

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

ABBVIE INC., *et al.*,

Plaintiffs,

v.

MIKE HILGERS, in his official capacity as
ATTORNEY GENERAL FOR THE STATE OF
NEBRASKA,

Defendant.

Case No. 4:25-cv-03089-SMB-RCC

**BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH,
NEBRASKA HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-
SYSTEM PHARMACISTS IN CONNECTION WITH DEFENDANT'S MOTION TO
DISMISS**

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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 Nebraska’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 for their members, 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 **Nebraska Hospital Association** (NHA) is a statewide trade association that has represented Nebraska’s hospitals and health systems since 1927. NHA serves as the influential voice of its members in the health care legislative and public arenas, promoting the delivery of quality health care and influencing public opinion of hospitals and health networks. Through its partnerships with representatives in the health care industry, legislators, government, and citizens, NHA promotes the development of strong, healthy communities.

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 served as a steadfast advocate for members and patients.

INTRODUCTION

Five years ago, nearly 40 drug companies, including Plaintiffs (collectively, AbbVie), broke with decades of precedent and suddenly refused to ship drugs purchased by 340B hospitals to contract pharmacies. The federal government believed 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

The drug companies fought that effort tooth and nail. In lawsuit after lawsuit, they argued that the federal government could not interfere with their contract pharmacy restrictions. At no point did the drug companies describe their contract pharmacy policies as price restrictions. Instead, they insisted that their policies were permissible because: (1) they were *delivery* restrictions,² and (2) the 340B statute had absolutely nothing to say about *delivery*. The drug

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#:~:text=Nothing%20in%20the%20340B%20statute%20grants%20a,cou%20covered%20out%20patient%20drugs%20purchased%20by%20covered%20entities.&text=HRSA%20expects%20AbbVie%20to%20provide%20an%20update,contract%20pharmacy%20arrangements%20by%20November%202018%20C%202022>.

² E.g., Novartis Opening Brief at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, Doc. 1949831 (D.C. Cir. June 8, 2022) (“Section 340B . . . is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies.”) (emphasis added); 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.”).

In fact, AbbVie’s counsel made the following argument to the Seventh Circuit on behalf of another drug company that, like AbbVie, receive a cease-and-desist letter from the federal government: “As the plain text of Section 340B makes clear, the only requirement the statute imposes on manufacturers is to offer covered entities the opportunity to purchase manufacturers’

companies won. *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, 707 (3d Cir. 2023) (Section 340B’s “text is silent about delivery” and “[l]egal duties do not spring from silence.”).

Now comes the whiplash. Banking the wins of its sister drug companies, AbbVie now contends that Nebraska’s law requiring shipment to contract pharmacies regulates price, not delivery. And as part of that *volte-face*, AbbVie now insists that States cannot fill the federal statutory gap that other manufacturers have spent years fighting for in sister circuits. AbbVie’s heads-I-win-tails-you-lose argument is as shameless as it is meritless.

This history is important—and not just because it exposes the hypocrisy in AbbVie’s legal position. It also reminds the Court *why* Nebraska chose to step into the federal statutory void. Put simply, Nebraska acted because the drug companies and other federal courts all but invited it to.

Faced with the drug industry’s unprecedented assault on Nebraska’s health care safety net and the acknowledged gap in federal law, the Nebraska legislature joined ten other states and passed Nebraska Legislative Bill 168 (L.B. 168). L.B. 168 does only what AbbVie and the federal courts said the *federal* law did not do—regulate the delivery of 340B drugs.

drugs at 340B-discounted prices. The statute does not impose an additional, orthogonal requirement to *deliver* 340B drugs to for-profit contract pharmacies whenever and wherever a covered entity demands.” Eli Lilly Opening Brief at 27, *Eli Lilly and Company. v. Becerra*, Nos. 21-3128 & 21-3405, Doc. 19 (7th Cir. May 25, 2022) (emphasis added); *see id.* at 2-3 (“Neither sentence (nor any other part of Section 340B) says anything at all about *delivery* or sale to third parties besides covered entities. . . . The 340B statute requires Lilly to offer its drugs to covered entities at discounted prices, and Lilly indisputably does so. The statute does not impose any additional obligation to *deliver* 340B drugs to contract pharmacies.”) (emphases added); *id.* at 30 (“The absence of language mandating delivery to contract pharmacies is no accident.”); *id.* at 41 (“At the core of the district court’s analysis is a fundamental mistake about the legal consequence of statutory silence.”).

The primary issue here is whether Nebraska, 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. The Eighth Circuit has said so in *PhRMA v. McClain*, 95 F.4th 1136, 1143–45 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024). This Court must, too.

AbbVie’s complaint fails to state a claim for relief for five reasons. *First*, L.B. 168 is not field preempted. Congress did not create or occupy any field through its 340B legislation. AbbVie’s entire field preemption argument is premised on the false notion that Section 340B “erects a comprehensive regulatory scheme governing an exclusively federal program.” *AbbVie, Inc. v. Bailey*, No. 4:24-cv-00996-SRC, 2024 WL 5247982 (E.D. Mo. Oct. 10, 2024). But comprehensiveness alone does not wrest traditional police power from the States. That has never been the rule in our federal system. *E.g.*, *Hillsborough Cnty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 717 (1985); *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990); *N.Y. Dep’t of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). And even if it were, the 340B statute is silent as to delivery of 340B drugs and contract pharmacies. As numerous courts across the country—including and especially the Eighth Circuit—have recognized, this gap in federal law is fatal to any field preemption claim. *E.g.*, *PhRMA v. McClain*, 95 F.4th at 1143–45; *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737, 747 (S.D. Miss. July 1, 2024); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507, at *4–9 (S.D. Miss. Dec. 23, 2024); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 489881, at *2–4 (W.D. Mo. Feb. 13, 2025).³

³ The only court to conclude that the drug manufacturers were likely to succeed on the merits of a preemption claim based its ruling on a fundamental misunderstanding of the 340B statute and program. *PhRMA v. Morrissey*, --- F. Supp. 3d ---, Nos. 2:24-cv-00271, 2:24-cv-00272, 2:24-cv-00298, 2024 WL 5147643 (S.D. W. Va. Dec. 17, 2024).

Second, L.B. 168 is not conflict preempted. Contrary to AbbVie’s assertions, Nebraska’s law does not transform contract pharmacies into new 340B entities; it does not contravene the federal government’s enforcement authority; and it does not regulate 340B price. The price of 340B drugs continues to be set by federal law. Nebraska’s law only affects *where* the 340B drugs (purchased by 340B hospitals) are shipped and stored. *See PhRMA v. McClain*, 95 F.4th at 1144-45 (“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. . . . Act 1103 does not require manufacturers to provide 340B pricing discounts to contract pharmacies. Act 1103 does not set or enforce discount pricing.”). It is, in essence, a non-discrimination provision. L.B. 168 allows *Nebraska* hospitals to choose where 340B drugs are to be shipped for its patients, rather than letting drug companies discriminate in favor of in-house hospital pharmacies. What’s more, State enforcement is limited to *only* this non-discrimination requirement. Nebraska does not enforce requirements under federal law; it enforces only the state law requirement under L.B. 168 that AbbVie deliver drugs (bought by Nebraska’s 340B hospitals) to contract pharmacies *on the same terms* as they deliver to Nebraska’s in-house hospital pharmacies.

Third, AbbVie’s challenge under the Takings Clause fails. It is blackletter law that “[g]overnmental regulation that affects a group’s property interests does not constitute a taking of property where the regulated group is not required to participate in the regulated industry.” *See AbbVie v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965, at *17 (S.D. Miss. July 22, 2024) (quoting *Burditt v. U.S. Dep’t of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991) (cleaned up)). AbbVie is not required to participate in the 340B Program. Its voluntary decision to participate in that Program is fatal to its Takings Clause claim.

Fourth, L.B. 168 is not an unconstitutional extraterritorial statute. In its argument to the contrary, AbbVie advances a sweeping reading of the dormant Commerce Clause that was recently rejected by the Supreme Court in *National Pork Producers Council v. Ross*, 598 U.S. 356, 375 (2023), and which would essentially bar any state law that has extraterritorial effects. Like the petitioners in that case, AbbVie advocates an “‘almost *per se*’ rule against laws that have the ‘practical effect’ of ‘controlling’ extraterritorial commerce [which] would cast a shadow over laws long understood to represent valid exercises of the States’ constitutionally reserved powers.” *Id.*

Fifth, AbbVie’s ancillary claim under the Due Process Clause likewise lacks merit. The commonly-used term “location” is easily understood. AbbVie’s arguments to the contrary do not meet the high bar required to prove that statutory language is unconstitutionally vague.

All in all, AbbVie’s attack on L.B. 168 is really an attack on federalism itself. At bottom, AbbVie tries to transform an acknowledged federal statutory silence into a reason to displace traditional state authority. That is not the law. “Pharmacy has traditionally been regulated on the state level.” *PhRMA v. McClain*, 95 F.4th 1136, 1144 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024). Invalidating Nebraska’s lawful exercise of State authority would turn upside down the very “federalism concerns” that underlie preemption questions and upend “the historic primacy of state regulation of matters of health and safety.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

FACTUAL BACKGROUND ON THE IMPORTANCE OF CONTRACT PHARMACY ARRANGEMENTS IN NEBRASKA

AbbVie 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 AbbVie, every 340B drug it refuses to deliver to a Nebraska contract pharmacy is an additional profit line on its balance sheets.

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 important here, the Nebraska legislature, with an unbiased interest in protecting its citizens, hospitals, and pharmacies, shares the Supreme Court’s view of the Program. When enacting L.B. 168, the Nebraska legislature rejected the drug companies’ efforts to denigrate the 340B Program and those who rely on it.

For good reason. The contract pharmacy arrangements that AbbVie honored for almost 30 years helped sustain hospitals and their patients. Nationwide, a quarter of hospitals’ 340B benefit historically came from drugs dispensed at contract pharmacies.⁴ The drugs industry’s efforts to stop 340B hospitals from relying on contract pharmacies has hurt 340B hospitals and adversely impacted their ability to serve at risk populations. For example, between 2019 and 2024, Thayer County Hospital (Thayer) saw an almost 50% decline in its contract pharmacy revenue—from \$830,366.88 to \$463,148.94. This has put Thayer’s critical services for low-income patients at risk because it depends on 340B savings to maintain outpatient infusion services such as chemotherapy.

Further, it is the 340B Drug Program that has allowed Merrick Medical Center (MMC) to help protect healthcare facilities from rising drug costs and reductions in reimbursement, which is crucial for maintaining financial stability. The program has enabled MMC to expand its services, including by constructing a new facility,⁵ onboarding a behavioral health provider, increasing

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.

⁵ Healthcare Design, *Bryan Health Merrick Medical Center Refreshes Its Critical Access Hospital* (March 13, 2023), <https://healthcaredesignmagazine.com/projects/bryan-health-merrick-medical-center-refreshes-its-critical-access-hospital/58701/>.

outpatient service offerings, and providing community education events. These expansions allow patients to access high quality care locally, which is particularly important in rural communities.⁶

Nebraska Medicine—a non-profit, integrated health care system comprised of two hospitals and nearly 70 specialty and primary healthcare clinics throughout the state—uses its 340B savings to make medications more accessible and to provide lifesaving care for its low-income patients.⁷ In FY23, 340B savings at Nebraska Medicine supported medication affordability programs that provided more than 64,000 prescriptions to 7,820 uninsured and underinsured patients across Nebraska for free or at a significantly reduced cost. Nebraska Medicine’s Medication Assistance Counselors helped an additional 3,816 patients to be able to access and afford more than 24,000 prescriptions. Overall, these services supported \$21M in patient savings for prescription drugs in FY23. This is on top of the tens of millions in financial assistance Nebraska Medicine provides annually for medical care. 340B savings also allow Nebraska Medicine to support critical service lines like behavioral health and OBGYN care, for which reimbursement does not cover the cost-of-service delivery, and to expand services across the state, including its new Kearney Cancer Center, ensuring cancer patients in central and western Nebraska have quality care close to home.⁸

⁶ Nebraska Hospitals, *How 340B Impacts Nebraska Hospitals*, https://www.nebraskahospitals.org/file_download/inline/b7a0dcc4-b1ca-490a-9cf2-4572a05c0764.

⁷ Nebraska Medicine, *Community Benefit Report 2023*, https://www.nebraskamed.com/sites/default/files/documents/About%20Us/community_benefit_report_2023.pdf.

⁸ Nebraska Medicine, *Central Nebraska’s Newest Cancer Center Now Open in Kearney* (Dec. 19, 2024), <https://www.nebraskamed.com/health/nebraska-medicine-news/cancer-care/central-nebraskas-newest-cancer-center-now-open-in>.

Johnson County Hospital (JCH) in Tecumseh also uses its 340B benefit to fund services that operate at a loss, like its Home Health Department and Paramedic Service that is on a continuous growth path, both in staffing and equipment.⁹ Without this 340B benefit, JCH would not be able to fund and operate these services.¹⁰

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.¹¹ 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.¹² Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy outside of its in-house pharmacy.¹³ Denied these and other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services.¹⁴

⁹ Johnson Cnty. Hosp., *340B in Action*, <https://jchosp.com/community-benefits/>; Am. Hosp. Ass’n, *The Value of the 340B Program Case Study*, <https://www.aha.org/case-studies/2025-04-22-johnson-county-hospital-nebraska>.

¹⁰ *Id.*

¹¹ 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.

¹² 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>.

¹³ 340B Health, *supra* note 4, at 7 (citing Adam J. Fein, Drug Channels Institute, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2022)).

¹⁴ *Id.*, 340B Health at 2, 5.

340B savings help Nebraska patients in a variety of ways. Without the 340B benefit they obtain from drugs dispensed at community pharmacies, these hospitals, which typically operate with razor thin (and often negative margins), report that they will have to curtail these vital programs or eliminate them entirely.

Big Pharma's assault on contract pharmacy relationships drastically reduces the savings that Nebraska's 340B hospitals rely on and jeopardizes the hospitals' ability to provide valuable services to their patients.

ARGUMENT

I. L.B. 168 IS NOT PREEMPTED BY FEDERAL LAW.

AbbVie's preemption claim is foreclosed by *PhRMA v. McClain*, which held that a materially identical Arkansas statute was not preempted by the federal 340B law. 95 F.4th at 1143–45. Like AbbVie here, the plaintiff in that case brought both field and conflict preemption claims. The Eighth Circuit rejected them all.

“‘The purpose of Congress is the ultimate touchstone’ of pre-emption analysis.” *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). In every preemption case, “and particularly in those in which Congress has ‘legislated in a field which 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)). AbbVie has the burden to show that Congress intended to preempt L.B. 168. *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,¹⁵ L.B. 168 is presumptively *not* preempted. AbbVie therefore must demonstrate Congress’s “clear and manifest purpose” to supersede Nebraska’s historic authority to regulate in the public health arena, *Lohr*, 518 U.S. at 485 (citation omitted), which it cannot do.

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

Field preemption occurs only in narrowly defined instances, “when federal law occupies a ‘field’ of regulation ‘so comprehensively that it has left no room for supplementary state legislation.’” *Murphy v. Nat’l Collegiate Athletic Ass’n*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, “[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the 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, the Supreme Court has rejected “the contention that pre-emption is to be inferred merely from the comprehensive character” of federal provisions. *Id.* 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. *Id.* And with the 340B program, “a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent.” *Id.* AbbVie cites *no authority* other than the comprehensiveness of the statute to support the notion that Congress intended to create (or occupy) this purported 340B “field.”¹⁶ Accordingly, AbbVie’s field preemption claim fails.

¹⁵ See, e.g., *Arizona v. United States*, 567 U.S. 387 (2012); *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363 (2000).

¹⁶ AbbVie continues to rely heavily on *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011). The Western District of Louisiana has persuasively explained why *Astra* is inapposite. *PhRMA v. Murrill*, Nos. 6:23-cv-00997, 6:23-cv-01042, 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

B. L.B. 168 Does Not Conflict with the 340B Statute.

As PhRMA did before the Eighth Circuit, AbbVie “raises the same arguments it raised with field preemption.” *PhRMA v. McClain*, 95 F.4th at 1145. Faced with these re-packaged assertions, this Court should “reject these same arguments again,”—just as the Eighth Circuit did. *Id.*

In essence, AbbVie tries to transform the federal statute’s silence about delivery into an intentional congressional decision to preempt state regulation. That cannot be. *E.g.*, *Iowa, Chicago & Eastern R.R. Corp. v. Washington Cnty.*, 384 F.3d 557, 561 (8th Cir. 2004) (“ICCTA did not address these problems. Its silence cannot reflect the requisite clear and manifest purpose of Congress to preempt traditional state regulation of public roads and bridges that Congress has encouraged in numerous other statutes.”) (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.’”) (citation omitted); *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 616 (1997) (Thomas, J., dissenting) (“Even where Congress has legislated in an area subject to its authority, our pre-emption jurisprudence explicitly rejects the notion that mere congressional silence on a particular issue may be read as preempting state law.”). Thus, the Louisiana district court put it well when it held that “if Section 340B does not address contract pharmacies or the relationship between covered entities and their contract pharmacies, a state statute that specifically addresses contract pharmacies cannot conflict with Section 340B.” *PhRMA v. Murrill*, 2024 WL 4361597, at *8.

States can fill gaps in federal law regarding 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.

When conducted properly, a 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 AbbVie comes nowhere close to meeting it. The 340B statute was passed to help covered entities “reach[] more eligible patients and provid[e] more comprehensive services.” *Am. Hosp. Ass’n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (internal quotation omitted), *rev’d on other grounds sub nom.*, *Am. Hosp. Ass’n v. Becerra*, 596 U.S. 724 (2022). L.B. 168, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer expanded healthcare to their patients. Therefore, not only does L.B. 168 not interfere with Congress’s 340B scheme; it “furthers” it. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 82 (1987). Or, to paraphrase the Eighth Circuit, L.B. 168 “does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: [L.B. 168] assists in fulfilling the purpose of 340B.” *PhRMA v. McClain*, 95 F.4th at 1144–45.

In a fruitless attempt to escape these binding Eighth Circuit holdings, AbbVie levels multiple attacks on the Nebraska statute, some of which rely on the Southern District of West Virginia’s erroneous preliminary injunction ruling. But that out-of-circuit district court decision was based on a flawed interpretation of the federal 340B statute and how the program operates. It not only ignores the presumption against preemption, *Lohr*, 518 U.S. 470, but at times reads as if that presumption is inverted. It is therefore telling that this outlier decision carried no weight with a Mississippi district court, which explicitly rejected the decision’s reasoning just a few days later. *AstraZeneca v. Fitch*, 2024 WL 5345507, at *9 (refusing to “disregard mainstream decisions and the Eighth Circuit’s ruling in *McClain* without clear precedential support”); *see also Novartis*

Pharms. Corp. v. Bailey, No. 2:24-cv-04131-MDH, 2025 WL 489881, at *2–5 (W.D. Mo. Feb. 13, 2025).

I. L.B. 168 Regulates Delivery, Not Price.

AbbVie’s argument that L.B. 168 regulates 340B drug price belies an analysis of the statute, which confirms that it is actually about the delivery of 340B drugs. L.B. 168 bars drug companies from discriminating between delivery locations for patients of Nebraska 340B hospitals. L.B. 168 § 3(1). It directly requires drug companies to let 340B hospitals determine the appropriate shipping address for their 340B patients. That is precisely why the Eighth Circuit upheld a similar statute, holding that Arkansas’ law “does not set or enforce discount pricing.” *PhRMA v. McClain*, 95 F.4th at 1145.

AbbVie nonetheless relies on the West Virginia decision, but that opinion turned on a fundamental misunderstanding of the so-called “replenishment model.” 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. It allows hospitals to buy drugs in bulk and replenish their 340B stocks when eligible patients purchase those drugs. Critically, the 340B hospital would pay that exact same price if it were replenishing its own inventory at its hospital pharmacy after a patient received the drug. Thus, replenishment would happen whether the 340B drug is delivered to the hospital’s pharmacy *or* the hospital’s contract pharmacy. And that is all the Nebraska law addresses—*where* drug companies must ship drugs that are purchased by Nebraska’s 340B hospitals.

Indeed, by regulating the delivery of 340B drugs, Nebraska is not expanding the number of patients eligible for 340B pricing under federal law. Nor is it altering the 340B price itself. Operating within the precise metes and bounds of the 340B statute—which is silent as to delivery and contract pharmacies, *PhRMA v. McClain*, 95 F.4th at 1142, 1143—Nebraska is

protecting its in-State hospitals' freedom to decide *where* they want drugs that they have purchased to be delivered. If a Nebraska hospital wants to buy a particular medication, the drug companies will ship to an in-house hospital pharmacy without restriction. L.B. 168 simply ensures that those companies *also deliver* those drugs to the pharmacies with which its in-State hospitals have contracts. Nothing in federal law forbids Nebraska from making that policy decision.

Ultimately, the parties are only fighting about logistics. There is no dispute that 340B hospitals are entitled to buy covered drugs at the federally-mandated price for their patients. The parties only disagree about the delivery address, where a hospital warehouses a drug, and back-end inventory management. The federal statute is *silent* about these logistical subjects. Nebraska's law, by contrast, addresses *only* these subjects. For this reason, the Eighth Circuit got it exactly right when it held that the analogous Arkansas law "does not set 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. Act 358 addresses only contract pharmacies, a matter that is not addressed in Section 340B.").

2. *L.B. 168 is Wholly Irrelevant to the Statutory Federal Audit Standards.*

AbbVie also urges that L.B. 168 would prevent drug companies from meeting the requisite "reasonable cause" standard to conduct an audit. Not so. Under the federal statute and HRSA guidance, "reasonable cause" is defined broadly to mean that a reasonable person could believe that a covered entity may have violated a requirement of section 340B(a)(5) (A) or (B) of the PHS Act. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996).

HRSA's guidance and practice confirm that the "reasonable cause" showing that a drug manufacturer must make to obtain authority to audit a covered entity is a modest one. According to long-standing HRSA guidance, manufacturers can satisfy this standard in various ways,

including by pointing to “[s]ignificant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity[.]” 61 Fed. Reg at 65,406. Critically, we are not aware of an instance when HRSA has *ever* required the claims or utilization data that the pharmaceutical companies now demand to initiate an audit. Nor has HRSA ever expected that a manufacturer would have access to claims data until *after* it conducted an audit. Tellingly, AbbVie *cannot point to a single instance* of HRSA rejecting a manufacturer’s audit plan due to the absence of claims data, and we are aware of none.

AbbVie’s reasoning turns the audit process upside down. The audit process designed by federal statute does not contemplate companies requiring hospitals to *prospectively* turn over massive amounts of data as a precondition to receiving 340B discounts. Instead, the statutory audit process is meant to *retrospectively* measure a covered entity’s compliance *after* 340B transactions have occurred. Indeed, longstanding HRSA guidance forbids manufacturers from “condition[ing] the offer of statutory discounts upon an entity’s assurance of compliance with section 340B provisions.” Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994); *see* Health Res. & Servs. Admin., 340B Drug Pricing Program Notice, Release No. 2011 – 1.1, Clarification of Non-Discrimination Policy (2012) (same).¹⁷

At bottom, for more than thirty years, the same agency that established and oversees the “reasonable cause” standard has taken the position that manufacturers *cannot* condition discounts on 340B compliance and *cannot* demand purchase data from 340B hospitals—exactly what

¹⁷ HHS’s analysis is precisely the type of agency interpretation that can assist this Court in construing the 340B statute. *See Bondi v. VanDerStock*, 145 S. Ct. 857, 874–75 (2025) (“[T]he contemporary and consistent views of a coordinate branch of government can provide evidence of the law’s meaning.”).

AbbVie admits it wishes to do here. It is therefore difficult to understand how a State law barring such preconditions could be an obstacle to HRSA's own compliance and audit processes.

3. *L.B. 168 Has Nothing to Do with Federal Efforts to Prevent Diversion.*

Likewise, AbbVie's repeated mention of diversion of drugs to non-eligible patients is wholly irrelevant to L.B. 168. The Nebraska statute regulates only the *delivery* of a 340B drug that has been purchased by a 340B hospital. The question in any State action to enforce L.B. 168 is whether the manufacturer refused to deliver a drug purchased by a 340B hospital to a contract pharmacy, not whether that drug was diverted to an ineligible patient. Under no circumstance would a State government official be required to answer questions of federal law about diversion. The issue of diversion is completely outside of the scope of the Nebraska law and therefore to this case.

By contrast, 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). Because the federal statute does not permit drug companies to take the law into their own hands *before delivery* to police suspected diversion,¹⁸ the audit and ADR forums are where questions of diversion would be determined. As such, L.B. 168 and the federal 340B statute enforce different things and therefore do not raise the possibility of conflicting enforcement decisions. State laws that require drug companies to deliver 340B drugs to contract pharmacies (on the same terms as they deliver to in-house hospital pharmacies) will *never* raise questions of diversion since those will be

¹⁸ *E.g.*, *Astra*, 563 U.S. at 113 (holding that Congress “assigned no auxiliary enforcement authority” to private actors); *Am. Hosp. Ass’n v. HHS*, No. 4:20-cv-08806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) (“Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process.”).

addressed, per the 340B statute, in the federal processes *after* the drugs have been delivered to those contract pharmacies.

Yet again, the Eighth Circuit already decided this question. When considering similar arguments in connection with the Arkansas law, it held:

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. 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 (citation omitted). This Court should adopt this reasoning not only because it is binding, but also because it is right.

II. L.B. 168 DOES NOT VIOLATE THE TAKINGS CLAUSE.

AbbVie's Fifth Amendment's Takings Clause claim likewise fails. To understand why, this Court need look no further than the Attorney General's persuasive discussion of this claim, Def.'s Mot. Dismiss at 10–20, ECF No. 27, or the District Court of Mississippi's point-by-point rejection of AbbVie's exact same arguments in *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20.

Amici focus on one dispositive flaw in AbbVie's Takings Clause claim: "voluntariness." *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied*, 469 U.S. 1215 (1985). AbbVie's voluntary participation in the 340B Program "forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." *Id.* To our knowledge, like the Eighth Circuit, no court has ever found that there is a property interest subject to Fifth Amendment protection where a healthcare provider or pharmaceutical company is *voluntarily participating* in the government program that it claims is taking its property. In fact, at

least ten courts have found no taking.¹⁹ Indeed, all three courts to consider this issue in the 340B context have rejected the Fifth Amendment challenges of pharmaceutical companies. *Eli Lilly*, 2021 WL 5039566, at *21; *Sanofi-Aventis*, 570 F. Supp. 3d at 207–10; *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20. In *Eli Lilly*, the court found that the plaintiff’s voluntary participation in the 340B Drug Program “forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation.” 2021 WL 5039566, at *21 (quoting *S.E. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016)). Although withdrawing from the 340B program—and therefore, necessarily, Medicaid and Medicare Part B (because 340B participation is required to participate in these markets)—would “result in a significant financial impact for” Eli Lilly, this consequence was insufficient to find legal compulsion for the purposes of the court’s takings analysis. *Id.*²⁰

¹⁹ *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014), *cert. denied*, 575 U.S. 1008 (2015); *Minn. Ass’n of Health Care Facilities*, 742 F.2d at 446; *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993), *cert. denied*, 510 U.S. 821 (1993); *Burditt*, 934 F.2d at 1376; *Whitney v. Heckler*, 780 F.2d 963, 968–73 (11th Cir. 1986), *cert. denied*, 479 U.S. 813 (1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984); *Eli Lilly & Co. v. U.S. Dep’t of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 207–10 (D.N.J. 2021), *rev’d on other grounds*, 58 F.4th 696 (3d Cir. 2023); *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20.

²⁰ *AbbVie* has argued in other challenges to State delivery laws that while it voluntarily accepted federal obligations in exchanges for the benefits of its participation in the 340B Program, it has received no benefits from the State in connection with the state delivery statute. But *AbbVie* cannot cite a single case to support that principle. At most, it cites a D.C. Circuit case, *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023), that did not involve any state law and that the D.C. Circuit itself said was “tied to the particular circumstances” of that case, *see id.* at 1239; *Bristol Myers Squibb Co. v. Becerra*, No. 23-3335, 2024 WL 1855054, at *8 (D.N.J. Apr. 29, 2024) (rejecting drug company reliance on *Valancourt Books*). Here, the “particular circumstances” differ immensely because, unlike the property owner in that *Valancourt Books*, L.B. 168 does not require *AbbVie* to *entirely* surrender its property with no economic value in return, especially since *AbbVie* receives some payment in return from hospitals for the drugs they buy that are shipped to contract pharmacies. What’s more, even if this invented requirement of an additional state-law benefit had some basis in precedent—and it does not—*AbbVie* plainly

The Southern District of Mississippi’s analysis in *AbbVie v. Fitch* is instructive. There, the court rejected AbbVie’s nearly identical allegations, finding that the similar Mississippi statute did not amount to an unconstitutional taking. *See AbbVie v. Fitch*, 2024 WL 3503965, at *16–20. The court concluded that because the Mississippi statute “does not compel Plaintiffs to directly sell 340B drugs to pharmacies, it does not cause takings for private use.” *Id.* at *19. Further, the court declined to find that the State law effected a *per se* taking because “Plaintiffs are still only required to sell at 340B discounts to covered entities, and [covered entities] can still only have drugs dispensed to their patients.” *Id.*

As an alternative basis for its holding, the court also applied the test for regulatory takings articulated by *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104 (1978), which “requires ‘balancing factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action.’” *AbbVie v. Fitch*, 2024 WL 3503965, at *17 (quoting *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021)). With respect to AbbVie’s “reasonable investment-backed expectations,” the court found that the Mississippi law “should have been foreseeable to Plaintiffs, as Section 340B has had a well-known ‘gap’ about how delivery must occur since Congress enacted it.” *Id.* at **18, 19 (quoting *Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996)). The district court concluded that enhanced regulation in the pharmaceutical industry—which “long has been the focus of great public concern and significant government regulation”—was foreseeable. *Id.* at *20 (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1008–09 (1984)). Further, the statute is “rationally

receives an important benefit from Nebraska in exchange for compliance with Nebraska law: the ability to receive a license to distribute drugs in the state. *See Neb. Rev. Stat. §§ 71-7447(1), 71-7457(1); Poor v. State*, 266 Neb. 183, 194 (2003) (“[E]vidence, specifically Poor’s involvement in the *unlawful* interstate distribution of GHB coupled with his lack of candor, is more than sufficient to establish this statutory ground for discipline.” (emphasis added)).

related to a legitimate Government interest,” given that “[t]he Mississippi Legislature has evidently determined that dispensation of 340B drugs at contract pharmacies advances public health, which falls squarely within its police powers.” *Id.* (internal citation and quotation marks omitted). Lastly, “‘the economic impact of the regulation’ is not drastic, and will not deprive Plaintiffs of all economically beneficial use of their products.” *Id.* (internal citations omitted). The same considerations apply here, as the Attorney General convincingly explains. Def.’s Mot. Dismiss at 14–20, ECF No. 27.

III. L.B. 168 IS NOT AN UNCONSTITUTIONAL EXTRATERRITORIAL REGULATION.

AbbVie also claims that L.B. 168 runs afoul of the dormant Commerce Clause because it “regulate[s] conduct that takes place wholly outside of” Nebraska. Compl. ¶ 158. But that claim is squarely foreclosed by *National Pork Producers* and has also been rejected by a Mississippi district court evaluating a challenge to an analogous Mississippi statute. *PhRMA v. Fitch*, 2024 WL 3277365, No. 1:24-CV-160-HSO-BWR, 2024 WL 3277365, at *13 (S.D. Miss. July 1, 2024); *see also Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 595189, at *3–5 (W.D. Mo. Feb. 24, 2025), *appeal docketed* (8th Cir. Mar. 28, 2025) (denying motion for preliminary injunction *inter alia* because Novartis did not show a likelihood of success on the merits of its dormant Commerce Clause claim against an analogous Missouri statute); *Nat’l Pork Producers Council v. Ross*, 598 U.S. 1142 (2023).

Like “many (maybe most) state laws,” L.B. 168 may indirectly impact “extraterritorial behavior” for drug companies that are headquartered outside of Nebraska. *Nat’l Pork Producers*, 598 U.S. at 374. But L.B. 168 does not target the regulation of extraterritorial activities. To the contrary, it is focused on drug dispensing to patients of Nebraskan 340B providers those that are *inside* of Nebraska’s borders. Even if AbbVie had a valid legal theory about extraterritorial effects,

it would not apply to L.B. 168 on the facts. *See Nat'l Pork Producers*, 598 U.S. at 375 (quoting *Hoyt v. Sprague*, 103 U. S. 613, 630 (1880)).

But AbbVie has no valid legal theory. *National Pork Producers* flatly rejected the “almost *per se*” extraterritoriality rule that AbbVie 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. Instead, the “very core” of its dormant Commerce Clause jurisprudence is the “antidiscrimination principle,” *i.e.*, whether a state engages in “economic protectionism” by privileging in-state competitors over out-of-state competitors. *Id.* at 369. AbbVie’s attempt to revive the “extraterritoriality doctrine” so shortly after the Supreme Court rejected it, *id.* at 371, is foreclosed by *National Pork Producers*. For the same reasons, the Southern District of Mississippi rejected PhRMA’s extraterritoriality challenge to that State’s materially identical law. *PhRMA v. Fitch*, 2024 WL 3277365, at *13. This Court should rule the same.

AbbVie tries to mislead the Court by arguing that, because L.B. 168 does not explicitly limit its effect to Nebraska 340B hospitals, it is an unconstitutional extraterritorial regulation. Compl. ¶ 19. This is unpersuasive for two reasons. *First*, like many other states, Nebraska follows a presumption against extraterritoriality, meaning that “statutes enacted by a state legislature apply to all rights which, and all persons who, come within the limits of the state.” *See Harper v. Silva*, 399 N.W.2d 826, 829 (Neb. 1987) (citing 73 Am. Jur. 2D Statutes § 356 (1974)); *see also PhRMA v. Fitch*, 2024 WL 3277365, at *13 (explaining that because an analogous Mississippi law “does not exhibit a clear intent to regulate out-of-state conduct,” that statute’s “‘general words’ referring to 340B entities, manufacturers, and pharmacies are *prima facie* operative only as to persons or things within the territorial jurisdiction of Mississippi”) (internal citation and quotation marks

omitted). The same is true of L.B. 168. *Second*, even if the statute could be construed to reach 340B covered entities outside of Nebraska, Section 5 of L.B. 168 makes clear that “[n]othing in the 340B Contract Pharmacy Protection Act shall be construed or applied to conflict with federal law or any other law of the State of Nebraska, if such law is compatible with applicable federal law.” As such, AbbVie’s reading of the law would be impermissible under Section 5.

IV. **L.B. 168 IS NOT VOID FOR VAGUENESS.**

A regulation is void for vagueness “when its terms are so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application.” *United States v. Zielinski*, 128 F.4th 961, 964 (8th Cir. 2025) (internal quotation marks and citation omitted). That is not the case here. That L.B. 168 does not include a definition of “location” does not render the statute unconstitutionally vague.²¹ This is because the entities subject to L.B. 168 can readily assess what the statute requires, including what it means by the term “location.”

In any event, it is disingenuous at best for AbbVie to argue that it that it does not know what “location” means in this context. Nebraska is specifically responding to AbbVie’s efforts to restrict contract pharmacy arrangements. It is also responding to the successful litigation campaign by drug companies to prevent the *federal* government from ensuring that drug companies like AbbVie deliver 340B drugs to contract pharmacies. *See infra* at 2 & n.2. For that reason, the Nebraska statute, aptly named “The 340B Contract Pharmacy Protection Act,” requires that drugs be delivered to the address—or “location”—where a 340B hospital wants the drugs to be delivered. AbbVie therefore knows exactly what the law requires.

²¹ Black’s Law Dictionary defines “location” as “[t]he designation of the boundaries of a particular piece of land, either upon record or on the land itself” *Location*, Black’s Law Dictionary (12th ed. 2024). Merriam-Webster defines “location” as “a position or site occupied or available for occupancy or marked by some distinguishing feature.” *Location*, Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/location>.

Courts must “interpret the relevant words not in a vacuum, but with reference to the statutory context, ‘structure, history, and purpose.’” *Abramski v. United States*, 573 U.S. 169, 179 (2014) (internal citation omitted). They also must use “common sense.” *Id.* (cited in *Janis v. United States*, 73 F.4th 628, 636 (8th Cir. 2023)). AbbVie’s proffered hypotheticals and disingenuous attempt to feign confusion about the meaning of “location” ignores those contextual clues and defies basic common sense. The statute is not vague, and AbbVie’s claim therefore fails.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court grant Defendant’s motion to dismiss.

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CERTIFICATE OF COMPLIANCE

I certify in accordance with the Court's Local Rule 7.1(d) that: according to the 2016 version of Microsoft Word used to prepare this brief, this brief includes 9,098 words, including the caption, headings, footnotes, and quotations; and, no generative artificial intelligence program was used in drafting the document, or to the extent such a program was used, a human signatory of the document verified the accuracy of all generated text, including all citations and legal authority

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CERTIFICATE OF SERVICE

I certify that on May 8, 2025, the foregoing Brief of American Hospital Association, 340B Health, Nebraska Hospital Association, and American Society of Health-System Pharmacists as *Amici Curiae* in Support of Defendant's Motion to Dismiss was filed electronically and has been served via the Court's ECF filing system on all registered counsel of record.

*/s/ Steven D. Davidson
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