UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* JEFFREY LANDRY, in his official capacity as Attorney General of Louisiana, *Defendant*.	Case No. 6:23-cv-00997-RRS-CBW

BRIEF OF *AMICI CURIAE* LOUISIANA HOSPITAL ASSOCIATION, RURAL HOSPITAL COALITION, INC., AMERICAN HOSPITAL ASSOCIATION, AND 340B HEALTH IN SUPPORT OF DEFENDANT JEFFREY LANDRY'S CROSS-MOTION FOR SUMMARY JUDGMENT

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INTERESTS OF *AMICI CURIAE*[1]

Amici are four hospital associations whose members receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies. *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 340B program is 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 **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 **Rural Hospital Coalition, Inc.** is a Louisiana non-profit corporation formed nearly 30 years ago that has been designated by the Internal Revenue Service as a 501(c)(6) tax exempt business league. Its membership consists of nearly 50 Louisiana rural hospitals, the majority of which participate in 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. The AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are considered in formulating health policy. One way in which the AHA promotes the interests of its members is by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

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[1] Pursuant to LR5.6, *Amici Curiae* state that that they are not-for-profit organizations. None of *Amici* has a parent company, and no publicly traded company holds ten percent or more interest in any of *Amici*.

340B Health is a national, not-for-profit organization founded in 1993 to advocate on behalf of 340B hospitals, which are a vital part of the nation's healthcare safety net. 340B Health represents more than 1,500 public and private nonprofit hospitals and health systems that participate in the 340B program.

INTRODUCTION[2]

Just over three years ago, in the midst of a devastating pandemic, Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca) and other members of Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) broke with decades of precedent and devised a plan to undermine the 340B drug discount program. Under the 340B program, drug companies that participate in Medicaid and Medicare Part B must provide discounts on drugs sold to patients of certain nonprofit hospitals and community health centers. *See* 42 U.S.C. §§ 256b(a)(1), (4). Previously, PhRMA's members, including AstraZeneca, had provided drug pricing discounts to eligible hospitals for drugs dispensed *both* through in-house pharmacies and community pharmacies. But in July 2020, one of PhRMA's members suddenly refused to provide these discounts for one of its drugs if dispensed to 340B patients at community pharmacies (or "contract pharmacies"), later expanding this new policy to cover essentially all of its drugs.[3] Recognizing an opportunity to pad its profits, AstraZeneca quickly followed suit,[4] as did 27 other major drug companies.[5]

The contract pharmacy arrangements that drug companies like AstraZeneca honored for almost 30 years helped sustain hospitals and their patients. Today, a quarter of hospitals' 340B

[2] Because Plaintiffs raise similar challenges to Louisiana law and for the sake of efficiency, *Amici* submit this same brief in both *PhRMA v. Landry*, 6:23-cv-997 (W.D. La.), and *AstraZeneca Pharm. LP v. Landry*, 6:23-cv-1042 (W.D. La.).

[3] *See* Maya Goldman, *Hospital groups worry as more drugmakers limit 340B discounts*, Modern Healthcare (Mar. 25, 2022), https://www.modernhealthcare.com/safety-net-hospitals/hospitals-worry-more-drugmakers-limit-340b-discounts.

[4] *See* AstraZeneca Compl. ¶ 4, ECF No. 1, No. 6:23-cv-1042 (W.D. La.).

[5] Collectively, 19 of these companies made more than $660 billion in profits in 2021. *See* 340B Informed, *Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021* (updated Jan. 13, 2023), https://340binformed.org/2023/01/updated-drugmakers-cutting-340b-discounts-reported-record-revenues-in-2021/.

benefit comes from drugs dispensed at contract pharmacies.[6] 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 sold at contract pharmacies. At least two additional members of the Louisiana Hospital Association have reported that between 90 to 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.[7] Even fewer—only one in five 340B hospitals—have in-house "specialty" pharmacies, which many payers 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.[8] Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy—often located more than 40 miles from the provider—to receive the 340B discount for their patients' high-priced specialty drugs.[9] In fact, more than three-quarters of the total 340B discount associated with the drugs of 11 of the 21 drug companies with restrictive contract pharmacy policies as of June 1, 2023 came from specialty

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[6] 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.

[7] 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.

[8] 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-specialtypharmacies.html; Specialty Drug Coverage and Reimbursement in Medicaid, HHS Office of Inspector General, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[9] 340B Health, *supra* note 7, at 7 (citing Adam J. Fein, Drug Channels Institute, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2022); Fein, *supra* note 8, at 12).

drugs.[10] Denied these and other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services, and patients have been denied discounts on their drugs.[11]

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.

In these ways and others, contract pharmacy arrangements allow Louisiana's 340B providers to meet their patients where they are, rather than forcing them to travel long and costly distances to pick up prescriptions at in-house pharmacies. 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 *amicus* Louisiana Hospital Association'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." Likewise, a

[10] *Id.*

[11] *Id.* at 1.

non-contract pharmacy was going to charge a patient without insurance $248 for his prescription, so DeSoto Parish Hospital, the patient's 340B provider, had the prescription transferred to Mansfield Drug, a contract pharmacy. DeSoto Parish Hospital printed the patient a "340B RX card"—which allowed the provider to pass the 340B discount along to the patient—and Mansfield Drug charged the patient just $34.67. This was only possible because the drug company honored the contract pharmacy arrangement.

The 340B benefit also allows hospitals to expand the services they provide to their patients. Louisiana Hospital Association's members report that the 340B benefit allows them to (i) fund cancer patient navigators to assist low-income patients navigate treatment; (ii) operate neonatal and pediatric intensive care units and renovate intensive care units; (iii) fund social workers to work in emergency departments to help patients navigate and complete follow-up appointments; (iv) fund mobile mammography to underserved communities; (v) sustain outpatient dialysis programs; (vi) hire specialty physicians, such as endocrinologists; (vii) support community benefit programs, such as health literacy and early-pregnancy education, and community breast feeding centers; (viii) support outpatient cancer and non-oncology infusion centers and services; (ix) pay staff to help with oral chemotherapy prior authorizations and patient assistance programs; (x) host programs focused on food insecurity and nutrition in low-income neighborhoods; and (xi) provide medication counseling, among many other services. Without the 340B benefit they obtain from drugs dispensed at community pharmacies, these hospitals report that they will have to curtail these vital programs or eliminate them entirely.

Savings from contract pharmacy relationships are especially important for another reason: the fragile state of hospital finances. In stark contrast to PhRMA's members, 340B hospitals

typically operate with razor-thin (and often negative) margins.[12] The reason why is not surprising: 340B hospitals provide a disproportionate amount of uncompensated care, community health services, and other services to the country's most vulnerable patients.[13] Savings from the 340B program help to offset the cost of providing uncompensated health care services to underserved populations. As the Supreme Court recently affirmed, "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *AHA v. Becerra*, 142 S. Ct. 1896, 1905–06 (2022).

Faced with the drug industry's unprecedented assault on Louisiana's health care safety net, the Louisiana legislature responded. It passed Act 358, the "Defending Affordable Prescription Drug Costs Act," by an overwhelming 135-2 vote. *See* La. Stat. Ann. §§ 40:2881–2886. As relevant here, Act 358 prohibits drug companies from denying Louisiana hospitals the same 340B discounts for drugs dispensed at community pharmacies as would be provided if the drugs were dispensed at an in-house pharmacy. *Id.* § 40:2884.

PhRMA and AstraZeneca quickly challenged Louisiana's exercise of its police power to protect public health and safety. Those challenges should be rejected. PhRMA and AstraZeneca cannot demonstrate that Congress intended to create (or occupy) any field through its 340B legislation. *See PhRMA v. McClain*, 645 F. Supp. 3d 890, 898–99 (E.D. Ark. 2022). Nor does Act 358 conflict with the federal 340B statute. *See id.* at 899–902. In reality, Act 358 *furthers*

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[12] *See* AHA, *Setting the Record Straight on 340B: Fact vs. Fiction* 2 (Mar. 2021), https://www.aha.org/system/files/2018-02/340BFactvsFiction.pdf; Allen Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 12–13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

[13] *See* L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf; AHA, *supra* note 12, at 2; Dobson et al., *supra* note 12, at 13–17.

Congress's goal in enacting the 340B program: to enable hospitals to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). This Court should reject Plaintiffs' attempts to harm hospitals, their patients, and the communities they serve.

Ultimately, this Court should not lose sight of the upheaval in the law that Plaintiffs' position would cause. At bottom, they maintain 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. Giving the 340B statute the preemptive effect that Plaintiffs seek would turn upside down the very "federalism concerns" that underlie preemption questions and eviscerate "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

ARGUMENT

"In determining a federal statute's preemptive reach, congressional purpose is 'the ultimate touchstone.'" *United Motorcoach Ass'n, Inc. v. City of Austin*, 851 F.3d 489, 492 (5th Cir. 2017) (quoting *Medtronic*, 518 U.S. at 485). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which the States have traditionally occupied,'" *Medtronic*, 518 U.S. at 485 (citation omitted), 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," *United Motorcoach*, 851 F.3d at 492 (quoting *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432 (2002)). PhRMA and AstraZeneca have the burden to show that Congress intended to preempt Act 358. *See Planned Parenthood of Houston & Se. Tex v. Sanchez*, 403 F.3d 324, 336 (5th Cir. 2005).

PhRMA and AstraZeneca do not claim that Act 358 is expressly preempted. Nor do they deny that States have police power over public health policy, including the regulation of

healthcare,[14] "the practice of pharmacy,"[15] and the regulation of drugs.[16] Thus, Act 358 is presumptively *not* preempted, and PhRMA and AstraZeneca have not demonstrated Congress's "clear and manifest purpose" to supersede Louisiana's historic authority to regulate in the public health arena. *Medtronic*, 518 U.S. at 485 (citation omitted).

I. ACT 358 IS NOT FIELD PREEMPTED.

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

"Field preemption of state law is disfavored." *Nat'l Press Photographers Ass'n v. McCraw*, 84 F.4th 632, 657 (5th Cir. 2023). In rare instances, it "occurs when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. NCAA*, 138 S. Ct. 1461, 1480 (2018) (citation omitted). But as the Supreme Court has explained, "[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.*; *see also English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990) ("Ordinarily, the mere existence of a federal regulatory or enforcement scheme, even one as detailed as § 210 [of the Energy Restoration Act of 1974], does not by itself imply pre-emption of state remedies."). With the 340B

[14] *See, e.g., N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995).

[15] *See, e.g., PhRMA v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021).

[16] *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009).

program, "a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent." *Dublino*, 413 U.S. at 415.

Notwithstanding this well-established precedent, PhRMA and AstraZeneca rely on the "comprehensive" character of the federal scheme to support their contention that Congress intended to occupy a field with the 340B program. *See* AstraZeneca Mem. Supp. Pl.'s Mot. Summ. J. ("AstraZeneca Mem.") 29–30, ECF No. 21-1, No. 6:23-cv-1042 (W.D. La.); PhRMA Mem. Supp. Mot. Summ. J. ("PhRMA Mem.") 19–22, ECF No. 21-1 6:23-cv-997 (W.D. La.). But neither AstraZeneca nor PhRMA cites authority—from the statute, governing regulations, or legislative history—for their assertions about Congress's *intent* to create (or occupy) this purported 340B "field." Instead, other than simply repeatedly asserting that Congress created a "comprehensive and exclusive federal scheme,"[17] Plaintiffs rely only on (i) a recitation of the 340B program's statutory components; (ii) a mischaracterization of the Supreme Court's analysis and decision in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011); and (iii) unsupported assertions about Congress's priorities. None of these contentions supports their argument that Congress created a "340B field" in which States cannot act.

First, PhRMA and AstraZeneca list components of the federal scheme as proof of Congress's intent to create an exclusively federal field. Specifically, Plaintiffs note that Congress (i) "carefully enumerated the fifteen categories of intended beneficiaries—the covered entities—with a high degree of specificity," PhRMA Mem. 20; *see also* AstraZeneca Mem. 30; (ii) "carefully delineated the obligation of manufacturers, providing that they must 'offer' drugs to 'covered entities' with a specific 'price' term—the 340B 'ceiling price,'" PhRMA Mem. 20; (iii) "expressly barred covered entities from 'reselling or otherwise transferring' 340B-discounted

[17] AstraZeneca Mem. 9; *see also id.* at 18, 29, 30, 31; PhRMA Mem. 7, 10, 19, 22, 23, 24, 25, 28.

drugs 'to a person who is not a patient of the entity,'" *id.* (alterations adopted) (quoting 42 U.S.C. § 256b(a)(5)(B)); *see also* AstraZeneca Mem. 30; and (iv) "created a multi-faceted administrative enforcement scheme centralized within [the Department of Health and Human Services (HHS)]." PhRMA Mem. 20–21; *see also* AstraZeneca Mem. 30. These features of the 340B program do not support the conclusion that Congress intended to create an exclusively federal field into which Louisiana may not tread.

The fact that Congress limited which providers can participate in the 340B program, dictated the maximum price at which drug companies can sell 340B drugs, prohibited duplicate discounts and diversion of 340B drugs, and developed federal enforcement mechanisms to enforce those requirements and prohibitions does not show that Congress intended to create (or occupy) a field. 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. *See English*, 496 U.S. at 89 ("Absent some *specific suggestion* in the text or legislative history of § 210 [of the Energy Restoration Act of 1974], which we are unable to find, we cannot conclude that Congress intended to pre-empt all state actions that permit the recovery of exemplary damages.") (emphasis added); *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985) ("To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence."); *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1177 (5th Cir. 1988) ("[Appellant] also argues that the Public Health Service Act and its attendant regulations represent a pervasive federal scheme, and as such, preempt state law products liability for vaccine manufacturers. As Justice Marshall explains in *Hillsborough*, this argument is over inclusive.").

Second, *Astra* does not support a contrary conclusion. Although Plaintiffs contend that *Astra* holds that "Congress had created 340B as a comprehensive, centralized, and exclusive program," PhRMA Mem. 24; AstraZeneca Mem. 30 (identical), the issue of whether the 340B program preempts state law was never presented to the Court, and the Court never addressed it. Instead, the Court addressed *only* whether covered entities could employ a third-party-beneficiary theory to overcome Congress's decision not to authorize a private right of action to enforce the 340B statute's requirements. *Astra*, 563 U.S. at 113. The Court's ruling that the 340B statute did not authorize thousands of 340B providers to sue to enforce the 340B statute's requirements has no bearing on whether Congress preempted the *States* from legislating in any purported "340B field." Significantly, the only *mention* of preemption in *Astra* is in a footnote concerning a different federal program, the Medicaid Drug Rebate Program. And there the Court expressly "t[ook] *no position*" regarding the correctness of the United States' position that "the statute establishing [that program] *does not preempt* States from maintaining state-law fraud claims based on fraudulent reporting of 'best prices' to [the Department of Health and Human Services (HHS)]." *Id.* at 120 n.5 (emphasis added).

PhRMA and AstraZeneca nevertheless assert that *Astra*'s discussion of the 340B program's centralized enforcement scheme proves the statute's preemptive effect. PhRMA Mem. 24–25; AstraZeneca Mem. 30–31. But nothing about *Astra* displaced the Supreme Court's well-established principle that "the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply pre-emption of state remedies." *English*, 496 U.S. at 87. Moreover, Plaintiffs' reliance on *Astra*'s reference to uniformity is further undermined by the federal government's decades-old recognition of State authority over contract pharmacy

arrangements.[18] Thus, the *Astra* Court's hesitance to allow "potentially thousands of covered entities" to sue to correct "errors in manufacturers' price calculations" has no bearing on whether *States* can legislate as Louisiana did here to restore contract pharmacies as an outlet for 340B drugs.

Third, PhRMA's and AstraZeneca's contentions about the need "to safeguard the delicate balance" "between providing [340B] discounts while not overly burdening manufacturers," PhRMA Mem. 19, 7, fail to demonstrate Congress's intent to create (or occupy) a 340B field. Fatal to Plaintiffs' "balance" argument is the fact that AstraZeneca and PhRMA's other members honored unlimited contract pharmacy arrangements *for a decade* without upsetting any purported "delicate balance." Congress's intent in enacting the 340B statute did not change when PhRMA's members suddenly reversed course in 2020 and imposed these unprecedented restrictions. Rather, the only thing that changed was the drug companies' desire to boost their bottom lines during a once-in-a-century pandemic.

Even more fatal to their "balance" argument, Plaintiffs do not cite *any* authority supporting their repeated assertions that Congress had an interest in not "overly burdening" drug companies. *Id.* at 7; *see also* AstraZeneca Mem. 25. Indeed, neither the Supreme Court in *Astra* nor, more importantly, Congress in the 340B statute or its legislative history stated that Congress's goal was to maintain the "balance" that Plaintiffs insist was Congress's primary concern. *See infra* pp. 20–21 (discussing commonly accepted congressional goal of the 340B program). AstraZeneca points

[18] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) (noting that, "[a]s a matter of State law, . . . covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs," and that, "[b]y issuing guidelines in this area, [the federal agency] is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law").

to Congress's recognition of "the need to 'assure the integrity of the drug price limitation program,'" AstraZeneca Mem. 10 (quoting H.R. Rep. No. 102-384(II) at 16), but in context, Congress expressly stated it was imposing "three requirements on 'covered entities' to assure the integrity" of the program: (i) a prohibition on duplicate discounts; (ii) a prohibition on diversion; and (iii) audits of covered entities. H.R. Rep. No. 102-384(II) at 16–17. Act 358 does not touch on these integrity-assuring components of the 340B statute. That Congress adopted these basic safeguards to protect the 340B program thus cannot support Plaintiffs' argument that Congress intended to occupy a field and prohibit State action *unrelated to* those specific safeguards against diversion and duplicate discounts.[19]

B. Act 358 Does Not Intrude into Any Purported 340B Field.

Even if Congress created a "340B field," Plaintiffs must further demonstrate that Act 358 intrudes into that field. But Plaintiffs' two arguments in this regard fail to do so.

First, PhRMA and AstraZeneca contend that Act 358 "seeks to expand the scope of the federal statute to new entities," AstraZeneca Mem. 21, or "effectively alters the definition of 'covered entity,'" *id.* at 26; *see also* PhRMA Mem. 25–26, apparently by converting contract

[19] Importantly, PhRMA's and AstraZeneca's assertions that 340B providers' use of contract pharmacies has been accompanied by a concerning increase in "potential" program abuses is both incorrect and irrelevant to the instant preemption question. *See* PhRMA Mem. 14–15; AstraZeneca Mem. 13–14. In fiscal years 2019 through 2022, the federal government conducted more than 600 audits of 340B hospitals, and almost 95 percent of those audits did not identify any instances of diversion related to contract pharmacies. *See* Health Res. & Servs. Admin., *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results; *Program Integrity: FY20 Audit Results*, https://www.hrsa.gov/opa/program-integrity/fy-20-audit-results; *Program Integrity: FY21 Audit Results*, https://www.hrsa.gov/opa/program-integrity/fy-21-audit-results; *Program Integrity: FY22 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-22-results. And to the extent AstraZeneca or PhRMA's other members have concerns about diversion (or duplicate discounts), the 340B statute provides for audits and enforcement. *See, e.g.*, PhRMA Mem. 21 (citing 42 U.S.C. § 256b(a)(5)(C)); AstraZeneca Mem. 27 (same). Act 358 does not impact the federal integrity measures at all.

pharmacies into covered entities when they receive and dispense the 340B-discounted drugs that hospitals and other 340B entities have purchased. This argument mischaracterizes how contract pharmacy arrangements work. When a 340B provider uses a contract pharmacy, the *provider* orders and pays for the drugs, which are shipped directly to the pharmacy to be dispensed (or to replenish drugs that have been dispensed[20]) to the provider's patients. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 700 (3d Cir. 2023) ("Covered entities using contract pharmacies would still order and pay for the drugs, but they would be shipped directly to the pharmacies."). At no point does the contract pharmacy itself become a "covered entity" under federal law.

Nothing about Act 358 changes the statutory definition of "covered entity" or this practical relationship between a covered entity and a contract pharmacy. *See* La. Stat. Ann. § 40:2882(1) (defining "340B drug" by reference to its being "purchased by a *covered entity* as defined in 42 U.S.C. 256b(a)(4)") (emphasis added); *id.* § 40:2882(2) (defining "340B entity" in part as "an entity participating or authorized to participate in the federal 340B drug discount program, as described in 42 U.S.C. 256b"); *see also id.* § 40:2886(B)(1) (requiring Act 358 to be "construed or applied" so as not "to be in conflict with . . . [a]pplicable federal law"). Thus, contract pharmacies operating under Act 358 are not "covered entities" any more than contract pharmacies were covered entities prior to 2020 when all PhRMA members, including AstraZeneca, delivered 340B drugs to pharmacies that had entered into contracts with 340B hospitals, without limitation. And there is simply no basis in the record or elsewhere for AstraZeneca's implication that Act 358

[20] The Supreme Court and the Federal Trade Commission have endorsed accounting systems like those used with the "replenishment model" as an appropriate way to distinguish drugs that qualify for a discount from those that do not. *See Abbott Labs. v. Portland Retail Druggist Ass'n, Inc.*, 425 U.S. 1, 20 n.11 (1976); Federal Trade Commission, University of Michigan Advisory Opinion 1 (Apr. 9, 2010), https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

expands the number of pharmacies with which hospitals and other covered entities may contract to distribute 340B drugs. *See* AstraZeneca Mem. 21, 26.

Second, Plaintiffs claim that Act 358 "interjects Louisiana's Attorney General as an additional enforcer of 340B obligations and an additional arbiter of appropriate penalties." PhRMA Mem. 23; *see also* AstraZeneca Mem. 30–31. But this again mischaracterizes Act 358, which does not authorize the Attorney General to enforce any restrictions or requirements in the 340B statute itself. In fact, to the extent a 340B provider fails to "meet[] the [340B statute's] anti-diversion, audit, and duplicate-discount requirements," AstraZeneca Mem. 26, HHS or a drug company remains entitled under the 340B statute to initiate an audit, and, if warranted, the drug company could then proceed through the administrative dispute resolution process. *See* 42 U.S.C. §§ 256b(d)(2), (3). Act 358, on the other hand, allows the Louisiana Attorney General *only* to enforce Act 358's state-law requirement that drug manufacturers not deny the 340B discount to covered entities that dispense 340B drugs to their patients at contract pharmacies or otherwise interfere with contract pharmacy arrangements.

II. ACT 358 IS NOT CONFLICT PREEMPTED.

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

PhRMA and AstraZeneca next claim that Act 358 is preempted because it conflicts with the federal 340B statute. Specifically, both plaintiffs contend that Act 358 "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citations omitted); *see* AstraZeneca Mem. 18; PhRMA Mem. 27.[21] But neither is able to identify any actual conflict between Act 358 and the 340B statute,

[21] AstraZeneca also states that Act 358 conflicts with the 340B statute because "compliance with both state and federal law is impossible," but it fails to identify how. AstraZeneca Mem. 18 (citation omitted). That is not surprising, as compliance with both Act 358 and federal law is

particularly since Act 358 only requires drug companies to continue a practice that had been in place for at least ten years. Consequently, Plaintiffs cannot meet the "high threshold [that] must be met if a state law is to be preempted for conflicting with the purposes of a federal Act." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citation omitted).

First, AstraZeneca contends that Act 358 conflicts with and "seeks to undo" the Third Circuit's decision in *Sanofi*, 58 F.4th 696. But AstraZeneca distorts that decision. In reality, the Third Circuit made clear that the 340B statute's "text is silent about delivery." *Id.* at 703; *id*. at 707 ("Legal duties do not spring from silence."). Likewise, *Sanofi* was focused on whether HHS (a *federal* agency) had the legal authority under Section 340B (a *federal* statute) to require drug companies to honor any and all contract pharmacy arrangements. *Id*. at 707 ("Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies. So by trying to enforce that supposed requirement, *the government* overstepped the statute's bounds.") (emphasis added). Critically, the Third Circuit said nothing about what *States* may do in the face of the federal law's "silence." AstraZeneca therefore cannot transform this statutory silence into preemptive substance. *See McClain*, 645 F. Supp. 3d at 899 ("[T]he 340B Program is silent on what role (if any) contract pharmacies play in its discount drug scheme . . . . Arkansas's covered entities have filled in this gap through contract pharmacy arrangements. The 340B Program is not 'so pervasive as to make reasonable the inference that Congress left no room for States' to protect their specific drug distribution systems.") (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)); *see also Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1143 (9th Cir. 2015) ("Silence, without more, does not preempt—a clear and manifest

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plainly possible: AstraZeneca successfully complied with the 340B statute while honoring unlimited contract pharmacy arrangements from at least 2010 until 2020.

purpose of pre-emption is always required."); *Frank Bros., Inc. v. Wis. Dep't of Transp.*, 409 F.3d 880, 891 (7th Cir. 2005) ("[S]ilence on the part of Congress alone is not only insufficient to demonstrate field preemption, it actually weighs in favor of holding that it was the intent of Congress *not* to occupy the field."); *cf. FDIC v. McFarland*, 243 F.3d 876, 888 (5th Cir. 2001) (acknowledging "comprehensive and detailed [federal] statutory scheme" but emphasizing that "[t]he Supreme Court has stated that we are not to 'adopt a court-made rule to supplement federal statutory regulation that is comprehensive and detailed; matters left unaddressed in such a scheme are presumably left subject to the disposition provided by state law'") (quoting *O'Melveny & Myers v. FDIC*, 512 U.S. 79, 85 (1994)).

Trying to create substance out of this statutory silence, Plaintiffs insist that "Congress intentionally chose not to adopt a model where contract pharmacies had a role in 340B." PhRMA Mem. 23 (emphasis omitted). But this is mistaken. For one, HHS first recognized the role of contract pharmacies in the 340B program in 1996,[22] and it finalized guidance (which it had proposed in 2007) allowing multiple contract pharmacies shortly before Congress amended the 340B statute in 2010.[23] As the Supreme Court has explained, "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lorillard v. Pons*, 434 U.S. 575, 580 (1978). And contract

[22] *See* 61 Fed. Reg. at 43,549–50 ("The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities. . . . If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance.").

[23] *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 42 Fed. Reg. 10,272, 10,272 (Mar. 5, 2010); Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (Mar. 21, 2010) (codified at 42 U.S.C. § 256b(a)(1)).

pharmacies continue to have a role in the 340B program now, even under AstraZeneca's and PhRMA's other members' restrictive contract pharmacy policies. *See, e.g.*, AstraZeneca Compl. ¶ 4, ECF No. 1, No. 6:23-cv-1042 (W.D. La.).

Moreover, the legislative history that AstraZeneca cites demonstrates that Congress did *not* reject the use of contract pharmacies when it enacted the 340B program. *See* AstraZeneca Mem. 10. An unenacted, earlier version of the bill addressed how and where 340B drugs must be dispensed, stating that 340B discounts would be required for drugs "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services with*," a covered entity. S. Rep. No. 102-259, at 2 (1992) (emphasis added). If that language had been retained, 340B discounts would have been allowed *only* for on-site pharmacy services, since the drugs would have had to have been "purchased and dispensed by, or under a contract entered into *for on-site pharmacy services*." *Id.* (emphasis added). The elimination of the phrases "dispensed by" and "on-site pharmacy services" changed the provision in ways that *permitted* contract pharmacy relationships.

Second, Plaintiffs rehash their meritless field preemption arguments in the guise of conflict preemption. PhRMA, for example, contends that Act 358 expands the "closed system created by Congress," broadens the "limited definition of 'covered entity,'" and "upsets the balance Congress struck in governing a federal benefits program." PhRMA Mem. 21, 23; *see also* AstraZeneca Mem. 21 (referring to purported "delicate balance"). AstraZeneca argues that Act 358 "disrupts the 340B Program's careful balance of federal interests," including by expanding the class of "covered entities." AstraZeneca Mem. 19; *see id*. at 23 ("The 340B Program is an exclusively federal field. *As explained*, Congress designed Section 340B to be a comprehensive and exclusive scheme for delivering a unique federal benefit.") (emphasis added). Plaintiffs' repackaged arguments fail for the same reasons discussed above. *See Janvey v. Democratic Senatorial Campaign Comm., Inc*.,

712 F.3d 185, 202 (5th Cir. 2013) ("This is a rehashing of the [Appellee's] argument regarding field preemption[,] . . . which we have already rejected.").

Third, PhRMA and AstraZeneca assert another false conflict, claiming that "Act 358 creates a wholly separate, state-run enforcement system that operates outside of, and in conflict with, the federal enforcement system." AstraZeneca Mem. 26; *see also* PhRMA Mem. 28. But the fact that Louisiana may impose additional, different penalties on drug companies that violate *Act 358* does not create a conflict with the penalties that federal law provides for diversion, duplicate discounts, or overcharging in violation of *Section 340B*. *See, e.g.*, *Medtronic*, 518 U.S. at 495 (holding that the presence of a state-law damages remedy tied to violations of Food and Drug Administration (FDA) requirements does not impose a conflicting requirement upon medical device manufacturers); *Dublino*, 413 U.S. at 422 ("[T]he [federal] Act allows for complementary state . . . programs and procedures incident thereto . . . . Such programs and procedures are not necessarily invalid, any more than other supplementary regulations promulgated within the legitimate sphere of state administration.").

Fourth, and perhaps most important, Plaintiffs' conflict preemption arguments miss the forest for the trees. In determining whether PhRMA and AstraZeneca can satisfy their high burden to establish conflict preemption, the core inquiry is "a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000); *see also Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 314 (5th Cir. 2023) (same). Here, it is universally recognized—including by all three branches of government—that Congress's purpose in enacting the 340B program was to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-

384(II), at 12 (1992); *see also, e.g.*, *AHA v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (quoting same), *rev'd on other grounds sub nom. AHA v. Becerra*, 142 S. Ct. 1896 (2022); Health Res. & Servs. Admin., *340B Drug Pricing Program* (Mar. 2023), https://www.hrsa.gov/opa (quoting same). 340B providers and their patients benefit greatly from the use of contract pharmacies, which allow hospitals to provide more comprehensive services and allow patients to access more affordable drugs, including by allowing them to pick up their medicines more conveniently at their local pharmacies. Act 358, in turn, enables 340B providers to reach more patients and to provide more comprehensive services. Therefore, Act 358 does not interfere with Congress's 340B scheme—it "furthers" it. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 82 (1987).

B. Act 358 Does Not Regulate Drug Pricing and Would Not Be Preempted Even if It Did.

AstraZeneca (but not PhRMA) offers a half-hearted, three-paragraph argument that Act 358 is preempted because it regulates drug pricing. AstraZeneca Mem. 23–24. It does not. On its face and in its practical effect, Act 358 addresses the "acquisition" by and "delivery" of prescription drugs to contract pharmacies.[24] All it requires is for drug companies like AstraZeneca to deliver 340B drugs to Louisiana's contract pharmacies if a 340B provider directs AstraZeneca to do so. Far from regulating pricing, Act 358 merely incorporates by reference the independent federal scheme, which Louisiana is free to do. *Cf. Hillsborough*, 471 U.S. at 710 (local ordinance not preempted even though "[t]he ordinance incorporates by reference the FDA's blood plasma regulations").

[24] AstraZeneca curiously takes issue with the fact that Act 358 does not address any "genuine feature of 'acquisition' and 'delivery,'" such as packaging or shipping costs. AstraZeneca Mem. 23. For one, what Act 358 *does not* regulate says nothing about what it *does* regulate. Moreover, it is hard to fault the Louisiana legislature for focusing on the immediate problem at hand—drug companies' refusal to deliver 340B drugs to contract pharmacies—rather than unnecessarily legislating on issues "such as packaging requirements [and] shipping conditions." *Id.*

Even if AstraZeneca's characterization of Act 358 as a pricing statute were correct, federal law still would not preempt Louisiana from imposing its own indirect pricing conditions. There is nothing in the 340B statute that "indicates whether [Congress] meant for it to be a regulatory floor or ceiling." *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 888 (8th Cir. 2005). Congress expressed *no view whatsoever* on whether States can supplement federal pricing standards through separate regulatory requirements that may indirectly impact drug pricing. *See Hillsborough*, 471 U.S. at 717 ("[M]erely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field.").

Here, Louisiana clearly has the authority to regulate various aspects of drug pricing (for example, through taxes on manufacturers, licensing fees, or sales taxes on drugs sold at community pharmacies), which AstraZeneca makes no effort to dispute. Louisiana is thus free to enact its own drug-pricing program for medicines dispensed at contract pharmacies, and it is free to incorporate by reference (and for the sake of efficiency) prices the federal government sets. Consequently, "the presumption against preemption obliges [this Court] to conclude that [the 340B program] does not preempt [Act 358]." *Wuebker*, 418 F.3d at 888.

It is also significant that AstraZeneca offers its "pricing" argument solely as a conflict preemption claim, not a field preemption claim—although it is not entirely clear with which federal law AstraZeneca asserts the conflict. Strikingly, nowhere in its three paragraphs does AstraZeneca explain how or why that law actually stands as an obstacle to either a federal pricing scheme or federal patent law. If AstraZeneca is asserting a conflict with the 340B statute, it would not be enough that the 340B statute and Act 358 both (purportedly) address drug pricing. *See Astraea Aviation Servs., Inc. v. Nations Air Inc.*, 172 F.3d 390, 396 (5th Cir. 1999) ("Although the

Supremacy Clause of the U.S. Constitution requires [courts] to make the preemption inquiry in cases involving areas where federal and state regulation coincide, [they] must also pay heed to the Supreme Court's admonishment that in 'areas of coincident federal and state regulation, the teaching of the Supreme Court's decisions enjoins seeking out conflicts between state and federal regulation where none clearly exists.'") (alterations adopted) (quoting *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 130 (1978)). And as to any asserted conflict with *either* the 340B statute or federal patent law, even accepting AstraZeneca's erroneous characterization of Act 358 as a pricing law, it is dispositive that Act 358 does not result in a higher or lower price than Section 340B requires; it merely adopts by reference the same price as federal law in an effort to further Congress's goal of allowing 340B hospitals "to stretch scares Federal resources as far as possible." *McClain*, 645 F. Supp. 3d at 896 (quoting H.R. Rep. No. 102-384(II) at 12). There is thus no conflict between prices—only coincidence.

For similar reasons, AstraZeneca's arguments about patent-law preemption lack merit. Relying on a single Federal Circuit case, *Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) ("*BIO I*"), AstraZeneca insists that Act 358 is preempted because "States are not permitted to set the price of patented drugs or 're-balance' the 'rewards and incentives' embodied in federal patent law." AstraZeneca Mem. 23 (quoting *BIO I*, 496 F.3d at 1374). But *BIO I* does not compel that conclusion. *See Biotech. Indus. Org. v. Dist. of Columbia*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) ("*BIO II*") (Gajarsa, J., concurring in the denial of the petition for rehearing en banc) ("The panel opinion's analysis rests, as all preemption analysis must, on the specifics of the D.C. statute, considered as a whole. Whether future efforts of states to regulate drug prices, which for example did not only target patent drugs or did not as significantly or

directly undermine the balance of the federal patent right, would also be preempted is a question that remains for another day.") (internal citation omitted).

As an initial matter, unlike the District of Columbia law at issue in that case, Act 358 is *not* "targeted at the patent right," and it does not "appl[y] only to patented drugs." *BIO I*, 496 F.3d at 1374. That distinction alone defeats AstraZeneca's patent preemption argument.

Critically, moreover, *BIO I* did not hold that States are barred from regulating every state law that touches upon patented drugs. *See BIO II*, 505 F.3d at 1346 n.1 (Gajarsa, J., concurring) ("It is well established that states can generally regulate patented products as part of their general exercise of police powers without preemption, even if this regulation incidentally affects the profits a patentee gains from its patent."). For example, notwithstanding federal patent law, States retain the power to tax patented products, regulate commercial contracts involving patents, and regulate deceptive practices involving patents. *See*, *e.g.*, *Webber v. Virginia*, 103 U.S. 344, 347–48 (1880) ("Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted."); *see also BIO II*, 505 F.3d at 1351 (Dyk, J., dissenting) ("There is not a word in the cited legislative history of the Hatch-Waxman Act suggesting any concern about state price regulation of patented pharmaceutical products."). Instead, *BIO I* narrowly held that the District of Columbia's penalties for excessive drug prices stood as an obstacle to Congress's determination of the "proper balance between innovators' profit and consumer access to medication." 496 F.3d at 1374; *see also BIO II*, 505 F.3d at 1348 (Gajarsa, J., concurring) ("[T]he dissent overstates the breadth of the panel opinion to the extent that it suggests that the opinion would require the preemption of 'any state law regulating the prices of patented pharmaceutical products.'") (citation omitted). Here, Congress has *already* concluded that 340B pricing

appropriately balances "rewards and incentives" for drug companies. *BIO I*, 496 F.3d at 1374. Conspicuously, AstraZeneca's discussion of federal patent preemption does not grapple with the 340B statute *at all*. *See* AstraZeneca Mem. 22–23.

Assuming for argument's sake that Act 358 somehow "regulates the price of patented drugs," *id.* at 22, all Act 358 requires is for drug companies to deliver those drugs, at certain congressionally-determined prices, to Louisiana's contract pharmacies. Nothing about Act 358 law upsets any federal "statutory framework of rewards and incentives," *BIO I*, 496 F.3d at 1374, because Congress *already* rebalanced the federal patent framework with the 340B framework. Act 358 simply incorporates by reference that congressionally-approved 340B pricing framework with respect to the acquisition and delivery of drugs in Louisiana. Federal patent law thus does not preempt Act 358.

CONCLUSION

For the foregoing reasons, and those outlined in Defendant's cross-motion, *Amici* respectfully request that the Court deny PhRMA's motion for summary judgment and grant Defendant's cross-motion for summary judgment.

Respectfully submitted,

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