25-3216

To Be Argued By:
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Assistant Attorney General

In the United States Court of Appeals for the Second Circuit

HEALTHCARE DISTRIBUTION ALLIANCE,
Plaintiff-Appellant

v.

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

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF CONNECTICUT

BRIEF OF DEFENDANTS-APPELLEES

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COUNTER-STATEMENT OF THE ISSUE

Whether the District Court abused its discretion in declining to preliminarily enjoin Connecticut's Public Act 25-168 §§ 345 to 347, which prevents all manufacturers and distributors of certain prescription drugs from selling those drugs in Connecticut at unjustifiably inflated prices.

INTRODUCTION

Over two millennia ago, Hippocrates proclaimed that "Wherever the art of medicine is loved, there is also a love of humanity." Today, however, members of the pharmaceutical industry are putting the Father of Medicine's words to the test by imposing outrageous and unwarranted price increases on essential, life-saving medications. They do so in markets where there is scant competition for the production and sale of such medications. And they do so for the sake of maximizing profit.

Connecticut residents are now in the crosshairs. They face extraordinary and irreparable harm to their health—physical, mental, and financial—from the Hobson's choice offered by the pharmaceutical industry: pay our crushing markups or suffer the consequences of not having your vital medications. Connecticut's General Assembly and Governor responded to this cruel predicament by enacting Public Act 25-168, Sections 345 to 347 ("Act"), which combats those unconscionable markups by capping the prices at which pharmaceutical manufacturers and wholesale distributors may sell certain prescription drugs in Connecticut. And the Act does so in a nondiscriminatory way that only furthers the goal of safeguarding the well-being of Connecticut residents.

The plaintiff-appellant, Healthcare Distribution Alliance ("HDA"), nevertheless sued and sought a preliminary injunction, which the District Court denied. HDA now asks this Court to reverse the District Court, declare the Act likely to be unconstitutional, and direct the District Court to enjoin its enforcement. But the Supreme Court has rejected the primary dormant Commerce Clause theory upon which HDA relies, the extraterritoriality theory, by explaining that state laws regulating in-state conduct in a way that has some extraterritorial effect violate the Clause only when those laws are protectionist or discriminatory. And HDA has failed to establish that the Act is protectionist or discriminatory because the Act treats all the entities it regulates the same regardless of their geographic location, making no distinction between in-state and out-of-state entities. So, HDA is unlikely to succeed on the merits. Further, the harms that HDA claims its members will suffer are not irreparable, and the equities weigh heavily in favor of the Defendants-Appellees (the "State"). The Court should affirm the District Court's decision.

STATEMENT OF THE CASE

I. The Pharmaceutical Supply Chain.

The parties largely agree on how the pharmaceutical supply chain works for those prescription drugs identified under the Act ("identified drugs"). Manufacturers make the identified drugs. Brief of Appellant Healthcare Distribution Alliance ("HDA Brief"), Dkt. No. 20 at 20.[1] Distributors (e.g., wholesalers) act as middlemen between the manufacturers and dispensers (e.g., pharmacies, hospitals), operating a network of drug distribution centers across the country; no distributor is based in Connecticut or has a distribution center in Connecticut. *Id.* at 20-22.[2] Dispensers provide patients with the identified drugs when prescribed. *Id*. at 21-22.

The manufacturers' "list price" for drugs is also known as the "Wholesale Acquisition Cost" ("WAC"). *Id.* at 12, 20; 42 U.S.C. § 1395w-3a(c)(6)(B). Manufacturers, not distributors, set the WAC on a national

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[1] Citations to documents filed on the docket in this case use the format Dkt. No. ##, while citations to documents on the district court docket use ECF No. ##. Citations to any document filed on a docket use the pagination in the document header applied by CM/ECF.

[2] HDA is the trade association for distributors. HDA Brief at 12; A026-27, ¶ 14.

basis; there is a single, nationwide WAC price. HDA Brief at 20. Distributors often pay less than the WAC by leveraging their market share or sales volume to negotiate discounts.[3] *See Mont. ex rel. Knudsen v. Eli Lilly & Co. (In re Insulin Pricing Litig.)*, No. 2:23-cv-04214, 2025 U.S. Dist. LEXIS 173773, at *83 (D.N.J. Sep. 5, 2025) ("pharmaceutical manufacturers typically sell their products to wholesalers at a negotiated price"); *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 68 (D. Mass. 2005) ("manufacturers actually sell drugs . . . at prices far below . . . WAC"). When dispensers purchase identified drugs from

[3] Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Supply Chain* 17 (Mar. 2005), https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf ("For generic products, the purchase price is highly variable, largely depending upon competition in the class and the ability of the wholesale distributor to drive market share or increase the volume sold. In this case, wholesale distributors play a larger role in the negotiation of the price of the product."). The Court may take notice of this information, and other information presented here as background, to provide context because "[t]his Court may take judicial notice of any fact that 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.'" *Punin v. Garland*, 108 F.4th 114, 120 n.3 (2d Cir. 2024) (quoting *Louis Vuitton Malletier S.A. v. LY USA, Inc.*, 676 F.3d 83, 88 n.2 (2d Cir. 2012), which was quoting Fed. R. Evid. 201(b)(2)).

distributors, they too negotiate the price such that individual dispensers may pay different prices when purchasing from the same distributor.[4]

II. Connecticut Passes the Act to Combat Soaring In-State Drug Prices.

Millions of Americans, including Connecticut residents, rely on prescription drugs to maintain their health and very lives.[5]

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[4] Neeraj Sood et al., USC Leonard D. Schaeffer Center for Health Policy & Economics, *The Flow of Money through the Pharmaceutical Distribution System* 2 (June 2017), https://schaeffer.usc.edu/wp-content/uploads/2024/10/The-Flow-of-Money-Through-the-Pharmaceutical-Distribution-System_Final_Spreadsheet.pdf ("Pharmacies in turn negotiate agreements with drug wholesalers, setting the wholesale rates at which they obtain the drugs, and wholesalers negotiate to buy drugs from manufacturers and distribute them to pharmacies.").

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

Approximately 90% of prescriptions are filled with generic drugs,[6] which *should* cost 80-85% less than brand-name drugs.[7]

Unfortunately, despite this potential for lower-cost prescriptions, patients face "skyrocketing drug prices, sometimes by more than 1,000%, and sometimes overnight." *Ass'n for Accessible Meds. v. Raoul*, No. 24 C 544, 2025 U.S. Dist. LEXIS 190215, at *1-2 (N.D. Ill. Sep. 26, 2025). This

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[6] Andrew W. Mulcahy & Vishnupriya Kareddy, RAND Corp., *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships* 2 (Oct. 27, 2021), https://www.rand.org/content/dam/rand/pubs/research_reports/RRA300/RRA328-1/RAND_RRA328-1.pdf.

[7] Federal Trade Commission, *How to Get Generic Drugs and Low-Cost Prescriptions*, Federal Trade Commission Consumer Advice (Feb. 26, 2026, 12:11 PM), https://consumer.ftc.gov/articles/generic-drugs-low-cost-prescriptions.

situation has been well documented across the country,[8] including in Connecticut.[9]

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[8] *See, e.g.*, *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 674 (4th Cir. 2018) (Wynn, J., dissenting) (discussing "series of high-profile incidents in which several generic pharmaceutical manufacturers imposed multiple-thousand-fold price increases for single-source generic drugs that treat rare and life-threatening conditions"); U.S. Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs* 3 (Dec. 2016), https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf (discussing "[s]taggering increases in the price of some prescription drugs" that "threaten not only the economic stability of American households, but also the health of individuals who discover that drugs they need are unaffordable and difficult to access"); U.S. Government Accountability Office, *Report to Congressional Requesters, Generic Drugs Under Medicare* 3-4 (Aug. 2016), https://www.gao.gov/assets/gao-16-706.pdf (noting the "extraordinary price increases" for many generic drugs), Andrew Pollack, *Drug Goes from $13.50 a Tablet to $750, Overnight*, N.Y. Times, Sept. 20, 2015, https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html.

[9] *See* OHS Report, *supra*, at 51 ("[H]igh costs continue to impede patient access to pharmaceuticals. A 2022 survey of Connecticut residents found that 23% of respondents had cut pills in half, skipped doses of medicine, or did not fill a prescription due to costs. High and rising prescription drug costs were a significant contributor to Connecticut's healthcare spending growth in 2023."); Liese Klein, *New Connecticut laws aim to tame surging prescription drug prices for patients, hospitals*, CT Insider, July 27, 2025, https://www.ctinsider.com/business/article/new-laws-target-rising-prescription-drug-costs-20786384.php ("Drug costs for hospitals in Connecticut rose at a higher rate in recent years compared to other Northeast states and have outpaced national averages . . . . The Connecticut Hospital Association warns that higher drug costs . . . are threatening the survival of the state's medical safety net.").

In 2025, Connecticut took several steps to help alleviate the pain, including by enacting a drug price cap. Conn. Pub. Act No. 25-168 §§ 345-47.[10] Starting on January 1, 2026, no manufacturer or distributor shall "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." *Id.* § 346(a)(1). The "reference price" is defined as the WAC on a particular date (depending on the status of the drug). *Id.* § 345(11). The "consumer price index" is defined as the consumer price index, annual average, for all urban consumers. *Id.* § 345(4). Put simply, the Act's drug price cap ties the cost of identified drugs to their WAC, adjusted for inflation. The Act applies only to sales "in this state," *id.* § 346(a)(1), and so applies only to transactions where title passes in Connecticut, and then only to the selling party in those in-

[10] *See also* Conn. Pub. Act No. 25-167 § 2 (requiring a pharmacy benefits manager to offer a health plan the option of being charged the same price for a prescription drug that the pharmacy benefits manager pays a pharmacy for that prescription drug); *id.* § 6 (authorizing the Commissioner of Economic and Community Development to use certain bond proceeds to support prescription drug production capacity in Connecticut); *id.* §§ 9-18 (authorizing a study on the feasibility of establishing a Canadian prescription drug importation program "to reduce prescription drug costs in the state.").

state transactions, *see* Conn. Gen. Stat. § 42a-2-106(1) (defining sale as "the passing of title from the seller to the buyer for a price").

A manufacturer or distributor that violates the Act is liable to the State for a civil penalty, which is imposed, calculated, and collected by the Commissioner of Revenue Services. Conn. Pub. Act No. 25-168 § 346(b)(1). The Act exempts prescription drugs that the federal government has identified as being "in shortage" in the United States. *Id.* § 346(a)(2). It also provides manufacturers and distributors with ways to obtain administrative and judicial relief from the Act. *Id.* § 346(f), (g). There is nothing in the Act that facially discriminates against out-of-state entities by treating out-of-state entities differently from in-state entities. *See generally id.* §§ 345-47.

III. HDA Asks the District Court to Invalidate the Act.

HDA filed suit on October 14, 2025, claiming the Act violates the dormant Commerce Clause, the Due Process Clause, the Equal Protection Clause, the Takings Clause, the Contracts Clause, the Supremacy Clause, and 42 U.S.C. § 1983. A031-37 ¶¶ 33-58. HDA brought this action on behalf of its member distributors, who it claims "face imminent and irreparable injury from the Drug Price Cap" because

they will make less money if they comply with the Act (or face the Act's penalties if they do not). A024-25 ¶ 7; A026-27 ¶ 14; *see* HDA Brief at 39-41.

HDA also asked the District Court to preliminarily enjoin the State from implementing or enforcing the Act against any of HDA's members. *See generally* A005, HDA's Motion for Preliminary Injunction, ECF No. 27. It did so primarily based on the contention that the Act violates the dormant Commerce Clause. *See* A005, ECF No. 27-1 at 14-29 (only 3 paragraphs of merits argument discuss claims other than dormant Commerce Clause). Because the Act went into effect at the beginning of 2026, HDA sought an accelerated briefing and hearing schedule (to which the State consented), and asked the District Court to issue a decision on an expedited basis. A005, ECF No. 31.

The District Court heard argument on December 9, 2025. A068. At that proceeding, the State's counsel explained that, from its plain language, the Act applies only to sales of identified drugs "in this state," and represented that it was the State's position that a sale occurs "in this

state" when title transfers in Connecticut. A072-73; A104-105.[11] Based on that representation, the District Court ordered the State to submit a supplemental brief on or before December 12, 2025, with HDA submitting a supplemental brief the following week. A006-07, ECF No. 41.

On December 24, 2025, the District Court (Williams, J.) denied HDA's request for a preliminary injunction. A126-144. In its decision, the District Court detailed the problems with the rising costs of prescription drugs across the country, including Connecticut; noted that Connecticut had empaneled a bipartisan task force to propose policies for lowering those costs; and stated that the Act was one of the task force's proposals. A127-29. It then rejected HDA's dormant Commerce Clause claim because the Act is not discriminatory or protectionist and does not impermissibly burden interstate commerce or violate any

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[11] This interpretation of the Act is consistent with Connecticut's Uniform Commercial Code, which defines a sale as "the passing of title from the seller to the buyer for a price." Conn. Gen. Stat. § 42a-2-106(1). In a related case, the State stipulated that the relevant sections of the Act "do not apply to sales of 'identified prescription drugs' (as defined in Act § 345(6)) in which title transfers outside of Connecticut, because such sales do not occur 'in this state' as that term is used" in the Act. Stipulation Regarding Defendants' Enforcement Position and Dismissal, *Ass'n for Accessible Meds. v. Boughton*, No. 3:25-cv-01757-OAW (D. Conn. Dec. 15, 2025), ECF No. 39 at 2.

extraterritoriality principle. A133-143.[12] Because HDA had not made a clear showing of likelihood of success on the merits, the District Court did not reach the remaining preliminary injunction factors. A143.

HDA appealed on December 26, 2025. Dkt. No. 1 at 1. It then filed an emergency motion on December 29, 2025, asking this Court to enjoin the Act "on or before" January 1, 2026, within three days of filing the motion. Dkt. No. 6 at 9. This Court denied that motion on December 31, 2025. Dkt. No. 15. HDA now asks this Court to reverse the District Court decision and order that court to enjoin the Act. HDA Brief at 17.

STANDARD OF REVIEW

A preliminary injunction "is an extraordinary and drastic remedy and should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *St. Joseph's Hosp. Health Ctr. v. Am. Anesthesiology of Syracuse, P.C.*, 131 F.4th 102, 106 (2d Cir. 2025)

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[12] The district court also rejected HDA's due process claim. It observed that "HDA devoted all but three paragraphs of its thirty-one-page initial memorandum of law, *see* ECF No. 27- 1, at 11-12, nearly all of its time at the December 9, 2025, hearing, *see* ECF No. 42, and the entirety of its supplemental memorandum of law, *see* ECF No. 44, to its dormant Commerce Clause claim," and that HDA's barely pressed due process argument failed "[g]iven Defendants' clarification of the Act's applicability." A133 n.5.

(internal quotation marks omitted). "To obtain a preliminary injunction that will affect government action taken in the public interest pursuant to a statute or regulatory scheme, the moving party must demonstrate (1) irreparable harm absent injunctive relief, (2) a likelihood of success on the merits, and (3) public interest weighing in favor of granting the injunction." *We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 279 (2d Cir. 2021) (internal quotation marks omitted). "The movant must also show that the balance of equities supports the issuance of an injunction." *Id.* at 280. "These requirements are demanding, for [a] preliminary injunction is an extraordinary remedy never awarded as of right." *Daileader v. Certain Underwriters at Lloyds London Syndicate 1861*, 96 F.4th 351, 356 (2d Cir. 2024) (internal quotation marks omitted, alteration in original).

"This Court reviews a district court's legal rulings *de novo* and its ultimate denial of a preliminary injunction for abuse of discretion." *N. Am. Soccer League, LLC v. United States Soccer Fed'n, Inc.*, 883 F.3d 32, 36 (2d Cir. 2018). A district court abuses its discretion "when its decision rests on an error of law (such as application of the wrong legal principle) or a clearly erroneous factual finding or cannot be located

within the range of permissible decisions." *We the Patriots USA*, 17 F.4th at 280 (internal quotation marks omitted).

SUMMARY OF ARGUMENT

The District Court acted well within its discretion in refusing to enjoin the Act, and this Court should affirm.

First: HDA showed no likelihood of success on the merits. It tried to meet its burden by relying primarily on the dormant Commerce Clause's extraterritoriality doctrine. But the Supreme Court practically eliminated this doctrine in its most recent dormant Commerce Clause case, *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). *Pork* explained that there is no *per se* prohibition on state laws with extraterritorial effects. Instead, a state law regulating in-state conduct has impermissible extraterritorial effects only when the law and its effects are protectionist or discriminatory. The Act is neither, applying equally to in-state and out-of-state manufacturers and distributors alike.

HDA's arguments that the Act is protectionist lack merit. It first claims the Act impermissibly provides in-state consumers an advantage over out-of-state consumers. But the Act does not limit its benefits to in-state consumers and so does not impermissibly give an intentional

preferential advantage in a market to in-state consumers that is denied to out-of-state consumers who patronize an in-state business in this market. Its second theory, that the Act discriminates in the commercial context against out-of-state distributors in favor of in-state retailers, also fails. Retailers are distributors' *customers*, not their *competitors*, so any purported differential treatment they receive does not implicate the concerns underlying the dormant Commerce Clause.

Nor can HDA establish a likelihood of success on the merits even under the pre-*Pork* extraterritoriality doctrine (or any vestiges of that doctrine left standing after *Pork*). Unlike the drug price cap laws considered in pre-*Pork* cases, where states sought to penalize out-of-state entities that sold drugs at high prices even if those sales were made outside the state, the Act applies only to Connecticut sales, where title to the drugs transfers in Connecticut. The Act does not directly control out-of-state commerce with no connection to Connecticut, and so it is lawful even under the pre-*Pork* extraterritoriality doctrine.

Second: HDA raises several new arguments, including new constitutional arguments under the Equal Protection and Due Process Clauses, in three scant paragraphs of its appellate brief. These

arguments are inadequately briefed under any standard, let alone the demanding requirements necessary to obtain a preliminary injunction. And HDA waived these new arguments by failing to make them before the District Court even though it had the opportunity to do so.

Third: HDA did not establish that the Act would cause it irreparable harm. The three harms HDA claims its members will suffer if the Act is enforced against them are not irreparable. The first, stemming from alleged constitutional violations, does not establish irreparable harm because the constitutional provisions HDA alleges the Act violates protect only structural rights. The second, a loss of money, is also not irreparable. Irreparable harm does not usually include remediable monetary harm, and Connecticut has a process permitting certain claims for monetary damages against the State. And the third, business disruption, is not irreparable unless HDA establishes that any disruption caused by the Act threatens the continued existence of its members' businesses. HDA has not attempted to meet this standard. Indeed, the several-month delay between Governor Lamont signing the Act and HDA filing suit confirms that the Act does not cause HDA's members an actual, imminent, and irreparable injury.

Fourth: The balance of equities and public interest both favor the State. When HDA discusses the equities, it relies on its arguments that the Act is unconstitutional and focuses on the financial burdens its members may face if they are required by the Act to alter their current business practices. But the Act addresses an emergency in Connecticut. Connecticut residents face skyrocketing drug prices that put critical medications out of reach, endangering their health. The balance of equities and public interest weigh strongly in favor of the Act.

ARGUMENT

"Companies that choose to sell products in various States must normally comply with the laws of those various States." *Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356, 364 (2023). And state laws are presumed to be constitutional. *Conn. ex rel. Blumenthal v. Crotty*, 346 F.3d 84, 102 (2d Cir. 2003); *see Lemon v. Kurtzman*, 411 U.S. 192, 208 (1973) ("[O]ne of the first principles of constitutional adjudication [is] the basic presumption of the constitutional validity of a duly enacted state or federal law." (internal quotation marks omitted)). That is the starting point of the analysis here.

I. The District Court Correctly Determined that HDA Is Unlikely to Succeed on the Merits.

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

Because the dormant Commerce Clause is "inferred" from the text of the U.S. Constitution, "extreme caution is warranted before a court deploys this implied authority" to "[p]revent[] state officials from enforcing a democratically adopted state law." *Id.* at 390. And because the dormant Commerce Clause is "a judge-made and enforced doctrine," its strictures "hav[ing] ebbed and flowed over time through case law, with the Supreme Court refining the doctrine's proper scope," the most recent pronouncement from the Supreme Court about the scope of the doctrine

is the touchstone of any dormant Commerce Clause claim. *Flynt v. Bonta*, 131 F.4th 918, 923 (9th Cir. 2025). Here, the Supreme Court's most recent dormant Commerce Clause case—*National Pork Producers Council v. Ross*, 598 U.S. 356 (2023) —"synthesized decades of dormant Commerce Clause jurisprudence into a few key principles," and these principles foreclose HDA's dormant Commerce Clause arguments. *N.J. Staffing All. v. Fais*, 110 F.4th 201, 205 (3d Cir. 2024) (hereinafter *Fais II).*

Before *Pork*, "[a] state statute violate[d] the dormant Commerce Clause if it: (1) 'clearly discriminate[d] against interstate commerce in favor of intrastate commerce'; (2) 'impose[d] a burden on interstate commerce incommensurate with the local benefits secured'; or (3) 'ha[d] the practical effect of extraterritorial control of commerce occurring entirely outside the boundaries of the state in question.'" *Nat'l Shooting Sports Found., Inc. v. James*, 144 F.4th 98, 113 (2d Cir. 2025) (quoting a pre-*Pork* case, *Grand River Enters. Six Nations, Ltd. v. Boughton*, 988 F.3d 114, 123 (2d Cir. 2021); *Pork* has changed the kinds of claims that can be brought under the third prong). On appeal, HDA alleges that the District Court erred in its extraterritoriality and discrimination

analyses. *See* HDA Brief at 27-38, 45-46 (extraterritoriality), 38-44 (discrimination); *id. passim* (no mention of burden and local benefit balancing or citation to the governing case under this theory, *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970)).[13]

HDA relies principally on what the author of *Pork* previously described as "the most dormant doctrine in dormant commerce clause jurisprudence": the extraterritoriality doctrine. *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1170 (10th Cir. 2015) (Gorsuch, J.). HDA recognizes that the Act "purports to regulate only in-state Connecticut sales," rather than directly regulating out-of-state transactions with no connection to Connecticut, and so it continues to argue primarily that extraterritorial effects caused by the Act's in-state regulation "doom" it. HDA Brief at 29. Yet *Pork* sharply limited the extraterritoriality doctrine. The Supreme Court explained that its prior cases finding impermissible extraterritorial effects from a state law—*Healy v. Beer Inst.*, 491 U.S. 324 (1989); *Brown-Forman Distillers Corp. v. N.Y. State*

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[13] HDA also argues on appeal, in three paragraphs, that the Act violates the Equal Protection Clause and due process principles. HDA Brief at 46-48.

Liquor Auth., 476 U.S. 573 (1986); and *Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511 (1935)—were really about protectionism: state laws with the "*specific* impermissible extraterritorial effect" of discriminating against interstate commerce. *Pork*, 598 U.S. at 374 (emphasis in original, internal quotation marks omitted). It thus moved extraterritorial effects claims like HDA's to the first prong of *Shooting Sports*, collapsing this kind of claim into the usual discrimination analysis required by the dormant Commerce Clause. And to the extent a "pure" extraterritoriality claim not involving discrimination survived *Pork*—the kind of claim that before *Pork* could have been brought only under the third prong from *Shooting Sports*—it is limited to state laws "that *directly* regulate[] out-of-state transactions by those with *no* connection to the State." *Pork*, 598 U.S. at 376 n.1 (emphasis in original). The Act neither discriminates nor directly regulates out-of-state transactions unconnected to Connecticut, so HDA is unlikely to succeed on the merits.

A. *Pork* established that the dormant Commerce Clause prohibits laws regulating in-state conduct with extraterritorial effects only when those laws are discriminatory.

Pork affirmed that "no State may use its laws to discriminate purposefully against out-of-state economic interests." *Pork*, 598 U.S. at

364. But it made clear that the dormant Commerce Clause does not invalidate a state law just because it has extraterritorial effects. Rather, the dormant Commerce Clause developed over time in response to state laws that attempted to "build up . . . domestic commerce through burdens upon the industry and business of other States, regardless of whether Congress has spoken." *Id.* at 369 (internal quotation marks omitted). "[T]his antidiscrimination principle lies at the very core of our dormant Commerce Clause jurisprudence," which "prohibits the enforcement of state laws driven by . . . economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Id.* (internal quotation marks omitted). "[A]bsent discrimination, a State may exclude from its territory, or prohibit the sale therein of any articles which, in its judgment, fairly exercised, are prejudicial to the interests of its citizens." *Id.* (internal quotation marks omitted).

Thus, in *Pork*, the Court upheld a California law that *completely banned* the sale of pork products in California derived from pigs subjected to cruel breeding and living conditions, notwithstanding that the law affected out-of-state pork producers' business practices and financial

interests. *See id.* at 363-67. The Court specified that the plaintiffs "begin in a tough spot" because there was no allegation that the California law "seeks to advantage in-state firms or disadvantage out-of-state rivals." *Id.* at 370. That lack of discrimination was fatal to the plaintiffs' dormant Commerce Clause challenge. *See id.* at 390-91.

Moreover, *Pork* expressly rejected the "more ambitious" theory that the dormant Commerce Clause embodies an "extraterritoriality doctrine" in which an "almost *per se*" rule forbids enforcement of state laws that "have the practical effect of controlling commerce outside the State, even when those laws do not purposely discriminate against out-of-state economic interests." *Id.* at 371 (internal quotation marks omitted). In doing so, the Court stated that "[t]his argument falters out of the gate" because the line of cases upon which the plaintiffs' relied for their theory—*Healy*, *Brown-Forman*, and *Baldwin*—"typifie[d] the familiar concern with preventing purposeful discrimination against out-of-state economic interests." *Id.* at 371. Indeed, the Court observed that the plaintiffs "read too much into too little" with respect to the cases they used to support their theory. *Id.* at 373. The Court concluded that the language from its earlier cases "appeared in a particular context and did

particular work[] [t]hroughout . . . explain[ing] that the challenged statutes had a *specific* impermissible extraterritorial effect—they deliberately prevent[ed out-of-state firms] from undertaking competitive pricing or deprive[d] businesses and consumers in other States of whatever competitive advantages they may possess." *Id*. at 374 (internal quotation marks omitted, emphasis in original, third and fourth alterations in original)).

In other words, *Pork* made clear that *Healy*, *Baldwin* and *Brown-Forman* are just examples of a discrimination claim under the first prong of dormant Commerce Clause analysis, and that there is no such thing as a free-standing extraterritorial effects claim untethered to the antidiscrimination principle. Several courts have read *Pork* to mean that there are now only two avenues for challenging a law under the dormant Commerce Clause post-*Pork*: (1) a discrimination claim; and (2) an undue burden claim under *Pike*. *See, e.g., Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 160 (2023) (Alito, J., concurring in part and concurring in the judgment) ("Under our modern framework, a state law may offend the Commerce Clause's negative restrictions in two circumstances: when the law discriminates against interstate commerce or when it imposes 'undue

burdens' on interstate commerce."); *N.J. Staffing All. v. Fais*, 749 F. Supp. 3d 511, 524 (D.N.J. 2023) (hereinafter *Fais I)* (reading *Pork* as clarifying that "extraterritorial effects alone are no longer sufficient to show a violation" and describing the extraterritoriality principle as "a dead letter"), *aff'd*, 110 F.4th 201 (3d Cir. 2024); *GenBioPro, Inc. v. Sorsaia*, No. 3:23-0058, 2023 U.S. Dist. LEXIS 149195, at *37 (S.D.W. Va. Aug. 24, 2023) (acknowledging that *Pork* "abrogated" the "principle against extraterritoriality" articulated in prior case law, including *Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018), relied on by HDA), *aff'd sub nom. GenBioPro, Inc. v. Raynes*, 144 F.4th 258 (4th Cir. 2025); *New York Times Co. v. Microsoft Corp.*, 777 F. Supp. 3d 283, 326 (S.D.N.Y. 2025) (acknowledging that *Pork* "rejected" the "theory" of extraterritoriality and limited the dormant Commerce Clause to discrimination and *Pike* claims); *Raoul*, 2025 U.S. Dist. LEXIS 190215, at *16 (noting that after *Pork* "[p]laintiffs can either challenge a state law because it (1) discriminate[s] against interstate commerce or (2) impose[s] an undue burden on interstate commerce and flunks *Pike* balancing" (internal quotation marks omitted, second and third alterations in original)).

1. HDA misconstrues *Pork* as preserving a practically *per se* prohibition against state price control laws.

Pork thus shows that HDA cannot establish a likelihood of success on its dormant Commerce Clause claim, and so the District Court did not abuse its discretion in declining to preliminarily enjoin the Act. On appeal, HDA continues to argue that hypothesized extraterritorial effects arising from the Act's regulation of in-state transactions "doom" it. HDA Brief at 29; *id.* at 45-46 (arguing that applying the Act only to sales where title transfers in Connecticut is "*more* extraterritorial" and thus "*more* unconstitutional" (emphasis in original)). To do so, HDA offers an implausible reading of *Pork* to salvage its pure extraterritoriality argument from the "*Pork* revolution." *Fais I*, 749 F. Supp. 3d at 525. But the Act's extraterritorial effects do not violate the dormant Commerce Clause unless they are protectionist or discriminatory.

HDA seeks to avoid this clear conclusion by claiming that *Pork* said "'nothing new'" about price-control laws specifically under the dormant Commerce Clause and that *Pork* recognized a continued *per se* rule that applied to these kinds of laws: "state 'price control or price affirmation statutes' are invalid if they tie 'the price of . . . in-state products to out-

of-state prices.'" HDA Brief at 33 (quoting *Pork*, 598 U.S. at 374). HDA omits key language from its quotations to reach this result, which is not even an accurate statement of the pre-*Pork* caselaw. *See, e.g., Vizio, Inc. v. Klee*, 886 F.3d 249, 255 (2d Cir. 2018) (more than tying prices is required pre-*Pork*; state law must have "the practical effect of *requiring* out-of-state commerce to be conducted at the regulating state's direction" (internal quotation marks omitted, emphasis in original)).

Pork actually stated that "[i]n recognizing this much, we say nothing new," where "this much" referred to the two sentences immediately preceding the quoted sentence. 598 U.S. at 374. And those two preceding sentences characterized the pre-*Pork* price control or price affirmation Supreme Court cases on which HDA relies for its claims that price control or affirmation statutes are *per se* invalid—*Healy*, *Brown-Forman*, and *Baldwin*—in a way that contradicts HDA's argument. *Healy*, *Brown-Forman*, and *Baldwin* concerned situations where "the challenged statutes had a *specific* impermissible 'extraterritorial effect'—they deliberately 'prevent[ed out-of-state firms] from undertaking competitive pricing' or 'deprive[d] businesses and consumers in other States of 'whatever competitive advantages they may possess.'" *Id.*

(quoting, alterations in original, *Healy*, 491 U.S. at 338-39, which was quoting *Brown-Forman*, 476 U.S. at 580). *Pork* thus did not create a special exception to the antidiscrimination principle that animates the dormant Commerce Clause for price control or affirmation statutes. As discussed above, it instead *rejected* the proposed "almost *per se*" rule that HDA appears to be championing now and characterized the cases upon which HDA relies as involving protectionist laws. *See Pork*, 598 U.S. at 371-74; *Fais II*, 110 F.4th at 205-06 ("the dormant Commerce Clause does not create a per se rule against state laws with extraterritorial effect": *Healy*, *Brown-Forman*, and *Baldwin* instead "illustrate how 'protectionism [takes] center stage'" (alteration in original)).

HDA commits the same error here that the *Pork* plaintiffs did, "read[ing] too much into too little" by pointing to language that "appeared in a particular context." *Id.* at 373-74. That context was a discriminatory or protectionist state statute. *See id.* ; *see also Baldwin*, 294 U.S. at 519 (New York laws that barred out-of-state dairy farmers from selling milk in New York unless the price paid to them matched the minimum price New York law guaranteed to in-state producers); *Brown-Forman*, 476 U.S. at 575-76 (New York law required liquor distillers to affirm that

their in-state prices were no higher than their out-of-state prices); *Healy*, 491 U.S. at 326 (Connecticut law required out-of-state beer merchants to affirm that their in-state prices were no higher than those they charged in neighboring states).

That is, in those cases, the states had enacted laws tethering the prices of their in-state products to those of out-of-state products in an effort to "erect[] an economic barrier protecting a . . . local industry against competition from without the State" (*Baldwin*), "force out-of-state [producers] to 'surrender' whatever cost advantages they enjoyed against their in-state rivals" (*Brown-Forman*), or "hoard commerce for the benefit of in-state merchants and discourage consumers from crossing state lines to make their purchases from nearby out-of-state vendors" (*Healy*). *Pork*, 598 U.S. at 372-73 (internal quotation marks omitted). In all those situations, "protectionism took center stage." *Id.* at 372. That was the context of the Supreme Court's language about "'[t]he rule that was applied in *Baldwin* and *Healy*' as addressing 'price control or price affirmation statutes' that tied 'the price of . . . in-state products to out-of-state prices.'" *Id.* at 374 (quoting, alterations in original, *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003)).

HDA's argument about tying the prices of in-state products to out-of-state products, HDA Brief 27-38, is thus a red herring. When *Baldwin*, *Brown-Forman*, and *Healy* discussed tying in-state product prices to out-of-state prices, they were talking about the prices of products produced in state in relation to those same products produced out of state (in an effort to eliminate any disadvantage the in-state products might face from out-of-state prices), or the prices merchants could charge in relation to prices in other states (in an effort to eliminate any disadvantage local merchants might face from out-of-state merchants and/or to eliminate any advantage out-of-state merchants might have over local merchants). As *Pork* makes clear, these cases, and the extraterritoriality doctrine derived from them, are really about protectionism and discrimination.[14]

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[14] Even if one accepts HDA's view that price control statutes tying in-state to out-of-state prices were assigned a special *per se* prohibition by *Pork*, HDA has failed to establish that the Act does this. As the District Court correctly observed, the Act does not tie an out-of-state price to an in-state price. A141. It instead sets in-state prices relative to the WAC, a price that manufacturers set *nationwide*. HDA Brief at 27. The Act does not insist that the WAC be a particular number. Nor does it direct that prescription drugs sold in Connecticut conform to the prices of a sister state. Instead, when a manufacturer or distributor sells an identified drug *in Connecticut*, the Act requires that manufacturer or distributor to set the price based on the appropriate *national* WAC. The referenced national WAC *is* (or was) the Connecticut price, as well as that for all the

2. The Act is not protectionist or discriminatory.

HDA must thus establish that the Act is discriminatory, and it has failed to do so. A state law discriminates under the dormant Commerce Clause when it treats "substantially similar," *GMC v. Tracy*, 519 U.S. 278, 298 (1997), "in-state and out-of-state economic interests" differently, in a way "that benefits the former and burdens the latter," *Or. Waste Sys. v. Dep't of Envtl. Quality*, 511 U.S. 93, 99 (1994). Here, though, the Act applies to any "pharmaceutical manufacturer or wholesale distributor" that does business in Connecticut, preventing all manufacturers and distributors from "sell[ing] an identified prescription drug in this state"—

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states. So, the Act does not tie an out-of-state price to an in-state price, a prerequisite for HDA's price tying arguments. This very issue was recognized in *Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001), *aff'd sub nom.*, *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003), which HDA references in support of its incorrect argument that the Act is unconstitutionally extraterritorial. HDA Brief at 33 n.8. *Concannon* concerned Maine's drug price law that tied the state's rebate amount to that calculated under the Federal Medicaid Rebate Program, i.e., at a national level. *Concannon*, 249 F.3d at 71. The First Circuit rejected the plaintiff's "per se" extraterritorial reach argument because Maine was "not tying the price of its in-state products to out-of-state prices. There is nothing within the Act that requires the rebate to be a certain amount dependent on the price of prescription drugs *in other states*." *Id.* at 82 (emphasis added). And the Supreme Court upheld that conclusion. *See Walsh*, 538 U.S. at 669.

i.e., Connecticut—at a price higher than the reference price defined in the Act. Conn. Pub. Act No. 25-168 § 346. It thus contains no facially discriminatory language, makes no distinction between in-state and out-of-state manufacturers and distributors, and so applies equally to all manufacturers and distributors, regardless of their geographic location. The Act applies equally to all that do business in Connecticut, imposing the same burdens on the in-state and out-of-state interests it affects.

Indeed, HDA, which is the trade association for distributors, represents that "it is undisputed that no member of HDA even has a distribution facility in Connecticut." HDA Brief at 13. Given that statement, it is unclear how the Act could have *any* discriminatory or protectionist effects on HDA's members. If all distributors are located outside Connecticut, then there are no substantially similar in-state economic entities that the Act could benefit at the expense of HDA's members. In short, the Act does not insulate in-state interests from the consequences of interstate commerce or advance any protectionist goals as to the pharmaceutical industry in Connecticut. The Act is thus not protectionist or discriminatory.

Because the Act is clearly not facially discriminatory, HDA must establish that it discriminates purposefully or in effect to succeed on the merits of its extraterritorial effects claim. *N.Y. Pet Welfare Ass'n v. City of N.Y.*, 850 F.3d 79, 90 (2d Cir. 2017). HDA has presented no evidence that Connecticut passed the Act purposefully to discriminate against out-of-state entities. Instead, it argues that the Act discriminates in two ways: (1) it discriminates in effect against out-of-state consumers by benefiting in-state consumers, and (2) it discriminates in effect against out-of-state distributors in favor of their in-state customers, retailers. HDA Brief at 38-44. Neither argument demonstrates that the Act is protectionist or discriminatory.

a. The Act does not discriminate against out-of-state consumers.

HDA first argues that the Act is protectionist as to Connecticut consumers. HDA Brief at 38-41. But the dormant Commerce Clause does not invalidate a state's laws simply because they might advantage (or disadvantage) the state's residents relative to out-of-state consumers.[15]

[15] To conclude otherwise would be absurd, as every state law affecting the pocketbook of its residents would be subject to challenge. For example, a state with lower sales or income tax rates than its neighbors (or no such

Rather, one state's law must "discriminate against another's producers or consumers." *Pork*, 598 U.S. at 393 (Barrett, J., concurring in part); *see id.* at 364 (laws may not "discriminate purposefully against out-of-state economic interests"). In the consumer context, a law is discriminatory when it "encourag[es] economic isolationism," such as by "encourag[ing] affected [in-state] entities to limit their out-of-state clientele" and so "penaliz[ing] the principally nonresident customers of [in-state] businesses catering to a primarily interstate market" or "burden[ing] out-of-state access" to in-state resources and services. *Camps Newfound/Owatonna v. Town of Harrison*, 520 U.S. 564, 576-78 (1997).

The impermissible "advantage over consumers in other States" that leads to "economic Balkanization," then, is when in-state consumers are given an intentional preferential advantage in a market by state law that is *denied* to out-of-state consumers who patronize an in-state business in this market. *Id.* at 577-78 (internal quotation marks omitted); *see Brown-Forman*, 476 U.S. at 580 ("a State may seek lower prices for its consumers"; what is impermissible is for a state law to require that

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taxes at all) is giving an advantage to local interests, but that is clearly not a violation of the dormant Commerce Clause.

"producers or consumers in other States surrender whatever competitive advantages they may possess," providing "local consumers an advantage over consumers in other States"). But there is nothing in the Act that prevents out-of-state consumers from taking advantage of the Act's provisions by purchasing identified drugs in Connecticut. HDA's discussion of the hypothetical effects of the Act on consumers in other states, HDA Brief at 38-41, is just a retooled version of its pure extraterritorial effects argument, which *Pork* rejected.

The Act itself does not say what other states may or may not do, tie prices in Connecticut to prices in other states, prevent distributors and manufacturers from pricing drugs however they like in other states, or limit its benefits to Connecticut residents. There is nothing in the Act that is discriminatory, and so the District Court correctly rejected HDA's consumer protectionism theory. A141-42.

b. The Act does not discriminate against distributors.

HDA argues next that the Act discriminates against out-of-state distributors in favor of their customers, in-state retailers. HDA Brief at 41-44. The District Court also correctly rejected this argument, noting that the Act is not discriminatory because it "applies to covered

distributors regardless of whether they are located or headquartered inside or outside of Connecticut." A136. And the Supreme Court has expressly said that, for purposes of the Commerce Clause, any notion of discrimination requires a comparison of "substantially similar entities." *Tracy*, 519 U.S. at 298.[16] The appropriate comparators for commercial dormant Commerce Clause discrimination claims are in-state and out-of-state *competitors*. *Rest. L. Ctr. v. City of N.Y.*, 90 F.4th 101, 107 (2d Cir. 2024) ("[t]o succeed" on dormant Commerce Clause discrimination claim, plaintiffs must show that state law "confers a competitive advantage upon local businesses at the expense of out-of-state competitors"); *id.* at 120 ("a law is only clearly discriminatory in its effect where it 'confer[s] a competitive advantage upon local business vis-à-vis out-of-state

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[16] HDA's attempt to distinguish *Tracy*, HDA Brief at 42-44, ignores that *Tracy* used a then-novel analytical technique to determine whether the entities in that case were substantially similar enough to be treated *as competitors*; it did not limit the requirement of substantial similarity only to cases involving *Tracy's* unique regulatory setting. *See Tracy*, 519 U.S. at 303-304 (weighing whether "opportunities for competition between marketers and [utilities] in the noncaptive market requires treating marketers and utilities as alike for dormant Commerce Clause purposes," or whether the entities should be treated as not competing because there existed a "noncompetitive, captive market in which the local utilities alone operate").

competitors'" (alteration in original, quoting *Town of Southold v. Town of E. Hampton*, 477 F.3d 38, 49 (2d Cir. 2007)).

HDA's contention—made without citation to any supporting authority—that its out-of-state distributor members are "'similarly situated' for constitutional purposes" to in-state retailers is thus incorrect. HDA Brief at 43. HDA compares apples to bowling balls when comparing its out-of-state distributor members to their in-state *customers*, rather than to any in-state competitor. HDA Brief at 22 (writing that HDA's members "ship drugs and products to their customers," which are "licensed Connecticut retailers, hospitals, and other patient-facing entities"). Wholesale distributors and retailers provide different services, serve different markets, and are not alike for Commerce Clause purposes.[17]

HDA also contends that the Act discriminates impermissibly between its distributor members. HDA Brief at 44. But none of HDA's distributor members are in Connecticut. HDA Brief at 31 ("no HDA member has a distribution facility in Connecticut"). This comparison

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[17] Indeed, the Act is silent as to retailers entirely, and therefore shows no favoritism to retailers, in-state or out-of-state, at all.

between only *out-of-state* distributor competitors is irrelevant to dormant Commerce Clause discrimination, which requires that any discrimination occur between in-state and out-of-state competitors. *Rest. L. Ctr.*, 90 F.4th at 107.

And HDA claims that the Act discriminates by forcing wholesale distributors "alone to bear the cost of Connecticut's program" instead of including in the scope of the Act other entities in the pharmaceutical supply chain. HDA Brief at 42. The Act also applies to manufacturers, though, so HDA's statement is simply untrue. In any event, a law is not discriminatory merely because it only applies to one kind of entity in an industry. As explained above, discrimination under the dormant Commerce Clause exists when in-state entities are advantaged, and similarly situated out-of-state entities are disadvantaged, by a state law regulating interstate commerce. Further, as a practical matter, because the Act applies to sales in Connecticut, its provisions might apply to one entity instead of another based on where those entities transact their business. But where a manufacturer or wholesale distributor sells identified drugs is outside of Connecticut's control.

B. The Act does not directly regulate out-of-state transactions, and so it does not implicate any remnant of the pure extraterritoriality doctrine left after *Pork* or even violate the doctrine as it existed before *Pork*.

Aside from limiting extraterritorial effects claims to discriminatory effects, *Pork* "left open the possibility that 'a law that *directly* regulated out-of-state transactions by those with *no* connection to the State' could violate the dormant Commerce Clause or some other constitutional limitation." *Flynt*, 131 F.4th at 924 (quoting, emphasis in original, *Pork*, 598 U.S. at 376 n.1, which sourced this possibility in the plurality opinion from *Edgar* v. *MITE Corp*., 457 U. S. 624, 641-43 (1982)). *Pork* was not clear on whether this limitation arose from the dormant Commerce Clause or from "the Constitution's horizontal separation of powers." *Pork*, 598 U.S. at 376 n.1.

To the extent the limitation arises from the dormant Commerce Clause, all that exists of the "pure" extraterritoriality doctrine after *Pork*, then, is a prohibition on state laws directly regulating out-of-state commerce with no connection to the state itself. This limitation aligns with this Court's recent characterization of "pure" extraterritoriality claims after *Pork*. *Shooting Sports*, 144 F.4th at 116 (modern extraterritoriality doctrine prohibits laws that "regulate[] commerce that

takes place wholly outside of the State's borders" and have "the practical effect of *requiring* [wholly] out-of-state commerce to be conducted at the regulating state's direction"; noting that the existence of a "state nexus requirement" tying law to conduct in the enacting state defeated extraterritoriality claim because law was "plainly focused on regulating conduct that occurs in or has a connection to" the state (internal quotation marks omitted, emphasis and alteration in original)).

The Act does not implicate this potential remnant of the pure extraterritoriality doctrine identified in *Pork*. By its plain language, it directly regulates only sales transactions "in this state," Conn. Pub. Act No. 25-168 § 346, sales that occur when title passes "from the seller to the buyer for a price" *in Connecticut*, Conn. Gen. Stat. § 42a-2-106(1). And it applies only to the parties to those in-state transactions, who clearly have a connection to Connecticut. Indeed, HDA admits as much and has not argued that the Act *directly* regulates transactions with no connection to Connecticut in violation of the dormant Commerce Clause. *See* HDA Brief at 29 (conceding that the Act "purports to regulate only in-state Connecticut sales").

Even under the pre-*Pork* extraterritoriality doctrine, which focused on the relationship between a state law and out-of-state transactions (like the vestige of extraterritoriality mentioned in *Pork*), HDA has failed to establish that the Act is unlawful because the Act does not *directly control* any out-of-state conduct. Before *Pork*, courts in this circuit assessed extraterritoriality claims by "focus[ing] squarely on whether the state law has 'the practical effect of *requiring* out-of-state commerce to be conducted at the regulating states direction." *Vizio*, 886 F.3d at 255 (internal quotation marks omitted, emphasis in original); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 110 (2d Cir. 2001) (law must "inescapably require" out-of-state commerce "to be conducted at the regulating state's direction"). When a state law "merely *considers* out-of-state activity" and so "merely influences national pricing decisions, rather than directly control[ling] out-of-state commerce," there is no violation even pre-*Pork*. *Vizio*, 886 F.3d at 255-56 (emphasis in original).

HDA's argument that the Act's "drug price determination" mechanism is unconstitutionally extraterritorial because it "refer[s] to *national* pricing benchmarks" gives the game away. HDA Brief at 27 (emphasis in original). By its plain language, the Act *references* the

national WAC, but referencing national benchmarks as part of regulating in-state conduct was permissible even pre-*Pork*. *See Vizio*, 886 F.3d at 256 (statute that created "fee structure . . . pegged to [plaintiff's] national activities, which will inevitably affect its . . . prices outside Connecticut . . . amounts to no more than upstream pricing impact because the law does not go a step further[and] control[] in-state *and* out-of-state pricing" (internal quotation marks omitted, alterations in original, emphasis added)). The only prices that the Act directly controls are the prices of transactions where the sale—i.e., the transfer of ownership—occurs in Connecticut. And only direct control of out-of-state conduct is forbidden by the pre-*Pork* extraterritoriality doctrine.[18]

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[18] *See also Concannon*, 249 F.3d at 81-82 ("Unlike the[] price affirmation and price control statutes [in *Baldwin*, *Brown-Forman*, and *Healy*], the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price. . . . Furthermore, unlike *Brown-Forman* and [*Baldwin*], the Maine Act does not impose direct controls on a transaction that occurs wholly out-of-state. . . . [And] [s]imply because the manufacturers' profits might be negatively affected by the Maine Act . . . does not necessarily mean that the Maine Act is regulating those profits. The Act does not regulate the transaction between manufacturers and wholesalers.").

As the district court recognized, distributors and manufacturers can sell drugs at whatever price they would like outside of Connecticut, and the Act imposes no consequences on them for doing so and so does not directly control their out-of-state conduct. A141-42. Manufacturers, too, recognized that the Act does not control any out-of-state conduct; they dismissed their suit challenging the Act on dormant Commerce Clause grounds because all their sales occur outside of Connecticut. *Ass'n for Accessible Meds.*, No. 3:25-cv-01757-OAW (D. Conn. Dec. 15, 2025), ECF No. 39. HDA continues its suit because its members sell drugs in Connecticut. HDA Brief at 46. The differing reactions of these upstream participants in the pharmaceutical supply chain—based on whether their sales occur in Connecticut—illustrates how the Act only directly controls in-state conduct. And if every state enacted a law like the Act, manufacturers and distributors would only have to comply with the law where title transfers; there is no danger of conflicting regulatory regimes.

Indeed, *Frosh*, on which HDA relies heavily, recognized the importance of direct control to pre-*Pork* extraterritoriality analysis. The Maryland law at issue in *Frosh* permitted "Maryland to enforce the Act against parties to a transaction that did not result in a single pill being

shipped to Maryland," "the lawfulness of a price increase [was] measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*," and the parties agreed that "nearly all of these transactions occur outside Maryland." *Frosh*, 887 F.3d at 671 (emphasis in original). The law in *Frosh* thus sought to "compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland" by "instruct[ing] manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland." *Id.* at 672. The Act does the exact opposite. It only applies to transactions for drugs that occur in Connecticut, it measures the lawfulness of the price by considering only the price charged in Connecticut, and so it directly controls only conduct in Connecticut. Even under pre-*Pork* law, the Act is "merely one of 'innumerable valid state laws affect[ing] pricing decisions in other States.'" *Vizio*, 886 F.3d at 256 (quoting *Healy*, 491 U.S. at 345 (Scalia, J., concurring in part and concurring in the judgment) (cautioning against allowing Commerce Clause jurisprudence to "degenerate into disputes over degree of economic effect")).

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Pork makes clear that the extraterritoriality doctrine remains somnolent. Extraterritorial effects claims do not exist independent from the discrimination prong of dormant Commerce Clause analysis, and the extraterritoriality doctrine—to the extent it still exists—now only prohibits states from directly regulating out-of-state transactions between entities with no connection to the state. Because HDA has failed to establish that the Act is discriminatory, and because the Act only directly regulates transactions that occur in Connecticut, HDA cannot establish a likelihood of success on its dormant Commerce Clause claim.

C. HDA's other arguments lack merit.

1. HDA ignores *Pork's* teaching that the dormant Commerce Clause does not protect particular business models.

HDA also argues that the District Court incorrectly held that "the dormant Commerce Clause does not 'protect[] the particular structure' or methods 'of operation' of a given industry." HDA Brief at 36 (quoting, alteration in original, A137–38 (citing *Flynt*, 131 F.4th at 928 (in turn quoting *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978)))).

But in *Pork*, the Court could not have been clearer: absent discrimination or protectionism, a state may enact a law applicable within the state's jurisdiction that otherwise has an extraterritorial

effect, even if it burdens out-of-state business practices and financial interests. That is exactly what the Court blessed in *Pork*—a state law that required all pork producers that sold their products in the state to comply with certain requirements, even though those requirements affected the business practices and finances of out-of-state businesses.[19] Undoubtedly, HDA's members have created a business model that furthers their financial interests. But a state is not prevented from acting just because it might disrupt a particular method of doing business. Nor may a business that operates in a particular state insulate itself from those state's laws based on how the business set up its market. To the contrary, there are many businesses that both have a nationwide (or worldwide) presence yet still must comply with state law. *Pork* shows the way:

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[19] *See Pork*, 598 U.S. at 367 (petitioner's alleged that "[m]uch of pork production today is vertically integrated, too, with farmers selling pigs to large processing firms that turn them into different 'cuts of meat' and distribute the 'different parts . . . all over to completely different end users,'" with changes to this system to comply with the law at issue "requir[ing] certain processing firms to make substantial new capital investments" that will raise costs primarily on out-of-state firms because "California imports almost all the pork it consumes"); *id.* at 371 (irrelevant that "the law will impose substantial new costs on out-of-state pork producers who wish to sell their products in California").

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

Pork, 598 U.S. at 374-75 (internal citations and quotation marks omitted). HDA asks this court to conclude that Connecticut is powerless to act with respect to the prices of identified drugs sold within its borders because the distributors and manufacturers have established a pricing system where they make the decisions for Connecticut's people outside of Connecticut. And HDA suggests—in a parade of horribles about the Act's hypothesized effects on national markets—that this situation must continue because the Act, if enforced, would "open a Pandora's box" from

which would escape conflicting laws that "fragment national markets and force interstate businesses to navigate different sets of rules." HDA Brief at 45. But *Pork* does not require Connecticut to sit on the sidelines, and this Court should decline to accept HDA's argument.

2. HDA cannot rely on the drug price cap cases it cites.

The State acknowledges that the cases considering state drug price caps over the years have not been uniformly decided, and HDA relies on several cases that found drug price caps unconstitutional. HDA Brief at 30-33. However, all but one of the drug price cap decisions relied on by HDA were decided before *Pork*. *See Ass'n for Accessible Meds. v. Ellison*, 140 F.4th 957 (8th Cir. 2025); *Frosh*, 887 F.3d 664; *Healthcare Distribution All. v. Zucker*, 353 F. Supp. 3d 235 (S.D.N.Y. 2018); *Pharm. Rsch. & Mfrs. of Am. v. Dist. of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005); *Pharm. Rsch. & Mfrs. of Am. v. Comm'r, Me. Dep't of Human Serv.*, Civil No. 00-157-B-H, 2000 U.S. Dist. LEXIS 17363 (D. Me. Oct. 26, 2000). The courts issuing those decisions did not have the benefit of the Supreme Court's *Pork* analysis instructing that antidiscrimination and non-protectionism lie at the very core of the dormant Commerce Clause analysis, even when a state law has extraterritorial consequences. And

even in those pre-*Pork* cases, there was disagreement with the pure extraterritoriality argument, which *Pork* later rejected and which HDA pursues now. *See, e.g.*, *Frosh*, 887 F.3d at 674-93 (Wynn, J., dissenting); *see also Pharm. Rsch.*, 2000 U.S. Dist. LEXIS 17363, at *8-16, *rev'd sub nom. Concannon*, 249 F.3d at 79-83, *aff'd sub nom. Walsh*, 538 U.S. 668-670.

Of all these drug price cap cases, HDA relies most heavily on *Frosh*, devoting over a page to comparing this case to it and claiming that "[t]he Supreme Court cited *Frosh* with approval" in *Pork*. HDA Brief at 30-32 (discussing *Frosh*, 887 F.3d 664). But as explained in Section I.B, *Frosh* does not support HDA here even if it is still correctly reasoned after *Pork*. The state law in *Frosh* directly controlled out-of-state transactions by imposing liability on the out-of-state parties to them even when the transaction did not occur in state. *Frosh*, 887 F.3d at 671-72. The Act only applies to in-state transactions and so does not directly control any out-of-state conduct. Further, the Supreme Court did not adopt *Frosh's* reasoning wholesale; it cited *Frosh* only once and for a narrow point: as an example of a court that read *Healy*, *Brown-Forman*, and *Baldwin* the same way that the Supreme Court did in *Pork*. *Pork*, 598 U.S. at 374. As

explained above, this reading required a state price control statute directed at in-state prices but with extraterritorial effects to be protectionist for it to violate the dormant Commerce Clause.

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

As Chief Judge Kendall explained in the most recent drug price cap case of which the State is aware, "[t]his is a misreading of [*Pork*]." *Raoul*, 2025 U.S. Dist. LEXIS 190215, at *13.[20] Instead, "[t]he 'specific

[20] *Raoul* involved a challenge to Illinois' drug price cap law, and Chief Judge Kendall found that the plaintiff (a drug trade association representing generic drug manufacturers and distributors) had failed to make the necessary showing of a likelihood of success on the merits to

impermissible extraterritorial effect' [*Pork*] observed of the state laws at issue in the *Baldwin-Healy* cases was that each 'deliberately prevented out-of-state firms from undertaking competitive pricing or deprived businesses and consumers in other States of whatever competitive advantages they may possess.'" *Id.* (quoting *Pork*, 598 U.S. at 374). "In other words, they were discriminatory and protectionist. Thus, the *Ellison* court's conclusion that the Minnesota law was unconstitutional simply because it impacted the price of out-of-state transactions again 'reads too much' into the *Baldwin-Healy* cases." *Id.* at *13-14 (quoting *Pork*, 598 U.S. at 373). That is, as Chief Judge Kendall correctly

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warrant a preliminary injunction based on a thorough reading and comprehensive application of *Pork*. *See Raoul*, 2025 U.S. Dist. LEXIS 190215, at *6-17. Chief Judge Kendall read *Pork* the same way the State does here, as limiting extraterritoriality claims to discriminatory laws. *See id.* at *10 ("[A] closer examination of [*Baldwin*, *Brown-Forman*, and *Healy*] reveals three laws that were plainly designed either to protect an in-state industry . . . or to hoard commerce for in-state merchants[.]"). And Chief Judge Kendall further observed that the Illinois law did not discriminate against out-of-state interests but rather regulated the price of drugs sold in Illinois without regard for their place of manufacture, and thus in no way favored local manufacturers or discouraged consumers from engaging across state lines. *Id.* at *10-11. As a result, she found the plaintiff's extraterritoriality argument under the dormant Commerce Clause to be unpersuasive in light of *Pork* and concluded the plaintiff had failed to show a likelihood of success on the merits. *Id.* at *17.

concluded, *Ellison* got *Pork* wrong. The State respectfully urges this Court, after considering the language of *Pork*, to conclude the same.

Further, *Ellison* provides little guidance here because the Minnesota law in that case is very different from the Act. The Minnesota law penalized out-of-state entities based only on their conduct out of state. *Ellison*, 140 F.4th at 960 (under the law, "a Colorado manufacturer would be penalized if it sold drugs to a New Jersey distributor at prices above those proscribed by the [Minnesota law] and those drugs ended up in Minnesota"). It was thus "nearly identical" to the law in *Frosh*. *Id.* As discussed in Section I.B, however, Connecticut's Act does not penalize any manufacturer or distributor for selling drugs outside of Connecticut at a price above the reference price, even if those drugs are later sold in Connecticut. The only transactions the Act considers are sales made in Connecticut, and any liability under the Act is imposed only on the parties to that in-state sale. Even if the *Ellison* court were correct about *Pork*, then, *Ellison* would not support HDA's merits argument.

3. HDA's three-paragraph argument that the Act violates the Equal Protection Clause and due process is inadequately briefed and insufficient to satisfy the standard for a preliminary injunction.

The lion's share of HDA's arguments about likelihood of success on the merits (and cases cited in support thereof) focus on the Commerce Clause. But HDA's brief also contains three throwaway paragraphs raising different claims. One argues that the Act is an unconstitutional arbitrary classification under the Equal Protection Clause. HDA Brief at 46-47. The next argues that the Act violates due process by penalizing distributors for pricing decisions made by manufacturers. HDA Brief at 47. And the last argues that the legislative record and "common sense" suggest that the General Assembly did not intend for the Act to be limited to sales that occurred in Connecticut. HDA Brief at 47-48.

The Court should not consider these claims because HDA has not adequately briefed them. *See Debique v. Garland*, 58 F.4th 676, 684 (2d Cir. 2023) ("We consider abandoned any claims not adequately presented in an appellant's brief, and an appellant's failure to make legal or factual arguments constitutes abandonment.") (internal quotation marks omitted); *United States v. Botti*, 711 F.3d 299, 313 (2d Cir. 2013) ("It is a settled . . . rule that issues adverted to in a perfunctory manner,

unaccompanied by some effort at developed argumentation, are deemed waived.") (internal quotation marks omitted); *Sioson v. Knights of Columbus*, 303 F.3d 458, 459-60 (2d Cir. 2002) (dismissing appeal because the brief, "in lieu of an argument" furnished only "a precis on the law," developed "not one contention," and constituted "a doctrinal recapitulation masquerading as a legal argument") (internal citations, quotation marks, and footnote omitted).[21]

HDA also presented its non-Commerce Clause arguments to the District Court in three short paragraphs, but in the District Court those arguments were based only on the territorial limitations on state power contained in the Due Process Clause of the Fourteenth Amendment. A005, ECF No. 27-1 at 18-19; A133 n.5. Now, HDA advances new constitutional arguments involving different constitutional provisions

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[21] Even had HDA adequately briefed these additional constitutional claims, its arguments do not survive a cursory review. For example, HDA claims that the Act arbitrarily affects only its members, ignoring that it still applies to manufacturers who may sell certain drugs in Connecticut. And HDA, in claiming that applying the Act to them is arbitrary because they do not "actually control prices," HDA Brief at 46-47, implausibly characterizes its distributor members as entities who purchase drugs from manufacturers and sell these drugs to retailers without increasing the price of these drugs to cover their distribution costs or generate a profit.

and different theories (still in three paragraphs). HDA has waived these new arguments. *Bogle-Assegai v. Connecticut*, 470 F.3d 498, 504 (2d Cir. 2006) ("[I]t is a well-established general rule that an appellate court will not consider an issue raised for the first time on appeal." (alteration in original, internal quotation marks omitted)); *see also Wal-Mart Stores, Inc. v. Visa U.S.A. Inc.*, 396 F.3d 96, 124 n.29 (2d Cir. 2005) ("The law in this Circuit is clear that where a party has shifted his position on appeal and advances arguments available but not pressed below, . . . waiver will bar raising the issue on appeal." (internal quotation marks omitted)). "Although waiver is a prudential rule, 'the circumstances normally do not militate in favor of an exercise of discretion to address new arguments on appeal where those arguments were available to the parties below and they proffer no reason for their failure to raise the arguments below.'" *Agarunova v. Stella Orton Home Care Agency, Inc.*, 794 F. App'x 138, 140 (2d Cir. 2020) (quoting *In re Nortel Networks Corp. Sec. Litig.*, 539 F.3d 129, 133 (2d Cir. 2008)).

The District Court correctly dismissed the versions of HDA's non-dormant Commerce Clause arguments presented to it. This Court should do the same for the new arguments HDA makes on appeal.

II. HDA Has Failed to Establish Irreparable Harm.

HDA recognizes that "the District Court did not make findings on the remaining preliminary injunction factors" because it determined that HDA was unlikely to succeed on the merits. HDA Brief at 49. It asks this Court to make those findings in the first instance and direct the District Court to enjoin the Act. *Id.* But because HDA still cannot establish a likelihood of success on the merits, this Court ought to affirm the District Court. *See Cty. of Nassau v. Leavitt*, 524 F.3d 408, 414 (2d Cir. 2008) (when "moving party seeks a preliminary injunction that will affect government action taken in the public interest pursuant to a statutory or regulatory scheme, the injunction should be granted only if the moving party meets the more rigorous likelihood-of-success standard"). And even if this Court proceeds further, HDA cannot establish that the Act causes its members irreparable harm or that the balance of equities and public interest are in its favor.

For HDA to establish irreparable harm, it must demonstrate that, absent a preliminary injunction, its members will suffer an actual and imminent injury that cannot be remedied if a court waits until the end of trial to resolve the harm. *Nat'l Ass'n for Gun Rights v. Lamont*, 153 F.4th

213, 248 (2d Cir. 2025). HDA argues that its members face three forms of irreparable harm sufficient to justify a preliminary injunction, one based on the alleged violation of its members' constitutional rights, another based on monetary loss, and a third based on alleged disruption to its members' businesses.

At the outset, though, HDA's delay in bringing this case undercuts their argument. Courts "should generally consider delay in assessing irreparable harm." *Tom Doherty Associates, Inc. v. Saban Entertainment Inc.*, 60 F.3d 27, 39 (2d Cir. 1995). That is because a preliminary injunction implies an "urgent need for speedy action to protect the plaintiffs' rights." *Citibank, N.A. v. Citytrust*, 756 F.2d 273, 276 (2d Cir. 1985). "Delay in seeking enforcement of those rights . . . tends to indicate at least a reduced need for such drastic, speedy action." *Id.*

Here, the Act was signed by Governor Lamont on June 30, 2025. HDA filed suit on October 14, 2025—approximately three and a half months later. *See* A022. While "[t]here is no bright-line rule for how much delay is too much, . . . courts in this Circuit 'typically decline to grant preliminary injunctions in the face of unexplained delays of more than two months.'" *Beyond Gravity Sweden AB v. Ensign-Bickford Aero. & Def.*

Co., No. 3:24-CV-2021, 2025 U.S. Dist. LEXIS 29227, at *12 (D. Conn. Feb. 19, 2025) (quoting *Monowise Ltd. Corp. v. Ozy Media, Inc.*, 17-cv-8028 (JMF), 2018 U.S. Dist. LEXIS 75312, at *4 (S.D.N.Y. May 3, 2018) (collecting cases)); *see Weight Watchers Int'l v. Luigino's, Inc.*, 423 F.3d 137, 144 (2d Cir. 2005) ("We have found delays of as little as ten weeks sufficient to defeat the presumption of irreparable harm that is essential to the issuance of a preliminary injunction.").

HDA's delay is a strong sign that the Act has not, and will not, cause its members irreparable harm. HDA claimed in its complaint that the potential enforcement of the Act would cause it "imminent" injury. A024-25 ¶ 7. On that basis, it sought expedited review of the Act in the District Court, A005, ECF No. 31, and before this Court, Dkt. No. 6. And at oral argument before the District Court on December 9, 2025, HDA argued that it would suffer immediate injury in January 2026 from the Act. A100-01 ("[A]s of January 1, 2026, distributors that have purchased drugs throughout 2025 at higher than the reference price WAC, because the WAC went up in 2025, they are sitting with inventory they will have to sell January 1, 2026, at reference price, which is lower. So that is an imminent, immediate injury. That's why we are here in December as

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

Yet HDA's brief, filed on January 14, 2026, does not mention whether the imminent and irreparable injury it prophesied in December 2025 actually occurred in January 2026, even though HDA chose to introduce new facts on appeal about other issues. *Compare* A138 n.8 (District Court noting that HDA did not provide specific facts about how WAC has increased in 2025 or how those WAC increases compared to the consumer price index), *with* HDA Brief at 50-51 n.13 (introducing new WAC price increase and consumer price index data responding to District Court's criticism). Instead, HDA only vaguely references that its members face a Hobson's choice without discussing whether the Act actually affected monetarily any of its members as of January 14, 2026. HDA Brief at 16-17; 50-51. HDA's conduct thus suggests there is no imminent, irreparable injury here.

Even without this Court considering delay, HDA's irreparable harm arguments fail. HDA first claims that, in the Second Circuit, an alleged violation of a constitutional right automatically triggers a finding of irreparable injury. HDA Brief at 50. But as discussed above, HDA has

failed to establish a likelihood of success on its constitutional claims, so there necessarily cannot be a presumption of irreparable harm on that basis. Regardless, HDA paints an incomplete picture because "the Second Circuit has 'not consistently presumed irreparable harm in cases involving allegations of the abridgement of' constitutional rights." *Chan v. United States DOT*, No. 23-cv-10365 (LJL), 2024 U.S. Dist. LEXIS 231658, at *153 (S.D.N.Y. Dec. 23, 2024) (quoting *Bronx Household of Faith v. Bd. of Educ.*, 331 F.3d 342, 349 (2d Cir. 2003)) (collecting cases); *see Lamont*, 153 F.4th at 248 ("To be sure, we have presumed irreparable harm for alleged deprivations of certain constitutional rights. . . . But the Supreme Court has never applied this presumption outside the First Amendment context. . . . And even in that context, our Court has not axiomatically applied the presumption[.]" (internal citations omitted)).

Instead, courts in the Second Circuit "have identified two primary exceptions in which alleged violations of constitutional rights are not presumed to be irreparably injurious: violations of non-personal constitutional rights and constitutional injuries that are compensable by money damages." *Chan*, 2024 U.S. Dist. LEXIS 231658, at *154 (collecting cases). Cases where courts have held that a constitutional

deprivation equals an irreparable harm are almost entirely restricted to infringement of personal rights that cannot be remedied by any subsequent relief. *Id.* at *155 (collecting cases). In contrast, a violation of "structural rights," such as those that allocate power to the states, does not necessarily injure at all, let alone cause irreparable injury. *Id.* at *155-56 (collecting cases). And "[t]he Commerce Clause . . . concern[s] the division of power between the states and the federal government and therefore enshrine[s] structural, rather than personal, rights." *Id.* at *156-57 (collecting cases). Therefore, contrary to HDA's contention, irreparable harm "cannot be presumed" with respect to its dormant Commerce Clause claim. *See id.* at *157; *see also USA Recycling v. Town of Babylon*, 66 F.3d 1272, 1295 (2d Cir. 1995) (in a preliminary injunction matter challenging a state law under the dormant Commerce Clause, concluding that "[b]ecause the record supports the district court's determination that plaintiffs' alleged injuries would be entirely financial—and therefore remediable by an award of money damages—we cannot say that the district court clearly erred when it found that the plaintiffs had not demonstrated irreparable harm.").

HDA claims that this Court has "applied" an automatic irreparable injury rule in the dormant Commerce Clause context. HDA Brief at 50 (citing only *Variscite NY Four, LLC v. N.Y. State Cannabis Control Bd.*, 152 F.4th 47, 60 (2d Cir. 2025)). In *Variscite*, this Court did note that "[w]hen, as here, a plaintiff alleges constitutional injury, 'a strong showing of a constitutional deprivation that results in noncompensable damages ordinarily warrants a finding of irreparable harm.'" 152 F.4th at 60 (quoting *A.H. ex rel. Hester v. French*, 985 F.3d 165, 176 (2d Cir. 2021), which involved only a personal right claim under the Free Exercise Clause). But the *Variscite* court did not actually apply this rule to a dormant Commerce Clause claim despite finding that the plaintiffs were likely to succeed on the merits. The Court instead determined that the district court erred in its merits analysis and in "assessing the remaining preliminary injunction factors under the assumption that Variscite would not suffer a constitutional injury." *Id.* at 66. It then vacated the district court's denial of a preliminary injunction and remanded "for further proceedings consistent with this opinion" without discussing the remaining injunction factors or ordering the district court to enter an injunction (the relief HDA requests here). *Id.* In *Variscite*, then, this

Court found a likelihood of success of the merits on a dormant Commerce Clause claim but did not itself apply any automatic irreparable injury rule, demonstrating that irreparable harm cannot be presumed as to HDA's dormant Commerce Clause claim

Additionally, "even when personal constitutional rights are violated and the harm that accompanies the violation is remediable or compensable, the damage is not irreparable." *Chan*, 2024 U.S. Dist. LEXIS 231658, at *157 (internal quotation marks omitted) (collecting cases). This addresses the second form of harm HDA alleges: a loss of money either through selling drugs at the Act's reference price, which may be below the prevailing WAC, or the payment of civil penalties after selling drugs above the reference price. *See* HDA Brief at 50-51.[22] But in the Second Circuit, it "has always been true that irreparable injury

[22] Although HDA mentions the Act's criminal penalties, it does not rely on those penalties for its "irreparable harm" argument. *See* HDA Brief at 39-41. And for good reason. Those penalties arise when individual officers or employees of HDA's members "wilfully" fail to comply with certain provisions of the Act. HDA does not claim to have standing to assert claims on behalf of the individual officers or employees of its members, and at this point, the imposition of such a penalty would be based on potential facts and circumstances that are too remote or speculative to necessitate the issuance of a preliminary injunction. *See Lamont*, 153 F.4th at 248.

means injury for which a monetary award cannot be adequate compensation and that where money damages is adequate compensation a preliminary injunction will not issue." *Jackson Dairy, Inc. v. H. P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979).

HDA's answer to that is that Connecticut's sovereign immunity and/or the Eleventh Amendment are an obstacle to any compensation. HDA Brief at 52. Of course, the State does not waive Connecticut's Eleventh Amendment immunity and cannot waive Connecticut's sovereign immunity. *See State v. Lombardo Bros. Mason Contractors*, Inc., 307 Conn. 412, 462 (2012). That being said, Connecticut's legislature has established a process for potential resolution of money claims against the state via the Office of the Claims Commissioner. *See generally* Conn. Gen. Stat. § 4-141 *et seq.* ("Claims Against the State"). So again, HDA's claim of monetary loss is insufficient to support a preliminary injunction.

Nor has HDA established that "changing the F.O.B. Destination term of delivery in distributors' customer contracts" would constitute irreparable harm. HDA Brief at 52. HDA claims that changing this contractual term would create the irreparable harm of "a '[m]ajor disruption of [distributors'] business.'" *Id.* (quoting, alterations in

original, *Nemer Jeep-Eagle, Inc. v. Jeep-Eagle Sales Corp.*, 992 F.2d 430, 435 (2d Cir. 1993)). Yet the only case HDA cites for this proposition, *Nemer*, reveals that a major disruption of business does not, on its own, establish irreparable injury; a disruption to a business can "constitute irreparable injury" when the disruption is so severe that it threatens "the continued existence of a business." *Nemer*, 992 F.2d at 435 (internal quotation marks omitted). Unlike the movant in *Nemer*, HDA has offered no evidence that the Act "seriously threaten[s] its continued existence and that money damages are inadequate compensation for such loss." *Id.* at 436. So HDA has failed to establish irreparable harm from any business disruption.

III. The Balance of Equities and the Public Interest Both Favor Affirming the District Court's Denial of a Preliminary Injunction.

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

omitted); *see United States SEC v. Citigroup Glob. Mkts., Inc.*, 673 F.3d 158, 163 n.1 (2d Cir. 2012) ("[W]hen a court orders injunctive relief, it should ensure that injunction does not cause harm to the public interest.").

An allegation of constitutional harm does not conclusively determine the balance-of-the-equities inquiry. *Lamont*, 153 F.4th at 249. Rather, when the government is a party to the suit, the inquiries into the public interest and the balance of the equities merge, and a court should pay special attention to the public consequences of any injunction. *We the Patriots USA*, 17 F.4th at 279, 295.

HDA's interests are vastly outweighed by the State's. The Second Circuit has recognized the harm governments suffer when enjoined from effectuating statutes enacted by the people's representatives. *See id*. at 295; *see also Trump v. CASA, Inc.*, 606 U.S. 831, 861 (2025) ("'[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury'") (quoting, alteration in original, *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers)). In this scenario, HDA's purported interest is not just outweighed by the public's interest, it conflicts with

the public's interest. That is, HDA is focused on the financial burdens its members may face if they are required to alter their current business practices. But as discussed above, those business practices have created a world in which people now face skyrocketing drug prices that put critical medications out of reach. The State's interest in the Act, on the other hand, is to improve the health and lives of Connecticut's residents by protecting them from oppressive drug price increases that have no purpose other than the amassing of wealth at the expense of those residents. This is not a close call: the balance of equities and public interest weigh strongly in favor of the Act.

CONCLUSION

For the foregoing reasons, the State respectfully requests that the Court affirm the District Court's decision.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

As required by Federal Rule of Appellate Procedure (FRAP) 32(g)(1), I hereby certify that this brief complies with the type-volume limitations of FRAP 32(a)(7)(B), as modified by Second Circuit Local Rule 32.1(a)(4), in that this brief contains 13,895 words, excluding the parts of the brief exempted by FRAP 32(f). I further certify that this brief complies with the typeface requirements of FRAP 32(a)(5) and the type style requirements of FRAP 32 (a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point Century Schoolbook font.

/s/ Patrick T. Ring
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Dated: March 2, 2026

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of March, 2026, I caused the foregoing brief to be filed electronically with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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