

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

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

v.

MARK D. BOUGHTON, in his official
capacity as Commissioner of the Connecticut
Department of Revenue Services; and

WILLIAM M. TONG, in his official capacity
as Attorney General of the State of
Connecticut,

Defendants.

Case No.: 3:25-cv-1757-OAW

PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 65(a), Plaintiff Association for Accessible Medicines (“AAM”), on behalf of its members, hereby moves the Court for a preliminary injunction enjoining Mark D. Boughton, in his official capacity as Commissioner of the Connecticut Department of Revenue Services; William M. Tong, in his official capacity as Attorney General of the State of Connecticut; and their officers, agents, servants, employees, and all persons in active concert or participation with them, from enforcing sections 345 through 347 of Connecticut Public Act No. 25-168 against AAM’s members, or their agents and licensees, based on their sales of generic drugs or biosimilars that occur outside of Connecticut.

This motion is based upon all the files, records, and proceedings herein, including the accompanying memorandum of law and supporting declarations, as well as any evidence that may

ORAL ARGUMENT REQUESTED

be submitted at the hearing on the motion. As established in the accompanying memorandum of law and declarations: (1) AAM is likely to succeed on the merits; (2) AAM's members will suffer irreparable harm if Defendants are not preliminarily enjoined from implementing or enforcing these provisions; (3) the balance of hardships favors an injunction; and (4) granting the requested preliminary injunction will further the public interest.

AAM requests that the Court require no security, because Defendant will suffer no injury from the issuance of a preliminary injunction.

WHEREFORE, Plaintiff respectfully requests that this Court issue an order granting a preliminary injunction as set forth above.

Dated: October 23, 2025

Respectfully submitted,

/s/ Paul Tuchmann

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

William M. Jay (PHV No. 208971)
Isabel M. Marin (PHV No. 208899)
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
Tel.: (202) 346-4000
Fax: (202) 346-4444
wjay@goodwinlaw.com
imarin@goodwinlaw.com

*Counsel for Plaintiff Association for Accessible
Medicines*

CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2025 I caused a copy of the foregoing to be served upon counsel for Defendants, by advance written consent, by e-mail to Assistant Attorney General Patrick Ring at patrick.ring@ct.gov.

/s/ Paul Tuchmann _____
Paul Tuchmann

Exhibit A

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

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

v.

MARK D. BOUGHTON, in his official
capacity as Commissioner of the Connecticut
Department of Revenue Services; and

WILLIAM M. TONG, in his official capacity
as Attorney General of the State of
Connecticut,

Defendants.

Case No.: 3:25-cv-1757

DECLARATION OF CHRISTINE BAEDER

I, Christine Baeder, declare as follows:

1. I am the President of Apotex Corp. (“Apotex”). I joined Apotex on December 11, 2023. My responsibilities include oversight of all commercial operations of Apotex. I have over 20 years of experience in several roles in pharmaceutical organizations, including in sales, supply chain management, and marketing.

2. I submit this declaration in support of the Association for Accessible Medicines’ complaint and motion for preliminary injunction in the above-captioned case. Based on my role and day-to-day responsibilities, I am familiar with Apotex’s distribution system, sales arrangements, and pricing decisions.

3. Apotex is a pharmaceutical corporation organized under the laws of the State of Delaware with its principal place of business in Weston, Florida. Apotex is a pharmaceutical company that commercializes and distributes generic pharmaceutical products.

4. Apotex sells all of its products in the United States to national wholesalers, none of which is located in Connecticut. Apotex does not make drug-pricing decisions on a state-by-state basis. Instead, Apotex provides wholesale distributors with a list price, known as the “Wholesale Acquisition Cost,” which is a nationwide price. Apotex then enters into pre-negotiated volume contracts. Apotex does not control where its products are sold, or for how much, once products enter the distribution channel.

5. Apotex markets [REDACTED] in the United States. [REDACTED] is manufactured in the [REDACTED] facility in [REDACTED].

6. [REDACTED] is a generic drug that has not been determined to be in shortage in the United States by the federal Secretary of Health and Human Services.

7. [REDACTED] is sold in Connecticut, but not by Apotex. Apotex’s sales of [REDACTED] occur outside Connecticut, and the drug reaches Connecticut through the actions of third parties such as the national wholesalers and distributors. I understand that Connecticut will take the position that this constitutes selling [REDACTED] “in this state.”

8. Apotex makes at least \$250,000 in total annual sales in Connecticut. It is likely that Apotex will exceed \$250,000 in total annual sales in Connecticut in 2026.

9. The wholesale acquisition cost (WAC) for [REDACTED] on January 1, 2025, was [REDACTED]. Therefore, Apotex would exceed Connecticut's cap if, after January 1, 2026, it sells [REDACTED] in Connecticut for more than [REDACTED], adjusted for the Consumer Price Index (currently 2.7%, which would make the adjusted amount [REDACTED]).

10. During calendar year 2025, Apotex increased its WAC for [REDACTED] to [REDACTED]. Therefore, unless the price-control provisions are enjoined or Apotex changes the price, Apotex will exceed Connecticut's cap as of January 1, 2026. Apotex must either lower the WAC and forgo the revenue (which Apotex will never get back), or pay the civil penalty for exceeding the cap.

11. A price increase is necessary because of increases in input costs, raw materials, regulatory costs, manufacturing costs, validation/testing, logistics, compliance overhead and market dynamics. These costs inform pricing decisions for [REDACTED] and other products. [REDACTED] is [REDACTED] prescription product. This product profile results in higher storage, distribution, and regulatory/compliance costs relative to other products, costs that have been increasing in the past few years which have been absorbed by Apotex. In addition, manufacturing costs for this product have also increased over the past few years. The price increase on [REDACTED] by Apotex in 2025 helped to offset these incremental costs for the product to continue to generate sufficient margin on the product to justify ongoing product commercialization.

12. The Connecticut civil penalty of 80% of the increase above Connecticut's cap will harm the profitability of [REDACTED] by limiting the

ability of Apotex to generate sufficient margin on the product to justify ongoing product commercialization. The Act's recordkeeping and filing requirements will also impose new compliance costs on Apotex for each product that is, or may be, subject to the Act's price cap. Apotex will need to begin bearing these compliance costs in 2025 in anticipation of the price cap taking effect.

13. These constraints will reduce planned R&D and product-support investments. The harms from these reductions in investment will be irreparable.

14. The Connecticut law's civil penalty provisions also forbid Apotex from withdrawing [REDACTED] from sale in Connecticut (if it were feasible for Apotex to prevent the drug from being sold in a single state) in order to avoid the civil penalty for price increases. Apotex could not recover the civil penalty for withdrawal once it is paid. As a result, the Connecticut law will force Apotex to continue selling [REDACTED] even if the Connecticut law's price control makes that product unprofitable or uneconomical. These consequences will result in further irreparable harm to Apotex's business, for which Apotex cannot recover compensation from the State.

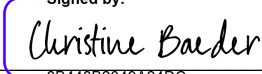
15. Apotex treats anticipated pricing decisions as confidential and maintains safeguards so that such plans are not disclosed to competitors or third parties, to preserve competitive position and comply with applicable law.

16. Public disclosure of non-public pricing plans (including the identity of products and the size/timing of anticipated changes) would enable competitors to adjust strategies and harm Apotex's competitive position.

17. There is no way to fully remedy these harms or recoup lost revenue through damages. Each time increased costs or other factors necessitate a price review, Apotex must either (a) forgo price adjustments and sacrifice margin; (b) adjust prices and incur exposure to civil penalties under Public Act No. 25-168; or (c) if a product becomes unprofitable without an adjustment, consider withdrawing it, resulting in unrecoverable lost revenue.

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

Executed on 10/22/2025, 2025.

Signed by:


8B448B2049A24D...
Christine Baeder
President

Exhibit B

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

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

v.

MARK D. BOUGHTON, in his official
capacity as Commissioner of the Connecticut
Department of Revenue Services; and

WILLIAM M. TONG, in his official capacity
as Attorney General of the State of
Connecticut,

Defendants.

Case No.: 3:25-cv-1757

DECLARATION OF BRANDON ROCKWELL

I, Brandon Rockwell, declare as follows:

1. I am the President of PAI Pharma (“PAI”). I joined PAI in February 2021. My current responsibilities include oversight of PAI’s commercial operations.
2. I submit this declaration in support of the Association for Accessible Medicines’ complaint and motion for preliminary injunction in the above-captioned case. PAI is a member of the association. Based on my role and day-to-day responsibilities, I am familiar with PAI’s distribution system, sales arrangements, and pricing decisions.
3. PAI Pharma is the trade name of a limited liability company organized under the laws of the State of South Carolina with its principal place of business in Greenville, South Carolina. PAI manufactures and sells generic pharmaceutical products.

4. PAI sells its products in the United States to national wholesalers, none of which are located in Connecticut. PAI does not control where its products are sold, nor for how much, once products enter the distribution channel.

5. PAI markets [REDACTED] in the United States.

6. [REDACTED] is a generic drug, approved pursuant to an abbreviated new drug application, that has not been determined to be in shortage in the United States by the federal Secretary of Health and Human Services. It is indicated to treat [REDACTED]. It is also indicated to [REDACTED].

7. [REDACTED] is sold in Connecticut, but not by PAI. All of PAI's sales of [REDACTED] occur outside Connecticut, and the drug reaches Connecticut through the actions of third parties such as the national wholesalers and distributors. I understand that Connecticut will take the position that this constitutes selling [REDACTED] "in this state."

8. PAI makes at least \$250,000 in total annual sales in Connecticut. It is likely that PAI will exceed \$250,000 in total annual sales in Connecticut in 2026.

9. The wholesale acquisition cost (WAC) for [REDACTED] on January 1, 2025, was [REDACTED]. PAI would exceed Connecticut's cap if, after January 1, 2026, it sells [REDACTED] in Connecticut for more [REDACTED], adjusted for the Consumer Price Index (currently 2.7%, which would make the adjusted amount [REDACTED]).

10. This product is not financially viable at its current price. It is expensive to manufacture, and the cost of manufacturing has increased substantially more than the Consumer Price Index. Accordingly, a price increase is necessary for this product to be viable on its own, without incurring a loss for the company.

11. For this reason, PAI has concrete plans to raise the price for [REDACTED] [REDACTED] to [REDACTED]. Connecticut's cap prohibits that increase.

12. A separate provision of Connecticut law prohibits PAI from withdrawing the product from sale in Connecticut before the price cap takes effect, even if it were feasible for a manufacturer to limit where a product is ultimately distributed after being sold to national wholesalers. PAI would have to pay a \$500,000 civil penalty if it withdrew a product from sale in Connecticut to avoid the price cap. PAI could not recover that civil penalty once it is paid.

13. As a result, beginning on January 1, 2026, the Connecticut law will force PAI to continue selling [REDACTED] at an uneconomical price. PAI has no way to recover the revenue that it will have to forgo as a result of Connecticut's decision to prohibit the price increase that PAI would otherwise make. And because the continued sale of the product at the current price results in PAI actually losing money, PAI will suffer further irreparable harm to its overall business, including money not available to develop and market new products. These economic and intangible harms cannot be alleviated through money damages from the government.

14. Products that are not economically viable are generally discontinued. PAI is the only company currently marketing [REDACTED] [REDACTED]. If PAI is not able to continue

offering that product, it will be gone from the U.S. market, leaving [REDACTED] patients who are currently receiving this treatment to seek alternative options.

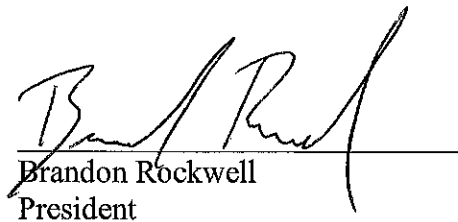
15. As Connecticut's price cap prevents more and more generic products from remaining financially viable, more generic products are likely to be discontinued.

16. PAI treats anticipated pricing decisions as confidential and maintains safeguards so that such plans are not disclosed to competitors or third parties, to preserve competitive position and comply with applicable law.

17. Public disclosure of non-public pricing plans (including the identity of products and the size/timing of anticipated changes) would enable competitors to adjust strategies and harm PAI's competitive position.

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

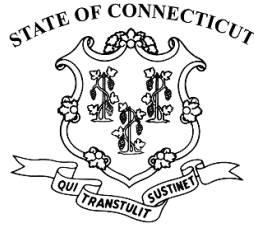
Executed on October 20th, 2025.



Brandon Rockwell
President

Exhibit C

EXCERPTS OF PUBLIC ACT NO. 25-168

**House Bill No. 7287****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

House Bill No. 7287

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;

House Bill No. 7287

(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;

House Bill No. 7287

(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

House Bill No. 7287

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

House Bill No. 7287

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

House Bill No. 7287

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

House Bill No. 7287

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

House Bill No. 7287

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

House Bill No. 7287

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

House Bill No. 7287

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

House Bill No. 7287

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.

House Bill No. 7287

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**

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

v.

MARK D. BOUGHTON, in his official
capacity as Commissioner of the Connecticut
Department of Revenue Services; and

WILLIAM M. TONG, in his official capacity
as Attorney General of the State of
Connecticut,

Defendants.

Case No.: 3:25-cv-1757-OAW

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

TABLE OF CONTENTS

	Page
INTRODUCTION	1
STATEMENT OF FACTS	5
I. THE IMPORTANCE OF GENERIC AND BIOSIMILAR MEDICINES	5
II. CONNECTICUT’S NEW PRICE-CONTROL LAW	8
STANDING	13
ARGUMENT	14
I. AAM IS LIKELY TO SUCCEED ON ITS CLAIMS THAT ENFORCEMENT OF THE ACT AGAINST OUT-OF-STATE TRANSACTIONS WILL VIOLATE THE CONSTITUTION.....	15
A. The Commerce Clause Prohibits States From Directly Regulating Transactions That Occur Wholly Out Of State.	15
1. Courts of Appeals Have Consistently Applied the Rule Against State Direct Regulation of Out-of-State Transactions to Invalidate State Price Control Laws Just Like the Act.	18
2. District Courts In This Circuit (and in Many Other Circuits) Have Consistently Held the Same.....	19
B. The Supreme Court’s Recent Decision in <i>Ross</i> Confirms That States May Not Directly Regulate Prices in Out-of-State Transactions.....	21
C. The Defendants’ Planned Enforcement of the Act Is Unconstitutional Because It Directly Regulates Prices Charged in Transactions Entirely Outside Connecticut.....	24
D. In Addition to Directly Regulating Wholly Out-of-State Transactions, Connecticut’s Law Is Unconstitutionally Discriminatory.....	25
E. Any Jurisdictional Objections Are Not Likely To Succeed.	26
II. AAM’S MEMBERS HAVE NO ADEQUATE REMEDY AT LAW AND WILL SUFFER IRREPARABLE HARM ABSENT AN INJUNCTION.	28
A. The Act Subjects AAM’s Members to Unconstitutional Regulation.	29
B. The Act Will Cause AAM’s Members Irreparable Economic Harm.	29
III. THE BALANCE OF HARDSHIPS AND PUBLIC INTEREST SUPPORT AN INJUNCTION.....	32
CONCLUSION.....	34

TABLE OF AUTHORITIES

	Page(s)
Cases:	
<i>A.H. Harris & Sons, Inc. v. Naso</i> , 94 F. Supp. 3d 280 (D. Conn. 2015).....	32
<i>AAM v. Bonta</i> , 766 F. Supp. 3d 1020 (E.D. Cal. 2025).....	24
<i>AAM v. Raoul</i> , No. 24 C 544, 2025 WL 2764558 (N.D. Ill. Sept. 26, 2025), appeal filed (Oct. 16, 2025)	24
<i>Am. Beverage Ass’n v. Snyder</i> , 735 F.3d 362 (6th Cir. 2013)	19
<i>Am. Trucking Ass’ns, Inc. v. City of L.A.</i> , 559 F.3d 1046 (9th Cir. 2009)	32
<i>America’s Health Ins. Plans v. Hudgens</i> , 742 F.3d 1319 (11th Cir. 2014)	31
<i>Ass’n for Accessible Meds. v. Ellison</i> , 140 F.4th 957 (8th Cir. 2025)	1, 2, 16, 17, 18, 19, 23
<i>Ass’n for Accessible Meds. v. Ellison</i> , 704 F. Supp. 3d 947 (D. Minn. 2023), <i>aff’d</i> , 140 F.4th 957 (8th Cir. 2025)	19, 21, 23
<i>Ass’n for Accessible Meds. v. Frosh</i> , 887 F.3d 664 (4th Cir. 2018)	2, 14, 18, 19
<i>Baldwin v. G. A. F. Seelig, Inc.</i> , 294 U.S. 511 (1935).....	1, 2, 17
<i>Bldg. & Const. Trades Council of Buffalo, New York & Vicinity v. Downtown Dev., Inc.</i> , 448 F.3d 138 (2d Cir. 2006).....	14
<i>Brown-Forman Distiller Corp. v. N.Y. State Liquor Auth.</i> , 476 U.S. 573 (1986).....	17
<i>CIC Services, LLC v. IRS</i> , 593 U.S. 209 (2021).....	27
<i>Connecticut Dep’t of Env’t Prot. v. O.S.H.A.</i> , 356 F.3d 226 (2d Cir. 2004).....	29

Edgar v. MITE Corp.,
457 U.S. 624 (1982).....16, 17, 23

Glidedowan, LLC v. New York State Dep’t of Health,
768 F. Supp. 3d 503 (W.D.N.Y. 2025).....29

Healthcare Distrib. All. v. Zucker,
353 F. Supp. 3d 235 (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).....15, 16, 20

Healy v. Beer Inst., Inc.,
491 U.S. 324 (1989).....2, 16, 17, 25, 26

Interlink Prods. Int’l, Inc. v. Crowfoot,
678 F. Supp. 3d 1216 (E.D. Cal. 2023).....22

John E. Andrus Mem’l, Inc. v. Daines,
600 F. Supp. 2d 563 (S.D.N.Y. 2009).....30

Legato Vapors LLC v. Cook,
847 F.3d 825 (7th Cir. 2017)17

Mahmoud v. Taylor,
145 S. Ct. 2332 (2025).....15

Mallory v. Norfolk S. Ry. Co.,
600 U.S. 122 (2023).....15

Martinez-Brooks v. Easter,
459 F. Supp. 3d 411 (D. Conn. 2020).....33

Metro. Transportation Auth. v. Duffy,
784 F. Supp. 3d 624 (S.D.N.Y. 2025).....32

Morales v. Trans World Airlines, Inc.,
504 U.S. 374 (1992).....31

Nat’l Fed’n of Indep. Bus. v. Sebelius (NFIB),
567 U.S. 519 (2012).....27, 28

Nat’l Pork Producers Council v. Ross,
598 U.S. 356 (2023).....3, 15, 21, 22, 23, 26

Nat’l Shooting Sports Found., Inc. v. James,
144 F.4th 98 (2d Cir. 2025)16

Nat’l Shooting Sports Found. v. Bonta,
718 F. Supp. 3d 1244 (S.D. Cal. 2024).....23

New York v. United States Dep’t of Homeland Sec.,
969 F.3d 42 (2d Cir. 2020).....14, 32, 33

Pharm. Rsch. & Mfrs. of Am. v. Comm’r, Maine Dep’t of Hum. Servs.,
2000 WL 34290605 (D. Me. Oct. 26, 2000).....20, 21

Pharm. Rsch. & Mfrs. of Am. v. Concannon,
249 F.3d 66 (1st Cir. 2001), *aff’d*, 538 U.S. 644 (2003).....21

Pharm. Rsch. & Mfrs. of Am. v. District of Columbia,
406 F. Supp. 2d 56 (D.D.C. 2005), *aff’d sub nom. Biotechnology Indus. Org.
v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).....20

PhRMA v. Walsh,
538 U.S. 644 (2003).....2

Pike v. Bruce Church, Inc.,
397 U.S. 137 (1970).....22

Regeneron Pharms., Inc. v. U.S. Dep’t of Health & Hum. Servs.,
510 F. Supp. 3d 29 (S.D.N.Y. 2020).....33

Sam Francis Found. v. Christies, Inc.,
784 F.3d 1320 (9th Cir. 2015) (en banc)19

State Farm Mut. Auto. Ins. Co. v. Tri-Borough NY Med. Prac. P.C.,
120 F.4th 59 (2d Cir. 2024)29

Statharos v. New York City Taxi & Limousine Comm’n,
198 F.3d 317 (2d Cir. 1999).....29

Styczinski v. Arnold,
46 F.4th 907 (8th Cir. 2022)19

Travelers Ins. Co. v. Cuomo,
14 F.3d 708 (2d Cir. 1994), *rev’d on other grounds sub nom.
N.Y. State Conference of Blue Cross & Blue Shield Plans v.
Travelers Ins. Co.*, 514 U.S. 645 (1995).....28

United States v. New York,
708 F.2d 92 (2d Cir. 1983).....30

Variscite NY Four, LLC v. New York State Cannabis Control Bd.,
152 F.4th 47 (2d Cir. 2025)29, 33

VIZIO, Inc. v. Klee,
886 F.3d 249 (2d Cir. 2018).....16

Weinberg v. Dep’t of Revenue Servs.,
596 F. Supp. 3d 386 (D. Conn. 2022).....28

Statutes:

21 U.S.C. § 355.....9

28 U.S.C. § 1341.....26, 27, 28

42 U.S.C. § 262(i)(1)9

42 U.S.C. § 262(i)(2), (k).....9

42 U.S.C. § 262(k)(4)(A).....9

42 U.S.C. § 1396b(w)28

42 U.S.C. § 1396b(w)(7)(F).....28

Conn. Gen. Stat. Ann. § 20-619(a)(4)(A)9

Conn. Gen. Stat. Ann. § 20-619(a)(4)(B)9

Conn. Gen. Stat. Ann. § 12-35(a)(3)(A)11

Public Act No. 25-1681, 4

 § 128.....27

 § 130.....27

 § 345(5).....9

 § 345(6).....9

 § 345(6)(A)26

 § 345(6)(B).....9

 § 345(7).....9

 § 346(a)11

 § 346(a)(1)9, 11, 25

 § 346(a)(2)10

 § 346(b).....31

 § 346(b)(1)11

§ 346(b)(2)12, 25

§ 346(e)31

§ 346(i)..... 11

§ 346(j).....13

§ 346(j)(1)31

§ 346(k).....28

§ 347(a).....13

§ 347(b).....13

§ 347(c).....13

Other Authorities:

42 C.F.R. § 447.5029

Adam J. Fein, *Big Three Wholesalers: Revenues and Channel Share Up, Profits Down, Drug Channels* (Oct. 2, 2019), <https://tinyurl.com/yfk5vujr>6

Active Pharmaceutical Ingredients Market Size, Precedence Research (Jan. 2023), <https://tinyurl.com/5ey4tzan>8

Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp. (2021), <https://tinyurl.com/bdzh4dnr>.....6

Conn. Dep’t of Consumer Protection, Drug Control Division & Univ. of Conn. Sch. of Pharmacy, *Prescription Drug Shortages in Connecticut* (Jan. 1, 2025), <https://tinyurl.com/4mbdnz7c> 7-8

FDA, *Drug Shortages: Root Causes and Potential Solutions* (Feb. 21, 2020), <https://www.fda.gov/media/131130/download>8

FDA, *Interpretation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009* (Dec. 2018), <https://www.fda.gov/media/119590/download>.....9

Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* (Mar. 2005), <https://tinyurl.com/5n77syew>6

Mariana P. Socal et al., *Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients*, 42 *Health Affairs* 407 (Mar. 2023), <https://tinyurl.com/2nxc44ph>.....8

Sarah Ibrahim, Ph.D., *Unlocking Global Access to Generic Drugs*, FDA (Sept. 2023), <https://www.fda.gov/media/177933/download>.....7

Transcript of Hearing before the Senate Human Services Comm., Mar. 11, 2025, <https://tinyurl.com/4dfuk346>12

U.S. Generic & Biosimilar Medicines Savings Report (Sept. 2025), <https://tinyurl.com/5xdpmtvv>5

U.S. Dep’t of Health & Hum. Servs., *Analysis of New Generic Markets, Effect of Market Entry on Generic Drug Prices: Medicare Data 2007-2022*, ASPE Issue Brief (January 16, 2025), <https://tinyurl.com/mrc8dj73>5

U.S. Dep’t of Health & Hum. Servs., *Understanding Recent Trends in Generic Drug Prices*, ASPE Issue Brief (Jan. 27, 2016), <https://tinyurl.com/yfr4sbza>5

INTRODUCTION

The fundamental question in this case is whether Connecticut may directly regulate the price of goods sold in other states. The answer is no. As the Eighth Circuit held earlier this year in invalidating a Minnesota law virtually identical to the Connecticut law at issue here, “controlling the price of wholly out-of-state transactions” is wholly beyond states’ power under our constitutional system, even when the goods sold in those out-of-state transactions are later resold in the regulating state. *Ass’n for Accessible Meds. v. Ellison*, 140 F.4th 957, 961 (8th Cir. 2025). The Constitution reserves such power to regulate *interstate* commerce to the national government.

That bedrock principle of constitutional law applies equally here and requires the same result. Connecticut has targeted generic and biosimilar manufacturers with a new price control: sections 345 through 347 of Public Act No. 25-168 (the “Act”) (Exhibit C). The Act does not regulate the price at which drugs are sold to patients at a pharmacy in Connecticut. Rather, starting January 1, it caps the price at which manufacturers and wholesale distributors may sell generic and biosimilar products—leaving retailers and other resellers in Connecticut free to impose price increases. The Act thus *exempts* most in-state transactions from its reach. On the flip side, all evidence indicates that Defendants—the Connecticut officials responsible for enforcing the Act—plan to apply the Act to govern sales between manufacturers and wholesalers *anywhere in the country*, so long as some of the product eventually arrives—through transactions with third parties—in Connecticut. Compl. ¶ 5. Defendants, then, seek to directly regulate transactions that take place wholly outside Connecticut between non-Connecticut entities.

None of that is consistent with the Constitution. Under our federal constitutional system, a state “has no power to project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there.” *Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). And this law is even more pernicious: Despite directly regulating the price of products in

transactions that take place *wholly outside the state* (and are perfectly legal in the states where they actually occur), Connecticut’s law does *not* regulate the prices that the consumer ultimately pays *in the state*. This sort of direct affront to interstate commerce is exactly what the Constitution was designed to prevent—and explains why the Eighth and Fourth Circuits struck down substantively identical Minnesota and Maryland laws. *Ellison*, 140 F.4th at 960-61; *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018). Because Connecticut is “insist[ing] that manufacturers sell their drugs to a wholesaler for a certain price” in “out-of-state transaction[s],” “[t]he rule that was applied in *Baldwin*” applies here. *Ellison*, 140 F.4th at 962 (quoting *PhRMA v. Walsh*, 538 U.S. 644, 669 (2003)).

Besides being mandated by precedent, that outcome makes good sense. If Connecticut can directly regulate the price of goods sold in other states just because they may wind up being resold in its state, then so can every other state. Allowing State *A* to regulate the wholesale prices that private parties can charge in State *B*, merely because the products in those sales might end up being resold in State *A*, would unleash a fifty-state race to regulate the national economy, usurp Congress’s role in regulating interstate commerce, and destroy our “national economic union.” *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989). That was worrisome enough at the Founding or even at the time of *Baldwin*; it is even more of a threat today, as the market for nearly every major product (and most minor products) is now national in scope. For that reason, the Supreme Court has cautioned that the question in a dormant Commerce Clause case is not just whether *one* state law will threaten our national market (though Connecticut’s certainly does), but “what effect would arise if not one, but many or every, State adopted similar legislation.” *Id.* There could be no interstate pharmaceutical market if every state could write its own nationally applicable price regulation, each covering distinct sets of drugs and imposing different price restrictions. In short,

Connecticut's new price control is unconstitutional under a straightforward application of precedent and a threat to the fundamental moorings of our federal constitutional republic.

It is also protectionist state legislation that the Commerce Clause unequivocally “prohibits.” *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 369 (2023). It is no secret that prescription drugs are expensive in this country. But the culprits for the often-sky-high prices are not generics and biosimilars. Quite the opposite: Brand-name drugs and biologic medicines drive patient costs. Generic and biosimilar medicines, by contrast, account for 90 percent of all prescriptions dispensed in the United States, but just 12 percent of the money spent on prescriptions. Yet the Act's price cap applies almost exclusively to generic drugs and (some) biosimilars. That topsy-turvy result has a practical explanation: the interests of Connecticut's in-state brand manufacturers. And it gets worse. The Act further panders to in-state interests by exempting in-state retailers and resellers from the price cap. In-state businesses can thus profit at the expense of consumers and out-of-state generic manufacturers and wholesalers who are forbidden from exceeding the price cap. The Act is therefore a classic example of economic protectionism—it was “designed to benefit in-state economic interests by burdening out-of-state competitors.” *Id.*

This Court should not allow the price cap and related provisions to begin regulating out-of-state transactions on January 1, 2026, while the merits of this case are litigated. The Act's price cap is exceptionally rigid: It is *permanently* tied to a drug's price on January 1, 2025, months before the Act was even enacted, and it *never* permits a price increase—no matter how much the cost of producing a covered product may increase due to factors out of a manufacturer's control like increases in ingredient cost—except to track the *general*, economy-wide rate of inflation as measured by the Consumer Price Index. The Act imposes a civil penalty on any company that

charges a price above Connecticut’s cap once it takes effect—and it exposes officers and employees of generic and biosimilar manufacturers to fines and imprisonment if the civil penalty is not paid. Worse still, manufacturers cannot simply remove their products from Connecticut to avoid the price cap; even if that were feasible, the Act also prohibits manufacturers and wholesale distributors from withdrawing any covered drug from Connecticut “for the purpose of avoiding the civil penalty.” In other words, there is no escaping Connecticut’s new, onerous regulation.

Because Connecticut’s unconstitutional new price control poses a direct threat to manufacturers of generic and biosimilar medicines, to the millions of Americans who rely on their lifesaving therapies, and to the national market, the Association for Accessible Medicines (“AAM”)—a nonprofit association representing leading generic and biosimilar manufacturers—has brought this action on behalf of its members and now seeks a preliminary injunction like those that barred enforcement of the Minnesota law and the Maryland law. Defendants likewise should be enjoined from enforcing the Act as to out-of-state transactions.

If not enjoined, the Act will irreparably injure AAM’s members by depriving them of their constitutional rights and by causing them severe economic losses that, given state sovereign immunity, cannot be recovered. By contrast, Connecticut will not be injured if prohibited from enforcing an unconstitutional law. Enjoining the law also will serve the public interest, as the price cap will threaten the viability of generic drugs, exacerbate the already severe drug-shortage problem plaguing the U.S. healthcare system, shield brand drugs from their primary source of competition—and *raise* patient costs rather than lower them.

For those reasons and the ones set forth below, the Court should grant a preliminary injunction barring Defendants from enforcing sections 345 through 347 of the Act against AAM’s members based on their out-of-state transactions, pending litigation of this case on the merits.

STATEMENT OF FACTS

I. The Importance Of Generic And Biosimilar Medicines

Generic and biosimilar medicines play a crucial role in reducing healthcare costs for Americans. *See* Compl. ¶ 25; U.S. Dep’t of Health & Hum. Servs., *Analysis of New Generic Markets, Effect of Market Entry on Generic Drug Prices: Medicare Data 2007-2022*, ASPE Issue Brief, 1-2 (January 16, 2025).¹ Through vigorous competition, generics “are consistently lower than brand-name prices across all market sizes and time periods.” *Id.* at 1. Generic entry into the market drives significant price decreases, causing prices to decline between 20 percent to 80 percent after three years of entry, depending on the number of generic competitors. *Id.* at 10-11; *see also* U.S. Dep’t of Health & Hum. Servs., *Understanding Recent Trends in Generic Drug Prices*, ASPE Issue Brief, 1 (Jan. 27, 2016) (Generic and biosimilar medicines have “drive[n] prices for generic drugs to be a fraction of that of the corresponding brand name drug.”).² Biosimilars likewise are lower-cost versions of biologics, which are complex medicines made from living cells (such as proteins). Generic and biosimilar medicines are thus equally safe and equally effective as their brand-name counterparts—but they cost considerably less. According to the most recent data, generic and biosimilar medicines account for 90 percent of all prescriptions dispensed in the United States but amount to only 12 percent of the money spent on prescriptions. *See* Ass’n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report 2*, 10 (Sept. 2025).³ These medicines have produced nearly \$3.4 trillion in savings to the U.S. healthcare system over the past decade, with \$467 billion in savings in 2024 alone—a \$27 billion increase over the prior year. *Id.* at 10-11.

¹ <https://tinyurl.com/mrc8dj73>.

² <https://tinyurl.com/yfr4sbza>.

³ <https://tinyurl.com/5xdpmtvv>.

AAM is the leading trade association for manufacturers of generic and biosimilar medicines. As is true of most pharmaceutical manufacturers, AAM’s manufacturer members generally do not sell their medicines directly to patients. Compl. ¶ 29. Instead, AAM’s manufacturer members are at the start of a long drug-supply chain. *Id.* They sell their products to large national wholesale distributors, who then resell those products to retail pharmacies, hospitals, or other healthcare facilities. *Id.*; see Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corp., 4-5 (2021)⁴; Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 1-2 (Mar. 2005).⁵ Three companies—Cencora, Cardinal Health, and McKesson, none based in Connecticut—control over 90 percent of the wholesale market.⁶ Nearly all sales from generic and biosimilar manufacturers to one of the big wholesalers occur wholly outside Connecticut.

Generic and biosimilar manufacturers, including AAM’s members, do not make drug-pricing or drug-distribution decisions on a state-by-state basis. Compl. ¶ 30; Baeder Decl. ¶ 4. Instead, they provide a nationwide list price for their medicines, which is termed the “Wholesale Acquisition Cost.” Compl. ¶ 30; Baeder Decl. ¶ 4. They then sell their medicines to wholesale distributors in pre-negotiated volume contracts. Compl. ¶ 30; Baeder Decl. ¶ 4. Furthermore, manufacturers do not control the prices at which wholesale distributors resell their medicines or where those products are ultimately resold. Compl. ¶ 30; Baeder Decl. ¶ 4; Rockwell Decl. ¶ 4.

⁴ <https://tinyurl.com/bdzh4dnr>.

⁵ <https://tinyurl.com/5n77syew>.

⁶ Adam J. Fein, *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, Drug Channels (Oct. 2, 2019), <https://tinyurl.com/yfk5vujr>; see Cencora, Inc., SEC Form 8-K (Sept. 3, 2025), <https://tinyurl.com/2uw568bn>; Cardinal Health, Inc., SEC Form 8-K (Aug. 27, 2025), <https://tinyurl.com/44w2k6pw>; McKesson Corp., SEC Form 8-K (Aug. 6, 2025), <https://tinyurl.com/4eskx7s9>.

Instead, a number of national and regional stakeholders, including the three large national wholesale distributors, as well as pharmacy benefit managers, retail pharmacy chains, health insurers, Medicaid and Medicare contractors, hospital networks, and others, play a role in determining the ultimate prices that patients actually pay for generic and biosimilar medications. Compl. ¶ 31; Baeder Decl. ¶ 7; Rockwell Decl. ¶ 7.

Unlike brand-name drug manufacturers, which can use patents and other exclusivities to enjoy monopoly pricing for years or even decades, generic and biosimilar manufacturers are sellers of commodity products in a market characterized by intense price competition, uncertain revenue streams, high investment requirements, supply chain vulnerabilities, regulatory complexity, and intellectual property challenges, all of which limit potential returns. Compl. ¶ 26; Sarah Ibrahim, Ph.D., *Unlocking Global Access to Generic Drugs*, FDA, 6 (Sept. 2023)⁷; FDA, *Drug Shortages: Root Causes and Potential Solutions* 22-23 (Feb. 21, 2020).⁸ As a result of these dynamics, generic manufacturers often operate on “[t]hin [p]rofit [m]argins” and are unable to afford to support redundant capacity. Ibrahim, *supra*, at 6; FDA, *Drug Shortages, supra*, at 23, 41. This is neither debatable nor disputed. Indeed, Connecticut itself recently came to the same conclusion, in a joint report by the Department of Consumer Protection and the UConn School of Pharmacy: “market economics” create “slim margins for profit” for generics. Conn. Dep’t of Consumer Protection, Drug Control Division & Univ. of Conn. Sch. of Pharmacy, *Prescription Drug Shortages in Connecticut* 8 (Jan. 1, 2025) (“*Prescription Drug Shortages in Connecticut*”).⁹

Numerous factors impact manufacturers’ thin profit margins and put upward pressure on generic and biosimilar drug prices. For example, “[m]ost generic drug manufacturers rely on other

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

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

⁹ <https://tinyurl.com/4mbdnz7c>.

companies to produce” the raw ingredients “for the drugs they produce,” Mariana P. Socal et al., *Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients*, 42 Health Affairs 407, 407 (Mar. 2023)¹⁰, and the “raw material prices for essential drugs” have risen sharply, by as much as 140 percent in the post-COVID era, *see Active Pharmaceutical Ingredients Market Size*, Precedence Research (Jan. 2023).¹¹ As for biosimilar medicines, they too face additional price pressure due to the need to recover substantial costs inherent in obtaining FDA approval, as well as increased costs arising from marketing, patient-support services, and other non-production related costs. Compl. ¶ 27.

The high cost of manufacturing generic and biosimilar products, combined with a complex array of other supply-chain challenges and disruptions often lead manufacturers to leave the market entirely or take specific products off the market permanently or temporarily. *Prescription Drug Shortages in Connecticut, supra*, at 2 (The “competition driving the cost of a drug down may cause participants to halt production or exit the market completely”); FDA, *Drug Shortages, supra*, at 7; *Prescription Drug Shortages in Connecticut, supra*, at 7. In other words, preventing manufacturers from recapturing their costs can lead directly to shortages in the supply of life-saving and cost-effective treatments to patients.

The Act’s restrictive price ceiling fails to account for the many significant barriers generic and biosimilar manufacturers face to enter and remain in the market and thus exacerbates the very problems it purports to address. Compl. ¶¶ 26-28.

II. Connecticut’s New Price-Control Law

Starting on January 1, 2026, the Act prohibits generic manufacturers and wholesalers—but

¹⁰ <https://tinyurl.com/2nxc44ph>.

¹¹ <https://tinyurl.com/5ey4tzan>.

not retailers, or anyone else who sells prescription drugs directly to consumers in Connecticut— from charging a price above a cap set by Connecticut. Because manufacturers sell their products to wholesalers outside Connecticut, Defendants intend to regulate transactions outside Connecticut between out-of-state manufacturers and out-of-state wholesalers.

Coverage: The products subject to the Act’s cap—the defined term “identified prescription drug[s],” Act §§ 345(6), 346(a)(1)—include all generic drugs¹² and some biosimilar medicines¹³ as well. Act § 345(6)(B). By contrast, brand-name drugs and biologics generally are *not* covered by the Act—even though they, not generic drugs and biosimilars, are the primary drivers of high pharmaceutical prices in this country. Under the Act, a brand-name drug or biologic is exempted from the price cap until “at least twenty-four months” after *all* exclusivities granted by federal patent and regulatory law have expired. *Id.* § 345(6)(A). Because most brand-name drugs and biologics are covered by at least one patent or exclusivity (as brand manufacturers can get multiple rounds of patents on a drug and its uses), most brand-name drugs will be exempted from

¹² A “generic drug” includes any prescription drug product that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 U.S.C. § 355—in other words, any drug approved as a generic through the abbreviated pathway that federal law provides—as well as an authorized generic drug as defined in 42 C.F.R. § 447.502. Act § 345(5).

¹³ An “identified prescription drug” includes an “interchangeable biological product,” which is a subset of biosimilars. Act § 345(6)(B). A biological product is a therapeutic product such as a protein, virus, or serum that federal law regulates under a special regime. 42 U.S.C. § 262(i)(1). A “biosimilar” is somewhat like a generic version of a biological product: it is highly similar to an already-approved product and so can be approved through an expedited regulatory pathway. *Id.* § 262(i)(2), (k). An *interchangeable* biological product is a biosimilar that meets an extra qualification: FDA has not only licensed it under the abbreviated pathway for biosimilars, but also determined it to be “expected to produce the same clinical result as the [brand-name] reference product.” *Id.* § 262(k)(4)(A); *see* Act § 345(7); Conn. Gen. Stat. Ann. § 20-619(a)(4)(A) (provision cross-referenced by the Act and in turn cross-referencing the federal statute).

The Connecticut definition also defines an interchangeable biological product to include “a biological product that ... is therapeutically equivalent to another biological product, as set forth in the latest edition of or supplement to the federal Food and Drug Administration’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “Orange Book”). Conn. Gen. Stat. Ann. § 20-619(a)(4)(B). Biological products were removed from the Orange Book in 2020, however, so the latter category is now a null set. *See* FDA, *Interpretation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009*, at 8-9 (Dec. 2018), <https://www.fda.gov/media/119590/download>.

Connecticut's cap indefinitely.

The Act allows manufacturers and wholesalers to charge higher prices for a drug that has been declared by the federal government to be “in shortage in the United States.” Act § 346(a)(2). The Act does not, however, permit manufacturers to exceed the cap to avoid *creating* a shortage.

Price Cap: The Act prohibits pharmaceutical manufacturers and wholesale distributors—but no one else—from exceeding Connecticut's price cap. Specifically, “no pharmaceutical manufacturer or wholesale distributor shall ... sell an[y] identified prescription drug in this state” at prices exceeding a cap that Connecticut sets *permanently* for each drug, adjusted only for increases in “the consumer price index.” Act § 346(a)(2). Connecticut calls the capped price the “[r]eference price”; for generic drugs and covered biosimilars that were on the market as of January 1, 2025, the reference price is forever set at the “wholesale acquisition cost” (WAC) on that date. *Id.* § 345(11)(B)(i). For generic drugs and covered biosimilars that come on the U.S. market later, the reference price is forever set at the WAC as of the date of first commercial marketing. *Id.* § 345(11)(B)(ii). And because the only adjustment in the cap is for increases in the *general* consumer price index—an economy-wide measure of inflation—the cap does not take into consideration increases in the cost of producing or marketing the particular drug that may justify a price increase.

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

measures to ensure compliance with the price-cap. Pharmaceutical manufacturers and distributors that violate the price cap not only must pay the civil penalty, they must also file “a statement” with Defendant Boughton (the Commissioner of the Department of Revenue Services) “containing all information” he determines should be required. *Id.* § 346(c)(1)(A). The Commissioner may also demand price-related information from manufacturers—by requiring recordkeeping, examining records, and compelling testimony under oath—to enforce the Act. *Id.* § 346(d)-(e), (h).¹⁴

Application to out-of-state transactions: Although the Act on its face refers to selling identified prescription drugs “in this state,” Act § 346(a)(1), Defendants intend to apply the Act’s price cap to prices charged in transactions between manufacturers and wholesalers *outside* Connecticut. Defendants evidently interpret that statute to reach transactions between manufacturers and wholesalers outside of Connecticut if the drug ends up in Connecticut—even if the drug winds up in Connecticut only through third-party transactions outside the manufacturer’s control. Under that interpretation, the Act regulates the *upstream* sales of “identified prescription drug[s]” that occur entirely outside Connecticut.¹⁵ Indeed, the Act requires no connection at all between the regulated sale and Connecticut: Although the Act exempts manufacturers and wholesalers from the civil penalty if they do not make “at least [\$250,000] in *total* annual sales in this state for the calendar year,” Act § 346(b)(2) (emphasis added), that reference to *total* sales means there is no requirement that the sales be connected to the product(s) whose price

¹⁴ Defendant Tong (the Attorney General) assists in collecting the civil penalty. *See* Act § 346(i) (incorporating Conn. Gen. Stat. Ann. § 12-35(a)(3)(A)).

¹⁵ For simplicity, as shorthand for Defendants’ intent to enforce the Act against wholly out-of-state transactions, at times this brief refers to the Act as regulating those transactions. To be clear, Plaintiff does not concede that the Act, properly read, *does* apply to out-of-state transactions. After all, the Act on its face applies only if a “pharmaceutical manufacturer or wholesale distributor ... sell[s] an identified prescription drug *in this state*.” Act § 346(a) (emphasis added). Nevertheless, all evidence indicates that Defendants intend to enforce the Act—in violation of the Constitution—against wholly out-of-state transactions. Compl. ¶ 5. Plaintiff seeks to enjoin Defendants from so doing.

Connecticut seeks to regulate.

Absent Defendants' sweeping interpretation, the Act effectively would not reach generic drug manufacturers (like AAM's members) because they almost always sell their products to wholesalers, and these transactions take place outside Connecticut. Indeed, no AAM member is located in Connecticut, and AAM understands that no national wholesaler is located or even has a distribution facility in Connecticut. Compl. ¶ 5. Thus, for most or all "identified prescription drugs," the *only* way the Act can apply to the manufacturers is to regulate the prices they charge to their wholesaler customers.

That Defendants intend to follow that interpretation is clear from legislative testimony about the provisions that ended up in the Act,¹⁶ including testimony by representatives of their chief supporter, the Governor, to whom Defendant Boughton reports. The Director of the Governor's Office of Health Strategy, testifying about the anticipated "savings" from the price control, opined: "Where that savings happens ... is, at the level of the wholesale transaction. ... [T]he idea is that those savings would also be passed on eventually to the consumer because those purchasing the wholesale drugs would be purchasing [them] at a much lower rate." Transcript of Hearing before the Senate Human Services Comm., Mar. 11, 2025, at 61-62, <https://tinyurl.com/4dfuk346> ("Gifford Testimony"). Thus, the Act does not regulate sales to consumers—only sales by manufacturers and wholesalers—and the manufacturers' sales to wholesalers occur entirely out of state.

Before bringing this action, AAM contacted the Attorney General to request that he disavow extraterritorial enforcement. Compl. ¶ 5. His representatives have declined to do so—

¹⁶ The General Assembly initially considered the price control in the 2025 session as separate legislation sponsored by the Governor, H.B. 6870, and a corresponding Senate bill, S.B. 11. It then rolled the price control provisions into the omnibus biennial budget legislation.

making this motion necessary.

Prohibition on withdrawing drugs from Connecticut: Even if it were possible for manufacturers to somehow ensure that wholesalers, retailers, or other resellers did not resell their drugs in Connecticut—a big if—Connecticut would not allow manufacturers to escape the price cap that way: The Act expressly forbids any manufacturer or wholesale distributor from withdrawing an identified prescription drug from sale in Connecticut “for the purpose of avoiding the civil penalty.” Act § 347(a). It also prohibits withdrawal of an identified prescription drug from sale in Connecticut for *any* reason until 180 days after the manufacturer or wholesale distributor gives notice of its intention to do so. *Id.* § 347(b). Any company that violates either of these provisions is liable for a separate civil penalty of \$500,000. *Id.* § 347(c).

Personal liability and criminal punishment: Officers and employees of pharmaceutical manufacturers and wholesale distributors who owe “a duty” to their company to pay the Act’s civil penalty and file the associated statement face fines *and criminal punishment* if they “wilfully fail[]” to pay the penalty, file the statement, or keep or turn over specified records. Act § 346(j).

STANDING

All of AAM’s members are located outside Connecticut. Compl. ¶ 5. But their medicines are available for sale (by third parties) in Connecticut and every other state in the Union. Since January 1, 2025, several of AAM’s members—none of which qualifies for the exemption for companies that make less than \$250,000 in total annual sales in Connecticut—have made competitively reasonable price adjustments to identified prescription drugs that exceed the Act’s price ceiling. Baeder Decl. ¶¶ 8, 10-11. As a result of the relevant products (which are not in shortage) being resold into Connecticut by third parties, the increased prices for those medicines will (or would) subject these AAM members to the civil penalty. Baeder Decl. ¶¶ 6, 10. Whether they pay the civil penalty or lower their prices to avoid it, the Act is causing them injury-in-fact

that an injunction would redress. Baeder Decl. ¶ 17. For example, in 2025, member Apotex Corp. has already increased the price of a generic drug by 15 percent above the “reference price,” which exceeds the increase permitted by the Consumer Price Index. Baeder Decl. ¶¶ 9-10. Unless the Act is enjoined or Apotex lowers the price, Apotex will exceed the cap as of January 1, 2026. Baeder Decl. ¶ 10. Other AAM members, all similarly above the statutory sales threshold, had planned to raise prices for certain identified prescription drugs not in shortage in an amount that would exceed Connecticut’s price cap, but are forgoing those price increases because of the Act. Rockwell Decl. ¶¶ 8, 11. By forcing them to forgo revenue, the Act is causing them injury-in-fact that an injunction would redress. For example, member PAI Pharma had concrete plans to increase the price of a generic drug by an amount that would exceed Connecticut’s price cap. Rockwell Decl. ¶¶ 9-10. PAI Pharma has changed its plan to adjust the price; but for the Act, it would have proceeded with its plan and increased its revenue. Rockwell Decl. ¶ 13.

This case is germane to AAM’s mission, *e.g.*, *Frosh*, 887 F.3d at 667, and does not require participation of AAM’s members as parties, as AAM seeks only equitable relief. Accordingly, AAM has associational standing to bring this lawsuit. *See, e.g., Bldg. & Const. Trades Council of Buffalo, New York & Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138, 144 (2d Cir. 2006).

ARGUMENT

A party seeking a preliminary injunction must show that it is “likely to succeed on the merits, that [it is] likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction would be in the public interest.” *E.g., Mahmoud v. Taylor*, 145 S. Ct. 2332, 2350 (2025); *New York v. United States Dep’t of Homeland Sec.*, 969 F.3d 42, 58 (2d Cir. 2020). All the relevant factors weigh decisively in favor of granting a preliminary injunction here.

I. AAM Is Likely To Succeed on Its Claims that Enforcement of the Act Against Out-Of-State Transactions Will Violate the Constitution.

AAM is likely to succeed on its claims that the Act violates the Constitution—and in particular the Commerce Clause—by directly regulating prices charged in transactions wholly outside of Connecticut.¹⁷ Courts of Appeals addressing highly similar state legislation have repeatedly held such laws unconstitutional. So has a fellow district court within the Second Circuit, in a holding so straightforward that the defendant (New York State) did not even appeal that portion of the case. *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 260, 261-62 (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). This Court should do the same.

The Healthcare Distribution Alliance has recently filed a complaint and preliminary injunction challenging the Act in this Court. *See Healthcare Distribution Alliance v. Boughton*, et al., No. 3:25-cv-1724 (OAW). Unlike HDA's motion, AAM's motion relies on the Commerce Clause's prohibition on direct regulation of transactions outside the State, which Connecticut's law violates by targeting out-of-state transactions while exempting in-state transactions.

A. The Commerce Clause Prohibits States From Directly Regulating Transactions That Occur Wholly Out Of State.

The “dormant” Commerce Clause refers to the rule that the power to regulate interstate commerce is primarily for the national government, not states. In giving effect to that bedrock principle of constitutional law, Supreme Court and Second Circuit case law going back decades (if not centuries) recognizes a clear dichotomy: On the one hand, state laws that directly regulate

¹⁷ The constitutional prohibition against direct state regulation of out-of-state transactions is not limited to the Commerce Clause but is also inherent in the Constitution's structure and implicit in its other provisions. *See Ross*, 598 U.S. at 376 n.1; *id.* at 404, 408-10 (Kavanaugh, J., concurring in part and dissenting in part); *Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 154 (2023) (Alito, J., concurring in part and concurring in the judgment); *see also* Compl. ¶¶ 62-67. AAM has raised a number of alternative constitutional arguments in its complaint, but this motion relies only on Count One, which invokes the dormant Commerce Clause's prohibition on extraterritorial regulation.

only *in-state* conduct are generally safe from Commerce Clause attack even if they have strong indirect *effects* on interstate commerce. But direct “state regulation of commerce occurring beyond the state’s borders” is prohibited. *Healthcare Distrib. All.*, 353 F. Supp. 3d at 260 (quoting *Healy*, 491 U.S. at 336); *see also Nat’l Shooting Sports Found., Inc. v. James*, 144 F.4th 98, 113 (2d Cir. 2025) (“A state statute violates the dormant Commerce Clause if it ... ‘control[s] commerce occurring entirely outside the boundaries of the state in question.’” (citation omitted)); *VIZIO, Inc. v. Klee*, 886 F.3d 249, 257 (2d Cir. 2018) (distinguishing between a state law that regulates in-state conduct, “merely affect[ing] pricing decisions” nationally, and those that “directly control[] commerce occurring wholly outside the boundaries of a State” (citation omitted)).

Here, Defendants’ enforcement of the Act falls decidedly in the latter camp. The problem is not that Connecticut’s law has an indirect *effect* on AAM members’ pricing decisions made in other States. Rather, the problem is Defendants’ “*direct* regulation” of wholly out-of-state transactions. AAM’s manufacturer members (none of which is based in Connecticut) will be subjected to Connecticut-law liability and Connecticut-law penalties based on the prices they charge *in other states*. But such direct regulation is prohibited. *Edgar v. MITE Corp.*, 457 U.S. 624, 640, 642 (1982) (plurality opinion) (Commerce Clause “precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders”). Indeed, that prohibition on “direct” extraterritorial regulation is both “clear” and “absolute.” *Healthcare Distrib. All.*, 353 F. Supp. 3d at 260.

The prohibition on direct regulation of wholly out-of-state transactions follows from the “inherent limits [on] the State’s power”—“any attempt ‘directly’ to assert extraterritorial jurisdiction over persons or property would offend sister States” and therefore “must be held invalid.” *Edgar*, 457 U.S. at 643 (plurality opinion) (citation omitted); *Ellison*, 140 F.4th at 960

(A state violates the Commerce Clause when it enacts “price control or price affirmation statutes that tie[] the price of in-state products to out-of-state-prices.” (citation omitted)). Under Supreme Court precedent, “the classic observation that [a state] has no power to project its legislation into [another state] by regulating the price to be paid in that state for drugs sold there remains good law.” *Ellison*, 140 F.4th at 960 (internal quotation marks and citations omitted). That law is not just good; it is incredibly well settled. As the Seventh Circuit noted a few years ago: “With almost two hundred years of precedents to consider, our review of prior dormant Commerce Clause decisions has not revealed a single appellate case permitting any direct regulation of out-of-state [commerce].” *Legato Vapors LLC v. Cook*, 847 F.3d 825, 829, 831 (7th Cir. 2017); *see also Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935); *Brown-Forman Distiller Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578 (1986).

A plurality of the Supreme Court explained this prohibition in *Edgar*, in an opinion that subsequent majority opinions have described as “significantly illuminat[ing] the contours of the constitutional prohibition on extraterritorial legislation.” *Healy*, 491 U.S. at 333 n.9. The Court in *Edgar* invalidated an Illinois law regulating tender offers—*i.e.*, offers to buy substantially all the shares of stock in a corporation. The law applied only to tender offers with some substantial ties to Illinois,¹⁸ but that was insufficient: The plurality opinion concluded that the Illinois statute “must be held invalid” because it “prevent[ed]” the would-be buyer from “concluding interstate transactions ... with those [shareholders] living in other States and having no connection with Illinois.” 457 U.S. at 642-43 (plurality opinion). Thus, the law “directly” regulated “interstate commerce, including commerce wholly outside the State.” *Id.* at 643. That was impermissible.

¹⁸ The law applied where (1) “shareholders located in Illinois own[ed] 10% of the class of equity securities subject to the offer”; or (2) “any two of the following three conditions are met: [a] the corporation ha[d] its principal executive office in Illinois, [b] [was] organized under the laws of Illinois, or [c] ha[d] at least 10% of its stated capital and paid-in surplus represented within the State.” *Edgar*, 457 U.S. at 626-27.

1. Courts of Appeals Have Consistently Applied the Rule Against State Direct Regulation of Out-of-State Transactions to Invalidate State Price Control Laws Just Like the Act.

Courts of appeals have continued to consistently apply the Commerce Clause’s prohibition on state laws directly regulating wholly out-of-state transactions to invalidate materially similar interstate restrictions on prescription-drug prices, including in AAM’s successful challenges to nearly identical laws enacted by Maryland and Minnesota. Like the Connecticut law, the Maryland law at issue in *Frosh* attempted to implement a price-ceiling on off-patent or generic drugs that were “made available for sale in [Maryland].” 887 F.3d at 666 (citations omitted). The Fourth Circuit held the law unconstitutional because it directly regulated “conduct that occur[red] entirely outside Maryland’s borders” and controlled the “prices ... in transactions that [did] not take place in Maryland.” *Id.* at 670-72. Although the law applied only to drugs “made available for sale” in Maryland (by anyone)—just like the Connecticut Act’s trigger of a sale “in this State”—that did not make it constitutional. The Maryland law did not “limit [its] application to sales that actually occur[red] within Maryland, nor [did] it restrict [its] operation to the context of a resale transaction with a Maryland consumer.” *Id.* at 671. Thus, it sought “to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland.” *Id.* at 672. “This,” the Fourth Circuit held, Maryland “cannot do.” *Id.*

The Eighth Circuit followed the same reasoning to affirm the injunction against a Minnesota law that also resembles Connecticut’s Act. The Minnesota law prohibited any generic or biosimilar manufacturer 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.” *Ellison*, 140 F.4th at 959 (quoting Minn. Stat. § 62J.842 subd. 1). Like the Defendants’ intended enforcement of Connecticut’s law to regulate out-of-state prices of essential medicines solely because they are ultimately sold in Connecticut, the Minnesota law “target[ed]

... the upstream pricing and sale of prescription drugs” by imposing liability on out-of-state manufacturers for wholly out-of-state sales simply because “somehow, someday, in some way, someone who is *not* a party to the transaction ... sell[s], dispense[s], or deliver[s] the drug to a[] consumer in Minnesota,” *Ass’n for Accessible Meds. v. Ellison*, 704 F. Supp. 3d 947, 956 (D. Minn. 2023), *aff’d*, 140 F.4th 957 (8th Cir. 2025). As the Eighth Circuit explained, “a Colorado manufacturer would be penalized if it sold drugs to a New Jersey distributor at prices above those proscribed by the Act and those drugs ended up in Minnesota.” 140 F.4th at 960. The Eighth Circuit held the Minnesota law was likely unconstitutional for the same reasons articulated by *Frosh*: The law “directly regulate[s] transactions which [take] place ... wholly outside the State.” *Id.* at 953.¹⁹ That finding on its own was enough to demonstrate unconstitutionality under the dormant Commerce Clause. *Id.*

2. District Courts In This Circuit (and in Many Other Circuits) Have Consistently Held the Same.

Courts in this Circuit have also applied the Commerce Clause’s prohibition on state laws directly regulating out-of-state transactions. For instance, the Southern District of New York recently considered a New York law that, on its face, purported to regulate out-of-state transactions: New York imposed an annual “assessment” relating to opioids on manufacturers and distributors, and it prohibited the subject companies from attempting to “pass” the cost of their assessment on to a purchaser *anywhere*, thus effectively barring certain price increases outside New York State. AAM and other plaintiffs challenged the law, and the district court held that the law would “clear[ly]” violate the Commerce Clause if interpreted to impose penalties on “wholly

¹⁹ These are only a few of the many decisions invalidating state laws under the Commerce Clause that directly regulated out-of-state transactions. *See, e.g., Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1321-24 (9th Cir. 2015) (en banc); *Styczinski v. Arnold*, 46 F.4th 907, 913 (8th Cir. 2022); *Am. Beverage Ass’n v. Snyder*, 735 F.3d 362, 366-76 (6th Cir. 2013).

out-of-state transactions” (the “clearest meaning” of the statute). *Healthcare Distribution All.*, 353 F. Supp. 3d at 261.²⁰ As noted, New York did not even appeal that holding.

Numerous other district courts have reached the same result when faced with statutes similar to this one. For instance, the Commerce Clause doomed a District of Columbia law prohibiting sales “that result[] in [a] prescription drug being sold in the District [of Columbia] for an excessive price.” *Pharm. Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 60 (D.D.C. 2005), *aff’d sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007). The court held that the District law impermissibly directly “regulate[d] transactions that occur[red] wholly out of state” because the “plaintiffs’ members s[old] ‘the overwhelming bulk’ of their ... drugs in out-of-state transactions to wholesalers or large retail chains.” *Id.* at 68, 70. That the law’s penalties were triggered by the drug’s eventual resale in the District—just as Defendants’ enforcement of the Act here is triggered by an eventual sale in Connecticut—made no constitutional difference, because “as soon as that drug [wa]s sold in the District, the manufacturer’s out-of-state sale bec[a]me[] the [law’s] primary target.” *Id.* at 69.

The same fate befell a Maine law prohibiting drug manufacturers (all “located outside the State of Maine”) from “exact[ing] or demand[ing] an unconscionable price” or “exact[ing] or demand[ing] prices or terms that lead to any unjust or unreasonable profit.” *Pharm. Rsch. & Mfrs. of Am. v. Comm’r, Maine Dep’t of Hum. Servs.*, 2000 WL 34290605, at *2 (D. Me. Oct. 26, 2000) (citation omitted). The court found the law unconstitutional because it attempted to regulate prices in wholly out-of-state transactions. *Id.* Again, the State did not even appeal that holding—even as it successfully litigated on appeal the constitutionality of *other* provisions of the same law that

²⁰ The court also held that the law would also violate the dormant Commerce Clause under the alternative constructions New York had proffered in an attempt to save the statute from unconstitutionality. 353 F. Supp. 3d at 262-63.

“d[id] not regulate the transaction between manufacturers and wholesalers.” *Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 72 n.2, 82 (1st Cir. 2001), *aff’d*, 538 U.S. 644 (2003).

B. The Supreme Court’s Recent Decision in *Ross* Confirms That States May Not Directly Regulate Prices in Out-of-State Transactions.

The Supreme Court’s decision in *Ross* confirms this settled precedent holding that state laws that *directly* regulate wholly out-of-state transactions are unconstitutional.

The California law at issue in *Ross* does not *directly* regulate any out-of-state conduct. Unlike the Act here, the law at issue there (California Proposition 12) “does not attempt to impose liability on out-of-state actors for engaging in out-of-state conduct; instead, it regulates in-state actors who engage in in-state conduct (specifically, in-state sales of meat that has been produced in a certain way).” *Ellison*, 704 F. Supp. 3d at 955-56, *aff’d*, 140 F.4th 957. Specifically, California Proposition 12 prohibits “the *in-state* sale of whole pork meat” from any pig that had been housed under conditions deemed cruel. *Ross*, 598 U.S. at 365 (emphasis added). But, under that law, no one can be held liable for anything they do out of state. *See id.* at 363. Unsurprisingly, then, the plaintiffs in *Ross* did not attempt to premise their Commerce Clause claim on a “direct-regulation” theory; they instead argued that even though Proposition 12 regulated only in-state conduct, California’s vast market share meant the statute indirectly had “the ‘*practical effect* of controlling commerce outside [California].” *Id.* at 371 (emphasis added).

The Supreme Court rejected that indirect-“practical-effects” argument, explaining that there is no “‘almost per se’ rule against state laws” that regulate in-state conduct but have indirect or incidental “extraterritorial effects.” *Id.* at 373. In the “particular context” of rejecting the *Ross* plaintiffs’ specific argument, *Ross* highlighted cases that accurately identified the anti-discrimination strand of Commerce Clause jurisprudence. *Id.* at 371-374. But, in doing so, the Court made clear that it was *not* disturbing the distinct prohibition against state laws that *directly*

regulate out-of-state commerce. *Id.* at 375-76 & n.1. And *Ross* certainly cannot be read to eliminate all strands of Commerce Clause jurisprudence that do not turn on state protectionism and discrimination against interstate commerce. The Court said explicitly that the “courtroom door” remains “open” to challenges to nondiscriminatory laws. *Id.* at 379-80. Both Justices Sotomayor and Kagan—critical for forming the five-Justice majority in *Ross*—expressly affirmed that same point. *Id.* at 392 (Sotomayor, J., concurring in part); *accord id.* at 395-96 (Roberts, C.J., dissenting). In particular, the concurring Justices did not sign on to “any fundamental reworking of th[e] doctrine” under *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), which can invalidate even state laws that “regulate[] even-handedly” (*i.e.*, non-discriminatorily). *See Ross*, 598 U.S. at 391 (Sotomayor, concurring in part) (quoting *Pike*, 397 U.S. at 142). Thus, *Ross* emphatically did not hold that all Commerce Clause challenges require allegations of discrimination. *Ross* therefore cannot plausibly be read to overturn either *Pike* balancing or the principle that states cannot directly regulate out-of-state transactions. Not to mention that the latter principle was not even before the Court.

In fact, the Court expressly distinguished California Proposition 12 (which regulates only in-state sales) from the Illinois tender-offer law invalidated in *Edgar*, reasoning that the Illinois law “*directly* regulated out-of-state transactions,” while the California law “regulate[d] only products that companies choose to sell ‘*within*’ California.” *Id.* at 376 n.1 (majority opinion); *see also Interlink Prods. Int’l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. 2023) (“[I]n clarifying that such laws with extraterritorial effects are not prohibited under the dormant Commerce Clause, the Supreme Court [in *Ross*] distinguished them from those in which ‘a law [] *directly* regulated out-of-state transactions’”) (citation omitted). As the court in AAM’s recent Minnesota case concluded, “[*Ross*] did not change the rule that a state may not directly regulate

transactions that take place wholly outside the state and have no connection to it.” *Ellison*, 704 F. Supp. 3d at 953; *see also id.* at 955 (distinguishing *Ross* because the Minnesota law “directly regulates upstream sales that take place wholly outside Minnesota,” whereas *Ross* addressed a law that “regulates in-state actors who engage in in-state conduct”); *Nat’l Shooting Sports Found. v. Bonta*, 718 F. Supp. 3d 1244, 1256 n.1 (S.D. Cal. 2024) (“*Ross* did not disturb the constitutional bar on state laws that ‘directly regulate[] out-of-state transactions by those with *no* connection to the State.’”). In fact, *Ross* approvingly cited not only the *Edgar* plurality, but also the Fourth Circuit’s decision in *AAM v. Frosh*, which invalidated Maryland’s generic-drug price-control law—one materially identical to Connecticut’s Act here—because it directly regulated out-of-state drug prices. 598 U.S. at 374.

Ross thus confirms what settled precedent from the Supreme Court, the Second Circuit, and other federal courts have long made crystal clear: Whereas state laws that regulate only in-state conduct, but have “incidental” effects out of state are typically valid, state laws that directly regulate out-of-state transactions are invalid, even if those out-of-state transactions produce in-state consequences. *Ross*, 598 U.S. at 376 n.1; *Edgar*, 457 U.S. at 640 (plurality opinion). Under the Commerce Clause and the Constitution’s “horizontal separation of powers,” laws that directly regulate wholly out-of-state transactions are invalid. *Ross*, 598 U.S. at 376 n.1.

For that reason, the Eighth Circuit rejected Minnesota’s attempt to argue that *Ross* had displaced all the prior precedent on extraterritoriality. Specifically, the Eighth Circuit held that *Ross* “did not overturn” the extraterritoriality principle, which “remains good law.” *Ellison*, 140 F.4th at 960. Similarly, in numerous other cases, federal courts have continued to apply pre-*Ross* precedent to invalidate state laws trying to regulate extraterritorial transactions. *E.g.*, *AAM v. Bonta*, 766 F. Supp. 3d 1020, 1032-1033 (E.D. Cal. 2025) (rejecting the argument that the Supreme

Court “curtailed” this precedent in *Ross* and explaining that the state statute at issue “is unlike [*Ross v.*] *Pork Producers* as the law can directly regulate out-of-state transactions by those with no connection to California,” which remains impermissible). In contrast to that mountain of authority, one federal court has held that *Ross* “casts doubt” on circuit precedent that would otherwise be binding, and that *Ross* therefore allows district courts to disregard that circuit precedent. *AAM v. Raoul*, No. 24 C 544, 2025 WL 2764558, at *4 (N.D. Ill. Sept. 26, 2025), *appeal filed* (Oct. 16, 2025). But that court also acknowledged that “*Ross* did not answer the precise question this case presents,” *id.*, which effectively concedes that the Supreme Court *could not* actually have overturned existing extraterritoriality precedent in that decision—especially given that, in footnote 1, the Court acknowledged the extraterritoriality principle without disturbing it.

C. The Defendants’ Planned Enforcement of the Act Is Unconstitutional Because It Directly Regulates Prices Charged in Transactions Entirely Outside Connecticut.

States have no authority to regulate at the national level. But Defendants intend to do so here by applying Connecticut’s price cap to transactions by manufacturers and wholesalers *outside* Connecticut—at “the level of the wholesale transaction.” Gifford Testimony at 61. As explained, all manufacturer-to-wholesaler transactions take place outside of Connecticut because no generic manufacturer and no national drug wholesale distributor is located in Connecticut. Compl. ¶ 5. Conversely, the Act does *not* regulate the in-state *retail* transactions through which Connecticut consumers actually pay for medicine; indeed, the Act does not care what *any* retail patient actually pays (which may reflect rebates secured by the consumer’s health-insurance coverage), only what the manufacturer or wholesale distributor charges. Defendants hope that by regulating transactions nationwide and pegging their price cap to the national WAC, consumers will somehow receive trickle-down savings when the prescription drug finally reaches them after “a whole chain of transactions,” none of which involve the WAC price. Gifford Testimony at 61-62; Compl. ¶ 5.

That is exactly the kind of state action that the Commerce Clause guards against.

Although the Act exempts manufacturers and wholesale distributors in years when they do not make \$250,000 in “total” sales in Connecticut, Act § 346(b)(2), that is emphatically *not* the same thing as limiting the Act’s reach to transactions in Connecticut. Indeed, AAM’s members include companies that make more than \$250,000 in *total* sales in Connecticut, but that manufacture and sell at least one “identified prescription drug” subject to the price cap without a single unit of *that* drug being sold directly to anyone in Connecticut. Baeder Decl. ¶ 7; Rockwell Decl. ¶ 7. And, as just noted, the Act does not regulate the price that any Connecticut consumer actually pays or any Connecticut retailer actually charges; it regulates only the price that manufacturers and wholesale distributors charge *their* customers. Again, AAM’s members conduct these transactions out of state. As applied to AAM’s members and their out-of-state transactions, therefore, the Act is unconstitutional.

As noted above, the Act *could* be read not to apply to these out-of-state transactions, because it regulates only sales “in this state.” Act § 346(a)(1). And limiting the Act to transactions that take place “in” Connecticut would eliminate the dormant Commerce Clause issue. But it is evident that Defendants intend to reject that interpretation. *See* pp. 11-14, *supra*. And extraterritorial regulation by state law is unconstitutional “regardless of whether the statute’s extraterritorial reach was intended by the legislature.” *Healy*, 491 U.S. at 336.

D. In Addition to Directly Regulating Wholly Out-of-State Transactions, Connecticut’s Law Is Unconstitutionally Discriminatory.

“The Commerce Clause problem with the Connecticut statute appears in even starker relief when it is recalled that if Connecticut may enact” price controls on wholly out-of-state transactions, “so may every other State in the Nation.” *Healy*, 491 U.S. at 339. That would quickly subject AAM’s members to a web of conflicting statutes and a race for each State to govern the

national economy. “This kind of potential regional and even national regulation of the pricing mechanism for goods is reserved by the Commerce Clause to the Federal Government and may not be accomplished piecemeal through the extraterritorial reach of individual state statutes.” *Id.*

The Act bears an additional hallmark of unconstitutionality given its obvious protectionist purposes. *Ross*, 598 U.S. at 369. Protectionism can include state laws “that although neutral on their face . . . were enacted at the instance of, and primarily benefit, in-state interests.” *Id.* at 379 n.2 (internal quotation marks and citations omitted). The Act’s price cap applies almost exclusively to generic drugs and biosimilars while expressly protecting brand-drugs until “at least twenty-four months” after *all* exclusivities granted by federal patent and regulatory law have expired. Act § 345(6)(A). And in reality, most brand-name drugs will be exempted from Connecticut’s cap indefinitely given that brand manufacturers can get multiple rounds of patents on a drug and its uses. The Act thus protects Connecticut’s in-state brand manufacturers while prejudicing generic manufacturers, all of which are out-of-state. On top of that, the Act protects in-state retailers and resellers by exempting them from the price cap altogether. In-state businesses can thus profit at the expense of consumers and out-of-state generic manufacturers and wholesalers who are forbidden from exceeding the price cap. The Act thus “seeks to advantage in-state firms or disadvantage out-of-state rivals.” *Ross*, 598 U.S. at 370.

E. Any Jurisdictional Objections Are Not Likely To Succeed.

Some defendants in Commerce Clause cases have argued that the lawsuits are barred by lack of standing, lack of ripeness, or the Tax Injunction Act. None of those jurisdictional objections applies here.

First, AAM has standing because it is plain that its member companies will be subjected to the law and already face injury as a result. The law applies to *every* generic drug and prohibits *all* price increases above the Consumer Price Index. *See* pp. 3-4, 19, *supra*.

Second, this is a classic case for a pre-enforcement challenge: The State has adopted a law that implicates regulated companies' constitutional rights, it intends to apply the law to out-of-state transactions, and it set the price cap low enough that AAM member companies are *already* exceeding it. Baeder Decl. ¶ 10. In other words, even without changing their behavior, AAM members will be subjected to the law as of January 1, only a short time away. Baeder Decl. ¶ 10. And other AAM members are already changing their behavior as a result of the Act. Rockwell Decl. ¶¶ 11, 13.

Third, the civil penalties in the law are not taxes, so the Tax Injunction Act, 28 U.S.C. § 1341, has no relevance here. The Act does not even *describe* them as taxes; it calls them “civil penalties” more than *thirty times*. The General Assembly’s “decision to label this exaction a ‘penalty’ rather than a ‘tax’ is significant because the [Act] describes many other exactions it creates as ‘taxes.’” *Nat’l Fed’n of Indep. Bus. v. Sebelius (NFIB)*, 567 U.S. 519, 544 (2012).²¹ The Act elsewhere uses the word “tax” hundreds of times. *E.g.*, § 128 (“a tax is hereby imposed on each cannabis retailer...”); § 130 (describing “the tax imposed under the provisions of section 12-330// of the general statutes.”).

The decision to impose a “penalty” was deliberate. Imposing a provider-specific “tax” would have triggered reductions in the funding the State would receive under the federal Medicaid statutes; the price-cap provisions make clear that the General Assembly did *not* want the State to bear those financial consequences, which is why the Act expressly declares that the civil penalty must be considered “a civil fine or penalty” for purposes of 42 U.S.C. § 1396b(w). Act § 346(k). And that subsection of federal law specifically defines a “civil fine or penalty” *not* to be a “tax.”

²¹ *NFIB* considered the Anti-Injunction Act, a statute relating to *federal* taxes on which the Tax Injunction Act is modeled. Words used in the two statutes are generally construed in the same way, and precedent construing one is therefore relevant to construing the other. *E.g.*, *CIC Services, LLC v. IRS*, 593 U.S. 209, 216 n.1 (2021).

42 U.S.C. § 1396b(w)(7)(F). Clearly, therefore, the General Assembly did not want to enact a tax. *NFIB*, 567 U.S. at 544 (identifying “the statutory text” as the “best evidence of [the legislature’s] intent”).²²

“[L]evies assessed for regulatory or punitive purposes, even though they may also raise revenues, are generally not ‘taxes.’” *Travelers Ins. Co. v. Cuomo*, 14 F.3d 708, 713 (2d Cir. 1994) (quotation omitted), *rev’d on other grounds sub nom. N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995); *Weinberg v. Dep’t of Revenue Servs.*, 596 F. Supp. 3d 386, 395 (D. Conn. 2022). Even if the Act were to raise any revenue—rather than just force compliance through its civil penalty—that would not make the Act a tax. The Act *forbids* certain action (“no pharmaceutical manufacturer ... shall ...”) and imposes what it calls a penalty more than thirty times. The Act’s aim is to ensure that manufacturers and wholesale distributors comply with a price cap. If the Act accomplishes its goal, the State would raise no revenue at all. That is why the legislative history emphasizes cost savings and never mentions revenue. Finally, the Act does not even provide any means (much less the “plain, speedy and efficient” means that a State must offer in order to invoke the Tax Injunction Act, 28 U.S.C. § 1341) for recovering the civil penalty for withdrawing a drug from the state.

II. AAM’s Members Have No Adequate Remedy At Law And Will Suffer Irreparable Harm Absent An Injunction.

Without a preliminary injunction, AAM members will suffer irreparable harm while this case is litigated, for which they have no adequate remedy at law. Irreparable harm exists “where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied.” *State Farm Mut.*

²² The closest the text comes to tax law in the text was to use some procedural mechanisms that parallel the tax system. That is not close enough, just as in *NFIB* it was insufficient that the relevant penalty was to be “‘assessed and collected in the same manner as taxes.’” 567 U.S. at 544.

Auto. Ins. Co. v. Tri-Borough NY Med. Prac. P.C., 120 F.4th 59, 80 (2d Cir. 2024) (citation omitted). AAM’s members will suffer irreparable harm twice over unless this Court steps in. First, AAM’s members will be irreparably injured by the imposition of unconstitutional regulation. Second, they will incur unrecoverable monetary losses—a classic form of irreparable injury.

A. The Act Subjects AAM’s Members to Unconstitutional Regulation.

The Act subjects AAM’s members to unconstitutional regulation, which is an irreparable injury with no remedy at law. The Second Circuit has repeatedly “held that the alleged violation of a constitutional right triggers a finding of irreparable injury.” *Connecticut Dep’t of Env’t Prot. v. O.S.H.A.*, 356 F.3d 226, 231 (2d Cir. 2004) (noting that, in such cases, the “real issue” becomes the likelihood-of-success prong); *Statharos v. New York City Taxi & Limousine Comm’n*, 198 F.3d 317, 322 (2d Cir. 1999) (“Because plaintiffs allege deprivation of a constitutional right, no separate showing of irreparable harm is necessary.”). That includes cases (like this one) alleging that state laws violate the Commerce Clause. *See, e.g., Variscite NY Four, LLC v. New York State Cannabis Control Bd.*, 152 F.4th 47, 60 (2d Cir. 2025) (A “strong showing of a constitutional deprivation that results in noncompensable damages ordinarily warrants a finding of irreparable harm.... Likelihood of success on the merits is therefore the dominant, if not the dispositive, factor in awarding preliminary relief.” (internal quotation marks and citations omitted)); *Glidedowan, LLC v. New York State Dep’t of Health*, 768 F. Supp. 3d 503, 516 (W.D.N.Y. 2025) (same).

B. The Act Will Cause AAM’s Members Irreparable Economic Harm.

The Defendants’ enforcement of the Act will also cause AAM’s members to suffer significant economic losses that they will not be able to recoup if AAM prevails in this lawsuit. They face a lose-lose-lose scenario: They can (1) forgo reasonable price increases on their generic and interchangeable biological products, including price increases necessary to maintain profitability; (2) raise prices on those products, but in doing so, trigger substantial civil penalties

and criminal liability for their officers and employees; or (3) withdraw the regulated generic products from Connecticut, and thus lose revenues from those products and also face a significant civil penalty for that withdrawal. Baeder Decl. ¶¶ 10, 17; Rockwell Decl. ¶¶ 11-13. Each option results in unrecoverable economic injury.

Lost revenue, penalties, and compliance costs are irreparable injuries when they are unrecoverable even after successful litigation—which is the case here because Defendants are “state official[s] entitled to sovereign immunity under the Eleventh Amendment” and so “the only relief available to the [Plaintiff] is injunctive.” *John E. Andrus Mem’l, Inc. v. Daines*, 600 F. Supp. 2d 563, 572 n.6 (S.D.N.Y. 2009); *United States v. New York*, 708 F.2d 92, 93 (2d Cir. 1983).

Complying with the Act’s unconstitutional price control will reduce AAM members’ revenues, resulting in significant financial loss. Baeder Decl. ¶¶ 11, 14; Rockwell Decl. ¶ 10, 13. There are a multitude of factors that make price-increases above the general rate of inflation necessary in order to maintain the economic viability of a prescription drug. Those increases may be necessary due to increases in the cost of production, validation and testing studies, compliance overhead, marketing, or patient outreach or support services. Baeder Decl. ¶ 11; Rockwell Decl. ¶ 10. Barring the necessary price increases on such products could mean not just less profit, but no profit at all. Those manufacturers sometimes operate on thin profit margins and are often unable to both absorb such increased costs and maintain existing prices while also remaining profitable. Baeder Decl. ¶ 11; Rockwell Decl. ¶¶ 10, 14. AAM members will also incur separate costs in complying with recordkeeping requirements that the Commissioner “may require,” Act § 346(e)—none of which will be recoverable. Baeder Decl. ¶ 12.

AAM members would also suffer unrecoverable financial injury if they were to try to avoid these economic losses. A manufacturer that managed to withdraw a product from the Connecticut

market would suffer the resulting loss of revenues from sales of that product. Baeder Decl. ¶ 17. And a manufacturer that keeps its product on the market and raises prices despite the Act, including to preserve product profitability (and, therefore, viability), faces a dual threat: any additional revenue would be subject to the civil penalty, *and* the company's officers and employees would be exposed to fines and imprisonment. Act § 346(b), (j)(1).

The Act thus makes unrecoverable economic loss a certainty. Baeder Decl. ¶ 17; Rockwell Decl. ¶ 13. AAM's members must either comply with the law's unconstitutional command and lose revenue, or else violate the Act and suffer crippling financial penalties. Such unrecoverable economic loss is quintessential irreparable harm. That harm is only exacerbated by the Act's nationwide reach, forcing AAM members to make this choice on a national scale, as there is no way to comply with the Act without changing practices out of state. Baeder Decl. ¶ 4. This type of no-win scenario is the paradigm of 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"); *America'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"); *Am. Trucking Ass'ns, Inc. v. City of L.A.*, 559 F.3d 1046, 1058 (9th Cir. 2009) (finding irreparable harm from regulatory agreements because plaintiff could either "refuse to sign" and suffer "a loss of customer goodwill" or "sign[]" and be subject to "conditions which are likely unconstitutional" and "incur large costs"); *Metro. Transportation Auth. v. Duffy*, 784 F. Supp. 3d 624, 693 (S.D.N.Y. 2025) ("Courts have repeatedly recognized the irreparable harm inherent to a situation such as the one in

which Defendants have presently placed Plaintiffs, in which a plaintiff can either accede to the government's presumptively unlawful threat or else disobey the government's directive and expose itself to potentially devastating injury throughout the pendency of the proceedings.”).

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

The balance of hardships and public interest also favor an injunction. *New York v. DHS*, 969 F.3d at 86 (noting that these two factors merge when the government is a party). The irreparable harm to AAM's members far outweighs any harm the Attorney General can claim from a preliminary injunction, and the public interest is best served by granting the injunction.

AAM's manufacturer members need to make pricing decisions now, in contracts negotiated on a nationwide basis, and they deserve clarity regarding whether Connecticut may lawfully apply its price cap to those transactions. Under Defendants' intended enforcement of the Act, AAM members face a lose-lose-lose scenario where financial loss becomes inevitable: their products may become economically unviable and need to be discontinued. An injunction would therefore prevent irreparable harm. *See A.H. Harris & Sons, Inc. v. Naso*, 94 F. Supp. 3d 280, 301 (D. Conn. 2015) (considering the prevention of further irreparable harm in balancing the equities). By contrast, Defendants have no valid interest in applying an unconstitutional price cap, and regulating AAM members' behavior nationwide, while this case proceeds. Finally, a preliminary injunction would maintain the *status quo ante*, further weighing in favor of granting AAM's motion.

“[N]o public interest is served by maintaining an unconstitutional policy when constitutional alternatives are available to achieve the same goal.” *Variscite*, 152 F.4th at 60 (applying that rule to alleged Commerce Clause violation); *Martinez-Brooks v. Easter*, 459 F. Supp. 3d 411, 448 (D. Conn. 2020) (The “public interest is best served by ensuring the constitutional rights of persons within the United States are upheld.”).

In addition, a preliminary injunction would serve the public interest by preventing the damaging consequences the Act will inflict on patients and the market for generics and biosimilars. Rockwell Decl. ¶ 14 (specific generic medication could be discontinued); *New York v. DHS*, 969 F.3d at 87 (affirming preliminary injunction in part because public interest favored preventing “[w]orse health outcomes, including increased prevalence of obesity and malnutrition” and “[i]ncreased prevalence of communicable diseases.”); *Regeneron Pharms., Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 510 F. Supp. 3d 29, 49-50 (S.D.N.Y. 2020) (granting preliminary injunction where enforcement of a rule would cause significant financial hardship, reduce research and development budgets, and risk limiting access to new prescription drugs). The generic industry is currently undergoing “severe financial strain” causing “drug shortages in the United States [to] approach[] record levels.” Compl. ¶ 16 (quoting Christina Jewett, *Drug Shortages Near an All-Time High, Leading to Rationing*, N.Y. Times (May 17, 2023)²³). Many generics, such as “the workhorses of modern medicine—from chemotherapy agents to anesthetics to simple saline solutions—are frequently and unpredictably out of reach.” *Id.* (quoting DrugPatentWatch, *The Persistent Problem: Why Hospitals Keep Running Out of Generic Drugs* (July 30, 2025)²⁴).

The Act’s penalties and restrictions will exacerbate drug shortages and threaten patient access to affordable medicines for patients in Connecticut and nationwide. Compl. ¶ 16. By forbidding price increases above the general rate of inflation, including those price increases necessary to keep certain products profitable, and threatening the generic and biosimilar manufacturers with severe civil penalties for exceeding that price cap, the Act will place increasing pressure on generic and biosimilar manufacturers to withdraw their products from the market

²³ <https://tinyurl.com/yh3p48m2>.

²⁴ <https://tinyurl.com/bdytradu>.

entirely. *See* Baeder Decl. ¶ 11, 12; Rockwell Decl. ¶ 14. Indeed, as PAI explains in its declaration, it may have to discontinue a product upon which patients currently rely—and for which there is no other manufacturer. Rockwell Decl. ¶ 14. Ultimately, Defendants’ enforcement of the Act will only make generics and biosimilars *less* available to patients in Connecticut, directly undermining the Act’s goal of increasing access to affordable medications.

CONCLUSION

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

October 23, 2025

Respectfully submitted,

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

William M. Jay (PHV No. 208971)
Isabel M. Marin (PHV No. 208899)
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
Tel.: (202) 346-4000
Fax: (202) 346-4444
wjay@goodwinlaw.com
imarin@goodwinlaw.com

*Counsel for Plaintiff Association for
Accessible Medicines*