UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

MARY HITCHCOCK MEMORIAL HOSPITAL *Plaintiff*, v. ELI LILLY AND COMPANY, *Defendant*.	:	Civil Case 1:26-cv-00616

BRIEF OF AMICUS CURIAE
WASHINGTON LEGAL FOUNDATION IN OPPOSITION
TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

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INTEREST OF AMICUS CURIAE[1]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus curiae in cases involving administration of the 340B program, urging courts to adhere to the program's statutory framework, which is codified at 42 U.S.C. § 256b. *See, e.g., Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024); *Sanofi Aventis U.S. LLC v. U.S. Dep't of HHS*, 58 F.4th 696 (3d Cir. 2023).

INTRODUCTION AND SUMMARY OF ARGUMENT

Mary Hitchcock Memorial Hospital's (MHMH) motion should be denied. It seeks to do something that Congress never authorized: privately enforce alleged violations of the 340B statute against a drug manufacturer in federal court. Since that dooms its case, MHMH tries to dress up its 340B dispute in state-law clothing. But the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011) forbids such a costume change. MHMH's suit seeks to expand 340B beyond Congress's boundaries and expectations, "inhibit[ing] the 340B program as a whole." *AbbVie Inc. v. Wrigley*, 832 F. Supp. 3d 920, 928 (D.N.D. 2026), appeal docketed, No. 26-1863 (8th Cir. May 5, 2026). The Court should not allow it.

In 1992 Congress enacted 340B to help safety-net providers serve the prescription-drug needs of low-income patients. To participate in Medicaid and

[1]No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission.

Medicare Part B, drug manufacturers must participate in 340B by offering discounts on drugs purchased by qualifying healthcare providers known as "covered entities." 42 U.S.C. § 256b(a); 42 U.S.C. § 1396r-8(a)(1). The statute's obligations flow through uniform "Pharmaceutical Pricing Agreements" (PPA) between the manufacturers and the Department of Health and Human Services (Department). 42 U.S.C. § 256b(a). To prevent program misuse by covered entities, Congress imposed two restrictions on them: a prohibition on providing 340B drugs to anyone who is not the covered entity's patient; and a prohibition on claiming Medicaid reimbursement for 340B prescriptions. 42 U.S.C. § 256b(a)(5).

The program has since grown far beyond its modest origins. In 1996 the Health Resources and Services Administration (HRSA), the Department's sub-agency that oversees the program, issued non-binding guidance allowing covered entities to use one outside pharmacy to dispense 340B drugs. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996). But years later, it lifted the one-pharmacy limit and permitted covered entities to contract with an unlimited number of pharmacies. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). Unsurprisingly, a program that once involved roughly 1,000 healthcare providers has today expanded into a mass of nearly 60,000 covered entity sites. U.S. Gov't Acct. Office, *340B Drug Discount Program*, GAO-26-108784 at 5 (Oct. 23, 2025). By 2025 annual 340B purchases exceeded $100 billion.

See HRSA, *2025 340B Covered Entity Purchases* (July 2026), https://perma.cc/5HPU-ADYH.

Financial incentives have fueled 340B's growth. Despite Congress's expectation that covered entities would use 340B discounts to help "low-income and uninsured patients," H.R. Rep. No. 102-384, pt. 2, at 10, the 340B statute doesn't expressly require covered entities to pass discounts on to patients. Thus, covered entities regularly buy drugs at the 340B price (which can be as low as a penny), bill insurers or patients at full price, and then pocket the difference, often sharing a portion with their contract pharmacies. Abuse of this practice has prompted commentators, courts, and lawmakers to lament that 340B has drifted away from Congress's intended goal of helping needy patients. *Wrigley*, 832 F. Supp. 3d at 928-29 (stating that 340B has become a "windfall to hospital[s]" and "pharmacies"); Wall St. J. Editorial Board, *The Great 340B Healthcare Grift*, The Wall Street Journal (May 7, 2026) (referring to 340B as "a cash cow for hospitals"); S. Comm. on Health, Educ., Labor & Pensions, 119th Cong., *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* 39 (Comm. Print 2025) (noting the need to ensure "a more transparent link between program savings and patient benefit").

MHMH now seeks to reshape the program even further—but in a corner that, to date, has managed to remain true to Congress's design: dispute resolution. With well-founded concerns that today's 340B model increases risk of duplicate discounts and diversion of 340B drugs, drug manufacturers, including Eli Lilly, have adopted conditions that require covered entities to submit claims data to receive 340B pricing.

But MHMH refused to provide the data, and so Lilly suspended the hospital's 340B discounts. MHMH asserts that it's entitled to the discounts anyway, but rather than pursue its claims through the dispute-resolution process that Congress required in 42 U.S.C. § 256b(d)(3), it has sued Lilly for the discounts in federal court under various state-law theories.

Under *Astra*, MHMH can't do that. Congress didn't allow private 340B suits, and no amount of state-law dress-up can oust the federal government from its position. U.S. Const. art. VI, cl. 2. Holding otherwise would sacrifice Congress's design of "unitary" agency enforcement for a "multitude of dispersed and uncoordinated lawsuits" that *Astra* warned against. *Astra,* 563 U.S. at 120. Under *Astra's* reasoning, private suits are barred "no matter the clothing in which 340B entities dress their claims." *Id.* at 114 (cleaned up). And if that's not enough, applicable law permits Lilly's claims-data condition.

MHMH faces an inescapable conundrum: to survive *Astra*, it must show its claims arise independently of section 340B; but to prevail on the merits, it must prove Lilly violated that very statute. MHMH can't avoid the contradiction at the heart of this case.

Because MHMH can't show a likelihood of success on the merits, its motion for preliminary injunction must fail. *See Arborjet, Inc. v. Rainbow Treecare Scientific Advancements, Inc.*, 794 F.3d 168, 173 (1st Cir. 2015) (explaining that likelihood of success on the merits is the "sine qua non" of preliminary-injunctive relief) (internal quotation marks omitted).

ARGUMENT

I. MHMH'S LAWSUIT IS AN IMPERMISSIBLE ATTEMPT TO PRIVATELY ENFORCE 340B PRICING.

This case begins and ends with *Astra*.

A. *Astra* bars attempts to end run 340B's lack of a private right to sue.

Section 340B doesn't authorize covered entities to sue manufacturers to enforce the statute's pricing requirements. *See Astra*, 563 U.S. at 113 ("Congress [has] authorized no private right of action under § 340B."). Yet that is what MHMH seeks to do here. Its complaint asserts that Lilly has acted "unlawful[ly]" by "imposing illegal terms and conditions on discounted drug pricing that it is statutorily required to offer." Compl. at 1. Each of MHMH's counts is a cause of action, masquerading as a state-law claim, to enforce 340B pricing. *Astra* forbids schemes to privately enforce 340B indirectly.

In *Astra*, a covered entity sued a drug manufacturer for allegedly charging above 340B's ceiling price. The plaintiff styled its claim as a federal-common-law contract action, asserting third-party-beneficiary rights under the manufacturer's PPA with the government. *Id*. at 118. But the Supreme Court rejected that theory. *Id*. at 118-19. The Court refused to let the plaintiff accomplish through crafty "label[ling]" what Congress had barred it from doing directly: suing in court to enforce the statute's pricing obligations. *Id*. at 114. Allowing covered entities to proceed that way, the Court explained, would render "[t]he absence of a private right to enforce

the statutory ceiling-price obligations . . . meaningless." *Id.* at 118. This case is no different.

B. MHMH's state-law claims are disguised efforts to enforce 340B pricing.

Every one of MHMH's claims seeks to enforce 340B pricing indirectly and is just like the third-party beneficiary claim rejected in *Astra*.

Start with MHMH's counts III, IV, and V, which assert contract or contract-adjacent theories to enforce alleged 340B discounts. The material duty on which each claim is based derives from 340B itself. Count III alleges a contractual duty arising from 42 U.S.C. § 256b. *See* Compl. ¶¶ 238, 242-246. Count IV predicates a duty of good faith and fair dealing on the same statute. *Id.* ¶¶ 251-52. And Count V asserts unjust enrichment on the basis that Lilly allegedly sold drugs "above the 340B Ceiling Price." *Id.* ¶¶ 257-58, 261. As in *Astra*, these claims don't seek to enforce any "independent substantive obligation" aside from 340B itself. *Astra*, 563 U.S. at 119. MHMH's assertion that Lilly "promise[d]" to comply with 42 U.S.C. § 256b (Compl. ¶¶ 244, 246-47) has no content apart from the statute. It can't use contract law to enforce statutory pricing that Congress chose not to make privately enforceable in court. *Astra*, 563 U.S. at 118.

Counts I and II try the same maneuver, albeit through state statutory law. Styled as claims under Vermont's drug pricing statute and New Hampshire's Consumer Protection Act, both rely on the contention that Lilly improperly conditioned access to 340B pricing on obtaining MHMH's claims data. *See* Compl. ¶¶

204-05, 218-20, 228-29, 234. Both seek damages and injunctive relief because Lilly allegedly denied MHMH access to 340B pricing. *Id.* ¶¶ 218-220, 234.

MHMH's own motion concedes that its suit "seeks to enforce public interests arising out of . . . the federal Veterans Health Care Act," which includes the 340B program. Mot. 37. Remove 340B from the complaint, and no claim remains. All that's left is a manufacturer selling drugs at list price to a buyer that declined its terms. Every alleged duty, every alleged injury, every requested remedy, and every theory of liability depends on the assertion that Lilly violated 340B pricing obligations. And so, this suit, which is "in essence a suit to enforce the [340B] statute" is barred. *Astra*, 563 U.S. at 118; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) (rejecting state-law claim seeking to enforce federal statute, where claim "exist[ed] solely by virtue of the [relevant federal statute's] disclosure requirements," which did not come with a private right of action).

C. *Astra*'s reasoning applies fully to MHMH's state-law claims.

MHMH can't avoid *Astra* by hiding under state law. This Court is bound, not just by *Astra's* result, but by its "reasoning." *See Heritage Homes of Attleboro, Inc. v. Seekonk Water Dist.*, 670 F.2d 1, 3 (1st Cir. 1982). *Astra*'s reasoning—which consists of two interrelated principles—applies all the same "no matter the clothing in which 340B entities dress their claims." *Astra*, 563 U.S. at 114 (cleaned up). It leaves "no room for distinguishing" the case. *Heritage Homes*, 670 F.2d at 3.

First, *Astra* emphasizes that Congress has chosen not to authorize private causes of action to enforce 340B but has instead decided to "centralize[] enforcement"

over the program in the Department. *Astra*, 563 U.S. at 119 (internal citations and quotation marks omitted). At the time of *Astra*, the Department, through HRSA, exclusively "handl[ed] overcharge complaints through informal procedures" and could require manufacturers to "reimburse" covered entities for overcharges. *Id*. at 115-16. The Court explained that this "unitary administrative and enforcement scheme" necessarily barred the imitation 340B claims before it. *Id*. at 120. To hold otherwise would defeat the very enforcement structure that Congress enacted. *Id*. at 118.

The same reasoning holds true—with even greater force today—to MHMH's state-law claims. Congress hasn't responded to *Astra* by creating a private right of action. It has continued to stand by its decision to centralize enforcement in the Department. In fact, while *Astra* was pending in the courts, Congress enacted 42 U.S.C. § 256b(d)(3) to further "strengthen and formalize" HRSA's enforcement authority. *Astra*, 563 U.S. at 121-22. That provision directs the Department to establish a robust "administrative process for the resolution of claims by covered entities." 42 U.S.C. § 256b(d)(3). And in the years since *Astra*, the Department has done just that, creating a process that covers alleged overcharge claims, including claims—just like the ones MHMH asserts here—"that a manufacturer has limited the covered entity's ability to purchase . . . drugs at or below the 340B ceiling price." 42 C.F.R. § 10.21.

The Department's process is comprehensive. It establishes claim review by a three-member panel, filing deadlines, procedures for discovery, written decisions by the panel, and a reconsideration process. 42 C.F.R. §§ 10.20–10.24. The statute also

authorizes the Department to award comprehensive remedies, including refunds for "overcharges," and to issue penalties. 42 U.S.C. § 256b(d)(1)(B). MHMH can't bypass Congress's and the Department's dispute-resolution framework through artful pleading of state-law claims, just as the plaintiff in *Astra* couldn't bypass the informal procedures that HRSA had in place at the time the case was decided. "[C]areful and thorough remedial scheme[s]" can't be "circumvented by artful pleading." *Brown v. Gen. Servs. Admin.*, 425 U.S. 820, 833 (1976).

Second, *Astra* also emphasized *why* Congress declined to rely on private actions. *Astra*, 563 U.S. at 120. The Court explained that centralized enforcement in the Department was needed to avoid "a multitude of dispersed and uncoordinated lawsuits," including the corresponding "risk of conflicting adjudications." *Id.* at 120. These concerns, the Court highlighted, are especially strong in the 340B context since 340B is "interdependent" with the federal Medicaid Drug Rebate Program. *Id.* (internal citations and quotes omitted). Because 340B prices are tied to Medicaid pricing—and manufacturers must participate in 340B to participate in Medicaid—enforcement must remain concentrated in a national agency capable of considering both programs together. *Id.* at 113, 115, 120.

The substantial risks posed by a "multitude of dispersed and uncoordinated lawsuits" that concerned the *Astra* Court have also grown since 2011. *Id.* at 120. What was once a program of roughly 1,000 providers now involves nearly 60,000 covered entity sites. *See* GAO-26-108784 at 5. Allowing this mass of providers to pursue different remedies, under different state laws, would usher in—and accelerate—the

very thing that *Astra* feared. And, as the United States recently told the First Circuit, "[i]f the costs of participating in these programs outstrip the benefits, . . . rational manufacturers can be expected to withdraw from them"—from Medicaid and 340B alike. Br. for the United States as Amicus Curiae Supporting Appellant at 16, *Pharm. Rsch. & Mfrs. of Am. v. Neronha*, No. 26-1039 (1st Cir. Feb. 25, 2026). State-law causes of action would disrupt the Department's ability to "administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis," at least as much as the third-party-beneficiary claim rejected in *Astra*. 563 U.S. at 120 (cleaned up).

State-law labels don't change the conclusion that MHMH's claims succumb to *Astra's* reasoning. The Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), confirms that, under the Supremacy Clause, state-law claims can't be used to create private rights of action where Congress has given exclusive enforcement to a federal agency. *Id.* at 353; U.S. Const. art. VI, cl. 2. The *Buckman* Court explained that permitting such claims would interfere with an agency's ability to police misconduct "consistently with [its] judgment and objectives," *id.* at 350, and would expose regulated entities to the very "unpredictable civil liability" Congress sought to avoid. *Id.* There is no "presumption against pre-emption" where claims arise from a "relationship between a federal agency and the entity it regulates." *Id.* at 347-48. Rather, state-law claims that "exist solely by virtue of [federal law]," are preempted where Congress has exclusively vested enforcement authority in the agency. *Id.* at 353.

Those are exactly the circumstances here. MHMH's claims exist only because 340B exists. *See* Section I(B) *supra*. The claims arise from Lilly's participation in 340B, Medicaid and Medicare, and its relationship with the Department, where its Pharmaceutical Pricing Agreement implements the 340B pricing that MHMH seeks to enforce. The fatal problem for MHMH is that the 340B statute gives only the Department that enforcement power. MHMH may avail itself of Congress's prescribed dispute-resolution process to secure the Department's enforcement, but it has improperly tried to bypass that process here.

It's no surprise, then, that courts since *Astra* have repeatedly applied its reasoning to bar claims seeking to enforce 340B pricing through various pleading labels and theories. *See, e.g., Sagebrush Health Servs. v. Amgen Inc.*, No. 2:26-cv-00466, 2026 WL 1030817, at *7 (C.D. Cal. Apr. 15, 2026), appeal docketed, No. 26-3248 (9th Cir. May 20, 2026) (applying *Astra* to bar California tort law claims seeking 340B pricing); *Am. Hosp. Ass'n v. Dep't of Health & Hum. Servs.*, No. 4:20-cv-08806, 2021 WL 616323, at *5 (N.D. Cal. Feb. 17, 2021) (applying *Astra* to bar APA claims seeking to enforce 340B pricing). These cases align with the law more broadly, which holds that a private plaintiff can't "use state common law to circumvent the absence of a private right of action under a federal statute." *Umland v. PLANCO Fin. Servs., Inc.*, 542 F.3d 59, 66 (3d Cir. 2008).

MHMH cites no law to the contrary. It instead relies on *United States ex rel. Adventist Health Sys. of West v. AbbVie Inc.*, 169 F.4th 1137 (9th Cir. 2026). Mot. 33. But *Adventist* was a False Claims Act case, not a case where a covered entity sought

"to recover losses" for "overcharges" on "Section 340B drugs." *Adventist*, 169 F.4th at 1141. That difference is dispositive. The FCA is an explicit federal cause of action where Congress has authorized private suit on the government's behalf while the government retains intervention and dismissal authority. *Adventist* provides no basis for circumventing *Astra* through state-law claims.

MHMH also can't seek help from *AbbVie, Inc. v. Murrill*, 180 F.4th 747 (5th Cir. 2026). There, the Fifth Circuit rejected a preemption challenge to a Louisiana law governing manufacturers' "delivery" of 340B drugs to pharmacies. *Murrill*, 180 F.4th at 759. But *Murrill* didn't involve a private covered entity's damages suit for 340B pricing; it involved the Louisiana Attorney General's enforcement of state rules governing drug deliveries. *Id.* at 756. The Fifth Circuit further distinguished "Congress's enforcement scheme," where the Department has "exclusive authority" to enforce 340B pricing, from the Louisiana law, which, it said, governs the "delivery logistics" of drugs. *Id.* at 760-61. Because MHMH's case seeks damages for 340B "overcharges" *see, e.g.*, Compl. ¶ 234, it falls on the 340B-pricing side of *Murrill's* "Venn Diagram" and is foreclosed by *Astra*, even under the Fifth Circuit's analysis. *Murrill* 180 F.4th at 761.

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MHMH's complaint is an impermissible effort to morph 340B's enforcement regime into something Congress never authorized. If *Astra* means anything, it means that MHMH can't bring this suit.

II. IN ANY EVENT, APPLICABLE LAW PERMITS LILLY'S CLAIMS-DATA CONDITION.

Even if *Astra* didn't exist, MHMH still can't establish a likelihood of success on the merits. *See HCC Specialty Underwriters, Inc. v. Woodbury*, 289 F. Supp. 3d 303, 307 (D.N.H. 2018) (explaining that the movant "bears the burden" on a motion for a preliminary injunction).

The 340B program was enacted for underinsured patients who need prescriptions but can't afford list price. To help ensure the program advances this end—and isn't used simply to enrich hospitals—the statute imposes two restrictions on covered entities: a covered entity can't obtain a 340B discount on a drug for which a Medicaid rebate is also paid and it can't dispense a 340B drug to someone who isn't its patient. *See* 42 U.S.C. § 256b(a)(5). Whether a given dispense qualifies for a 340B discount thus turns on whether the patient is the entity's patient and whether Medicaid paid a rebate on the same unit. A purchase invoice doesn't capture these facts, but claims data does. That's why the data that Lilly has requested is not merely incidental to program integrity; it is essential to verify the program's patient protections.

MHMH identifies no provision of the 340B statute that prohibits manufacturers from conditioning access to discount drugs on the submission of claims data needed to verify program compliance. On the contrary, its state-law claims fail precisely because they are anchored in federal law that *permits* Lilly's claims-data request. Three sets of authorities show how.

First, appellate authority addressing manufacturer conditions under federal law agrees that reasonable claims-data conditions are permissible. In *Sanofi Aventis U.S. LLC v. U.S. Dep't of HHS*, 58 F.4th 696 (3d Cir. 2023) and *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024) the courts rejected categorical interpretations of 340B that would prohibit manufacturers from imposing conditions on the distribution of discounted drugs. *Novartis* specifically concluded that one manufacturer's requirement that "contract pharmacies provide claims data for contract-pharmacy orders" did not violate "section 340B on [its] face." *Novartis*, 102 F.4th at 463–64. In reaching that conclusion, the court explained that HRSA's 1994 guidance permits manufacturers to require "standard information" from covered entities and that the burden of providing claims data would be "minimal." *Id.* at 463.

Second, HRSA's audit framework, far from advancing MHMH's argument (Mot. 12-13), reinforces why claims-data conditions are permitted. To initiate an audit, HRSA requires a manufacturer to "set forth a clear description of why it has reasonable cause to believe" that a covered entity has violated 340B. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406, 65410 (Dec. 12, 1996). But that "reasonable cause" can't be assembled from purchase records alone. Claims data is the only evidence from which such cause is formed.

Another district court has agreed. *See Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 453 (S.D. W. Va. 2024), aff'd sub nom. *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, 171 F.4th 675 (4th Cir. 2026), vacated and reh'g en banc granted, 176 F.4th 830 (4th Cir. 2026). There, the court observed that a manufacturer who is

denied claims data is left with "no alternatives" and may be unable to "formulate the 'reasonable cause' necessary to conduct an audit in the first place." *Morrisey*, 760 F. Supp. 3d at 453 (explaining that a regime that allows a covered entity to decide whether to release its data showing program noncompliance is akin to "the fox guard[ing] the hen house"). Under MHMH's reading, the manufacturer retains a right to audit but has no means of invoking it. The "340B Program certainly did not establish" such a system. *Id.*

Third, HRSA's guidance from last month confirms that claims data impose little burden on covered entities but serve the important interests of program integrity. In proposing a 340B rebate-model pilot, HRSA explained that "use of standardized claims-level data" may "improve the identification and prevention of duplicate discounts." *See* Notice Regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48883, 48890 (Aug. 3, 2026). It further concluded that "[t]he burden associated with limited claims-level reporting" is "justified by the importance of ensuring program integrity, duplicate discount prevention, and coordination across federal pricing programs." *Id.* at 48896.

A preliminary injunction requires a "clear showing" that a movant "is likely to succeed on the merits." *Beers v. N.H. State Prison Warden*, 752 F. Supp. 3d 431, 434 (D.N.H. 2024) (internal citations and quotation marks omitted). But instead of doing that, MHMH posits a novel theory that is unsupported by statute and runs contrary to regulatory and appellate authority.

Finally, MHMH's reliance on 18 V.S.A. § 4682—a *Vermont statute*—doesn't lend any merit to its claims. Indeed, the fact that MHMH must look beyond federal and New Hampshire law to locate a statutory prohibition underscores a fatal defect in its case: No generally applicable law prohibits Lilly's claims-data condition.

Other problems with MHMH's reliance on the Vermont law abound. MHMH's motion fails to undertake a choice-of-law analysis showing why Vermont law should apply to a dispute involving a New Hampshire hospital, New Hampshire purchases, and an alleged New Hampshire injury. *Fujifilm N. Am. Corp. v. M&R Printing Equip., Inc.*, 565 F. Supp. 3d 222, 232, 234 (D.N.H. 2021) (explaining that the party seeking application of out-of-state law bears the burden of showing it applies). For the reasons in Lilly's brief (Opp. at 24-31), the Vermont statute is preempted. And to top it off, the statute directly conflicts with New Hampshire's policy judgment, which rejected a bill that would have barred manufacturers from conditioning 340B delivery on claims data. *See* Bill text: NH SB253, LegiScan, (March 6, 2025); *see also BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 571–73 (1996) (explaining that no state may "impose its own policy choice on neighboring states").

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One doesn't need to look far to see that the 340B program suffers from integrity challenges and that the absence of program transparency hasn't inured to the benefit of patients. As the *New York Times* recently reported, patients often have no way of knowing whether 340B discounts are being used to reduce their costs or simply to generate revenue for hospitals. *See* Ellen Gabler, *How a Company Makes Millions Off*

a Hospital Program Meant to Help the Poor, N.Y. Times, Jan. 15, 2025, at A1. In 2018, the New England Journal of Medicine found no evidence that the covered entities it studied used 340B savings to expand care for low-income patients or improve care for low-income groups in ways that reduce mortality. *See* Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 New Eng. J. Med. 539, 546 (2018). Whether 340B's promise of helping needy patients is being fulfilled depends on what happens between the manufacturer's discount and the patient's bill. MHMH's position is that a manufacturer acts unlawfully when it asks to see the claims data that would show what happens. For the reasons above, that theory conflicts with both the law and the program's design.

Even if *Astra* didn't independently bar this suit—and it does—MHMH still can't carry its burden.

CONCLUSION

Congress never created a private right of action to enforce 340B pricing. MHMH nevertheless asks this Court to recognize one under the banner of state law. *Astra* rejected that maneuver fifteen years ago and forecloses it today. Because MHMH seeks to accomplish indirectly what Congress and the Supreme Court have not allowed directly and because applicable law permits Lilly's claims-data condition, the motion for preliminary injunction should be denied.

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