

No. 24-30651

**UNITED STATES COURT OF
APPEALS FOR THE FIFTH CIRCUIT**

ASTRAZENECA PHARMACEUTICALS, L.P.,
Plaintiff-Appellant,

v.

LIZ MURRILL, IN HER OFFICIAL CAPACITY AS ATTORNEY GENERAL OF LOUISIANA,
Defendant-Appellee,

LOUISIANA PRIMARY CARE ASSOCIATION,
Intervenor Defendant-Appellee.

On appeal from the United States District Court
for the Western District of Louisiana
No. 6:23-cv-01042
District Judge Robert R. Summerhays

**BRIEF OF AMERICAN HOSPITAL ASSOCIATION, LOUISIANA
HOSPITAL ASSOCIATION, 340B HEALTH, AND AMERICAN
SOCIETY OF HEALTH-SYSTEM PHARMACISTS AS *AMICI CURIAE*
IN SUPPORT OF DEFENDANT-APPELLEE AND INTERVENOR
DEFENDANT-APPELLEE**

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

AstraZeneca Pharmaceuticals, L.P. v. Murrill, No. 24-30651

In addition to the persons and entities listed in Plaintiff-Appellant's Certificate of Interested Persons, undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Amici Curiae

American Hospital Association

340B Health

Louisiana Hospital Association

American Society for Health-System Pharmacists

Amici are all non-profit organizations, none of which has a parent corporation nor issues stock.

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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 Louisiana’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.

¹ No party’s counsel authored this brief in whole or in part. No one other than *Amici* or their counsel contributed any money to fund its preparation or submission. The parties consent to the filing of this brief.

The **Louisiana Hospital Association** has worked for the betterment of Louisiana hospitals for almost 100 years. It represents more than 150 individual hospital members, including many that participate in the 340B program.

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 AstraZeneca, 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.²

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://perma.cc/TC4W-5KWL>.

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,³ and (2) the 340B statute had absolutely nothing to say about *delivery*. The drug 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 those wins, AstraZeneca reversed course in this litigation. AstraZeneca now contends that Louisiana’s law requiring shipment to contract pharmacies regulates price, not delivery. And as part of that *volte-face*, AstraZeneca now insists that States cannot fill the federal statutory gap that it spent years fighting for in sister circuits. AstraZeneca’s heads-I-win-tails-you-lose argument is as shameless as it is meritless.

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, *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.”).

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

Faced with the drug industry’s unprecedented assault on Louisiana’s health care safety net and the acknowledged gap in federal law, the Louisiana legislature passed Act 358, the “Defending Affordable Prescription Drug Costs Act,” by an overwhelming 135-2 vote. Act 358 does only what AstraZeneca and the federal courts said the *federal* law did not do—regulate the delivery of 340B drugs. *See* La. Stat. Ann. § 40:2884 (2023).

The primary issue here is whether Louisiana, 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. And despite what AstraZeneca would now have this Court believe, the Louisiana statute *does* regulate delivery and *does not* regulate the 340B price. The price of 340B drugs continues to be set by federal law, and Louisiana’s law only affects *where* the 340B drugs (purchased by 340B hospitals) are shipped and stored for later dispensing to 340B patients. It is, in essence, a non-discrimination provision. Act 358 allows Louisiana hospitals to choose where 340B drugs are to be

delivered, rather than letting drug companies discriminate in favor of in-house pharmacies.

Put differently, Louisiana is merely exerting its independent state “sovereignty” to regulate drugs that “pass[] within [its] own territory.” *Zyla Life Scis. LLC v. Wells Pharma of Houston LLC*, No. 23-20533, --- F.4th ----, 2025 WL 1076889, at *7 (5th Cir. Apr. 10, 2025) (internal quotation marks omitted). Exercising its “traditional prerogative,” *id.*, the State seeks to ensure that drugs (prescribed to *Louisiana* residents⁴) shipped to pharmacies that *Louisiana* hospitals contract with are treated on the same terms as drugs shipped directly to *Louisiana* in-house hospital pharmacies. AstraZeneca’s attempt to prevent Louisiana from legislating about the delivery of drugs to contract pharmacies for residents physically located within its state borders, bought by hospitals within its state borders, simply because Act 358 “touches” on something that federal law also regulates, cannot be squared with this Court’s most recent conflict preemption precedent and, more importantly, foundational “principles of federalism.” *Id.* at *6, 7.

In this litigation, AstraZeneca does not dispute three aspects of the 340B program. *First*, drug companies must deliver 340B drugs to in-house pharmacies at 340B hospitals. *Second*, the 340B statute is silent about delivery. *Third*, the 340B

⁴ See La. Stat. Ann. § 40:2882(5) (narrowly defining “pharmacy” to ensure that “residents who are provided pharmacy care shall be physically located in this state”).

price is set by federal law—not Louisiana’s statute. The 340B price of a drug is exactly the same if it is sold to a 340B hospital for delivery to its in-house pharmacy or for delivery to a contract pharmacy.

Act 358 regulates only one thing. Under that law, the purchaser of the drugs (a Louisiana 340B hospital) remains the same. The federally-established 340B price of those drugs remains the same. The 340B hospital’s patient remains the same, whether the patient receives the drug from the in-house or contract pharmacy. The *only* difference—and the *only* thing the Louisiana law regulates—is the literal address where the drug is delivered. Act 358 merely requires that drug companies deliver 340B discounted drugs purchased by 340B hospitals to the hospital’s contract pharmacies *on the same terms* as they sell those drugs to 340B hospitals with in-house pharmacies. This arrangement had been in place for almost 30 years before the drug industry’s sudden U-turn in 2020. All Louisiana’s law does is restore that decades-old arrangement by filling the gap in federal law that AstraZeneca fought for in earlier litigation.

The district court’s well-reasoned opinion rejected AstraZeneca’s efforts to squeeze 340B hospitals and upheld Louisiana’s lawful exercise of its police power over matters of health and safety. This Court should affirm.

**FACTUAL BACKGROUND ON THE IMPORTANCE OF CONTRACT
PHARMACY ARRANGEMENTS IN LOUISIANA**

AstraZeneca 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 AstraZeneca, every 340B drug it refuses to deliver to a Louisiana 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 Louisiana legislature, with an unbiased interest in protecting its citizens, hospitals, and pharmacies, shares the Supreme Court’s view of the Program. When enacting Act 358, the Louisiana 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 AstraZeneca honored for almost 30 years helped sustain hospitals and their patients. Nationwide, a quarter of hospitals’ 340B benefit comes from drugs dispensed at contract

pharmacies.⁵ In Louisiana, *at least 90 percent* of some hospitals’ 340B benefit comes from drugs dispensed using contract pharmacies. For example, *the entirety* of Allen Parish Hospital’s 340B benefit comes from drugs dispensed at contract pharmacies. At least two other members of the Louisiana Hospital Association (LHA) have reported that between 90 and 100 percent of their 340B benefit derives from the use of contract pharmacies.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.⁶ 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

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.

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>; Specialty Drug Coverage and Reimbursement in Medicaid, HHS Office of Inspector General,

at least one specialty pharmacy outside of its in-house pharmacy.⁸ Denied these and other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services.⁹

340B savings help Louisiana patients in a variety of ways. To take just one example, 340B providers such as Savoy Medical Center in Mamou and InclusivCare in Jefferson Parish testified before the Louisiana legislature that they use 340B savings to support door-to-door transportation for patients who otherwise would have to rely on bicycles or limited public transportation, or who would tragically forgo needed medical care. Similarly, Woman's Hospital in Baton Rouge uses its 340B benefit to fund the delivery of medicines directly to patients at home. Without the 340B savings that flow from contract pharmacy arrangements, these vital programs are at risk.¹⁰

In these ways and others, contract pharmacy arrangements allow Louisiana's 340B providers to buy drugs at 340B prices to be delivered closer to where their

<https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp>.

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.

¹⁰ 340B Health, *340B Health Annual Survey 2022: Vital 340B Supported Services Threatened as Manufacturer Restrictions Cut Into Savings* (Jul. 2023), https://www.340bhealth.org/files/340B_Health_Survey_Report_2022_FINAL.pdf.

patients live. A significant portion of the population that 340B hospitals serve live in rural communities. Their patients may live more than 100 miles from an in-house pharmacy. This is true for 340B providers like Lake Charles Memorial Health System, which serves a five-parish area covering more than 5,000 square miles.

Although not required to do so, many Louisiana hospitals pass the 340B discount directly on to patients—including those who otherwise could not afford their medications. One of LHA’s members reported that, through these direct discounts, its “uninsured patients paid an average of \$7.77 for retail prescriptions and \$48.05 for specialty medications, compared to the non-340B price of \$78.13 and \$3,937.10, respectively.” This was possible only because the drug company honored the contract pharmacy arrangement.

The 340B benefit also allows hospitals to expand the services they provide to their patients. LHA’s members report that the 340B benefit allows them to, among other things, fund:

- neonatal and pediatric intensive care units;
- outpatient cancer and non-oncology infusion centers;
- cancer patient navigators to assist low-income patients with their treatments;
- mobile mammography units; and
- medication counseling services.

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 Louisiana's 340B hospitals rely on and jeopardizes the hospitals' ability to provide valuable services to their patients.

ARGUMENT

As the district court held, AstraZeneca's claims are meritless. *First*, Louisiana's law is not preempted because Congress did not create or occupy any field through its 340B legislation, nor does it conflict with the 340B statute. At bottom, AstraZeneca contends that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. To the contrary, as the Eighth Circuit explained, "[p]harmacy has traditionally been regulated at the state level, and [courts] must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *PhRMA v. McClain*, 95 F.4th 1136, 1144 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024) (citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)); *see MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023 (5th Cir. 1994). For this reason,

courts that have considered the issue, including the Eighth Circuit and the district court below, have routinely rejected preemption claims regarding materially similar state laws. *See, 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 (E.D. Mo. Feb. 13, 2025).¹¹

Second, the district court correctly found that Act 358 is not void for vagueness. The commonly-used term “interfere” is easily understood. AstraZeneca’s arguments to the contrary do not meet the high bar required to prove that statutory language is unconstitutionally vague.

I. ACT 358 IS NOT PREEMPTED BY FEDERAL LAW.

“‘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

¹¹ 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*, --- 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), *appeal docketed*, Nos. 25-1054, 25-1055, 25-1056 (4th Cir. Jan. 16, 2025). As explained *infra* at 18–19, this Court should reject that flawed analysis and follow the consistent approach of other courts around the country.

particularly in those in which Congress has ‘legislated in a field which the States have traditionally occupied,’” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), 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)). AstraZeneca has the burden to show that Congress intended to preempt Act 358. *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,¹² Act 358 is presumptively *not* preempted. AstraZeneca therefore must demonstrate Congress’s “clear and manifest purpose” to supersede Louisiana’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

¹² *See, e.g., Arizona v. United States*, 567 U.S. 387 (2012); *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363 (2000).

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.* AstraZeneca 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.” Accordingly, its field preemption claim fails.

B. Act 358 Does Not Conflict with the 340B Statute.

“In arguing conflict preemption, Plaintiffs’ re-urge most of the same arguments urged with respect to their field preemption claims.” *See PhRMA v. Murrill*, Nos. 6:23-cv-00997, 6:23-cv-01042, 6:23-cv-01307, 2024 WL 4361597, at *8 (W.D. La. Sept. 30, 2024). These re-packaged arguments fail for the same reasons.

In essence, AstraZeneca tries to transform the federal statute’s silence about delivery into an intentional congressional decision to preempt state regulation. That

cannot be. *E.g.*, *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 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 Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011), and AstraZeneca 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). Act 358, 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 Act 358 not interfere with Congress’s 340B scheme; it “furthers” it. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 82 (1987); *PhRMA v. McClain*, 95 F.4th at 1144–45; *PhRMA v. Murrill*, 2024 WL 4361597, at *9 (“Act 358 arguably *advances* Congress’ objectives with respect to the Section 340B program.”).

C. The Lone District Court to Find Preemption Did So on the Basis of a Misunderstanding of the 340B Statute and Program.

To support its arguments, AstraZeneca relies on the Southern District of West Virginia’s preliminary injunction ruling. But that 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”).

The West Virginia district court erred in several critical respects. *First*, it wrongly concluded that its State statute regulates 340B drug price and not delivery. This finding cannot survive this Court’s recent analysis in *Zyla Life Scis. LLC v. Wells Pharma of Houston LLC*. Neither the West Virginia court nor AstraZeneca

disputes that the federal government sets the purchase price for 340B drugs. Act 358 regulates only *where* the drug must be shipped for a Louisiana resident. And, as this Court confirmed, “one of the fundamental features of sovereignty is the power to regulate ‘every thing that passes’ within one’s own territory.” *Zyla Life Scis.*, 2025 WL 1076889, at *7 (citation omitted).

Here, Act 358 simply bars drug companies from discriminating between delivery locations for residents “physically located in” *Louisiana*. See La. Stat. Ann. § 40:2882(5). Act 358 requires drug companies to let 340B hospitals within State borders determine the appropriate shipping address for 340B patients living within its borders. It makes no difference that this delivery non-discrimination provision “touches” federal law, *id.*, “expressly incorporates federal law into state law,” *id.* at *1, or indirectly addresses the same “primary conduct” of the federal 340B statute (*i.e.*, providing discounted drugs to 340B covered entities), *id.* at *7; *see also id.* (“States may generally regulate the same conduct the Federal Government does.”).¹³

¹³ AstraZeneca cannot distinguish *Zyla* by arguing that the state law at issue there was identical to the relevant federal statute for two important reasons. *First*, *Zyla* specifically explained that “[i]f regulating the same primary conduct in different ways does not upset federal enforcement prerogatives, it follows *a fortiori* that regulating it in parallel ways does not either.” 2025 WL 1076889, at *8; *see id.* at *7. *Second*, AstraZeneca’s argument is even more aggressive than the one rejected in *Zyla*. Here, the federal law is silent as to delivery. Thus, Louisiana isn’t even regulating “concurrently” with federal law. It is filling a gap in the 340B statute consistent with the “historic primacy of state regulations of matters of health and safety.” *Id.* at 2 (citation omitted).

If Louisiana cannot require drug companies to deliver drugs purchased by 340B hospitals at their contract pharmacies *on the same terms as* they deliver those drugs to in-house hospital pharmacies, then we are truly entering the world of an “all-powerful federal overlord.” *Id.* at *7.

Further, the West Virginia court’s decision rested on a fundamental misunderstanding of the replenishment model. It reasoned that, “[b]ecause the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy, the question is not about delivery of the drug. The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one.” *PhRMA v. Morrissey*, 2024 WL 5147643, at *6. That is not true. 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. The 340B hospital would pay that exact same price if it were replenishing its own inventory after a patient received the drug at its pharmacy. Thus, replenishment at the 340B price would happen whether the 340B drug is delivered to the hospital’s pharmacy *or* the hospital’s contract pharmacy. And that is all the Louisiana law addresses—*where* drug companies must ship those drugs for in-State Louisiana patients to receive them.

Indeed, by regulating the delivery of 340B drugs, Louisiana 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—Louisiana is protecting its in-State hospitals’ freedom to decide *where* they want drugs that they have purchased to be delivered. If a Louisiana hospital wants to buy a particular medication, the drug companies will ship to an in-house hospital pharmacy without restriction. Act 358 simply ensures that those companies *also deliver* those drugs to the pharmacies with which its in-State hospitals have contracts, thereby making it easier for in-State hospitals to reach their patients closer to where they actually live. Nothing in federal law forbids Louisiana 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 concededly silent about these logistical subjects. Louisiana’s law, by contrast, addresses *only* these subjects. For this reason, the district court in *this* case—and not the district court in West Virginia—got it exactly right when it held that the price “discounts 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.” *PhRMA v. Murrill*, 2024 WL 4361597, at *9.

Second, the West Virginia district court misapprehended the true purpose of the 340B statute. Drawing on language from a congressional report, numerous courts have held that the “program was intended to enable certain hospitals and clinics ‘to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.’” *Am. Hosp. Ass’n v. Hargan*, 289 F. Supp. 3d 45, 47 (D.D.C. 2017), *aff’d sub nom.*, *Am. Hosp. Assoc. v. Azar*, 895 F.3d 822 (2018) (quoting H.R. Rep. No. 102–384, pt. 2, at 12 (1992)). Thus, the statute’s provisions regarding diversion and duplicate discounts do not create “twin” statutory purposes. *PhRMA v. Morrissey*, 2024 WL 5147643, at *6. That court’s misunderstanding of the actual purpose of the 340B statute infected its entire conflict preemption analysis, which, when done properly, turns on identifying whether a state law stands as an obstacle to Congress’ *actual* purpose. Yet again, the district court in this case got it right when it identified the true purpose of the 340B program and concluded that Louisiana’s law “arguably advanced” it. *PhRMA v. Murrill*, 2024 WL 4361597, at *9.

Third, based on its clear misunderstanding of the federal 340B audit process, the West Virginia court incorrectly found obstacle preemption on the grounds that by restricting drugs companies’ ability to demand claims data as a condition for

ordering 340B drugs the State statute “hampers the ability of drug manufacturers to formulate the ‘reasonable cause’ necessary to conduct an audit[.]” *PhRMA v. Morrissey*, 2024 WL 5147643, at *7. Under the federal statute and HRSA guidance, however, when a manufacturer wishes to conduct an audit of a covered entity, it must demonstrate “reasonable cause,” 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, AstraZeneca *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.

The district court’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).¹⁴

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 AstraZeneca admits it wishes to do here. It is

¹⁴ 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.”).

therefore difficult to understand how a State law barring such preconditions could be an obstacle to HRSA's own compliance and audit processes.

Fourth, the West Virginia court erred by ruling that the enforcement provision in its statute is likely preempted because State actors would be tasked with determining questions of federal law, such as whether a 340B “drug is being diverted to non-[340B] patients in violation of federal law.” *PhRMA v. Morrissey*, 2024 WL 5147643, at *16. Even if this were true—and it is not—this Court recently held that dual enforcement responsibilities *do not* establish conflict preemption. *Zyla Life Scis.*, 2025 WL 1076889, at *8.

But under no circumstance would a State government official be required to answer federal questions. The Louisiana 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 Act 358 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. The issue of diversion is completely outside of the scope of the Louisiana 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

like AstraZeneca to take the law into its own hands *before delivery* to police suspected diversion,¹⁵ the audit and ADR forums are where questions of diversion would be determined. As such, Act 358 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. There is simply no risk of conflicting determinations about diversion because that determination will be made long after 340B drugs are delivered to contract pharmacies and the narrow legal force of Act 358 (*i.e.*, a delivery mandate) has ceased. Yet again, the district court in this case correctly understood this distinction in a way the West Virginia court did not. *See PhRMA v. Murrill*, 2024 WL 4361597, at *8 (“[T]he Louisiana statute creates an enforcement mechanism, but that mechanism pertains solely to pharmaceutical companies’ actions toward pharmacies who enter into contracts with covered entities under the Section 340B program. The Louisiana statute does not address the pharmaceutical companies’ agreements with

¹⁵ *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.”).

HHS or the pricing, patient definition, or ‘double dipping’ restrictions addressed in the HHS’ enforcement scheme.”).

II. ACT 358 DOES NOT VIOLATE THE CONTRACTS CLAUSE.

The district court also correctly rejected AstraZeneca’s Contracts Clause claim. *PhRMA v. Murrill*, 2024 WL 4361597, at **12–13. The Contracts Clause prohibits States from passing any law that “impair[s] the Obligations of Contracts[.]” U.S. Const. art. I, § 10. The Supreme Court’s two-step analysis for Contracts Clause challenges requires first that a court determine whether the State law at issue substantially impairs a contractual relationship, and if so, whether it did so for a legitimate purpose. *Sveen v. Melin*, 584 U.S. 811, 819 (2018).

AstraZeneca’s Contracts Clause challenge fails at the first step. The contract that AstraZeneca relies on, the PPA, is unaffected by the Louisiana statute. The terms of the PPA mirror the federal 340B statute. As the Supreme Court has explained, “the PPAs simply incorporate statutory obligations and record the manufacturers’ agreement to abide by them. The form agreements, composed by HHS, contain no negotiable terms [T]he 340B Program agreements serve as the means by which drug manufacturers opt into the statutory scheme.” *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011).

AstraZeneca is incorrect that Act 358 “seeks to expand AstraZeneca’s obligations for participating in the 340B Program, by requiring AstraZeneca to

‘deliver’ 340B-discounted drugs (*i.e.*, to provide 340B discounts) for a *different* category of transactions (unlimited contract pharmacy sales) that are not required by AstraZeneca’s PPA.” AstraZeneca Opening Br. at 38–39 (Doc. 36, filed Jan. 9, 2025). The Louisiana law does not change or expand the definition of covered entities that are entitled to 340B discounts. Nor does Act 358 change what prices drug companies may charge covered entities. Rather, it only affects the *delivery* of 340B drugs, which is not addressed in the PPA. AstraZeneca cannot identify any way in which the provision expands or contradicts its PPA because, by simply incorporating the 340B statute, the PPA is silent as to delivery.

AstraZeneca relies on an inapposite case to support its argument. In *Allied Structural Steel Co. v. Spannaus*, the Supreme Court struck down a Minnesota law that required a company to provide additional pension benefits after it had agreed to provide such benefits under a specific contractual provision. 438 U.S. 234, 245–46, *reh’g denied*, 439 U.S. 886 (1978). Unlike the Louisiana statute here, where the terms of the PPA remain unchanged, the law in that case effectively changed the terms of the contract.

Moreover, even if Act 358 did substantially impair the contractual relationship between AstraZeneca and HHS (it does not), the Louisiana legislature had a legitimate purpose. The Supreme Court has “repeatedly held that unless the State is itself a contracting party, courts should ‘properly defer to legislative judgment as to

the necessity and reasonableness of a particular measure.’” *Keystone Bituminous Coal Ass’n v. DeBenedictis*, 480 U.S. 470, 505 (1987) (quoting *Energy Reserves Group, Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 413 (1983) (internal citations omitted)). About five years ago, AstraZeneca suddenly refused to provide 340B discounts to covered entities that relied on contract pharmacies to dispense their drugs to 340B patients, even though until then, it had been doing just that. Now, AstraZeneca only permits a 340B covered entity to rely on a single contract pharmacy if it has no in-house pharmacy. For the reasons explained above, savings from 340B discounts allow covered entities to provide life-saving health care and programs in Louisiana. Act 358 merely requires that drug companies continue to do what they were doing prior to 2020—that is, provide the 340B discount to drugs purchased by patients of statutorily-defined covered entities, even when the covered entities rely on contract pharmacies to dispense those drugs.

Faced with the drug industry’s synchronized strike on Louisiana’s health care safety net, the Louisiana legislature had a significant and legitimate justification for passing Act 358. Any impact the legislation has on drug companies is reasonable and necessary. It is reasonable because the impact on the drug industry of requiring such discounts is minimal when compared to its profits¹⁶ and because it simply

¹⁶ See Fred D. Ledley, M.D., *et al.*, *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, 323(9) JAMA 834–43 (Mar. 3, 2020), <https://jamanetwork.com/journals/jama/fullarticle/2762308>.

restores the arrangement that had been in place since 2010, while the impact of not permitting the discounts is devastating to covered entities that often operate on negative margins.

CONCLUSION

For all these reasons and those set forth in Appellees' Briefs, this Court should affirm the district court's judgment.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 18, 2025, the foregoing Brief of American Hospital Association, 340B Health, Louisiana Hospital Association, and American Society of Health-System Pharmacists as *Amici Curiae* in Support of Defendant-Appellee was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and Local Rule 32(b) because it contains 6,408 words, excluding the parts of the brief exempted by Rule 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Rule 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in fourteen-point Times New Roman font.

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