UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, *v.* AARON M. FREY, in his official capacity as ATTORNEY GENERAL OF MAINE, *Defendant*.	Case No. 25-cv-407 (JAW)

BRIEF OF *AMICI CURIAE* THE AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MAINE HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Edward MacColl
THOMPSON, BASS & MACCOLL, LLC
15 Monument Square, 4th Floor
Portland, Maine 04101
Tel: (207) 774-7600
emaccoll@thomport.com

Counsel of Record

William B. Schultz*
Margaret M. Dotzel*
Alyssa M. Howard*
Courtney Christensen*
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
ahoward@zuckerman.com
cchristensen@zuckerman.com

** pro hac vice motion forthcoming*

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INTEREST OF *AMICI CURIAE*

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Maine's legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences, including cases related to the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Maine Hospital Association** (MHA) represents 32 community-governed hospitals in Maine and is the primary advocate for hospitals in the Maine State Legislature, the U.S. Congress and state and federal regulatory agencies. It also provides educational services and serves as a clearinghouse for comprehensive information for its hospital members, lawmakers, and the public. MHA is a leader in developing healthcare policy and works to stimulate public debate on important healthcare issues that affect all of Maine's citizens.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation

in pharmacy practice, advanced education, and professional development, and has served as a steadfast advocate for members and patients.

INTRODUCTION

Five years ago, nearly 40 drug companies, including Plaintiff Novartis Pharmaceuticals Corporation ("Novartis"), broke with decades of precedent and suddenly restricted the shipment of drugs purchased by 340B hospitals to contract pharmacies. The contract pharmacy arrangements that drug companies like Novartis honored for almost thirty years helped sustain hospitals and their patients. The federal government determined that this was unlawful and sought to require manufacturers to continue delivering these drugs to contract pharmacies on the same terms to which they delivered those drugs to 340B in-house hospital pharmacies.[1]

"Section 340B, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to offer discounted drugs to covered entities for purchase. It is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies." Br. for Appellee Novartis Pharms. Corp. at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, 2022 WL 2072941 (D.C. Cir. June 8, 2022).[2] Novartis submitted these exact words to the United States Court of Appeals for the D.C. Circuit only three years ago when faced with the federal government's attempt to penalize the company's harsh restrictions on contract pharmacy arrangements. In lawsuit after lawsuit, at no point did Novartis or its sister drug companies describe their contract pharmacy policies as price restrictions. Instead, they insisted that their policies were permissible because (1) they were *delivery* restrictions, and

[1] *See, e.g.*, Letter from Dep't of Health & Hum. Servs., Health Resources & Servs. Admin. Administrator C. Johnson to AbbVie, Inc. Vice Pres., U.S. Market Access C. Compisi (Oct. 17, 2022), https://www.hrsa.gov/sites/default/files/hrsa/opa/programintegrity/hrsa-letter-abbvie-covered-entities.pdf.

[2] *E.g.*, AstraZeneca Opening Br. at 4, *AstraZeneca Pharms. L.P. v. U.S. Dep't of Health & Hum. Servs.*, No. 22-01676 (3d Cir. July 21, 2022) ("Section 340B is 'silent' on the role of contract pharmacies under the program. That silence means the statute does not impose contract pharmacy obligations on manufacturers.").

(2) the 340B statute had absolutely nothing to say about *delivery*. Novartis' arguments have carried the day. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d Cir. 2023) (Section 340B's "text is silent about delivery").

Like many other states, Maine has filled the federal statutory gap that Novartis spent years fighting for by requiring drug companies to ship drugs to 340B entities' contract pharmacies on the same terms as they ship those drugs to 340B entities' in-house pharmacies. Faced with the drug industry's unprecedented assault on Maine's health care safety net and the acknowledged gap in federal law, the Maine legislature enacted Chapter 103 of the State's Insurance Code. Chapter 103 does only what Novartis and the federal courts said the *federal* law did not do: regulate the delivery of 340B drugs. Chapter 103 § 7753(1) states that "[a] manufacturer . . . may not deny, restrict, prohibit or otherwise interfere with . . . the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B contract pharmacy on behalf of a 340B entity unless receipt of that 340B drug is prohibited by [HHS]." Essentially, this provision prohibits manufacturers from preventing Maine hospitals from contracting with outside pharmacies to dispense 340B discounted drugs.

Now comes the whiplash. Banking its prior win, Novartis claims in its Complaint that Chapter 103 "is a state drug-pricing statute" whose enforceability "is solely an issue of price, not delivery." Compl., ECF No. 1 ¶ 13. Even though Maine has legislated in precisely the area that Novartis successfully insisted was *not* addressed under federal law—the delivery of 340B drugs—the company has reversed course in this litigation to claim that Chapter 103 is preempted by federal law. And as part of that about-face, Novartis now insists that states cannot fill the federal statutory gap that drug companies (including Novartis) spent years fighting for.

This history is important—and not just because it exposes the hypocrisy in Novartis's legal position. It also serves as a reminder of *why* Maine chose to step into the federal statutory void—Novartis, its sister drug companies, and the federal courts all but invited it to do so.

The primary issue here is whether Maine, exercising its historic police power over health and safety, can fill the gap in the federal 340B statute and regulate the delivery of 340B drugs (purchased by 340B hospitals) to contract pharmacies. It can. Numerous district courts have said so,[3] as has the Eighth Circuit in the only Court of Appeals decision to date addressing a drug industry challenge to a state contract pharmacy statute. *See PhRMA v. McClain*, 95 F.4th 1136, 1143–45 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024).

At bottom, Novartis's attack on Chapter 103 is an attack on federalism itself. Novartis tries to transform an acknowledged federal statutory silence into a reason to displace "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). This Court should reject Novartis's claims seeking to undermine Maine's lawful exercise of traditional state authority.

FACTUAL BACKGROUND ON THE IMPORTANCE OF CONTRACT PHARMACY ARRANGEMENTS IN MAINE

Novartis spends page after page maligning the 340B program and the covered entities that rely on it. Needless to say, it is in its financial interest to do so. For Novartis, every 340B drug it refuses to deliver to a Maine contract pharmacy is an additional profit line on its balance sheets.

[3] *See AbbVie v. Skrmetti*, 2025 WL 1805271, at *16 (M.D. Tenn. June 30, 2025); *AstraZeneca Pharms. LP v. Bailey*, No. 2:24-cv-4143-MDH, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 489881 (W.D. Mo. Feb. 13, 2025); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507 (S.D. Miss. Dec. 23, 2024); *PhRMA v. Murrill*, No. 6:23-cv-997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024); *AbbVie Inc. v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. 2024).

But this is not how the Supreme Court has viewed the program. As Justice Kavanaugh wrote for a unanimous Supreme Court just a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). And more significant here, the Maine legislature, with an unbiased interest in protecting its citizens, hospitals, and pharmacies, shares the Supreme Court's view of the Program. When enacting Chapter 103, the Maine legislature rejected the drug companies' efforts to denigrate the 340B program.

For good reason. The contract pharmacy arrangements that Novartis honored for almost thirty years helped sustain hospitals and their patients. Nationwide, a quarter of hospitals' 340B benefit comes from drugs dispensed at contract pharmacies.[4] The drug industry's efforts to stop 340B hospitals from relying on contract pharmacies has hurt 340B hospitals and adversely affected their ability to serve Maine's most vulnerable patients.

For example, Down East Community Hospital uses its savings from the 340B program to provide free care for uninsured patients and help offset the significant cost of patient responsibility/bad debts. Similarly, St. Mary's Regional Medical Center uses 340B savings to subsidize the cost of providing behavioral services to Maine residents. In 2024, St. Mary's had over 1,600 patients admitted to its inpatient behavioral unit from 15 of Maine's 16 counties. Northern Light Eastern Maine Medical Center uses 340B funding to continue its Oral Oncology Program, which assists cancer patients in managing their prescriptions and helps with coordination of patient care. And C.A. Dean Memorial uses support from the 340B program to provide the only long-term care unit in its area, allowing many older residents to stay closer to their families and

[4] 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

necessary healthcare resources. It also uses savings from the 340B program to help offset the cost of community paramedicine, where paramedics conduct home visits for patients.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[5] Even fewer—only one in five 340B hospitals—have in-house "specialty" pharmacies, which many insurers require for the dispensing of "specialty" drugs. These drugs are typically used to treat chronic, serious, or life-threatening conditions, and are generally priced much higher than non-specialty drugs.[6] Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy outside of its in-house pharmacy.[7] Denied these and other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services.[8]

ARGUMENT

Novartis is not likely to succeed on the merits of any of its claims. Accordingly, this Court should deny its motion for preliminary injunction.

I. NOVARTIS'S SUPREMACY CLAUSE CLAIMS FAIL BECAUSE CHAPTER 103 IS NOT PREEMPTED.

"The purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotation marks and citation omitted). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which

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[5] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* 2, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[6] Adam J. Fein, Drug Channels Institute, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?* (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html; Specialty Drug Coverage and Reimbursement in Medicaid, HHS Office of Inspector General, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[7] 340B Health, *supra* note 5, at 7 (citing Adam J. Fein, Drug Channels Institute, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2022). https://drugchannelsinstitute.com/files/2022-PharmacyPBM-DCI-Overview.pdf.

[8] *Id.*, 340B Health at 2, 5.

the States have traditionally occupied,'" *Lohr*, 518 U.S. at 485, courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432 (2002); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). That is "particularly" true in "matters of health," given "the historic primacy of state regulation" in that area. *Lohr*, 518 U.S. at 485.

Novartis has the burden to show that Congress intended to preempt Chapter 103. *See PhRMA v. Walsh*, 538 U.S. 644, 661–62 (2003). Unlike state laws that intrude into uniquely federal areas such as immigration and foreign relations,[9] Chapter 103 is presumptively *not* preempted. Novartis therefore must demonstrate Congress's "clear and manifest purpose" to supersede Maine's historic authority to regulate in the public health arena, *Lohr*, 518 U.S. at 485, which it cannot do. This Court should reject both of Novartis's preemption theories—just as the Eighth Circuit and numerous district courts have done with preemption challenges to substantially similar state contract pharmacy statutes.[10]

A. Congress Did Not Create Or Occupy A Field When It Established the 340B Program.

Novartis's field-preemption theory, *see* Pl.'s Mot. for Prelim. Inj. with Mem. of Law (MPI) at 13–17, ECF No. 17, both misapplies the relevant standard and mischaracterizes the 340B statute. Field preemption occurs only in narrow circumstances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. NCAA*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[t]he subjects of modern

[9] *See, e.g.*, *Arizona v. United States*, 567 U.S. 387 (2012); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000).

[10] *See PhRMA v. McClain*, 95 F.4th at 1143–45; *see also, e.g.*, *Novartis v. Fitch*, 738 F. Supp. 3d at 747; *AstraZeneca v. Fitch*, 2024 WL 5345507, at *4–9; *Novartis v. Bailey*, 2025 WL 489881, at *2–4.

social and regulatory legislation often by their very nature require intricate and complex responses from Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, both the Supreme Court and the First Circuit have "reject[ed] . . . the contention that pre-emption is to be inferred merely from the comprehensive character" of a federal statute. *Id.*; *see Capron v. Off. of Atty. Gen. of Mass.*, 944 F.3d 9, 24 (1st Cir. 2019); *Ellenwood v. Exxon Shipping Co*., 984 F.2d 1270, 1275 (1st Cir. 1993). If it did, every time Congress created a federal program, it would create an exclusively federal field into which states cannot intrude. But that is not the law. *Dublino*, 413 U.S. at 415. And with the 340B program, "a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent." *Id.*

Novartis's field-preemption theory relies entirely on the (supposed) comprehensiveness of the 340B statute and its dispute-resolution system.[11] *See* MPI at 13–17; Compl. ¶ 84. But Novartis is wrong to characterize regulation of the 340B statute as "pervasive." MPI at 16. Novartis should know this: Novartis and many other drug companies vehemently argued, and convinced federal courts, that the 340B statute is "silent about delivery conditions." *Novartis v. Johnson*, 102 F.4th at 460. And for precisely that reason, the Eighth Circuit and several district courts have rejected field preemption challenges to a state contract pharmacy statute substantially similar to Chapter 103. *See, e.g., PhRMA v. McClain*, 95 F.4th at 1143 ("Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field."); *AbbVie*

[11] Novartis also relies on *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), which does not address preemption. The Western District of Louisiana has persuasively explained why *Astra* is inapposite. *PhRMA v. Murrill*, Nos. 6:23-cv-00997, 6:23-cv-01061, 6:23-cv-01307, 2024 WL 4361597, at *7 (W.D. La. Sept. 30, 2024). Put simply, the *Astra* Court's hesitance to allow "potentially thousands of" private parties to sue to correct "errors in manufacturers' price calculations" has no bearing on whether *States* can fill gaps in federal law about the delivery of 340B drugs. *Astra*, 563 U.S. at 114. Indeed, the only mention of preemption in *Astra* is in a footnote concerning a different federal program, the Medicaid Drug Rebate Program. *Id.* at 120 n.5.

Inc. v. Fitch, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965, at *14. This Court should follow the Eighth Circuit's reasoning and reject Novartis's field preemption theory.

In addition, and as detailed below, HRSA's exclusive authority to resolve certain disputes arising under the 340B statute itself is no reason to doubt Maine's authority to impose and enforce *its own* requirements—which, as Novartis repeatedly emphasizes, are *different* from the requirements of the 340B statute. *See, e.g.*, MPI at 20-24.

B. Chapter 103 Does Not Conflict With the 340B Statute.

A proper conflict preemption analysis requires parties to demonstrate that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This is a "high threshold," *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011), and Novartis comes nowhere close to meeting it. Although framed as a separate cause of action, "[i]n arguing conflict preemption, [Novartis] re-urge[s] many of the same arguments [it] urge[d] with respect to [its] field preemption claims." *PhRMA v. Murrill*, 2024 WL 4361597, at *8. The Court should also follow the Eighth Circuit and a growing chorus of district courts in rejecting Novartis's conflict preemption theories. *See, e.g.*, *PhRMA v. McClain*, 95 F.4th at 1144–45.

The 340B statute was passed to help covered healthcare providers "reach[] more eligible patients and provid[e] more comprehensive services." HRSA, *Final Rule, 340B Drug Pricing Program; ADR Regulation*, 89 Fed. Reg. 28,643, 28,643 (Apr. 19, 2024) (hereinafter, "ADR Rule"). Maine's Chapter 103, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer expanded healthcare to their patients. Thus, not only does Chapter 103 not stand as an obstacle to the purposes of the 340B statute, "it does the opposite: [Chapter 103] assists in fulfilling the purpose of 340B." *PhRMA v. McClain*, 95 F.4th at 1144–45;

see also CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69, 83 (1987) (rejecting conflict preemption challenge because the state's additional requirements "further[ed] the federal policy" embodied by the federal statute).

1. Chapter 103 does not expand the scope of the 340B Program's federal requirements because it regulates delivery, not price.

Novartis tries to transform the federal statute's silence about delivery into an intentional congressional decision to preempt state regulation. That is not the law in this Circuit. *Schafer v. Am. Cyanamid Co.,* 20 F.3d 1, 6 (1st Cir. 1994) ("Pre-emption law, for example, cautions us against finding that a congressional act pre-empts a state law through silence." (citing *Maryland v. Louisiana,* 451 U.S. 725, 746 (1981)). Nor is it the law elsewhere.[12]

The crux of Novartis's attack on Chapter 103 is that it expands the scope of the federal 340B Drug Pricing Program by allegedly requiring Novartis to offer "discounted pricing in situations where the federal 340B statue does not," thus purportedly imposing more onerous conditions than required by federal law. Comp. ¶ 152; *see* MPI at 1, 17–18. But Chapter 103 does not expand *federal* requirements; it sets forth Maine's own requirements regarding drug delivery, with their own consequences. The federal 340B statute dictates what price manufacturers must offer (the "ceiling price") and to whom (340B "covered entities"). Chapter 103 does not alter either requirement. Critically, Chapter 103 does *not* set the price of any drug sales. To borrow from the Eighth Circuit's description of a substantially similar Arkansas statute, Chapter 103 "does not set

[12] *See, e.g., Conway v. United States*, 997 F.3d 1198, 1211 (Fed. Cir. 2021) ("Congress' silence is powerful evidence that Congress did not intend to preempt state law fixing creditors' rights during insolvency." (citation and internal quotation marks omitted)); *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1143 (9th Cir. 2015) ("Silence, without more, does not preempt—'a clear and manifest purpose of pre-emption is always required.'"); *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't Health*, 699 F.3d 962, 985 (7th Cir. 2011) ("As we have noted, congressional and regulatory silence usually *defeats* a claim of preemption, not the other way around.") (emphasis in the original); *Iowa, Chi. & E. R.R. Corp. v. Washington Cnty.*, 384 F.3d 557, 561 (8th Cir. 2004); *Paul v. Monts*, 906 F.2d 1468, 1475 n.8 (10th Cir. 1990).

or enforce discount pricing." *PhRMA v. McClain*, 95 F.4th at 1145; *see also PhRMA v. Murrill*, 2024 WL 4361597, at *9 ("[D]iscounts are set by the federal government, not the State of Louisiana or Act 358.").

Rather, Chapter 103 bars drug companies from discriminating against Maine's 340B hospitals based on their chosen delivery location. The law takes the federal price as given and instead only allows in-state hospitals to choose the shipping address for drugs they have purchased at that federal price. The only thing that Chapter 103 does is let 340B hospitals within Maine's borders determine the shipping address for drugs they have purchased. In so doing, it simply requires drug companies to allow covered entities to be treated like any other purchaser of those drugs, with the same freedom to select where their drugs will be delivered. *See, e.g.*, *PhRMA v. Fitch*, No. 1:24-cv-160-HSO-BWR, 2024 WL 3277365, at *11 (S.D. Miss. July 1, 2024) ("While federal law comprehensively regulates the determination of ceiling prices on Section 340B drugs . . . , Congress has not precluded Mississippi from enacting its own policy governing delivery of Section 340B drugs."); *id.* at *9 ("House Bill 728 prohibits manufacturers from interfering with covered entities ordering delivery of Section 340B drugs to pharmacies for distribution—something Section 340B may not require but does not implicitly preclude either.").

Relying on the Third Circuit and D.C. Circuits' decisions in *Sanofi* and *Novartis*, *Sanofi Aventis U.S. LLC,* 58 F.4th at 703; *Novartis Pharms. Corp. v. Johnson,* 102 F.4th at 460, Novartis next argues that Chapter 103 interferes with the conditions it was permitted to place on its "offer" to sell 340B drugs to 340B covered entities. But those decisions actually refute its position. *See PhRMA v. Murrill*, 2024 WL 4361597, at *8. While those courts permitted *drug companies* to place some reasonable conditions in the face of the federal law's "silence" about delivery, neither court addressed what the *States*, armed with their historic police powers over health and safety, may do

in the face of that silence. *Sanofi Aventis U.S. LLC,* 58 F.4th at 703; *Novartis Pharms. Corp. v. Johnson,* 102 F.4th at 460. Nothing about those cases barred States from filling the statutory gap. To the contrary, in arguing for such a gap, Novartis all but invited the States to do so.

Novartis's mischaracterization of the "replenishment model" is a red herring. *See* MPI at 18–19. The "replenishment model" is an inventory management system that tracks patient and drug data to ensure that 340B hospitals only pay the 340B price for drugs received by their eligible patients. *See, e.g.*, *AbbVie v. Fitch*, 2024 WL 3503965, at *14.

In the context of contract pharmacies, replenishment works as follows: The contract pharmacy buys drugs in bulk from a drug company at market price. Then, the hospital identifies the patients who received drugs that are eligible for the 340B discount. Once the pharmacy has dispensed a full package of the drug to patients who have been identified as patients of that covered entity (say, a 340B hospital), back-end software determines that the 340B hospital should pay the 340B discounted price from that portion of the contract pharmacy's general supply to replace that package. By contrast, if a contract pharmacy dispenses a drug to a patient of a non-340B hospital, then the back-end inventory will not be replenished at the discounted price. If it worked any other way, the pharmacy would have to keep separate stocks of drugs: one for the covered entity and one for non-covered entities. It is more efficiently handled by treating the drugs as they are—fungible commodities—and handling the discount pricing on the back-end, not the front-end.

Most hospitals use the same type of inventory control method in their in-house pharmacies. 340B providers make an initial purchase of a drug at its full price and add that to their single inventory. Some of the purchased drugs may be used for patients of 340B entities and some for patients of non-340B entities. After the pharmacy has dispensed a full package of that drug to

340B patients, it replenishes (or re-stocks) the supply of that drug by purchasing a package of that drug at the 340B-discounted price.

Ultimately, by regulating the delivery of 340B drugs, Maine is not "requiring that manufacturers provide 340B pricing in situations where the federal statute does not." MPI at 17. Nothing about that law alters the fact that the hospital is the only purchaser of 340B drugs. The contract pharmacy itself *never* purchases 340B discounted drugs and is never a "covered entity" entitled to receive a 340B discount. The law simply permits the purchaser—the 340B hospital—choose where the drugs it will be delivered—its own in-house pharmacy or a contract pharmacy.

Operating within the precise metes and bounds of the 340B statute—which is silent as to delivery—Maine is protecting its in-state hospitals' flexibility to decide *where* they want drugs that they have purchased to be delivered. If a Maine hospital wants to buy a particular medication, the drug companies do not contest their obligation to ship that drug to the hospital's in-house pharmacy. Chapter 103 simply mandates that those companies *also deliver* that drug to the pharmacies with which its in-state hospitals have contracts. Nothing in federal law forbids Maine from making that policy decision.

2. Chapter 103 does not interfere with 340B's enforcement regime.

Further, contrary to Novartis's assertion, Chapter 103 does not authorize the state of Maine to enforce the federal 340B Program. Instead, Chapter 103 strictly provides for the enforcement of *its own* requirements. *See* Chapter 103 § 7757; Chapter 13.1 title 6.

As the Eighth Circuit explained with respect to a similar Arkansas statute:

> Act 1103 ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the Arkansas Insurance Division to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies. Ark. Code Ann. § 23-92-604(c). The 340B Program, on the other hand, addresses discount pricing. ***Therefore, HHS has jurisdiction over different disputes***: disputes between covered entities and manufacturers regarding

> pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs.

PhRMA v. McClain, 95 F.4th at 1144 (emphasis added). Because the requirements that can be enforced under Chapter 103 (like the statute in *PhRMA v. McClain*) are different from the 340B program requirements, it does not conflict with the 340B program's enforcement regime.

Novartis argues that enforcement of Chapter 103 would also require Maine decisionmakers to adjudicate multiple questions of federal law, such as whether a drug is a "340B drug." Not so. The Maine statute regulates the delivery of a 340B drug that has been purchased by a 340B hospital. Again, the question in any state action to enforce Chapter 103 would be whether the manufacturer refused to deliver a drug purchased by a 340B hospital to a contract pharmacy. If a manufacturer wants to argue that a drug was dispensed to a non-340B patient or that the company has been forced to pay a duplicate discount, then it must take that that argument to HRSA, not the state. And there is nothing improper or unusual about a state statute defining its reach by reference to federal law or incorporating the federal government's definition of a term into the state statue (and then imposing its own requirements)—or even a state whose "regulatory object" is a federal program. *See, e.g.*, *Chamber of Com.*, 563 U.S. at 611 (rejecting preemption challenge to a state statute under which employers had to check their employees' *federal* immigration status using a specified *federal* database); *see, e.g.*, Me. Rev. Stat. Ann. tit. 20-A, § 6001(3) (defining "education records" that may be disseminated to criminal justice agencies by reference to federal law); Me. Rev. Stat. Ann. tit. 20-A, § 6602 (requiring public schools to participate in the National School Lunch Program and provide "Type A meals" as determined by the U.S. Department of Agriculture); *see also Pharm. Rsch. & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 75 (1st Cir. 2001), *aff'd sub nom. Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 249 F.3d 66, 123 S. Ct. 1855, 155 L. Ed. 2d 889 (2003) (finding that a state statute that incorporates Medicaid requirements is not preempted).

Novartis's mentions of diversion of drugs to non-eligible patients is also irrelevant. As discussed, the question in any state action arising under the Maine statute is whether the manufacturer refused to deliver a drug purchased by a 340B hospital to a contract pharmacy. So, the issue of diversion, which relates to dispensing drugs to a non-340B patient, is outside the scope of the Maine law. And this makes sense because if diversion had been raised as an issue, the federal 340B statute requires that HRSA determine whether the 340B drug purchase complied with federal law *after the fact* either through an audit or in the *post hoc* Alternative Dispute Resolution process. 42 U.S.C. §§ 256b(d)(2)(B)(iv) & (3). As such, Chapter 103 and the federal 340B statute enforce different things and therefore do not raise the possibility of conflicting enforcement decisions.

3. Chapter 103 does not interfere with ADR and audit processes.

Novartis' complaint that Chapter 103 poses an obstacle to the Federal ADR and audit process relies on a misleading description of the process. Under the 340B statute, a manufacturer must audit a covered entity before initiating the statute's administrative dispute resolution (ADR) process. 42 U.S.C. § 256b(d)(3)(B)(iv). As HRSA has explicitly stated, the threshold that a drug manufacturer must meet when seeking approval to audit a 340B entity is "*not overly burdensome*" and does not "present *any barriers* to a manufacturer's ability to perform an audit of a covered entity." ADR Rule, 89 Fed. Reg. at 28,646 (emphasis added). The "reasonable cause" standard is satisfied whenever "a reasonable person *could* believe that a covered entity *may have* violated [certain provisions of the 340B statute]." HRSA, *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). This standard can be met in various ways that do not require claims data. For example, it can be met by pointing to "[s]ignificant changes in quantities of specific drugs ordered by a covered entity," or by citing "complaints from patients/other manufacturers about activities of a covered entity[.]" *Id.* at 65,406;

Or. Health & Sci. Univ. v. Engels, 2025 WL 1707630, at *5 (D.D.C. June 17, 2025); *see, e.g.*, Ex. A, Decl. of Chantelle V. Britton, HRSA Office of Pharmacy Affairs, at ¶ 9 (Dec. 19, 2024) (noting HRSA's approval of a manufacturer's audit request that was "based on a stark increase in [a provider's] utilization of the 340B program," not claims data).[13]

In addition, the 340B statute contemplates that manufacturers will collect specific evidence of covered entities' potential statutory violations *through an audit*—not as a prerequisite to conducting one. The statute expressly addresses a manufacturer's access to "the records of [a 340B] entity that directly pertain to the entity's compliance with [the 340B statute] with respect to the drugs of the manufacturer." 42 U.S.C. § 256b(a)(5)(C). It provides that a manufacturer can access those records *via an* "*audit*." *Id.* (emphasis added). HRSA guidance similarly explains that, in the ADR process, manufacturers can establish covered entity violations because they "have the ability to gather needed information through the audits." ADR Rule, 89 Fed. Reg. at 28,652.

In fact, manufacturers seldom ask to conduct audits, and even when they do, manufacturers frequently fail to follow through with them. *See* Ex. A, Decl. of Chantelle Britton at ¶ 15 (noting that, "over the past decade-plus," HRSA approved 37 manufacturer audit requests, but only 18 audits were conducted).[14] And more fundamentally, *amici* are not aware of a single instance when HRSA has *ever* required, as a condition of authorizing a manufacturer audit, the sort of data that Novartis now claims its members must be allowed to demand from covered entities.

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[13] As the Director of HRSA's Office of Pharmacy Affairs ("OPA"), Ms. Britton "oversee[s] the OPA staff that reviews requests by drugmakers that participate in the 340B Program to audit covered entities." Ex. A at ¶ 2. HRSA submitted Ms. Britton's declaration in *University of Washington Med. Ctr. v. Becerra,* Case No. 1:24-cv-2998-RC (D.D.C) which is associated connection with *Or. Health & Sci. Univ. v. Engels*, Case No. 1:24-cv-2184-RC (D.D.C.).

[14] In contrast, HRSA itself audits approximately 200 covered entities each year for compliance with their 340B obligations. *See* U.S. Gov't Accountability Office, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements* at 11 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf. This includes "targeted" audits of covered entities when HRSA receives "information from stakeholders such as drug manufacturers about potential noncompliance." *Id.* at 11 n.22.

HRSA's recently approved Rebate Pilot Program also does not alter the preemption analysis. Under that pilot program, manufacturers of ten drugs subject to the Medicare Drug Price Negotiation Program[15] would be permitted, for one year, to provide 340B discounts in the form of rebates. This, in turn, will require 340B covered entities to provide manufacturers with a limited amount of claims data, some of which would overlap with what the drug companies have sought under their contract pharmacy restrictions. The Pilot was introduced as only a "test" to better understand how a rebate model would operate,[16] and to date, HRSA has not approved a single application for a drug manufacturer to participate in the Pilot.

Furthermore, the question of whether the 340B statute even permits HRSA to authorize manufacturers to effectuate 340B pricing through rebates is still being contested; in fact, the D.C. Circuit is currently considering this statutory question. *Novartis v. Kennedy*, 25-5177 (D.C. Cir.). As such, any preemption claim based on the Pilot is significantly premature. It is black-letter law that "[t]he existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *Rice v. Norman Williams Co*., 458 U.S. 654, 659 (1982).

However, even if the claim of preemption were suitable for review, Chapter 103 clearly does not conflict with the Pilot. Chapter 103's prohibition on claims data specifically, states that manufacturers are permitted to request claims data if "the claims or utilization data sharing is required by the United States Department of Health and Human Services." § 7753. As such, there is clearly no conflict between the Pilot's allowance of claims data collection and Chapter 103.

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[15] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (CMS DPNP Guidance), 1 at https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[16] HRSA, *HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment*, https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program.

In any event, Chapter 103 dictates that nothing in this chapter is to be construed or applied to be in conflict with applicable federal law and related regulations. § 7758. As such, should HRSA's Pilot Program continue, and should a manufacturer be granted permission to apply a rebate for one of the ten eligible drugs, this Court should construe any alleged conflict between Chapter 103 and the Pilot as inapplicable for that one drug. And, if any such potential conflict did arise as to those specific drugs; that limited conflict cannot justify striking down an entire state law. *E.g.*, *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 449 (2008) ("[A] plaintiff can only succeed in a facial challenge by 'establish[ing] that no set of circumstances exists under which the Act would be valid,' *i.e.,* that the law is unconstitutional in all of its applications.") (quoting *U.S. v. Salerno*, 481 U.S. 739 (1987)).

II. CHAPTER 103 IS NOT AN IMPERMISSIBLE EXTRATERRITORIAL REGULATION.

Novartis's dormant Commerce Clause claim is squarely foreclosed by the Supreme Court's decision in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), and has been rejected by several district courts evaluating similar efforts to enjoin state contract-pharmacy statutes. *See PhRMA v. Fitch*, 2024 WL 3277365, at *12–13 (Mississippi); *Novartis v. Bailey*, 2025 WL 595189, at *3–5 (Missouri).

National Pork Producers flatly rejected the "almost *per se*" extraterritoriality rule that Novartis seeks, holding that the dormant Commerce Clause does *not* forbid "enforcement of state laws that have the 'practical effect of controlling commerce outside the State[.]" *Nat'l Pork Producers*, 598 U.S. at 371. And Novartis offers no coherent argument that Chapter 103 violates the "antidiscrimination principle" that "lies at the 'very core'" of the Supreme Court's dormant Commerce Clause cases. *Id.* at 369. That principle is implicated only by state laws that privilege "in-state economic interests" over "out-of-state *competitors*." *Id.* (emphasis added). Therefore,

"there is a threshold question whether the companies are indeed similarly situated for constitutional purposes" before determining whether a regulation impermissibly violates the antidiscrimination principle of the dormant Commerce Clause. *Ass'n To Pres. & Protect Loc. Livelihoods v. Sidman*, Nos. 24-1317, 24-1318, 24-1385, 2025 WL 2304915, at *14 (1st Cir. Aug. 11, 2025).

Although Novartis alleges that "Chapter 103[] intentionally discriminates against interstate commerce," it gives away the game by complaining of discrimination between "in-state healthcare providers and pharmacies" and "out-of-state *manufacturers*." Compl. ¶ 158 (emphasis added). Novartis does not purport to argue, nor could it, that healthcare providers and drug manufacturers are "similarly situated" for purposes of the dormant Commerce Clause. *See also* MPI at 28–31. Nonetheless, Novartis feebly alleges that it competes with "in-state contract pharmacies and covered entities" because it "operate[s] within the same chain of distribution" and "sell[s] the same products to a single market of healthcare consumers." MPI at 29–30. But even assuming that is true, competition between entities does not mean that they are "similarly situated." *Ass'n To Pres. & Protect Loc. Livelihoods*, 2025 WL 2304915, at *14–19.

Without any colorable claim of discrimination, Novartis is left to repeatedly contend that Chapter 103 "regulat[es] wholly out-of-state transactions between drug manufacturers . . . and out-of-state wholesalers." Compl. ¶ 157. But Chapter 103 does not directly regulate drug purchases by distributors or wholesalers—it regulates the "acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B contract pharmacy on behalf of a 340B entity," and forbids manufacturers from "otherwise interfer[ing] directly or indirectly with a 340B entity," § 7753(1), (3).

Finally, Novartis asserts that Chapter 103 fails the balancing test set out by the Supreme Court in *Pike v. Bruce*, 397 U.S. 137 (1970), which requires that the local benefits of a law be balanced against the burdens placed on out of state entities. In *National Pork Producers*, the Court

clarified that it would be an "overstate[ment]" to argue that "*Pike* and its progeny depart from the antidiscrimination rule that lies at the core of our dormant Commerce Clause jurisprudence." 598 U.S. at 377. Moreover, even under the test in *Pike*, the test invalidates a law only if the out of state burden is "clearly excessive in relation to the putative local benefits," *Nat'l Pork Producers*, 598 U.S. at 377 (quoting *Pike*, 397 U.S. at 142), which Novartis hasn't proven. At most, Novartis points to certain ambiguous "administrative costs" associated with "state-specific exceptions to formerly national contract pharmacy policies." MPI at 31. Neither its Verified Complaint nor its Memorandum puts a number on these costs. It is hard to imagine that Novartis is unable to easily comply with laws that vary across jurisdictions.

It is even harder to imagine these compliance costs outweigh the benefits of Chapter 103, which Novartis ignores. And these benefits are enhanced by the fact that, for decades, Novartis and the other drug companies provided 340B discounts to hospitals that contracted with pharmacies outside the hospital. Given this history of 340B discounts and contract pharmacies, it is difficult to characterize the statute as imposing any meaningful burden on Novartis, and any burden certainly cannot be characterized as "clearly excessive in relation to the putative local benefits." *Nat'l Pork Producers*, 598 U.S. at 377.

CONCLUSION

For the foregoing reasons, Novartis's Motion for a Preliminary Injunction should be denied.

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Respectfully submitted,

/s/ Edward MacColl

Edward MacColl
THOMPSON, BASS & MACCOLL, LLC
15 Monument Square, 4th Floor
Portland, Maine 04101
Tel: (207) 774-7600
emaccoll@thomport.com

Counsel of Record

William B. Schultz*
Margaret M. Dotzel*
Alyssa M. Howard*
Courtney Christensen*
ZUCKERMAN SPAEDER LLP
2100 L Street NW, Suite 400
Washington, DC 20037
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
ahoward@zuckerman.com
achou@zuckerman.com

Counsel for Amici Curiae

** pro hac vice motion filed contemporaneously*

CERTIFICATE OF SERVICE

I certify that on September 10, 2025, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

/s/ Edward MacColl

Counsel for Amici Curiae