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

HEALTHCARE DISTRIBUTION ALLIANCE, : CIVIL ACTION NO.

3:25-cv-01724-OAW

Plaintiff,

MARK D. BOUGHTON, in his official capacity

v.

as Commissioner of the Connecticut
Department of Revenue Services, and

Department of Revenue Services, and : WILLIAM TONG, in his official capacity as : Attorney General for the State of Connecticut, :

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Defendants. : November 17, 2025

# <u>DEFENDANTS' MEMORANDUM IN OPPOSITION TO</u> PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

#### I. INTRODUCTION

Over two millennia ago, Hippocrates proclaimed that "Wherever the art of medicine is loved, there is also a love of humanity." Flash-forward to today, however, and members of 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 it 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 the Public Act 25-168 §§ 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, Healthcare Distribution Alliance (HDA), nevertheless sued, asking the Court to declare the Act unconstitutional and enjoin its implementation and enforcement. As part of that effort, HDA now moves for a preliminary injunction (PI Motion), Dkt. #27, based on its claim that the Act violates the dormant Commerce Clause. But because the Supreme Court has rejected the dormant Commerce Clause theory that HDA proposes, HDA is unlikely to succeed on the merits. The financial harm that HDA purports its members will suffer is not irreparable. And the equities weigh heavily in favor of the defendants. The Court should deny HDA's PI Motion.

#### II. **BACKGROUND**

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. Memo. of Law in Support of Pl.'s Mot. for a Preliminary

<sup>&</sup>lt;sup>1</sup> The Act defines "identified prescription drugs" as (1) generic drugs or interchangeable biological products; or (2) brand-name drugs or biological products to which all exclusive marketing rights granted under the Food, Drug, and Cosmetic Act have expired for at least twenty-four months. PA 25-168 § 345(6). Under the Act, see PA § 345(1), a "biological product" has the same meaning that as provided in Section 20-619 of the Connecticut General Statutes, which in turn gives "biological product" the same meaning as that under the 42 U.S.C. § 262, the Public Health Services Act. See 42 U.S.C. § 262(i)(1) ("The term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."); see also Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 6 (2017) ("A biologic is a type of drug derived from natural, biological sources such as animals or microorganisms. Biologics thus differ from traditional drugs, which are typically synthesized from chemicals.").

Injunction, Dkt. # 27-1 (PI Memo), p. 4. 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. *Id.* <sup>2</sup> Dispensers provide patients with the identified drugs when prescribed. *Id.* 

The manufacturers' "list price" for drugs is also known as the "Wholesale Acquisition Cost" (WAC). Id., pp. 1 & 4; see 42 U.S.C. § 1395w-3a(c)(6)(B) ("The term 'wholesale acquisition cost' means . . . the manufacturer's list price for the drug or biological to wholesalers . . ., not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data."). Manufacturers, not distributors, set the WAC. PI Memo, p. 1 & 4. Distributors often pay less than the WAC by leveraging their market share or sales volume to obtain discounts. <sup>3</sup> 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)

<sup>&</sup>lt;sup>2</sup> HDA is a trade association for distributors. PI Memo, p. 1; Complaint, Dkt. # 1 ¶ 14.

<sup>&</sup>lt;sup>3</sup> Follow the Pill: Understanding the U.S. Commercial Supply Chain, The Kaiser Family Foundation (March 2005), p. 18 ("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."), available at https://www.kff.org/wp-content/uploads/2013/01/follow-the-pillunderstanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf. The Court may take notice of this information, and other information presented here as background, to provide context because "District Courts may take judicial notice of facts 'not subject to reasonable dispute' when they 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Kravitz v. Tavlarios, No. 20-2579-cv, 2021 U.S. App. LEXIS 34224, at \*8-9 (2d Cir. Nov. 18, 2021) (quoting Fed. R. Evid. 201(b)(2)).

(discussing how prescription drugs "move through a complex distribution chain where pharmaceutical manufacturers typically sell their products to wholesalers at a negotiated price."). When dispensers purchase identified drugs from distributors, they negotiate the price such that individual dispensers may pay different prices when purchasing from the same distributor.4

It is undisputed that millions of Americans, including Connecticut residents, rely on prescription drugs to maintain their health and very lives.<sup>5</sup> And 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."

<sup>&</sup>lt;sup>4</sup> Flow of Money through the Pharmaceutical Distribution System, USC Leonard D. Schaeffer Institute for Public Policy & Government Service (June 2017), p. 2 ("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."), available at https://schaeffer.usc.edu/wp-content/uploads/2024/10/The-Flow-of-Money-Throughthe-Pharmaceutical-Distribution-System Final Spreadsheet.pdf.

<sup>&</sup>lt;sup>5</sup> See Cost Growth Benchmark Initiative Report, Connecticut Office of Health Strategy (April 24, 2025) (OHS Report), p. 51 ("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."), available at <a href="https://portal.ct.gov/ohs/-/media/ohs/cost-growth-">https://portal.ct.gov/ohs/-/media/ohs/cost-growth-</a> benchmark/benchmark-reports-py2023/ohs-hcbi-cost-growth-benchmark-reportpy2023-rev-04 24 2025.pdf; cf. PI Memo, Declarations of Martin Igel, Christopher Reed, and Chris Van Norman.

<sup>&</sup>lt;sup>6</sup> Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An* Overview of Stakeholders and Relationships, RAND Corp. (Oct. 27, 2021), p. 2, available at https://www.rand.org/pubs/research reports/RRA328-1.html).

<sup>&</sup>lt;sup>7</sup> FTC, How to Get Generic Drugs and Low-Cost Prescriptions, October 2023 (available at https://consumer.ftc.gov/articles/generic-drugs-low-cost-prescriptions).

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) (Raoul). Those skyrocketing prices stem from a variety of causes, including a lack of competition within the industry.<sup>8</sup> This situation has been well documented across the country. Connecticut residents have not been spared, feeling the pain sharply.10

https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf; U.S. Government Accountability Office, Report to Congressional Requesters, Generic Drugs Under Medicare (Aug. 2016) (noting the "extraordinary price increase" for some generic drugs), available at https://www.gao.gov/assets/gao-16-706.pdf; Andrew Pollack, Drug Goes from \$13.50 a Tablet to \$750, Overnight, NY Times (Sept. 20, 2015), available at https://www.nytimes.com/2015/09/21/business/a-huge-overnightincrease-in-a-drugs-price-raises-protests.html.

<sup>&</sup>lt;sup>8</sup> See Ellen Andrews, Ph.D., Connecticut Is a National Leader in Fight to Control Drug Costs, CT News Junkie (July 3, 2025) ("But price fixing and collusion are not the only way generic drug prices are kept artificially high. Too often, even when drug patents expire, no company comes forward to create a competitor medication." (discussing Martin Shkreli, who bought the manufacturer of Daraprim and then raised the price by 5,000%, even though the drug was developed in the 1950s)), available at https://ctnewsjunkie.com/2025/07/03/analysis-connecticut-is-a-national-leader-infight-to-control-drug-costs/.

<sup>&</sup>lt;sup>9</sup> See, e.g., Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 674 (4th Cir. 2018) (Frosh) (Wynn, J., dissenting) ("After a 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, the Maryland legislature enacted legislation prohibiting 'unconscionable' price increases for certain generic drugs 'made available for sale' to Maryland consumers."); U.S. Senate Special Committee on Aging. Sudden Price Spikes in Off-Patent Prescription Drugs (Dec. 2016), available at

<sup>&</sup>lt;sup>10</sup> See OHS Report, supra, p. 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) ("Drug costs for hospitals in Connecticut rose as 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."), available at https://www.ctinsider.com/business/article/new-laws-target-rising-prescription-drug-

To help alleviate that pain, in 2025, Connecticut entered the fray<sup>11</sup> by enacting, among other things, <sup>12</sup> a drug price cap. Public Act 25-168 §§ 345 to 347. Starting on January 1, 2026, no manufacturer or distributor shall "sell an identified 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 cost of identified drugs to their WAC, adjusted for inflation. <sup>13</sup>

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<sup>&</sup>quot;I Governor Lamont Announces 2025 Legislative Proposal: Reduce Prescription Drug Costs (Feb. 2, 2025), available at <a href="https://portal.ct.gov/governor/news/press-releases/2025/02-2025/governor-lamont-announces-2025-legislative-proposal-reduce-prescription-drug-costs?language=en\_US; New Connecticut laws, CT Insider, supra ("Lamont plans an official ceremony . . . to highlight the newly approved package of a dozen new measures aimed at drug costs, which earned bipartisan support."); Connecticut Is a National Leader, CT News Junkie, supra ("This year, Connecticut passed meaningful laws to control stubbornly-high prescription drug prices.").

<sup>&</sup>lt;sup>12</sup> See also PA 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); § 6 (authorizing the Commissioner of Economic and Community Development to use certain bond proceeds to support prescription drug production capacity in Connecticut); §§ 9-18 (authorizing a study on the feasibility of establishing a Canadian prescription drug importation program "to reduce prescription drug costs in the state.").

<sup>&</sup>lt;sup>13</sup> See Connecticut Is a National Leader, CT News Junkie, supra ("The Governor's generic drug price proposal that passed in Connecticut's big budget bill . . . caps future increases at the level of general inflation."); Ed Silverman, Generic drugmakers seek to thwart a Connecticut law that would cap rising prices, Stat+ (Oct. 27, 2025) ("The law, which goes into effect in January, prohibits drugmakers from raising the prices of their medicines above the inflation rate."), available at Generic drugmakers seek to thwart a Connecticut law that would cap rising prices | STAT.

A manufacturer or distributor that violates the Act then becomes liable to the state for a civil penalty, which is imposed, calculated, and collected by the Commissioner of Revenue Services. *Id.* § 346(b)(1). However, the Act exempts from its requirements 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 administrative and judicial relief with respect to such penalties. *Id.* § 346(f) & (g). There is nothing in the Act that discriminates against out-of-state persons or entities or furthers any protectionist goals. *See generally id.* §§ 345 to 347.

HDA filed suit on October 14, 2025, seeking to invalidate Connecticut's efforts to protect its residents by alleging that the Act violates the dormant Commerce Clause, the Due Process Clause, the Contracts Clause, the Supremacy Clause, and 42 U.S.C. § 1983. Complaint, Dkt. # 1. HDA brings this action on behalf of its member distributors, claiming that those members "face imminent and irreparable injury from the Drug Price Cap," which essentially boils down to making less money if they comply with the Act (or facing the Act's penalties if they do not). *Id.* ¶¶ 7, 14; *see* PI Memo, pp. 17-19.

HDA now asks this Court to preliminarily enjoin the defendants from implementing or enforcing the Act against any of HDA's members. *See generally* PI Memo. It does so based on the contention that the Act violates the dormant Commerce Clause "and additional constitutional principles."

### III. LEGAL STANDARD

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) (internal quotation marks omitted). "A plaintiff seeking a

preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Gazzola v. Hochul*, 88 F.4th 186, 194 (2d Cir. 2023) (internal quotation marks omitted). These requirements are "demanding" because a preliminary injunction is never awarded as of right and should not be routinely granted. *Daileader v. Certain Underwriters at Lloyds London Syndicate 1861*, 96 F.4th 351, 356 (2d Cir. 2024); *We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 279 (2d Cir. 2021). An allegation of constitutional harm does not conclusively determine balance-of-the-equities inquiry. *Nat'l Ass'n for Gun Rights v. Lamont*, 153 F.4th 213, 2025 U.S. App. LEXIS 21570 at \*65 (2d Cir. 2025). Rather, when the government is a party to the suit, the inquiries into the public interest and the balance of the equities merge, and "courts should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *We the Patriots USA*, 17 F.4th at 279 & 295 (internal quotation marks omitted).

### IV. ARGUMENT

In its PI Memo, HDA raises Commerce Clause arguments and theories that the Supreme Court recently rejected. *See Nat'l Pork Producers Council v. Ross*, 598 U.S. 356 (2023) (*Pork*). And remarkably, HDA relies on language from cases that *Pork* had to clarify or correct (or on incomplete language from *Pork* itself) to support its claim that Connecticut lacks the authority to protect the health of its citizens through the drug price cap. Because HDA is unlikely to succeed on the merits, the Court should deny the PI Motion on that basis alone.

HDA also has failed to demonstrate irreparable harm. HDA argues that its allegation of a violation of a constitutional right triggers an automatic finding of

irreparable injury. PI Memo, pp. 17-18. But because HDA is unlikely to succeed on the merits, its irreparable harm argument necessarily fails. Also, HDA's delay in suing indicates that its members are not facing the kind of irreparable harm that requires the urgent relief of a preliminary injunction. In any event, in this Circuit, there is no automatic presumption of irreparable harm based only on a claim of the abridgement of a constitutional right. Such a presumption arises only when the violations involve personal constitutional rights and injuries that are not compensable by money damages. The Commerce Clause enshrines structural, not personal, rights. And even if that were not the case, the harm here is a loss of money, for which HDA's members would have statutory avenues to seek compensation.

Finally, the public interest and balance of equities strongly favor the defendants. The purpose of the Act is to protect the health and lives of the Connecticut people. The purpose of requested injunction is to keep money flowing into the pockets of HDA's members at the expense of the health of the Connecticut people. Therefore, there is no real "public interest" that supports enjoining the Act, and the equities are as unbalanced as an ant and elephant on a seesaw. The Court should deny the HDA's Motion.

# A. HDA Is Unlikely to Succeed on the Merits of Its Claim that the Act Is Unconstitutional.

"Companies that choose to sell products in various States must normally comply with the laws of those various States." *Pork*, 598 U.S. at 364. 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."). That is the starting point of the analysis here.

1. The Act does not violate the dormant Commerce Clause because it is nondiscriminatory and not driven by economic protectionism.

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). This is the so-called dormant Commerce Clause. *Id*.

Under the dormant Commerce Clause, "no State may use its laws to discriminate purposefully against out-of-state economic interests." *Pork*, 598 U.S. at 364. But in *Pork*, the Supreme Court made it clear that the dormant Commerce Clause does not invalidate a state law just because it has extraterritorial effect. Rather, it is a principle that developed over time in circumstances where state laws 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 ultimately upheld a California law that *completely banned* the sale of pork products 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 364-67. 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 370-71. That lack of discrimination was fatal to the plaintiffs' "normal" dormant Commerce Clause challenge. *See id.* 

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 "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).

These *Pork* principles defeat HDA's dormant Commerce Clause arguments. Connecticut has passed a law prohibiting manufacturers and distributors from selling identified drugs in this state at a price that exceeds their reference price (i.e., WAC on a certain date), adjusted for inflation. The Act does not contain any facially discriminatory language, as it makes no distinction between in-state and out-of-state interests. It applies equally to all that do business in Connecticut, imposing the same burdens on any in-state and out-of-state manufacturers and distributors. And HDA does not claim that the Act evidences a discriminatory or protectionist intent or would have a discriminatory or protectionist effect. See generally PI Motion & Memo.<sup>14</sup> In short, the Act does not insulate in-state interests from the consequences of interstate commerce or further any economic protectionist goals with respect to the pharmaceutical industry in Connecticut. Therefore, HDA's challenge under the dormant Commerce Clause is unlikely to prevail. See Nat'l Shooting Sports Found., Inc. v. James, 144 F.4th 98, 113 (2d Cir. 2025) ("[T]he dormant Commerce Clause's scope is not absolute. . . . Rather, states retain broad power to legislate and regulate, even in ways that may bear adversely upon interstate commerce. . . . And courts are not to wield the dormant Commerce Clause as a roving license . . . to decide what activities are

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<sup>&</sup>lt;sup>14</sup> As discussed below, HDA apparently rejects the notion that *Pork* stands for the proposition that discrimination or protectionism must be shown to maintain a dormant Commerce Clause claim (i.e., that dormant Commerce Clause is inherently antidiscriminatory), *see* PI Memo, p. 15, even though *Pork* made clear that "[t]he antidiscrimination principle lies at the 'very core' of [the] dormant Commerce Clause jurisprudence[,]" *Pork*, 598 U.S. at 369.

appropriate for state and local government to undertake.") (internal citations and quotation marks omitted).

2. HDA's arguments in support of its dormant Commerce Clause claim conflict with or misconstrue the clear language of *Pork* and otherwise lack merit by raising immaterial distinctions between the facts here and those in *Pork*.

In *Pork*, the Court could not have been clearer: absent discrimination or protectionism, a state may enact laws applicable within the state's jurisdiction that otherwise have an extraterritorial effect, even if it burdens out-of-state business practices and financial interests. That is exactly what the Court blessed in *Pork*, namely, 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 practices and finances of out-of-state businesses.

Yet HDA inexplicably asserts that *Pork* does not require a showing of discrimination or protectionism to implicate the dormant Commerce Clause. *See, e.g.,* PI Memo, p. 15 (criticizing the *Raoul* decision for "erroneously" reading *Pork* "to require a showing of discrimination or protectionism (in addition to extraterritoriality)[.]"). Indeed, it seems that HDA is relying on the "almost *per se*" rule of extraterritoriality that the *Pork* Court rejected.

For example, HDA's first argument is that "states may not regulate transactions and pricing decisions that occur wholly outside the state," because "price control or price affirmation statutes' are invalid if they tie 'the price of . . . in-state products to out-of-state prices." PI Memo, p. 15 (quoting *Pork*, 598 U.S. at 374). So, under HDA's theory, manufacturers and distributors may (1) make pricing decisions about essential medications completely outside Connecticut, (2) enjoy the privilege of selling those

products in Connecticut, and (3) thumb their noses at Connecticut's nondiscriminatory pricing laws that are intended to help the people as a whole.

But in light of *Pork*, HDA's theory has no legal basis. In fact, the language HDA quoted from Pork was part of a broader discussion where the Court rejected the proposed "almost per se" rule that HDA appears to be championing now. See Pork, 598 U.S. at 373-74. In rejecting the "almost per se" rule, the Court was looking at the language from its earlier decisions in which the plaintiffs (like HDA) "read too much into too little." See id. And throughout that broader discussion, the Court emphasized that the decisions upon which the plaintiffs had relied for their extraterritoriality argument all involved discriminatory or protectionist state statutes. See id.; see also Baldwin v. G. A. F. Seelig, Inc., 294 U.S. 511 (1935) (New York laws that barred out-ofstate 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 Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573 (1986) (New York law required liquor distillers to affirm that their in-state prices were no higher than their out-of-state prices); Healy v. Beer Inst., 491 U.S. 324 (1989) (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. So that was the context of the Court's language that "[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." *Pork*, 598 U.S. at 74 (quoting *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003)). <sup>15</sup>

HDA's argument about tying the prices of in-state products to out-of-state products 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). But that is not the situation here. The Act provides no similar benefit

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<sup>&</sup>lt;sup>15</sup> HDA does this throughout the PI Memo, namely, quote portions of *Pork* where the Court is quoting language from earlier decisions that the plaintiffs relied on to support their "almost per se" rule. For example, on page 8 of the PI Memo, HDA states: "The Supreme Court has opined that 'whether a state law "is addressed only to [in-state] sales is irrelevant if the 'practical effect' of the law is to control" out of state prices." [sic]. But this is inaccurate. To begin with, the Court did not "opine" this in *Pork*. Rather, the Court was referencing the plaintiffs' observation that language from the Court's earlier decisions *suggested* the principle the plaintiffs were advocating. *See Pork*, 598 U.S. at 373. In fact, the PI Memo is even missing a citation and quotation marks, as *Pork* was not directly quoting *Brown-Forman* there, but instead was quoting the plaintiffs' brief (which, in turn, quoted *Brown-Forman*). *See Pork*, 598 U.S. at 373. Also, *Pork* quoted this language as part of the discussion concluding that the plaintiffs "read too much into too little" with respect to the Court's earlier decisions. And that is exactly what HDA is doing now, even using the same quotes from the same earlier decisions to make the same arguments that the Court rejected in *Pork*.

to local manufacturers or distributors.<sup>16</sup> It simply sets a price cap that applies to all such entities who do business in Connecticut.

Yet HDA considers this to be a "constitutional flaw" that "seeks to tie Connecticut prices to prices outside the state[.]" PI Memo, p. 9. The problem with that contention is that (unlike the situation in, say, *Healy*) there are no "Connecticut prices" vs. "out-of-state" prices in the first place. The price cap is based on the WAC, an amount that the manufacturers themselves establish *nationwide*. PI Memo, p. 4. Connecticut is not insisting that the WAC must be a particular number, nor is it directing that prescription drugs sold in Connecticut must 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 fix the price to the *national* WAC. Or put another way, the WAC *is* the Connecticut price, as well as that for all the states.

This very issue was recognized in *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001) (*Concannon*), aff'd sub nom., *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003) (*Walsh*), to which HDA references in support of its incorrect proposition that the Act violates the dormant Commerce Clause because it ties "in-state" prices to "out-of-state" prices. *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

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<sup>&</sup>lt;sup>16</sup> Indeed, HDA represents that "no member of HDA has any distribution facility inside Connecticut at all." PI Memo, p. 2. Given that statement, it is unclear how the Act could have *any* discriminatory or protectionist effect vis-à-vis HDA or its members.

<sup>&</sup>lt;sup>17</sup> HDA itself acknowledges that, under the business model that its members have created with manufacturers, "[a]ll the relevant pricing decisions are made outside Connecticut." PI Memo, p. 4.

ultimately rejected the plaintiff's "per se" extraterritorial reach argument under the dormant Commerce Clause, concluding that "Maine is 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.

HDA's parade of horribles about the Act's effects fares no better. Boiled down, HDA urges the Court to invalidate the Act because it would "disrupt the uniformity of the national pharmaceutical market." PI Memo, p. 11.<sup>19</sup> Undoubtedly, the

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<sup>&</sup>lt;sup>18</sup> 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 [Healy], 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.")

<sup>&</sup>lt;sup>19</sup> HDA relies on *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005) (*Pharm. Research v. DC*), *aff'd sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) here. But again, HDA ignores the import of *Pork*, which was decided almost twenty years later. In *Pharmaceutical Research*, the district court found that a District of Columbia act prohibiting excessive prices of prescription drugs had, inter alia, "a *per se* invalid extraterritorial reach in violation of the Commerce Clause as applied to transactions between manufacturers and wholesalers that occur wholly out of state." *Pharm. Research v. DC*, 406 F. Supp. 2d at 68. But as discussed above, *Pork* expressly rejected a *per se* rule. Even the dissent in *Pork* disavowed such a rule. *See Pork*, 598 U.S. at 394 ("I also agree with the Court's conclusion that our precedent does not support a *per se* rule against state laws with 'extraterritorial' effects.) (Roberts, C.J., dissenting in part). Therefore, *Pharmaceutical Research* is of little help to HDA.

manufacturers and distributors have created a business model that is advantageous to 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 is a myriad of businesses that both have a nationwide (or worldwide) presence yet still must comply with state law. Again, *Pork* shows the way:

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).<sup>20</sup>

Further, the national pharmaceutical market is not as uniform as HDA implies.

Although the WAC may be established nationwide, as noted above, the price of

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<sup>&</sup>lt;sup>20</sup> HDA dedicates a section of the PI Memo to arguing that *Pork* "confirms" that states may not regulate prices set out-of-state because *Pork* "did not involve a state price regulation statute," but rather "involved a California law barring sales of whole pork meat in California[.]" PI Memo, pp. 15-16. But *Pork* did not say that its holding applies to some types of dormant Commerce Claims and not others, nor did it say that the antidiscrimination principles that lie at the "very core" of its dormant Commerce Clause jurisprudence becomes irrelevant when the issue concerns the regulation of prices. And for good reason, as that would make no sense. Indeed, it would be absurd to hold that a state may to ban an entire product from its borders in a nondiscriminatory way yet be powerless to set nondiscriminatory prices for products that come into its jurisdiction.

identified drugs sold by distributors to dispensers is negotiated on a contract-bycontract basis. There is no standardized sale price, and therefore no national uniformity

To summarize, 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. But *Pork* does not require Connecticut to sit on the sidelines, and the Court should decline to accept HDA's argument.<sup>21</sup>

3. Based on the clear holdings of *Pork*, the most recent case to consider a state's drug price cap has denied the request for a preliminary injunction blocking the state law.

The defendants acknowledge that the cases considering state drug prices caps have not been uniformly decided. However, the most recent relevant case the defendants are aware of is *Raoul*, where Chief Judge Kendall concluded that, in a challenge to Illinois' drug price cap, the plaintiff (a drug trade association representing

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to be disrupted.

<sup>&</sup>lt;sup>21</sup> PI Motion and PI Memo do not invoke *Pike v. Bruce Church*, 397 U.S. 137 (1970) for the principle that a facially neutral state law that serves a legitimate local interest might violate the dormant Commerce Clause if the burden it imposes on out-of-state commerce is clearly excessive in relation to the local benefit. This is unsurprising, given the uncertain status of *Pike* and its application in a post-*Pork* world. *See Pork*, 598 U.S. at 377-89 (*Pike* discussion in Part IV-A is the Court's opinion, while *Pike* discussion in Parts IV-B, IV-C, and IV-D is Justice Gorsuch's opinion in which some other justices joined); *id.* at 391-94 (Sotomayor, J., concurring in part) (discussing *Pike*); *id.* at 394-403 (Roberts, C.J., concurring in part and dissenting in part) (discussing *Pike*); *id.* at 403 (Kavanaugh, J., concurring in part and dissenting in part (noting the Court's "fractured decision" with respect to *Pike*). In any event, because HDA does not raise *Pike* in the PI Motion, the defendants do not address it here.

generic drug manufacturers and distributors)<sup>22</sup> had failed to make the required showing of its likelihood of success on the merits based on a thorough reading and comprehensive application of *Pork. See Raoul*, 2025 U.S. Dist. LEXIS 190215, at \*6-17. And *Raoul* concerned essentially the same claims and arguments raised here. *See id.* at \*4-5 ("While [the] Complaint alleges six independent causes of action, the throughline is whether the Constitution permits Illinois to regulate the prices of wholly out-of-state sales. . . . [The plaintiff] asks the Court to enjoin the Act based on Count One of its Complaint, which alleges the Act violates the dormant Commerce Clause's prohibition against extraterritorial state legislation.").

Chief Judge Kendall stated that the plaintiff was relying on the "extraterritoriality principle" that the Supreme Court addressed in *Pork*. Id. at \*7-8. She noted that the case before her presented "an inverse" of the facts in *Pork*, because "[w]here the California law . . . regulated in-state commerce based on upstream conduct, the [Illinois] Act regulates upstream commerce based on downstream effects." *Id.* at \*8. She then stated that, while *Pork* did not squarely address that issue, "it offered a robust discussion on three cases that have long been linked to the extraterritoriality principle," clarifying that those cases "did not prohibit extraterritorial legislation writ large, but only legislation with a 'specific impermissible extraterritorial effect' tracing directly back to the antidiscrimination principle." *Id.* at \*9-10 (quoting *Pork*, 598 U.S. at 374); *see id.* at \*10 ("[A] closer examination of [*Baldwin, Brown-Forman*, and *Healy*] reveals three

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<sup>&</sup>lt;sup>22</sup> The plaintiff in *Raoul* is also challenging Connecticut's Act in a related case. *See Ass'n for Accessible Meds. v. Boughton et al.*, Case No. 3:25-cv-01757-OAW (D. Conn.).

laws that were plainly designed either to protect an in-state industry . . . or to hoard commerce for in-state merchants[.]").

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.

The defendants recognize that there are other decisions that have come out the other way, as referenced in HDA's PI Memo. See Ass'n for Accessible Meds. v. Ellison, 140 F.4th 957 (8th Cir. 2025) (Ellison); Frosh, 887 F.3d 664; Healthcare Distribution All. v. Zucker, 353 F. Supp. 3d 235 (S.D.N.Y. 2018); Pharm. Research v. DC, 406 F. Supp. 2d 56 (D.D.C. 2005); Pharm. Research & 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) (Pharm. Research v. Maine). The problem with most of those cases, however, is that all but one are pre-Pork. Therefore, they did not have the benefit of the Supreme Court's analysis instructing that antidiscrimination and non-protectionism lie at the very core of the dormant Commerce Clause analysis, even when there are extraterritorial consequences. And even in those pre-Pork cases, there was disagreement with the extraterritorial argument, which Pork later rejected and HDA pursues now. See Frosh, 887 F.3d at 674-93 (Wynn, J., dissenting); see also Pharm. Research v. Maine, 2000 U.S. Dist. LEXIS 17363, at \*8-16, rev'd sub nom. Concannon, 249 F.3d at 80-83, aff'd sub nom. Walsh, 538 U.S. 668-670.

That leaves *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.4<sup>th</sup> 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.

"This is a misreading of [Pork]." Raoul, 2025 U.S. Dist. LEXIS 190215, at \*13. Instead, "[t]he 'specific 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. (quoting Pork, 598 U.S. at 373). That is, as Chief Judge Kendall correctly concluded, Ellison got Pork wrong. The defendants respectfully urge this court, after considering the language of Pork, to conclude the same.

4. HDA's argument that the Act violates "due process and additional constitutional principles" 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 citied in support thereof) focused on the Commerce Clause. *See* PI Memo,

pp. 7-17. But within that, the PI Memo contains three throwaway paragraphs raising claim that the Act violates "due process[] and additional constitutional principles" other than the dormant Commerce Clause. *See id.*, pp. 11-12. The PI Memo goes on to cite case law providing general due process principles relating to state authority, and no case law concerning any other "additional constitutional principles."

The defendants need not belabor the point that HDA has not adequately briefed these additional constitutional claims under any standard, let alone the "demanding" requirements necessary to obtain a preliminary injunction. The unspecified "additional" constitutional principles for which there are no case cites or substantive analysis are obviously abandoned or waived for the purposes of the PI Motion. See Debique v. Garland, 58 F.4th 676, 684 (2d Cir. 2023) ("We consider abandoned any claims not adequately presented in a[]...brief, and [a party's] failure to make legal or factual arguments constitutes abandonment.") (internal quotation marks omitted). The same holds true for due process, as the PI Memo contains cursory case citations standing for broad principles, with no real substantive analysis or development of the issues. See *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).

Even if it had not inadequately briefed due process, HDA still has not shown a likelihood of success on the merits. Most of the cases to which HDA cites do not directly

address the type of issue presented here. For example, some involve the extent to which a state court could exercise jurisdiction in a particular case and therefore are of limited use here. See Bristol-Myers Squibb Co. v. Superior Court, 582 U.S. 255 (2017) (California state court lacked specific jurisdiction over claims of more than 600 plaintiffs, most of whom are not California residents, asserting a variety of state-law claims based on injuries allegedly caused by the defendant's product); World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286 (1980) (Oklahoma state court lacked in personam jurisdiction over nonresident automobile retailer and distributor when their only connection to Oklahoma was the fact that an automobile sold in New York to New York residents became involved in an accident in Oklahoma).

Another involves whether a state court's award of punitive damages against a tortfeasor with nationwide operations offended due process for being "grossly excessive." *See BMW of N. Am. v. Gore*, 517 U.S. 559 (1996). And in that case, the Supreme Court made clear a state law does not offend due process when it was not enacted with the intent to change lawful conduct in other states, but rather addressed conduct that effected that state and its residents. *See id.* at 572-73 ("[A] State may not impose economic sanctions on violators of its laws *with the intent of changing . . . lawful conduct in other States. . . .* To avoid such encroachment, the economic penalties that a State . . . inflicts on those who transgress its laws, whether the penalties take the form of legislatively authorized fines or judicially imposed punitive damages, must be supported by the State's interest in protecting its own consumers and its own economy. [A State] may insist that [a business] adhere to a particular . . . policy in that State. [A State] does not have the power, however, to punish . . . for conduct that was lawful

where it occurred and that had no impact on [that State] or its residents.") (emphasis added).

Yet another, which probably represents the closest circumstance to the situation here, concerned whether a Louisiana law permitting direct lawsuits against insurance companies that issued policies to persons who inflicted injury when those policies were negotiated, issued, and delivered out-of-state and contained language under out-of-state law prohibiting direct actions against the insurance companies. Watson v. Emp'rs Liab. Assurance Corp., 348 U.S. 66 (1954). There, the Supreme Court rejected the extraterritorial argument HDA raises here, holding that the state law did not violate due process, even though the insurance policies were negotiated and issued out of state. *Id.* at 71-73 ("[A]s this case illustrates, a vast part of the business affairs of this Nation does not present . . . simple local situations. . . . As a consequence of the modern practice of conducting widespread business activities throughout the entire United States, this Court has in a series of cases held that more states than one may seize hold of local activities which are part of multistate transactions and may regulate to protect interests of its own people, even though other phases of the same transactions might justify regulatory legislation in other states. . . . In view of that interest, the direct action provisions here challenged do not violate due process.") (internal citations omitted). That is, the due process analysis in *Watson* favors upholding the Act.

Finally, HDA's last case concerned whether the Supreme Court could exercise jurisdiction over a matter in which New York and New Hampshire, on behalf of their citizens, could sue Louisiana to collect debts owed to those citizens. *New Hampshire v. Louisiana*, 108 U.S. 76 (1883) (the answer to that question was "no," per the Eleventh Amendment). The term "due process" does not appear in *New Hampshire* at all. Again,

this case is of limited use here. Therefore, the HDA has not demonstrated that it is likely to succeed on the merits of these "additional constitutional principles," either.

# B. HDA Has Failed to Establish that Its Members Are Likely to Suffer Irreparable Harm Absent a Preliminary Injunction.

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. *Lamont*, 2025 U.S. App. LEXIS 21570 at \*62. HDA argues that its members face two forms of irreparable harm sufficient to justify a preliminary injunction, one based on its allegation of a violation of a constitutional right and the other based monetary loss.

At the outset, though, HDA's delay in bringing this case undercuts their argument. A district court should consider delay in assessing irreparable harm. *Beyond Gravity Sweden AB v. Ensign-Bickford Aero*. & *Def. Co.*, No. 3:24-CV-2021 (OAW), 2025 U.S. Dist. LEXIS 29227, at \*11 (D. Conn. Feb. 19, 2025); *see 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 plaintiff['s] rights." *Beyond Gravity*, 2025 U.S. Dist. LEXIS 29227, at \*11 (quoting *Citibank, N.A. v. Citytrust*, 756 F.2d 273, 276 (2d Cir. 1985)). "[D]elay 'indicates an absence of the kind of irreparable harm required to support a preliminary injunction." *Id.* at \*11-12 (quoting *Citibank*, 756 F.2d at 276). 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* Complaint, Dkt. # 1. 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, 2025 U.S. Dist. LEXIS 29227, at \*12 (quoting Monowise Ltd. Corp. v. Ozy Media, Inc., 17-cv-8028 (JMF), 2018 U.S. Dist. LEXIS 75312, 2018 WL 2089342, at \*2 (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.").

Even without that 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. PI Memo, p. 17. 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, 2025 U.S. App. LEXIS 21570 at \*62-63 ("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). "The Commerce Clause . . . concern[s] the division of power between the states and the federal government and . . . enshrine[s] structural, rather than personal, rights." Id. at \*156 (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.").

Additionally, "even when 'personal' constitutional rights are violated and the harm that accompanies the violation is remediable or compensable, the damage is not irreparable." *Id.* (internal quotation marks omitted) (collecting cases). This addresses the second form of harm HDA alleges—a loss of money. *See* PI Memo, pp. 18-19.<sup>23</sup> But

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<sup>&</sup>lt;sup>23</sup> Although HDA mentions the Act's criminal penalties, *see* PI Memo, pp. 1 & 3, it does not rely on those penalties for its "irreparable harm" argument, *see id.*, pp. 17-19. 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

in the Second Circuit, it "has always been true that irreparable injury 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. *See* PI Memo, p. 18-19 & n. 5. Of course, the defendants do 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* Chapter 53 of the Connecticut General Statutes ("Claims Against the State"). So again, HDA's claim of monetary loss is insufficient to support a preliminary injunction.

# C. The Balance of Equities and Public Interest Weigh Strongly in Favor of the Act and Against a Preliminary Injunction.

Finally, the 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, the 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

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

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."). These two factors merge when the state is a party to the suit. *Lamont*, 2025 U.S. App. LEXIS 21570 at \*64.

HDA's interests are vastly outweighed by Connecticut's. The Second Circuit has recognized the harm governments suffer when enjoined from effectuating statutes enacted by the people's representatives. See id.; 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 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.

### V. CONCLUSION

For the foregoing reasons, the defendants respectfully request that the court deny HDA's motion for a preliminary injunction.

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### **CERTIFICATION**

I hereby certify that on November 17, 2025, a copy of the foregoing was filed electronically. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the court's CM/ECF System.

/s/ Patrick T. Ring Assistant Attorney General