General Assembly empaneled a “bipartisan, bicameral” task force to propose policies for lowering prescription drug costs. Conn. Gen. Assembly’s Prescription Drug Task Force, Final Rep. and Recommendations, at 2 (Feb. 26, 2025) (available at https://www.cga.ct.gov/hs/taskforce.asp?TF=20241204_Prescription%20Drug%20Task%20Force). Governor Ned Lamont also proposed policies with the same goal. Press Release, Governor Lamont Announces 2025 Legislative Proposal: Reduce Prescription Drug Costs (Feb. 6, 2025) (available at [---

¹ The court “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 as Tr. of Aegean Litig. Tr. v. Tavlarios*, No. 20-2579-CV, 2021 WL 5365582, at *3 \(2d Cir. Nov. 18, 2021\) \(summary order\) \(quoting Fed. R. Evid. 201\(b\)\(2\)\).](https://portal.ct.</p>
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gov/governor/news/press-releases/2025/02-2025/governor-lamont-announces-2025-legislative-proposal-reduce-prescription-drug-costs?language=en_US). In July 2025, several of the governor's and the task force's proposals became laws, including the Act. ECF Nos. 27-1, at 7; 34, at 6; see Margaret A. Bartiromo and Stephen M. Cowherd, *New Connecticut Health Care Laws Effective in the New Year*, Pullman & Comley Conn. Health Blog (Nov. 5, 2025), <https://www.pullcom.com/connecticut-health-law-blog/connecticut-health-care-laws-effective-in-the-new-year>).

B. The Act

The Act regulates sales of certain prescription drugs² in Connecticut by certain manufacturers and distributors,³ but not sales by retailers. ECF Nos. 27-1, at 3; 34, at 6. “This is largely a function of how the . . . prescription drug industry is structured.” *Raoul*, 2025 WL 2764558, at *1; see also ECF Nos. 27-1, at 3–4; 34 at 2–6. Put simply, manufacturers of prescription drugs “sell nationally” to distributors, who then “resell” to retailers, “who in turn sell to patients.” *Raoul*, 2025 WL 2764558, at *1 (internal citation and quotation marks omitted); see also *Ass’n for Accessible Medicines v. Ellison*, 140 F.4th 957, 959 (8th Cir. 2025). The price set by manufacturers is called the “wholesale acquisition cost” (hereinafter, “WAC”). *Raoul*, 2025 WL 2764558, at *1; see also ECF Nos. 27-1, at 1–2, 4; 34, at 2–4. Manufacturers “actually sell drugs” to distributors at negotiated prices, oftentimes “far below . . . WAC.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 68 (D. Mass. 2005); see also ECF No. 34, at 3–4.

² The Act applies to sales of any “brand-name drug or biological product to which all exclusive marketing rights granted under . . . [federal law] have expired for at least twenty-four months,” and any “generic drug.” See Public Act No. 25-168, § 345(6).

³ The Act applies to manufacturers and distributors who earn at least \$250,000 “in total annual sales in this state.” See Public Act No. 25-168, § 346(b)(2).

Nevertheless, a drug's WAC "serves as the benchmark" for how it is priced by distributors and retailers. *Raoul*, 2025 WL 2764558, at *1 (internal citation and quotation marks omitted); see also *Ellison*, 140 F.4th at 959 (describing the WAC as "the baseline price").

While the Act has many elements,⁴ its primary operation is as a "drug price cap." ECF No. 34, at 6; see also ECF No. 27-1, at 1–3. Beginning on January 1, 2026, covered manufacturers and distributors will be prohibited from selling "an identified prescription drug in this state" at a price that exceeds the WAC set on January 1, 2025, as "adjusted for any increase in the consumer price index" (hereinafter, the "Reference Price"). Public Act No. 25-168, §§ 345(11), 346(a)(1); see also ECF Nos. 27-1, at 2; 34, at 6. Unless determined to be "in shortage" by the Secretary of Health and Human Services, selling an identified drug above its Reference Price will result in a civil penalty "equal to eighty per cent of the difference" between the revenue of the non-compliant sales and the revenue that would have been earned if such sales had complied with the Reference Price. Public Act No. 25-168 §§ 345(a)(2), 346(b)(1)(A)–(B); see also ECF Nos. 27-1, at 2–3; 34, at 7.

C. The Motion for a Preliminary Injunction

HDA brought this action against Defendants on behalf of its members, all of whom are distributors located outside of Connecticut. ECF No. 1; see also ECF No. 27-1, at 2. The Association for Accessible Medicines (hereinafter, "AAM"), a national trade association representing manufacturers, brought a related action against Defendants. *Ass'n for Accessible Medicines v. Boughton et al*, No. 3:25-cv-01757-OAW, ECF No. 1

⁴ For example, it is a violation of the Act for covered manufacturers and distributors to withdraw their prescription drugs from Connecticut to avoid compliance therewith. See Public Act No. 25-168, § 347(a). The Act also requires certain officers and employees of such manufacturers and distributors to report certain information to the Connecticut Department of Revenue Services. See *id.*, § 346(j)(1).

(D. Conn. Oct. 17, 2025). On October 23, 2025, HDA and AAM filed separate motions for preliminary injunction. ECF No. 27; *Boughton*, No. 3:25-cv-01757-OAW, at ECF No. 20. At their request, the court held a consolidated hearing thereupon, on December 9, 2025. ECF Nos. 31, 32, 40; *Boughton*, No. 3:25-cv-01757-OAW, at ECF Nos. 25, 27, 32.

HDA and AAM contemplated a broad interpretation of the Act in their initial memoranda of law, as if the Act encompassed identified drugs sold outside of Connecticut but later made available by third-parties to patients in Connecticut. See ECF No. 27-1, at 7–11, 12–17; 35, at 1–7; see also *Boughton*, No. 3:25-cv-01757-OAW, at ECF Nos. 20-1, 30. Laws similar to the Act operate (or have operated) in this manner in other states. See, e.g., *Raoul*, 2025 WL 2764558, at *1 (describing a similar state law in Illinois); *Ellison*, 140 F.4th at 959 (describing a similar state law in Minnesota); *Pharm. Rsch. & Manufacturers of Am. v. Comm'r, Maine Dep't of Hum. Servs.*, No. CIV. 00-157-B-H, 2000 WL 34290605, at *1–*2 (D. Me. Oct. 26, 2000), *rev'd sub nom. Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001), *aff'd sub nom. Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, (2003) (describing a similar state law in Maine); *Pharm. Rsch. & Mfrs. of Am. v. D.C.*, 406 F. Supp. 2d 56, 60–61 (D.D.C. 2005), *aff'd sub nom. Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362 (Fed. Cir. 2007) (describing a similar law in the District of Columbia).

At the hearing, Defendants clarified “*for the first time*” that they do not interpret the Act so broadly, and only intend to enforce it against covered manufacturers and distributors selling identified drugs where title is taken in Connecticut. ECF No. 41 (emphasis in original); see also ECF Nos. 42, at 38:3–8; 43, at 2. Accordingly, the court ordered the parties to submit “limited supplemental briefing” explaining how Defendants’

“position on the Act’s applicability . . . as articulated at the hearing, affects the merits” of HDA’s and AAM’s motions for preliminary injunctions. ECF No. 41. On December 12, 2025, Defendants confirmed their position on the Act’s applicability in their supplemental memoranda of law. ECF No. 43, at 2; see also *Boughton*, No. 3:25-cv-01757-OAW, at ECF No. 36.

Because AAM’s members do not sell identified drugs to any distributors who take title to such drugs in Connecticut, AAM voluntarily dismissed its action against Defendants on December 16, 2025. *Boughton*, No. 3:25-cv-01757-OAW, at ECF Nos. 39, 40. HDA’s members *do* sell identified drugs to retailers who take title to such drugs in Connecticut. ECF No. 44, at 1–3. Accordingly, HDA submitted a supplemental memorandum of law on December 16, 2025, urging the court to grant its Motion for a Preliminary Injunction and arguing that the Act violates the dormant Commerce Clause of the United States Constitution. *Id.* at 3–10; see also ECF Nos. 27-1, at 7–11, 12–17; 35, at 1–7.

II. LEGAL STANDARD

A preliminary injunction is “not a matter of right.” *Auracle Homes, LLC v. Lamont*, 478 F. Supp. 3d 199, 217 (D. Conn. 2020). It is “an extraordinary and drastic remedy, one that should not be granted unless the movant, by a *clear showing*, carries the burden of persuasion.” *Sussman v. Crawford*, 488 F.3d 136, 139 (2d Cir. 2007) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (emphasis in original)).

Where, as here, the movant “seeks a preliminary injunction that will affect government action taken in the public interest pursuant to a statutory or regulatory scheme, the injunction should be granted only if the moving party meets the . . . likelihood-

of-success standard.” *Cnty. of Nassau, N.Y. v. Leavitt*, 524 F.3d 408, 414 (2d Cir. 2008) (citing *Wright v. Giuliani*, 230 F.3d 543, 547 (2d Cir. 2000)). To do so, HDA must demonstrate, by “a better than fifty percent probability,” see *Nat'l Ass'n for Gun Rts. v. Lamont*, 685 F. Supp. 3d 63, 76 (D. Conn. 2023), *aff'd*, 153 F.4th 213 (2d Cir. 2025) (internal citations and quotation marks omitted), that (i) it is “likely to succeed on the merits” of its claims, (ii) its members are “likely to suffer irreparable harm” absent a preliminary injunction, (iii) the “balance of equities tips” in its favor, and (iv) a preliminary injunction “would be in the public interest,” see *Mahmoud v. Taylor*, 606 U.S. 522, 546 (2025); see also *Salinger v. Colting*, 607 F.3d 68, 79–80 (2d Cir. 2010).

The United States Court of Appeals for the Second Circuit (hereinafter, the “Second Circuit”) “reviews a grant or denial of a preliminary injunction for abuse of discretion.” *Sunward Elecs., Inc. v. McDonald*, 362 F.3d 17, 24 (2d Cir. 2004). However, “where allegations of error in a preliminary injunction involve questions of law . . . review is *de novo*.” *Briggs v. Bremby*, 792 F.3d 239, 241 (2d Cir. 2015); see also *Nat'l Ass'n for Gun Rts. v. Lamont*, 153 F.4th 213, 228–229 (2d Cir. 2025).

III. DISCUSSION

HDA claims that the Act violates the dormant Commerce Clause. ECF Nos. 27-1, at 7–11, 12–17; 35, at 1–7; 44, at 3–10.⁵

⁵ HDA devoted all but three paragraphs of its thirty-one-page initial memorandum of law, see ECF No. 27-1, at 11–12, nearly all of its time at the December 9, 2025, hearing, see ECF No. 42, and the entirety of its supplemental memorandum of law, see ECF No. 44, to its dormant Commerce Clause claim. Nonetheless, HDA also alleges that the Act violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution by attempting to “regulate and control activities wholly beyond its boundaries.” ECF No. 27-1, at 12 (quoting *Watson v. Emps. Liab. Assur. Corp.*, 348 U.S. 66, 70 (1954)). Given Defendants’ clarification of the Act’s applicability, see ECF Nos. 41, 43, the court does not find that HDA is likely to succeed on the merits of its Due Process Clause claim.

A. Likelihood of Success on the Merits

The Commerce Clause vests United States Congress with the exclusive authority to “regulate Commerce . . . among the several States.” *Rest. L. Ctr. v. City of New York*, 90 F.4th 101, 118 (2d Cir. 2024) (citing U.S. Const. art. I, § 8, cl. 3). Within it, “the Supreme Court has interpreted a negative implication known as the ‘dormant’ Commerce Clause, intended to prevent ‘economic protectionism’ by prohibiting state laws that “benefit in-state economic interests by burdening out-of-state competitors.”” *Id.* (quoting *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273, (1988)). “As a judge-made and enforced doctrine, the strictures of the dormant Commerce Clause have ebbed and flowed over time through case law, with the Supreme Court refining the doctrine’s proper scope.” *Flynt v. Bonta*, 131 F.4th 918, 923 (9th Cir. 2025). It did so most recently in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). See, e.g., *id.* at 924 (acknowledging that *Pork Producers* “substantially clarified” the dormant Commerce Clause); *New Jersey Staffing All. v. Fais*, 749 F. Supp. 3d 511, 525 (D.N.J. 2023), *aff’d*, 110 F.4th 201 (3d Cir. 2024) (describing *Pork Producers* as a “revolution”).

A state law generally violates the dormant Commerce Clause if it **(i)** “clearly discriminates against interstate commerce in favor of intrastate commerce,” **(ii)** “imposes a burden on interstate commerce incommensurate with the local benefits secured,” or **(iii)** “has the practical effect of extraterritorial control of commerce occurring entirely outside the boundaries of the state in question.” *Nat’l Shooting Sports Found., Inc. v. James*, 144 F.4th 98, 113 (2d Cir. 2025) (quoting *Grand River Enters. Six Nations, Ltd. v. Boughton*, 988 F.3d 114, 123 (2d Cir. 2021)). “For many years,” courts accepted the theory that “a challenged law’s extraterritorial effects” could render it unconstitutional

under the dormant Commerce Clause. *Fais*, 749 F. Supp. 3d at 524, *aff'd*, 110 F.4th at 209. However, *Pork Producers* clarified that “extraterritorial effects alone are no longer sufficient to show a violation.” *Id.* (describing the extraterritoriality principle as “a dead letter” after *Pork Producers*); *see also GenBioPro, Inc. v. Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *11 (S.D.W. Va. Aug. 24, 2023), *aff'd sub nom. GenBioPro, Inc. v. Raynes*, 144 F.4th 258 (4th Cir. 2025) (acknowledging that *Pork Producers* “abrogated” the “principle against extraterritoriality” as articulated in prior case law, including *Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018)); *New York Times Co. v. Microsoft Corp.*, 777 F. Supp. 3d 283, 326 (S.D.N.Y. 2025) (acknowledging that *Pork Producers* “rejected” the “theory” of extraterritoriality). In the modern, “interconnected national marketplace, many (maybe most) state laws,” “long understood to represent valid exercises of the [s]tates’ constitutionally reserved powers,” necessarily will have extraterritorial effects. *Pork Producers*, 598 U.S. at 374–375. Accordingly, a challenged law must have the “specific impermissible ‘extraterritorial effect’” of discriminating against interstate commerce, *see id.* at 373–374 (citing *Baldwin v. G.A.F. Seelig, Inc.* 294 U.S. 511 (1935); *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573 (1986); *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (1989)), or “directly” regulating commerce occurring “wholly” out-of-state, *see id.* at 376 n. 1 (citing *Edgar v. MITE Corp.*, 457 U.S. 624, (1982)), to run afoul of the dormant Commerce Clause.

The Supreme Court’s “dormant Commerce Clause jurisprudence has ‘eschewed formalism for a sensitive, case-by-case analysis of purposes and effects.’” *Rest. L. Ctr.*, 90 F.4th at 119 (citing *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 201 (1994)). That is because “the dormant Commerce Clause’s scope is not ‘absolute.’” *Id.* at 118

(citing *Maine v. Taylor*, 477 U.S. 131, 138 (1986)). Indeed, “states retain ‘broad power’ to regulate their own affairs, even if they ‘bear adversely upon interstate commerce.’” *Id.* (citing *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 531–32 (1949)). Therefore, the Second Circuit warns judges “not to wield the dormant Commerce Clause as ‘a roving license . . . to decide what activities are appropriate for state and local government to undertake.’” *Id.* (citing *Pork Producers*, 598 U.S. at 380 (Gorsuch, J., plurality opinion)).

(i) Discrimination

Under the dormant Commerce Clause, a state law is clearly discriminatory if it authorizes “differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter.” *Rest. L. Ctr.*, 90 F.4th at 118 (internal citation and quotation marks omitted). Here, the Act applies to covered distributors regardless of whether they are located or headquartered inside or outside of Connecticut. See ECF Nos. 41; 43, at 2. Because the Act treats all covered distributors the same, it is not clearly discriminatory.⁶ See, e.g., *Iowa Pork Producers Ass’n v. Bonta*, No. 22-55336, 2024 WL 3158532, at *1 (9th Cir. June 25, 2024), *cert. denied*, 145 S. Ct. 2866, 222 L. Ed. 2d 1147 (2025) (finding that, because the challenged statute “treats all [covered] companies exactly the same,’ it ‘does not discriminate against interstate commerce’”) (quoting *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 342 (2007)); *Fais*, 110 F.4th at 207 (finding that, because the challenged act “applies equally to in-

⁶ For this reason, HDA also fails to demonstrate that the Act is discriminatory “in its effect.” *Rest. L. Ctr.*, 90 F.4th at 12 (acknowledging that “a law is only clearly discriminatory in its effect where it ‘confer[s] a competitive advantage upon local business vis-à-vis out-of-state competitors’”) (citing *Town of Southold v. Town of E. Hampton*, 477 F.3d 38, 49 (2d Cir. 2007)). Although HDA argues that the Act advantages in-state retailers vis-a-vis out-of-state distributors, the comparison is inapposite, as retailers and distributors do not perform the same functions in the pharmaceutical industry, and therefore are not “competitors.” *Id.*; see also *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 298 (1997) (recognizing that “any notion of [economic] discrimination assumes a comparison of substantially similar entities”).

state and out-of-state [covered] firms,” it is not discriminatory); *Flynt*, 131 F.4th at 926 (finding that the challenged act is not discriminatory because it “appl[ies] evenly to Californians and non-Californians alike”).

(ii) Undue Burden

“Even laws that do not explicitly discriminate against interstate commerce may incidentally, and impermissibly, burden interstate commerce.” *Nat'l Shooting Sports Found., Inc.*, 144 F.4th at 114. HDA does not argue that the Act would fail the “permissive *Pike* balancing test” used to determine “whether a given statute imposes such a burden.” *Id.* (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142, (1970)). However, its focus on the “potential . . . burdens on interstate commerce” which may result from the Act implies such an argument. *Rest. L. Ctr.*, 90 F.4th at 121–122.

HDA’s members sell prescription drugs “Free On Board (‘F.O.B.’) Destination,” meaning that “title does not pass until the drug . . . is delivered to the [retailer] inside Connecticut.”⁷ ECF No. 44, at 1–2. To avoid liability under the Act for exceeding Reference Prices, HDA argues that its members would have to “completely overturn their existing business models,” which depend on F.O.B. delivery. *Id.* at 5. It argues that doing so would be “not just impractical” but also “operationally impossible” before the Act takes effect on January 1, 2026. *Id.* at 2, 4–5. That argument fails the *Pike* test, as “regulations that impose wholesale change on a market’s structure do not impermissibly burden commerce.” *Fais*, 749 F. Supp. 3d at 527, *aff’d*, 110 F.4th at 209 (citing *Exxon Corp. v. Gov. of Md.*, 437 U.S. 117, 127, (1978)); see also *Flynt*, 131 F.4th at 928 (recognizing that the dormant Commerce Clause does not “protect[] the particular structure of

⁷ And the F.O.B. industry standard reinforces the fact that the Act is not discriminatory, as it applies to *all* distributors making sales in Connecticut, regardless of where such distributors are based.

operation” of a given industry) (quoting *Exxon Corp.*, 437 U.S. at 127); *Rest. L. Ctr.*, 90 F.4th at 120 (finding that “the dormant Commerce Clause ‘protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations’”) (citing *Exxon Corp.*, 437 U.S. at 127).

HDA also argues that the Act is “Kafkaesque.” ECF No. 44, at 3. Because it does not apply to retailers who sell to patients, or manufacturers who set the WAC, distributors may “face potentially endless increases in WAC with no recourse” to maintain their current profitability and operations, and patients in Connecticut may continue facing rising costs.⁸ *Id.* at 3–5; *see also* ECF No. 27-1, at 9–11. The court appreciates HDA’s concerns, and does not deny the importance of distributors to the prescription drug industry. See ECF No. 27-1, at 3–4 (explaining that “distributors move approximately 10.5 million medical products across the nation every day from manufacturers” to retailers, thereby “reduc[ing] the number of transactions that would occur if . . . retailers had to order products directly from manufacturers”). Yet the court also appreciates that Connecticut enacted the Act “after compiling ample legislative findings” over the course of several months, *see Rest. L. Ctr.* 90 F.4th at 122, including from a “bipartisan, bicameral” task force comprised of “legislators, healthcare providers, pharmacists, patient advocates, pharmaceutical industry experts, insurers, manufacturers, pharmacy benefit managers, state agencies, and other key stakeholders,” *see Conn. Gen. Assembly’s Prescription Drug Task Force, Final Rep. and Recommendations*, at 2 (Feb. 26, 2025) (available at

⁸ HDA laments that the WAC for several identified drugs has increased since January 1, 2025, but it fails to assert *by how much*. ECF Nos. 27-1, at 5–6; 44, at 2 n.3. If such increases were nominal, or otherwise less than (or even equal to) corresponding increases in the consumer price index, then it would seem that HDA’s members could easily maintain their current profitability under the Act. See Public Act No. 25-168, §§ 345(11), 346(a)(1); *see also* ECF Nos. 27-1, at 2; 34, at 6.

https://www.cga.ct.gov/hs/taskforce.asp?TF=20241204_Prescription%20Drug%20Task%20Force). “Whatever the policy ramifications” of Connecticut’s decision to focus on the prices charged, in particular, by distributors, see *Fais*, 110 F.4th at 207, the court may not enjoin “duly enacted state laws regulating the in-state sale of ordinary consumer goods,” like prescription drugs, “based on nothing more” than HDA’s “assessment” of the Act’s “costs and benefits.” *Pork Producers*, 598 U.S. at 380 (Gorsuch, J., plurality opinion); see also *Rest. L. Ctr.* 90 F.4th at 118 (reminding district courts that “the dormant Commerce Clause’s scope is not absolute,” that “states retain broad power to regulate their own affairs,” and that judges should “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).

(iii) Extraterritoriality

HDA argues that the Act will have the same “specific impermissible extraterritorial effect[s]” as the challenged laws in *Baldwin v. G.A.F. Seelig, Inc.* 294 U.S. 511 (1935), *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573 (1986), and *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (1989). ECF No. 27-1, at 8–10, 15–16, 35, at 4–6; 44, at 8. The court disagrees.

In *Baldwin*, the Supreme Court invalidated New York’s law effectively prohibiting out-of-state dairy farmers from selling milk in New York for less than the minimum price legally guaranteed to in-state dairy farmers. 294 U.S. at 519–522 (explaining that “a state may not, in any form or under any guise, directly burden the prosecution of interstate business”). In *Brown-Forman*, the Court invalidated New York’s law effectively prohibiting liquor distillers from charging less for liquor in any other state than they charged for liquor

in New York. 476 U.S. at 582 (explaining that such law “regulates out-of-state transactions in violation of the [dormant] Commerce Clause”). And in *Healy*, the Court invalidated Connecticut’s law effectively prohibiting beer merchants from selling beer at a cheaper price in any neighboring states than in Connecticut. 491 U.S. at 337 (explaining such law’s “undeniable effect of controlling commercial activity occurring wholly outside the boundary of [Connecticut]”). The Court “struck down” these laws for being “plainly protectionist.” *Fais*, 749 F. Supp. 3d at 525, *aff’d*, 110 F.4th at 209; *see also Pork Producers*, 589 U.S. at 371–375.

To the extent HDA suggests that disrupting “established business practices” was among the specific impermissible extraterritorial effects of the laws challenged in *Baldwin*, *Brown-Forman*, and *Healy*, *see ECF No. 44*, at 5–6, the dormant Commerce Clause does not “protect[] the particular structure or methods of operation” of a given industry, *see Flynt*, 131 F.4th at 928; *see also Pork Producers*, 589 U.S. at 371 (finding, instead, that “each” of *Baldwin*, *Brown-Forman*, and *Healy* “typifies the familiar concern with preventing purposeful discrimination against out-of-state economic interests”).

HDA asserts that tying “the price of . . . in-state products to out-of-state prices” was among the specific impermissible extraterritorial effects. *ECF No. 44*, at 8 (quoting *Pork Producers*, 589 U.S. at 374); *see also 27-1*, at 9–10, 15–16. While the challenged laws in *Baldwin*, *Brown-Forman*, and *Healy* indeed tied in-state prices for milk, liquor, and beer to the prices of such products in specific other states, *see 294 U.S. at 519–522*; 476 U.S. at 582; 491 U.S. at 337, the Supreme Court did not invalidate such laws merely for taking the regulatory form of a price affirmation or price control, but because they “deliberately prevent[ed out-of-state firms] from undertaking competitive pricing” in other

states and “deprive[ed] businesses and consumers in other [s]tates of whatever competitive advantages they may possess.” *Pork Producers*, 598 U.S. at 374 (internal citations and quotation marks omitted). Unlike such laws, the Act does not tether an identified drug’s Reference Price to prices in any other *state*, but to such drug’s WAC, which manufacturers (and not distributors, such as HDA’s members) set *nationally*. See ECF Nos. 27-1, at 4; 34, at 2–4. And whereas in *Brown-Forman* the challenged law impacted liquor prices in other states, see 476 U.S. at 583 (finding “that once a distiller’s posted price is in effect in New York, it must seek the approval of the New York State Liquor Authority before it may lower its price for the same item in other [s]tates), there is no similar applicable provision in the Act.

HDA also asserts that the Act has the “specific impermissible extraterritorial effect” of “mandat[ing] an artificially lower price” for identified drugs sold by covered distributors in Connecticut “than the prevailing WAC in other states,” which will “give local consumers an advantage over consumers in other [s]tates.” ECF No. 44, at 8 (internal citation and quotation marks omitted); see also ECF Nos. 27-1, at 17; 35, at 1, 4–6. However, the Act does not mandate that HDA’s members sell identified drugs in Connecticut at prices lower than anywhere else, as did the challenged laws in *Brown-Forman* and *Healy*. See ECF Nos. 27-1, 1–3; 34, at 6. HDA’s members are free to sell identified drugs in other states at prices lower or higher than the Reference Price. Cf. *Healy*, 491 U.S. at 336 (noting that the dormant Commerce Clause prevents a state from regulating commerce which takes place “wholly outside” its borders) (emphasis added). Instead, the Act prohibits HDA’s members from selling such drugs in Connecticut at prices that exceed what Connecticut’s General Assembly considers to be safe and affordable, regardless of what

prices they may be charging elsewhere. See ECF Nos. 27-1, 1–3; 34, at 6; see also ECF No. 27-1, at 8 (recognizing that “price regulation statutes’ are impermissible if they ‘require[] out-of-state commerce to be conducted according to in-state terms,’” but not otherwise) (quoting *Nat'l Elec. Mfrs. Ass'n v/ Sorrell*, 272 F.3d 104, 110 (2d Cir. 2001)); *Fais*, 749 F. Supp. 3d at 526, *aff'd*, 110 F.4th at 209 (finding that the challenged law “is nothing like those Connecticut and New York laws” in *Baldwin*, *Brown-Forman*, and *Healy* because it “applies equally to New Jersey businesses and out-of-state businesses, so out-of-state businesses are on no way disadvantaged as compared to their New jersey competitors,” and because “every burden imposed upon out-of-state businesses is likewise imposed on New Jersey businesses”).

Finally, HDA expresses concern that other states may follow Connecticut’s legislative lead.⁹ ECF No. 27-1, at 9, 11. The Supreme Court noted in *Healy* that the challenged law “might be enacted” by other states if not invalidated, thereby creating “just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude.” *Healy*, 491 U.S. at 337. But, as discussed *infra*, the Act is not comparable to the challenged law in *Healy*, as it does not prevent HDA’s members from increasing or decreasing their drug prices in other states. See ECF Nos. 27-1, 1–3; 34, at 6. Nor does it otherwise prevent or discourage competition among distributors, who may still offer volume discounts outside of Connecticut, as they wish, free from interference by Connecticut. *Id.*

⁹ The court notes that there is some irony in arguing that a state’s action to protect against price gouging or oppressive pricing essentially amounts to a concerted effort (or at least inspires the possibility) for states to do the opposite in similarly protecting their citizens from predatory but constitutional pricing.

Antidiscrimination “lies at the ‘very core’” of the dormant Commerce Clause. *Pork Producers*, 598 U.S. at 369 (citing *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 581 (1997)). Because HDA has not shown that the Act is protectionist or discriminatory, the court finds that it is unlikely to succeed on the merits of its dormant Commerce Clause claim. Heeding the Second Circuit’s warning “not to wield the dormant Commerce Clause as ‘a roving license . . . to decide what activities are appropriate for state and local government to undertake,’” the court will not enjoin Defendants from enforcing the Act based on HDA’s arguments about effectiveness. *Rest. L. Ctr.*, 90 F.4th at 119. (citing *Pork Producers*, 598 U.S. at 380 (Gorsuch, J., plurality opinion)).

B. Remaining Preliminary Injunction Factors

The court cannot “stay” Defendants’ enforcement of the Act absent a clear showing of HDA’s “likelihood of success on the merits” of its claims. *Nat’l Ass’n for Gun Rts.*, 685 F. Supp. 3d at 75 (quoting *Plaza Health Laboratories, Inc. v. Perales*, 878 F.2d 577, 580 (2d Cir. 1989)). HDA has not made such a showing. See *infra*, 11-18. Accordingly, the court “need not reach the remaining preliminary injunction factors” before denying its Motion for a Preliminary Injunction. *Id.* at 113.

IV. CONCLUSION

For all the foregoing reasons, it hereby is **ORDERED AND ADJUDGED** as follows:

- (1)** The Motion for a Preliminary Injunction is **DENIED**;
- (2)** HDA **SHALL** file either an amended complaint accounting for Defendants’ clarifications concerning the Act’s applicability, or a notice that it does not intend to amend the Complaint, on or before **January 23, 2026**; and

(3) Defendants **SHALL** file a response to the operative complaint within **twenty-one days** of HDA filing its amendment or notice, see ECF No. 32, or on or before **February 13, 2026**, whichever date is sooner.

IT IS SO ORDERED in Hartford, Connecticut, this 24th day of December, 2025.

/s/

OMAR A. WILLIAMS
UNITED STATES DISTRICT JUDGE

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

NOTICE OF APPEAL

Pursuant to 28 U.S.C. §§ 1291 and 1292(a)(1) and Rule 3 of the Federal Rules of Appellate Procedure, Plaintiff Healthcare Distribution Alliance hereby gives notice that it appeals to the United States Court of Appeals for the Second Circuit from the Order entered in the above-captioned case on December 24, 2025 (ECF No. 45), denying Plaintiff’s Motion for Preliminary Injunction (ECF No. 27).

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Dated: December 26, 2025
Hartford, Connecticut

Respectfully submitted,

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