UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA
CENTRAL DIVISION

ABBVIE INC., *et al.*, *Plaintiffs*, *v.* MARTY JACKLEY, in his official capacity as ATTORNEY GENERAL FOR THE STATE OF SOUTH DAKOTA, and LARRY D. DEITER, in his official capacity as DIRECTOR OF THE SOUTH DAKOTA DIVISION OF INSURANCE, *Defendants*.	Case No. 3:25-cv-3006-RAL

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, SOUTH DAKOTA ASSOCIATION OF HEALTHCARE ORGANIZATIONS, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Delia M. Druley
EVANS HAIGH & ARNDT LLP
225 11th Street, Suite 201
Sioux Falls, SD 57101
Tel: (605) 275-9602
ddruley@ehalawyers.com

William B. Schultz
Margaret M. Dotzel
Ezra B. Marcus
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
emarcus@zuckerman.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

AGENCY GUIDANCE

OTHER AUTHORITIES

INTEREST OF *AMICI CURIAE*[1]

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 South Dakota'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 **South Dakota Association of Healthcare Organizations** (SDAHO) serves as the voice for South Dakota's hospitals and healthcare organizations encompassing the full continuum of care. SDAHO represents a diverse membership with the goal of ensuring the highest quality of health care for South Dakotans. The association is a not-for-profit organization spanning various types of institutional ownership, geographic location, size, and complexities of service. Members include hospitals, health care systems, nursing facilities, home health agencies, assisted living centers, and hospice organizations.

[1] Counsel for *amici* have conferred with counsel for all parties regarding *amici*'s motion for leave to file this brief. Plaintiffs state that they take no position. Defendants do not oppose the filing of this brief.

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 and 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 Plaintiffs (collectively, AbbVie), broke with decades of precedent and suddenly refused to ship drugs purchased by 340B hospitals to their 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 on which they delivered those drugs to 340B in-house hospital pharmacies.[2]

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. The drug companies began with the premise that the federal 340B statute had absolutely nothing to say about delivery—*i.e.*, how and where drugs can and cannot be delivered. And they insisted that their new policies were *delivery* restrictions—not price restrictions.[3] The drug companies won. *See Novartis*

---

[2] *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,covered%20outpatient%20drugs%20purchased%20by%20covered%20entities.&text=HRSA%20expects%20AbbVie%20to%20provide%20an%20update,contract%20pharmacy%20arrangements%20by%20November%2018%2C%202022.

[3] *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,

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.").

Like many other states, South Dakota has filled the federal statutory gap that drug companies spent years fighting for by requiring shipment of 340B drugs to contract pharmacies. Faced with the drug industry's unprecedented assault on South Dakota's health care safety net and the acknowledged gap in federal law, the South Dakota legislature joined many other states and enacted Senate Bill 154 ("S.B. 154"). S.B. 154 does only what the pharmaceutical industry and the federal courts said the *federal* law did not do—regulate the delivery of 340B drugs. *See* S.B. 154 § 3 (prohibiting drug companies from restricting "the acquisition of a 340B drug or the delivery of a 340B drug *to a location* that is authorized to receive the drug by a 340B entity or pharmacy" (emphasis added)).

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' 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.")

Now comes the whiplash: AbbVie now claims that "S.B. 154 is a *price* regulation." Compl. ¶ 139 (emphasis added). Even though South Dakota has plainly legislated in precisely the area that AbbVie successfully insisted was not addressed under federal law—the delivery of 340B drugs—AbbVie has reversed course in this litigation to claim that S.B. 154 is preempted by federal law. And as part of that about-face, AbbVie now insists that states cannot fill the federal statutory gap that drug companies spent years fighting for in sister circuits.

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

The primary issue here is whether South Dakota, 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 connection with a materially identical Arkansas statute in *PhRMA v. McClain*, 95 F.4th 1136, 1143–45 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024).

AbbVie's complaint fails to state a claim for relief for four reasons. *First*, S.B. 154 is not field preempted. Congress did not create or occupy any field through its 340B legislation. AbbVie's entire field preemption argument turns on the false notion that the 340B statute is "comprehensive," specifying "[e]very detail of the 340B program." Compl. ¶ 138. 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 Cty., Fla. 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 many courts across the country have

recognized—including and especially the Eighth Circuit—this gap in federal law dooms any field preemption claim. *E.g.*, *PhRMA v. McClain*, 95 F.4th 1136, 1143–45 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024); *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 595189, at *3 (E.D. Mo. Feb. 24, 2025).[4]

Second, S.B. 154 is not conflict preempted. Contrary to AbbVie's assertions, South Dakota'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. South Dakota's law only affects *where* the 340B drugs (purchased by 340B hospitals) are shipped and stored. *See PhRMA*, 95 F.4th at 1145 (Arkansas' similar statute "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. . . . [It] does not require manufacturers to provide 340B pricing discounts to contract pharmacies. [It] does not set or enforce discount pricing."). It is, in essence, a non-discrimination provision. S.B. 154 allows *South Dakota* 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. South Dakota does not enforce requirements under federal law; it enforces only the state law requirement under S.B. 154

[4] The only court to conclude that the drug manufacturers were likely to succeed on the merits of their preemption claim based its ruling on a fundamental misunderstanding of the 340B statute and program. *PhRMA v. Morrissey*, 760 F. Supp. 3d 439 (S.D. W. Va. 2024).

that AbbVie deliver drugs (bought by South Dakota's 340B hospitals) to contract pharmacies *on the same terms* as they deliver to South Dakota's in-house hospital pharmacies.

Third, AbbVie's challenge under the Takings Clause fails. AbbVie characterizes S.B. 154 as requiring certain transactions involving 340B drugs "as a condition of participating in Medicaid." Compl. ¶ 13. But the Eighth Circuit has repeatedly "rejected [plaintiffs'] attempt[s] to characterize a loss of business associated with a condition on Medicaid participation as a taking," because the "choice to participate in Medicaid [is] voluntary," and "this voluntariness forecloses the possibility that the statute could result in an imposed taking of private property." *Key Med. Supply, Inc. v. Burwell*, 764 F.3d 955, 965 (8th Cir. 2014) (quoting *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984)). AbbVie's voluntary participation in Medicaid and the 340B program is fatal to its Takings Clause claim.

Fourth, S.B. 154 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.*

All in all, AbbVie's attack on S.B. 154 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 at 1114. Invalidating South Dakota'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 SOUTH DAKOTA

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 South Dakota 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).

Savings from the 340B program are crucial in enabling 340B hospitals to continue serving these communities. For example, the Faulkton Area Medical Center ("FAMC"), located in Faulkton, South Dakota, has historically used savings from the 340B program to relax its criteria for providing financial assistance to patients, enabling FAMC to provide total forgiveness to patients with income up to 200% of the Federal Poverty Guidelines instead of 100%. Savings and revenue from the 340B program are critical in FAMC's ability to remain viable in light of the population that it serves.

Fall River Health Services ("Fall River"), located in Hot Springs, South Dakota, similarly uses savings from the 340B program to help offset the cost of serving the very large percentage of individuals in its community who are below the Federal poverty line. Each year, roughly 70-75% of patients in Fall River's Long-Term Care facility are on Medicaid, but the State of South Dakota

cannot afford to fully pay for the cost of their care. Fall River ordinarily subsidizes a significant portion of the cost of these individuals' care, which savings from the 340B program help to offset.

Avera Health, headquartered in Sioux Falls, South Dakota, has used savings from the 340B program to support 21 different specialties at 31 locations across South Dakota. For example, One Avera Health location in Wagner, South Dakota has been able to support over 2,600 dialysis visits per year using savings from the 340B program. Avera Health also uses savings from the 340B program to support over 1,000 air ambulance flights each year.

And Sanford Health, also headquartered in Sioux Falls, has used 340B program savings to support a number of specialties across its locations, including adding rural obstetrics providers in central South Dakota in response to community need. Those providers now perform approximately 100 deliveries per year with support from 340B program savings.

The South Dakota legislature, with an unbiased interest in protecting its citizens, hospitals, and pharmacies, has acted to protect the 340B program. When enacting S.B. 154, the South Dakota legislature rejected the drug companies' efforts to denigrate the 340B program and those who rely on it by discriminating against hospitals with contract pharmacy arrangements.

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.[5] The drug 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.

---

[5] 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.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[6] "This is in large part due to the fact that building or maintaining a pharmacy is cost-prohibitive for many covered entities." *PhRMA*, 95 F.4th at 1139. 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.[7] Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy outside of its in-house pharmacy.[8] Using contract pharmacies also "has allowed for drug dispensation closer to where low-income patients reside." *PhRMA*, 95 F.4th at 1139. Denied these and other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services.[9]

For example, in the years since the drug industry began its campaign against contract pharmacies, Fall River has lost a substantial majority of its 340B program savings. Fall River's contract pharmacy revenue declined by approximately 73% between 2020 and 2023, forcing it to eliminate or reduce services that had been supported by 340B program savings—including eliminating its surgery department and reducing its psychiatry services.

---

[6] 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.

[7] 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.

[8] 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)).

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

340B savings help South Dakota 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.

The pharmaceutical industry's assault on contract pharmacy relationships drastically reduces the savings that South Dakota's 340B hospitals rely on and jeopardizes the hospitals' ability to provide valuable services to their patients.

ARGUMENT

I. ABBVIE'S PREEMPTION CLAIM FAILS.

AbbVie's preemption claim here is directly foreclosed by *PhRMA v. McClain*, in which the Eighth Circuit rejected a preemption challenge to an Arkansas statute materially identical to S.B. 154. *See* 95 F.4th at 1143–45. Like AbbVie, the plaintiff in *PhRMA* asserted both field preemption and conflict preemption theories. The Eighth Circuit rejected them both, using reasoning that applies equally here.

AbbVie has the burden to show that Congress intended to preempt S.B. 154. *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,[10] S.B. 154 is presumptively *not* preempted because it addresses the protection of public health and the operation of pharmacies—areas "traditionally left to state regulation." *PhRMA*, 95 F.4th at 1143 (pharmacy practice); *see also Lohr*, 518 U.S. at 475 (protecting public health). AbbVie therefore must demonstrate Congress's "clear and manifest

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

purpose" to supersede South Dakota's historic regulatory authority, *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.

The Eighth Circuit's binding decision in *PhRMA* held that, "in enacting Section 340B, Congress *did not intend to preempt the field*." 95 F.4th at 1144 (emphasis added); *see also id.* ("Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field."). Unfazed, AbbVie asserts a field-preemption theory based on the assertion that "[e]very detail of the 340B program is determined by federal law," and that the statute "leaves no room for states to interfere with the carefully designed 340B program." Compl. ¶¶ 138, 140. AbbVie's field-preemption theory runs headlong into *PhRMA* and fails for that reason alone.

AbbVie also is wrong in its characterization of the federal 340B statute. 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.* 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."[11] And as the Eight Circuit recognized in *PhRMA*, the 340B statute is *not* comprehensive because it is "silent about delivery of drugs to patients." 95 F.4th at 1143. This negates any possible inference of congressional intent to preempt the field on that issue.

B. S.B. 154 Does Not Conflict with the 340B Statute.

Just as PhRMA did before the Eighth Circuit, AbbVie "raises the same arguments it raised with field preemption" in asserting a conflict-preemption challenge. *PhRMA*, 95 F.4th at 1145. This Court should "reject these same arguments again," *id.*, just as the Eighth Circuit did.

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 Cty., Iowa*, 384 F.3d 557, 561 (8th Cir. 2004) (a federal statute's "silence cannot reflect the requisite clear and manifest purpose of Congress to preempt traditional state regulation") (citation 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

[11] AbbVie relies heavily on *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011). *See* Compl. ¶¶ 5, 38, 47, 104, 141–42. But the Eight Circuit was well aware of *Astra*, citing it multiple times in its *PhRMA* decision. *See* 95 F.4th at 1141. And the Western District of Louisiana has persuasively explained why *Astra* is inapposite. *See PhRMA v. Murrill*, Nos. 6:23-cv-00997, 6:23-cv-01042, 6:23-cv-01307, 2024 WL 4361597, at *7–8 (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 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.

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.

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 Commerce 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). S.B. 154, 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 S.B. 154 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, S.B. 154 "does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: [S.B. 154] assists in fulfilling the purpose of 340B." *PhRMA v. McClain*, 95 F.4th at 1144–45.

In a fruitless attempt to escape the Eighth Circuit's binding decision in *PhRMA*, AbbVie levels multiple attacks on S.B. 154, relying heavily on an outlier preliminary injunction ruling from the Southern District of West Virginia that conflicts with the Eighth Circuit's decision in *PhRMA* and that *amici* respectfully submit was wrongly decided. *See* Compl. ¶¶ 138–39 (citing

PhRMA v. Morrissey, 760 F. Supp. 3d 439 (S.D. W. Va. 2024)).[12] Each of AbbVie's arguments should be rejected.

1. S.B. 154 Regulates Delivery, Not Price.

AbbVie's argument that S.B. 154 regulates 340B drug price belies an analysis of the statute, which confirms that it actually addresses the delivery of 340B drugs. S.B. 154 bars drug companies from discriminating between delivery locations for patients of South Dakota 340B hospitals. S.B. 154 § 3. It requires drug companies to let 340B hospitals determine the appropriate shipping address for their 340B patients. That is precisely why the Eighth Circuit upheld Arkansas' similar statute, holding that it "does not set or enforce discount pricing." *PhRMA*, 95 F.4th at 1145.

AbbVie nonetheless relies on the West Virginia decision, but that decision 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 South Dakota law addresses—*where* drug companies must ship drugs that are purchased by South Dakota's 340B hospitals.

[12] 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 the decision carried no weight with a Mississippi district court, which explicitly rejected its 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").

Indeed, by regulating the delivery of 340B drugs, South Dakota 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*, 95 F.4th at 1142–43—South Dakota is protecting its in-state hospitals' freedom to decide *where* they want drugs that they have purchased to be delivered. If a South Dakota hospital wants to buy a particular medication, the drug companies will ship to an in-house hospital pharmacy without restriction. S.B. 154 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 South Dakota 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. South Dakota'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*, 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. S.B. 154 is Irrelevant to the Statutory Federal Audit Standards.

AbbVie also urges that S.B. 154's prohibition on collection of claims and utilization data, *see* S.B. 154 § 4, poses an obstacle to the audit process set forth in the federal 340B statute. *See* Compl. ¶ 135. Although never directly saying so, AbbVie appears to suggest that S.B. 154's data-collection provision prevents drug companies from meeting the "reasonable cause" standard to conduct an audit that is set forth in federal guidance. *See id.*

Not so. Even if guidance from a federal agency (here, the Health Resources & Services Administration, or "HRSA") could somehow manifest Congress's intent to preempt state law, S.B. 154 poses no obstacle to the HRSA guidance that AbbVie cites. HRSA's guidance and practice confirm that the "reasonable cause" threshold that a drug manufacturer must meet before auditing a covered entity is modest and does not require the sort of data addressed by S.B. 154. HRSA guidance defines "reasonable cause" broadly to mean "that 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). Manufacturers can meet this standard in various ways that require little evidence (and certainly do not require claims data)—for example, 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[.]" 61 Fed. Reg at 65,406. Critically, *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 AbbVie now claims it must be allowed to collect. Nor has HRSA ever expected that a manufacturer would have access to such data until *after* it conducted an audit.

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).[13]

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 AbbVie admits it wishes to do here. A state law barring such preconditions cannot be an obstacle to HRSA's own compliance and audit processes.

3. S.B. 154 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 S.B. 154. South Dakota's statute regulates only the delivery of a 340B drug that has been purchased by a 340B hospital "to a location that is *authorized* to receive the drug by a 340B entity or pharmacy." S.B. 154 § 3 (emphasis added). The question in any state action to enforce S.B. 154 is whether a 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 circumstances would a state government official be required to answer federal questions about diversion. The issue of diversion is completely outside the scope of the South Dakota law.

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

[13] 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.").

statute does not permit drug companies to take the law into their own hands *before delivery* to police suspected diversion,[14] the audit and ADR forums are where questions of diversion would be determined. As such, S.B. 154 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 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 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. 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, 95 F.4th at 1144. This Court should adopt this reasoning not only because it is binding, but also because it is right.

II. S.B. 154 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 District Court of Mississippi's point-by-point rejection of

[14] *E.g.*, *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011) (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.").

AbbVie's exact same arguments—regarding a materially identical Mississippi statute—in *AbbVie v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965, at *16–20 (S.D. Miss. July 22, 2024).

Amici focus on one dispositive flaw in AbbVie's Takings Clause claim: "voluntariness." *Minn. Ass'n of Health Care Facilities*, 742 F.2d at 444. "Drug manufacturers *opt in* to the 340B Program." *Astra USA*, 563 U.S. at 113 (emphasis added). 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." *Minn. Ass'n of Health Care Facilities*, 742 F.2d at 446. To our knowledge, *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—including the Eighth Circuit in *Minnesota Association of Health Care Facilities*, 742 F.2d 442—have found no taking under such circumstances.[15] In the 340B context, all three courts to consider this issue have rejected drug companies' Takings Clause challenges. *See 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.

As the court found in *Eli Lilly*, a drug manufacturer's voluntary participation in the 340B Drug Program "forecloses the possibility that the statute could result in an imposed taking of

[15] *See 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 v, U.S. Dep't of Health & Human Servs.*, 934 F.2d 1362, 1376 (5th Cir, 1991); *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.

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.*[16]

The Southern District of Mississippi's analysis in *AbbVie v. Fitch* is also 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

[16] 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 *Valancourt Books*, AbbVie is not required under S.B. 154 to *entirely* surrender its property with no economic value in return: AbbVie receives payment from hospitals for the drugs they buy that are shipped to contract pharmacies.

Even if AbbVie were correct that some additional State benefit were required—and it is not—there is plainly one here. AbbVie seems to forget that Medicaid is a "joint federal-state program." *Portland Residence, Inc. v. Steffen*, 34 F.3d 668, 670 (8th Cir. 1994). And state Medicaid coverage of outpatient drugs is largely optional, not mandatory. *See* 42 U.S.C. § 1396a(54); *see also* Letter from Tim Hill, Acting Director, Center for Medicaid & CHIP Services, Centers for Medicare & Medicaid Services, to Daniel Tsai, Assistant Secretary, MassHealth, June 27, 2018, at 2 ("[t]he state could then be provided flexibility to exclude certain drugs from coverage. . ."). South Dakota's decision to cover such drugs confers a specific benefit on AbbVie and other drug manufacturers. South Dakota could revisit that decision, along with others that benefit AbbVie and other drug manufacturers, if they refuse to comply with its laws concerning delivery of 340B drugs. This is more than enough to meet the "additional-State-benefit" standard that AbbVie has invented out of whole cloth.

sell 340B drugs to pharmacies, it does not cause takings for private use." *Id.* at *19. The court also 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 *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 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 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.

III. S.B. 154 IS NOT AN UNCONSTITUTIONAL EXTRATERRITORIAL REGULATION.

AbbVie also claims that S.B. 154 runs afoul of the Commerce Clause, but AbbVie's claim ignores the text and context of S.B. 154, is squarely foreclosed by the Supreme Court's recent application of the dormant Commerce Clause in *National Pork Producers*, and has been rejected by district courts evaluating challenges to contract-pharmacy statutes. *See PhRMA v. Fitch*, No. 1:24-cv-160-HSO-BWR, 2024 WL 3277365, at *12–13 (S.D. Miss. July 1, 2024) (Mississippi); *Novartis v. Bailey*, 2025 WL 595189, at *3–5 (Missouri).

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.

Like "many (maybe most) state laws," S.B. 154 may indirectly impact "extraterritorial behavior" for drug companies that are headquartered outside of South Dakota. *Nat'l Pork Producers*, 598 U.S. at 374. But the statute does not *target* extraterritorial activity or privilege in-state actors over their out-of-state competitors; its prohibitions apply equally to in- and out-of-state sellers of drugs. 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 do likewise.

In attempting to miscast S.B. 154 as discriminatory, AbbVie argues that it "privilege[s] state *hospitals and pharmacies* over out-of-state *manufacturers*." Compl. ¶ 151 (emphasis added). But "the dormant Commerce Clause doesn't prohibit differential treatment of companies that perform *different services*." *Paul's Indus. Garage, Inc. v. Goodhue Cty.*, 35 F.4th 1097, 1099–1100 (8th Cir. 2022) (emphasis in original). AbbVie's allegation that S.B. 154 preferences certain *types* of businesses (hospitals and pharmacies) over others (drug manufacturers), even if true, does not suggest discrimination among "substantially similar entities," and it therefore does not implicate the dormant Commerce Clause. *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 342–43 (2008) (citation omitted); *see also, e.g.*, *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 125 (1978) (rejecting dormant Commerce Clause challenge to state statute that allegedly favored in-state *retailers* over out-of-state *producers* because the state was not "discriminating against interstate commerce at the retail level").

Nor can AbbVie claim that S.B. 154 "regulat[es] commerce occurring entirely outside South Dakota." Compl. ¶ 1. AbbVie attempts to argue that, because S.B. 154 does not explicitly limit its effect to South Dakota 340B hospitals, it is an unconstitutional extraterritorial regulation. *See* Compl. ¶ 162. This is unpersuasive for two reasons. First, courts in South Dakota, as in many other states, generally read the state's statues *not* to apply outside South Dakota's borders. *See Dakota Indus., Inc. v. Cabela's.com, Inc.*, 766 N.W.2d 510, 513 (S.D. 2009) ("South Dakota's trademark law . . . cannot extend to extraterritorial conduct." (citation omitted)); *Veigel v. Dakota Trust & Sav. Bank*, 225 N.W. 657, 659 (S.D. 1929) ("Further, section 8961 can only apply to banks within this state; it has no extraterritorial force."). Accordingly, S.B. 154 is best read to apply only to covered entities (*i.e.*, hospitals) within South Dakota, and thus it does not implicate any prohibition on regulating wholly extraterritorial conduct. *See 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).

Second, in attempting to argue that S.B. 154 "regulat[es] commerce occurring entirely outside South Dakota," Compl. ¶ 1, AbbVie repeatedly highlights the statute's definition of "Pharmacy," which encompasses physical pharmacy locations "within or outside this state." *See id.* ¶¶ 18 (quoting S.B. 154 § 2(2)); 101 (same); 160 (same). But for a pharmacy to come within S.B. 154's definition, it must be "licensed by the State Board of Pharmacy" of South Dakota[17] and thus subject to South Dakota's regulatory jurisdiction. S.B. 154 § 2(2). A "Pharmacy" as defined under S.B. 154 must also be a "place . . . where drugs are dispensed . . . to residents of this state." *Id.* The statute's definition of "Pharmacy" does not take S.B. 154 beyond South Dakota's reach so as to offend the dormant Commerce Clause.

CONCLUSION

For the foregoing reasons, *Amici* ask the Court to grant Defendants' motion to dismiss.

Dated: May 14, 2025

Respectfully submitted,

/s/ Delia M. Druley
Delia M. Druley
EVANS HAIGH & ARNDT LLP
225 11th Street, Suite 201
Sioux Falls, SD 57101
Tel: (605) 275-9602
ddruley@ehalawyers.com

William B. Schultz*
Margaret M. Dotzel*

[17] In S.B. 154, "the State Board of Pharmacy" refers to the South Dakota Board of Pharmacy. *See* S.D. Code § 36-11-2 (defining "Board" and "board of pharmacy" to mean "the State Board of Pharmacy in South Dakota"); *see generally* S.D. Code Ch. 36-11 (referring throughout to "the State Board of Pharmacy").

Ezra B. Marcus*
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
emarcus@zuckerman.com

Counsel for Amici Curiae

* *pro hac vice motion pending*

CERTIFICATE OF SERVICE

I certify that on May 14, 2025, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

/s/ Delia M. Druley
Counsel for Amici Curiae