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*.	:	Civil Action No.: 3:25-cv-01724-OAW OCTOBER 23, 2025

PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 65(a), Plaintiff Healthcare Distribution Alliance ("HDA"), on behalf of its members, hereby moves for a preliminary injunction against 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, from implementing or enforcing against any of HDA's members, the Connecticut Drug Price Cap of Public Act No. 25-168, §§ 345-47 ("the Drug Price Cap"), which is effective on January 1, 2026. As demonstrated in the accompanying memorandum of law: (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.

Together with its memorandum of law and supporting declarations, HDA respectfully requests that the Court grant its motion through entry of a preliminary injunction.

ORAL ARGUMENT
REQUESTED

Dated: October 23, 2025
Hartford, Connecticut

Respectfully submitted,

/s/ Thomas J. Finn

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CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2025, a copy of the foregoing document was filed electronically and served by mail on anyone unable to accept electronic filing. 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.

By: */s/ Thomas J. Finn*
Thomas J. Finn (ct20929)

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
56C38E81542F4E0...

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 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*.	**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 NICOLETTE LOUISSAINT 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 HCI 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:

Year	Reported WAC Increases on Covered Products
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*.	: : : : : : : : : : : :	Civil Action No.: 3:25-cv-01724-OAW OCTOBER 23, 2025

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S
MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiff Healthcare Distribution Alliance ("HDA") seeks preliminary injunctive relief against an extraordinary Connecticut law, the Drug Price Cap of Public Act No. 25-168 ("the Drug Price Cap"), which as of January 1, 2026, will cap the prices charged by pharmaceutical manufacturers and wholesale distributors for off-patent branded drugs, generic drugs, and interchangeable biologic products. HDA is the trade association for wholesale distributors, which play the key role of ensuring the safe, efficient, and reliable delivery of 10.5 million healthcare products every day from manufacturers to pharmacies, hospitals, and other healthcare providers. The Drug Price Cap threatens to disrupt the essential logistical function performed by wholesale distributors and to cause irreparable harm not only to them but to the patients who depend on reliable access to critical medicines.

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 are subject to the Drug Price Cap ***even though they do not set or control the WAC for drug products***. 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 manufacturer-driven pricing decisions outside the distributors' control.

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 and other constitutional provisions. Drug manufacturers (not wholesale distributors) set the WAC, and they do so on a national, not state-by-state, basis. Wholesale

distributors operate on an interstate (rather than a state-by-state) basis, under contracts with manufacturers and downstream customers with multistate operations like pharmacy chains that apply uniformly on an interstate basis. Indeed, no member of HDA has any distribution facility inside Connecticut at all. By capping prices set at the national level, Connecticut's law will impermissibly regulate commerce beyond the boundaries of the state.

Other state-level drug price regulations have been invalidated in Maryland, Minnesota, and the District of Columbia, in decisions by the Fourth, Eighth, and Federal Circuits. No federal appellate court has sustained the constitutionality of a similar state drug price cap.

If allowed to go into effect, the Connecticut Drug Price Cap will cause irreparable harm to HDA members that distribute critical medicines in the state. Both HDA members and the public at large will suffer. Accordingly, HDA seeks a preliminary injunction against the implementation and enforcement of the Drug Price Cap.

STATEMENT OF FACTS

I. Connecticut's 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. 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 the WAC when the product is first commercially available. *Id.* § 345(11).

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 HHS as being in shortage. *Id.* § 346(a). 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).

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 include a fine of up to $1,000/day, one year imprisonment, or imposition of a Class D felony. *Id.* § 346(j). The law also 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. *Id*. § 347.

Tellingly, 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, which applies only to out-of-state manufacturers and wholesale distributors. *Id*. § 346.

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

Wholesale distributors move approximately 10.5 million medical products across the nation every day from manufacturers to licensed healthcare institutions, providers, and pharmacies.[1] Distributors do not manufacture, produce, or prescribe pharmaceutical products, nor do they engage in pharmaceutical research and development. Rather, they coordinate receipt and

[1] Healthcare Distribution Alliance Factbook (96th ed. 2025), at 4.

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. Igel Decl. ¶¶ 2–3; Reed Decl. ¶¶ 2–3; Van Norman Decl. ¶¶ 2–3.

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.[2] 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.

All of the relevant drug pricing decisions are made outside Connecticut. Drug manufacturers (not wholesale distributors) set the WAC, and they do so on a national basis, outside Connecticut. Igel Decl. ¶ 5; Reed Decl. ¶ 5; Van Norman Decl. ¶ 5. Similarly, wholesale distributors operate on an interstate, rather than state-by-state, basis. Igel Decl. ¶ 5; Reed Decl. ¶ 5; Van Norman Decl. ¶ 5. 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. Igel Decl. ¶ 5; Reed Decl. ¶ 5; Van Norman Decl. ¶ 5.

No member of HDA has any distribution facility inside Connecticut. Products distributed in Connecticut are shipped from distribution centers located outside the state. Igel Decl. ¶ 4; Reed Decl. ¶ 4; Van Norman Decl. ¶ 4.

[2] *Id.*

LEGAL STANDARD

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); *see also Du v. U.S. Dep't of Homeland Sec'y*, No. 3:25-cv-644 (OAW), 2025 WL 1549098, *5 (D. Conn. May 31, 2025) (Williams, J.) (granting preliminary injunction against the government); *Carr v. Becerra*, No. 3:22-cv-988 (MPS), 2022 WL 16744351, *4 (D. Conn. Nov. 7, 2022) (Williams, J.) (granting preliminary injunction against the government). HDA can meet this standard.

STANDING AND RIPENESS

An organization has standing to bring claims on behalf of its members "when: (a) its members would otherwise have standing to sue in their own right; (b) the interest it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). HDA satisfies this standard. Its members have standing to sue in their own right, the protection of their interest is germane to its purpose, and neither the claims nor the relief requested requires the participation of individual members in this lawsuit.

"[A] person exposed to a risk of future harm may pursue forward-looking, injunctive relief to prevent the harm from occurring, at least so long as the risk of harm is sufficiently imminent and substantial." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 435 (2021). HDA can meet this standard because its members face imminent and irreparable injury from the Drug Price Cap. Indeed, WAC prices for numerous covered drug products have ***already*** increased during calendar

year 2025 or are set to increase before the end of 2025. Louissaint Decl. ¶ 6. 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), which plainly results in harm, 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 drug products above the January 1, 2025 WAC (adjusted by the CPI). Louissaint Decl. ¶ 7. And if wholesale distributors attempt to avoid the Drug Price Cap by withdrawing a covered drug or product from Connecticut, they will face a separate $500,000 civil penalty. In any scenario, HDA members will suffer injury in fact. Indeed, the legislative history that ultimately led to the Drug Price Cap shows that the legislature understood these economic impacts.[3]

The showing of harm in this case is more specific than in many cases where standing has been sustained. *See, e.g.*, *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153, 154 (2010) ("'reasonable probability"' and "significant risk" of injury) (citation omitted); *Davis v. FEC*, 554 U.S. 724, 734 (2008) ("realistic and impending threat of direct injury"); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 129 (2007) ("genuine threat of enforcement"); *Dep't of Com. v. U.S. House of Representatives*, 525 U.S. 316, 333 (1999) ("substantially likely" harm) (internal

[3] *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.

quotation marks omitted); *Clinton v. City of New York*, 524 U.S. 417, 432 (1998) ("sufficient likelihood of economic injury"); *Pennell v. San Jose*, 485 U.S. 1, 8 (1988) ("realistic danger" of harm) (internal quotation marks omitted).

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). A plaintiff need not "await the consummation of threatened injury to obtain preventative relief." *Valmonte v. Bane*, 18 F.3d 992, 999 (2d Cir. 1994). If the "perceived threat due to the putatively illegal conduct of the [defendants] is sufficiently real and immediate to constitute an existing controversy," the claim is ripe. *Id.* (citing *Blum v. Yaretsky*, 457 U.S. 991, 1000 (1982)).

ARGUMENT

I. HDA Is Likely to Succeed on Its Claim That The Drug Price Cap is Unconstitutional.

A. States May Not Regulate Transactions and Pricing Decisions That Occur Wholly Outside the State.

The Constitution's structure and provisions, including the Commerce Clause (U.S. Const. Art. I, § 8, cl. 3), the Due Process Clause of the Fourteenth Amendment (U.S. Const. amend. XIV, § 1), and principles of State sovereignty and federalism, prohibit a State from regulating transactions occurring outside its borders. The Drug Price Cap is unconstitutional for multiple reasons.

First, the Commerce Clause prohibits States from adopting price control statutes that interfere with interstate commerce by tying in-state prices to an out-of-state price index like the WAC. The Supreme Court has held that state "price control or price affirmation statutes" are invalid if they tie "the price of . . . in-state products to out-of-state prices." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 374 (2023) (quoting *Pharm. Rsch. and Mfrs. of Am. v. Walsh*, 538

U.S. 644, 669 (2003)). The Second Circuit 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 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)).

It is immaterial whether a state law is written so that it is triggered only by an in-state sale. The Supreme Court has opined that "whether 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, 579, 583 (1986)). Thus, in *Brown-Forman*, the Supreme Court invalidated a New York price regulation statute requiring distillers to affirm that the prices by 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; *see also id.* at 580 ("The mere fact that the effects of New York's ABC Law are triggered only by sales of liquor within the State of New York . . . does not validate the law if it regulates the out-of-state transactions of distillers who sell in-state.").[4]

[4] *Brown-Forman* involved a claim "that the statute must be declared unconstitutional on its face." *Brown-Forman Distillers Corp. v. State Liquor Auth.*, 479 N.E.2d 764, 768 (N.Y. 1985).

The Supreme Court has noted the risk that state price control statutes could prompt neighboring states to adopt similar measures, resulting in the kind of interstate race-to-the-bottom that the Commerce Clause was meant to prevent. For example, in *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (1989), the 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[ed] 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.* The Supreme Court recently reaffirmed this aspect of *Healy's* holding, explaining 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." *Pork Producers*, 598 U.S. at 373 (quoting *Healy*, 491 U.S. at 339-40).

The Connecticut Drug Price Cap suffers from all of these constitutional flaws. It seeks to tie Connecticut prices to prices outside the state—i.e., to a nationally set list of interstate prices at the January 1, 2025 WAC (adjusted by the CPI). Drug manufacturers (not wholesale distributors) set the WAC, and they do so on an interstate, not state-by-state, basis. Igel Decl. ¶ 5; Reed Decl. ¶ 5; Van Norman Decl. ¶ 5. Just like the price-cap statutes that were invalidated in *Healy* and *Brown-Forman Distillers*, the Drug Price Cap attempts to control the prices at which goods are sold in the state by tying them to the prices charged in other states. That is the very constitutional infirmity that the Supreme Court has repeatedly condemned.

Even the Drug Price Cap itself acknowledges the interstate nature of drug price determinations, by referring to ***national*** pricing benchmarks in connection with its own price provisions. Under § 345(11) of the Connecticut statute, the term "wholesale acquisition cost," commonly known as the 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").

Wholesale distributors also operate on an interstate (rather than a state-by-state) basis, under contracts with manufacturers that are not tailored to individual states and contracts with multistate customers that apply uniformly across states. Igel Decl. ¶ 5; Reed Decl. ¶ 5; Van Norman Decl. ¶ 5. Indeed, no member of HDA has a distribution facility inside Connecticut. Igel Decl. ¶ 4; Reed Decl. ¶ 4; Van Norman Decl. ¶ 4. In short, all of the relevant pricing decisions are made on an interstate basis, outside Connecticut. By imposing state-specific pricing controls, the Drug Price Cap impermissibly regulates out-of-state commerce.

Tellingly, the Drug Price Cap, by its own terms, is not focused on the price that Connecticut consumers ultimately pay for a drug. 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. Only manufacturers and wholesale distributors, whose pricing decisions and transactions occur outside Connecticut, are subject to the Drug Price Cap. This structure makes clear that the law targets the out-of-state pricing of covered drugs and products.

Further, the Drug Price Cap would disrupt the uniformity of the national pharmaceutical market. The law attempts to favor Connecticut purchasers by mandating a lower price than the manufacturer's list price. But Connecticut's law invites other states to apply their own views of what price increases are permissible nationwide, resulting in a patchwork of different pricing regimes. As one court noted in striking down a drug price regulation, "similar legislation throughout the country would undoubtedly result in an artificial race between legislatures to set the lowest [reference price for drugs]. Such races to the bottom of the marketplace can be as dangerous to the interstate market as any other type of market failure, such as a monopoly or price-tying measures." *Pharm. Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 70 (D.D.C. 2005), *aff'd sub nom. Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007). Wholesale 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.

The Commerce Clause is not the only constitutional provision offended by the Drug Price Cap. "To resolve disputes about the reach of one State's power," the Supreme Court "has long consulted . . . the Constitution's structure and the principles of 'sovereignty and comity' it embraces," along with "the Due Process Clause." *Pork Producers*, 598 U.S. at 376 (citation omitted). "The sovereignty of each State, in turn, implie[s] a limitation on the sovereignty of all of its sister States—a limitation express or implicit in both the original scheme of the Constitution and the Fourteenth Amendment." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 293 (1980). The Due Process Clause of the Fourteenth Amendment imposes "territorial limitations on the power of the respective States." *Bristol-Myers Squibb Co. v. Superior Ct. of Cal.*, 582 U.S.

255, 263 (2017) (quoting *Hanson v. Denckla*, 357 U.S. 235, 251 (1958)). It is a well-established "due process principle that a state is without power to exercise 'extra territorial jurisdiction,' that is, to regulate and control activities wholly beyond its boundaries." *Watson v. Emps. Liab. Assur. Corp.*, 348 U.S. 66, 70 (1954) (citing *Home Ins. Co. v. Dick*, 281 U.S. 397 (1930)). No single State can enact policies for the entire Nation, nor can a State "even impose its own policy choice on neighboring States." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 570-71 (1996). "The states are not nations, either as between themselves or towards foreign nations," and "their sovereignty stops short of nationality." *New Hampshire v. Louisiana*, 108 U.S. 76, 90 (1883).

The Connecticut Drug Price Cap violates these fundamental principles and exceeds the territorial limitations on the power of the Connecticut General Assembly. Both manufacturers and wholesalers operate on an interstate (rather than a state-by-state) basis. Manufacturers set the WAC on a nationwide basis, outside Connecticut. The Drug Price Cap directly targets WAC price determinations (and thus commerce) occurring exclusively outside Connecticut and therefore offends due process, federalism, and the inherent limitations of state authority under the Constitution.

In sum, Plaintiff is likely to succeed on its claim that the Drug Price Cap violates the Commerce Clause, due process, and additional constitutional principles.

B. Courts Have Repeatedly Invalidated State Price Control Laws Like Connecticut's.

No federal appellate court has sustained the constitutionality of a similar state drug price cap on the merits. Highly instructive here is the Fourth Circuit's decision in *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018), which invalidated a state drug price cap prohibiting "[a] manufacturer or wholesale distributor [from] engag[ing] in price gouging in

the sale of an essential off-patent or generic drug." *Id.* at 666 (first and third alterations in original) (quoting Md. Gen. Health Code § 2-802(a)).

The Fourth Circuit held that the Maryland drug price cap was unconstitutional for reasons squarely applicable to the Connecticut Drug Price Cap. The Fourth Circuit found that "the Act controls the prices of transactions that occur outside the state." *Id.* at 670. The Court explained: "The Act, by its own terms, is not fixated on the price the Maryland consumer ultimately pays for the drug. Instead, the lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges . . . . 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.* at 671 (second alteration in original). "This structure makes clear that the . . . 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." *Id.* at 671–72. Precisely the same is true with respect to the Connecticut Drug Price Cap, which 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. Only out-of-state pricing determinations by manufacturers and wholesalers are targeted.

The Fourth Circuit also observed that the law, "if similarly enacted by other states, would impose a significant burden on interstate commerce involving prescription drugs." *Id.* at 670. "Because the Act targets wholesale rather than retail pricing, an analogous restriction imposed by a state other than Maryland has the potential to subject prescription drug manufacturers to conflicting state requirements." *Id.* at 673. The Connecticut Drug Price Cap poses the same danger.

In addition, the Fourth Circuit explained that the state's goal of reducing drug prices could not justify a violation of the Constitution: "Maryland cannot, even in an effort to protect its consumers from skyrocketing prescription drug costs, impose its preferences in this manner." *Id.* at 673. That principle governs here as well.

More recently, the Eighth Circuit held that a similar Minnesota drug price cap statute had "the specific impermissible extraterritorial effect of controlling prices outside of Minnesota." *Ass'n for Accessible Meds. v. Ellison*, 140 F.4th 957, 960 (8th Cir. 2025). The Court of Appeals concluded that the Minnesota law was invalid because it sought to "regulate[] the price of out-of-state transactions." *Id.* at 961. The same is true here.

Similarly, in *Pharmaceutical Research and Manufacturers of America v. District of Columbia*, the court held that a District of Columbia drug price cap had "a *per se* invalid extraterritorial reach in violation of the Commerce Clause as applied to transactions between manufacturers and wholesalers that occur wholly out of state." 406 F. Supp. 2d at 68. The court noted that manufacturers "sell 'the overwhelming bulk' of their . . . drugs in out-of-state transactions to wholesalers or large retail chains that maintain their own warehousing and retail distribution system" outside the District of Columbia, and thus "the overwhelming majority" of drug sales "occur entirely outside the District of Columbia between out-of-state manufacturers and out-of-state wholesalers." *Id.* (citation omitted). The court therefore held that the law "effect[ed] an impermissible extraterritorial reach," noting that "all of the wholesalers to whom [manufacturers] sell their products are also found out of state," even though the law's application was "triggered by an in-state sale." *Id.* at 69–70; *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 because "all the drug manufacturers represented by the

plaintiff are located outside the State of Maine," and "by far the greater bulk of their customers—wholesalers and distributors—are likewise outside Maine"), *rev'd on other grounds sub nom. Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001); *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 261–62 (S.D.N.Y. 2018) (holding that New York law banning distributors and others from passing through any portion of state opioid tax to their customers "violate[d] the Commerce Clause's prohibition on extraterritorial state legislation," because its bar on "pass-through" charges was not limited to New York transactions, a determination which the state did not challenge on appeal), *rev'd in part on other grounds sub nom. Ass'n for Accessible Meds. v. James*, 974 F.3d 216, 228 (2d Cir. 2020).

C. The Supreme Court's *Pork Producers* Decision Confirms That States May Not Regulate Prices Set Out-of-State.

In denying a motion for preliminary injunction based on a Commerce Clause challenge to an Illinois drug price regulation, a federal district court in the Northern District of Illinois recently (and erroneously) read the Supreme Court's *Pork Producers* decision to require a showing of discrimination or protectionism (in addition to extraterritoriality) in order to invalidate a state drug price regulation. *Ass'n for Accessible Meds. v. Raoul*, Case No. 1:24-cv-00544, 2025 WL 2764558 (N.D. Ill. Sept. 26, 2025). That interpretation of *Pork Producers* is incorrect because it ignores the Supreme Court's express statement that "price control or price affirmation statutes" are invalid if they tie "the price of . . . in-state products to out-of-state prices." *Pork Producers*, 598 U.S. at 374 (quoting *Walsh*, 538 U.S. at 669 (internal quotation marks omitted)). That is exactly the vice of the Drug Price Cap, which seeks to tie the Connecticut price of covered drugs and products to out-of-state prices (in the form of the WAC).

Although *Pork Producers* upheld a state law against a Commerce Clause challenge, it did not involve a state price regulation statute, let alone one tying in-state prices to an out-of-state

price index. Rather, it involved a California law barring sales of whole pork meat in California sourced from animals confined in a manner inconsistent with state standards—the kind of non-price regulation that does not raise the concerns presented here. *See id.* at 365–67. Indeed, the Court's decision in *Pork Producers* cited with approval the Fourth Circuit's decision invalidating the Maryland drug-price-cap statute in *Frosh*. *Pork Producers*, 598 U.S. at 374 (citing *Frosh*, 887 F.3d at 669). In addition, *Pork Producers* opined that 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 outside their borders. *Id.* at 376 & n.1 (citation omitted).

The ruling by the Northern District of Illinois conflicts with the Eighth Circuit's decision striking down the Minnesota drug price regulation and with the Eighth Circuit's interpretation of *Pork Producers*. The Eighth Circuit observed that "the Court [in *Pork Producers*] did not overturn its cases that applied the dormant Commerce Clause to invalidate statutes that have the specific impermissible extraterritorial effect of controlling prices." *Ellison*, 140 F.4th at 961. "So the 'classic observation that "[a state] has no power to project its legislation into [another state] by regulating the price to be paid in that state"' for drugs sold there remains good law." *Id.* at 960 (alterations in original) (quoting *Walsh*, 538 U.S. at 669).

Further, even if *Pork Producers* were read as requiring some element of protectionism or in-state favoritism, the Connecticut Drug Price Cap displays just such constitutional flaws. By mandating a lower price for Connecticut than the manufacturer's list price, the Drug Price Cap displays impermissible in-state favoritism and protectionism because it favors Connecticut

purchasers over those in other states. Further, the Drug Price Cap prefers in-state sellers of covered drugs. The Cap does not apply at all to the downstream sellers of drugs in Connecticut (in-state medical practices, hospitals, and other licensed healthcare providers), but only to upstream manufacturers and wholesalers located out of state. By targeting the upstream out-of-state sellers, the Drug Price Cap "prevent[s] [out-of-state firms] from undertaking competitive pricing" and "deprive[s] businesses and consumers in other States of 'whatever competitive advantages they may possess.'" *Pork Producers*, 598 U.S. at 374 (quoting *Healy*, 491 U.S. at 339-40). In addition, the Drug Price Cap invites other states to retaliate with drug price regulations of their own, precipitating the very kind of "race to the bottom" that the Commerce Clause was meant to prevent. *Pharm. Rsch. & Mfrs. of Am.*, 406 F. Supp. 2d at 70. Thus, the Drug Price Cap would be invalid even under the Northern District of Illinois's approach.

II. HDA's Members Will Suffer Irreparable Harm Absent An Injunction.

"Within this circuit, irreparable harm is 'harm shown to be non-compensable in terms of money damages.'" *Carr*, 2022 WL 16744351, *9 (quoting *LaForest v. Former Clean Air Holding Co.*, 376 F.3d 48, 55 (2d Cir. 2004)). To warrant a preliminary injunction, a plaintiff must demonstrate merely that irreparable injury is "*likely*." *Du*, 2025 WL 1549098, *5 (emphasis in original). HDA readily satisfies this standard because the Drug Price Cap poses imminent harm to its members.

HDA's members face at least two forms of irreparable harm sufficient to justify preliminary injunctive relief. First, "[i]n the Second Circuit, it is well-settled that an alleged constitutional violation constitutes irreparable harm." *Martinez-Brooks v. Easter*, 459 F. Supp. 3d 411, 448 (D. Conn. 2020) (citation omitted); *see Conn. Dep't of Envtl. Prot. v. O.S.H.A.*, 356 F.3d 226, 231 (2d Cir. 2004) ("[W]e have held that the alleged violation of a constitutional right triggers a finding of irreparable injury." (internal quotation marks and citations omitted)); *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."). The Second Circuit 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 members can demonstrate irreparable harm because WAC prices for numerous covered drug products have ***already*** increased during calendar year 2025 and others are set to increase before the end of 2025. Louissaint Decl. ¶ 6. 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 drug products above the January 1, 2025 WAC (adjusted by the CPI). Louissaint Decl. ¶ 7. And if wholesale distributors attempt to avoid the Drug Price Cap by withdrawing a covered drug or product from Connecticut, they will face a separate $500,000 civil penalty. Under any scenario, HDA's members face irreparable harm. *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 either to incur the costs of compliance with a preempted state law or face the possibility of penalties"). In light of the State of Connecticut's

sovereign immunity under the Eleventh Amendment, there is a high likelihood that an after-the-fact monetary award would not be available to compensate HDA members for their losses.[5]

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

Both the balance of hardships and the public interest favor Plaintiff. Here, a preliminary injunction will simply preserve the status quo in Connecticut that has always existed prior to the enactment of Public Act No. 25-168. "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 Plaintiff here.

Balancing the equities favors preliminary injunctive relief. HDA members face clear irreparable harm. In contrast, "the Government does not have an interest in the enforcement of an unconstitutional law." *N.Y. Progress and Prot. PAC v. Walsh*, 733 F.3d 483, 488 (2d Cir. 2013) (citation and internal quotation marks omitted); *cf. Du*, 2025 WL 1549098, *9 ("[T]here is generally no public interest in the perpetuation of unlawful agency action.") (citation omitted). "No public interest is served by maintaining an unconstitutional policy when constitutional alternatives are available to achieve the same goal." *Agudath Israel of Am.*, 983 F.3d at 637. That

[5] *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) (affirming the district court's finding that "[the plaintiff's] injury was irreparable even though [its] losses were only pecuniary because a suit in federal court against [the defendant,] New York[,] to recover the damages sustained by the plaintiff would be barred by the Eleventh Amendment"); *Regeneron Pharms., Inc. v. U.S. Dep't of Health and Hum. Servs.*, 510 F.Supp.3d 29, 39 (S.D.N.Y. 2020) ("[W]here a plaintiff cannot recover damages due to sovereign immunity, monetary loss may amount to irreparable harm."); *see also Odebrecht Const., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013) ("In the context of preliminary injunctions, numerous courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable."); *Chamber of Com. v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010) ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury."); *Iowa Utilities Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss . . . does qualify as irreparable harm.").

lesson is particularly salient, because multiple provisions of federal law already address drug prices. For example, Medicare, which covers over 68 million Americans,[6] includes two major prescription drug programs. Part B covers medically necessary and preventive healthcare services, including drugs administered by a physician, 42 U.S.C. §§ 1395k (a)(l), 1395x (s)(2)(A), and contains a specific price provision. *Id.* § 1395w-3a. In addition, Medicare Part D allows beneficiaries to enroll in privately operated insurance plans covering self-administered prescription drugs, *id.* § 1395w-102, and it contains a specific price provision as well. *Id*. § 1395w-111(i)(l).

Other federal drug price initiatives include (i) the Inflation Reduction Act's Drug 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 and thereby "shifts the price-setting mechanism for many of America's highest-selling drugs from the free market to a government-run process," *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 494 (5th Cir. 2024); (ii) 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; and (iii) a plan to bring U.S. drug prices in line with the lowest paid by other developed nations (known as the most-favored-nation, or MFN, price).[7] Connecticut's Drug Price Cap flies in the face of these federal programs.

[6] CMS, Medicare Enrollment Dashboard, https://perma.cc/9KSR-ZPAA (last updated May 2025).

[7] *See Fact Sheet: President Donald J. Trump Announces First Deal to Bring Most-Favored-Nation Pricing to American Patients*, White House (Sept. 30, 2025), https://www.whitehouse.gov/fact-sheets/2025/09/fact-sheet-president-donald-j-trump-announces-first-deal-to-bring-most-favored-nation-pricing-to-american-patients/.

Further, the Drug Price Cap will disrupt the national pharmaceutical market, which is not in the public interest. The law threatens to disturb the essential logistical function performed by wholesale distributors and ultimately imperil patient access to important medicines. Submissions to the General Assembly regarding legislative proposals containing the Drug Price Cap showed that the law "will fail to reduce out-of-pocket costs for patients and may limit access to medications."[8] The Drug Price Cap will thus cause irreparable harm not only to wholesale distributors but also to patients and their families.

CONCLUSION

Plaintiff's motion for preliminary injunction should be granted.

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[8] Statement of The Greater New Haven Chamber of Commerce and Quinnipiac Chamber of Commerce before Connecticut General Assembly (March 11, 2025), available at 2025SB-00011-R000311-Sheehan, Garrett, President and CEO-GNHCC-Opposes-TMY.PDF. *See also*:

• Statement of Biotechnology Innovation Organization before Connecticut General Assembly (March 11, 2025) ("This bill attempts to regulate free-market prices and creates a price ceiling in the form of a reference price tied to WAC. However, this bill will not lower prescription drug costs for patients because it does not address out-of-pocket costs. Nearly 90% of patients pay a given price based on what their health insurer determines. Out-of-pocket costs have been rising for patients because of decisions made by health insurers. . . . [M]any insurers require more and more patients to pay for their drug costs through deductibles and cost-sharing rather than an established copayment, increasing their out-of-pocket costs. A May 2021 Congressional Research Service report found that insurers are imposing higher levels of cost sharing and forcing some patients, i.e., the chronically ill, to pay a greater financial burden than others."), available at https://www.cga.ct.gov/2025/hsdata/TMY/2025SB-00011-R000311-Burm,%20Stephen,%20Dir%20State%20Government%20Affairs-Biotechnology%20Innovation%20Org-Opposes-TMY.PDF.

• Testimony of Paul R. Pescatello, JD, PhD, Connecticut Bioscience Growth Council Organization before Connecticut General Assembly (March 11, 2025) (stating the bill "ignores the fact that the CPI is an average of a broad spectrum of products. The CPI does not reflect the rate of inflation for any one specific product category. The overall January CPI, for example, was three percent, but for eggs it was 15.2%. The components of the drug supply chain, including the supply chain for generic and off-patent drugs, are many and variable. They are sourced from around the world. This is especially the case for the complex manufacturing applicable to injectable and infused biologics. The price increases suppliers in the generic and off-patent drug supply chain charge for ingredients can often exceed the CPI. Since many parts of and ingredients used in drug manufacturing are sourced from overseas, currency fluctuations can have a dramatic effect on

prices significantly in excess of the CPI."), available at https://www.cga.ct.gov/2025/insdata/TMY/2025HB-06870-R000218-Pescatello,%20Paul,%20Sr%20Counsel-Executive%20Director-CT%20Bioscience%20Growth%20Council-Opposes-TMY.PDF.

• Statement of PhRMA before Connecticut General Assembly (March 11, 2025) ("This legislation threatens to drastically reduce development of new medicines at a time of remarkable scientific promise, undermining U.S. global leadership in biopharmaceutical innovation. Government price setting diminishes the incentive for biopharmaceutical manufacturers to invest in the research and development of new medicines. By imposing significant penalties for sales of a prescription drug over a reference price, this legislation creates a price control on these medicines that could have the long-term effect of decreasing access to medications."), available at 2025SB-00011-R000311-Cottle Latham, Rachel, Sr Director - State Policy-PhRMA-Opposes-TMY.PDF.

• Testimony of Dawn Holcombe on behalf of the Connecticut Oncology Association before Connecticut General Assembly (March 10, 2025) ("Setting caps and reference pricing on manufacturer and wholesale distributors also misses the boat completely on the disconnect between acquisition costs paid by treating providers and pharmacies unaffiliated with PBMs or health plans and the reimbursement rates 'allowed' by health plans to those providers. . . . Another significant adverse consequence of selected drug price fixing by state policy rather than market competition, would be to artificially reduce prices of already low priced drugs. When drug prices are suppressed below the costs of manufacturing, fewer manufacturers continue to produce the drug. That leads to drug shortages when a natural or other disaster strikes the sole major manufacturing source left, as we have seen in recent years from hurricanes and flooding. Artificial price suppression such as the . . . reference pricing proposal can do more harm to patients by creating drug shortages."), available at https://www.cga.ct.gov/2025/hsdata/TMY/2025SB-00011-R000311-Holcombe,%20Dawn,%20Executive%20Director-Connecticut%20Oncology%20Association-Opposes-TMY.PDF.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2025, a copy of the foregoing document was filed electronically and served by mail on anyone unable to accept electronic filing. 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.

By: */s/ Thomas J. Finn*
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