UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

ABBVIE INC. *et al.*, *Plaintiffs*, *v.* LIZ MURRILL, in her official capacity as Attorney General of Louisiana, *Defendant*.	Case No. 6:23-cv-01307-RRS-CBW

BRIEF OF *AMICI CURIAE* LOUISIANA HOSPITAL ASSOCIATION, RURAL HOSPITAL COALITION INC., AMERICAN HOSPITAL ASSOCIATION, AND 340B HEALTH IN SUPPORT OF DEFENDANT LIZ MURRILL'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

Plaintiffs (together, AbbVie), like their fellow drug company AstraZeneca and the trade association representing their confederates, want to have their cake and eat it too. AbbVie recognizes, at it must, that the 340B statute is silent as to contract pharmacy arrangements. But without citing any evidence (textual or otherwise) that Congress affirmatively intended to prevent states from addressing that issue, AbbVie insists that Congress's silence has broad preemptive effect. The Court should reject that argument, which, at risk of mixing confectionary metaphors, is nothing more than an attempt by multibillion-dollar pharmaceutical companies to tell struggling healthcare providers and their poorest patients to "let them eat cake."

Amici earlier filed essentially identical briefs in *Pharmaceutical Research & Manufacturers of America v. Landry*, No. 6:23-cv-997 (W.D. La.) (*PhRMA*), and *AstraZeneca Pharmaceuticals LP v. Landry*, No. 6:23-cv-1042 (W.D. La.) (*AstraZeneca*). *Amici* refer the Court to those briefs for the background on Louisiana's 340B hospitals' use of contract pharmacy arrangements and their significant benefit to Louisiana's neediest patients, which belies AbbVie's assertion that its "policy in no way affects patient access to 340B drugs." Pls.' Mem. Law Supp. Their Mot. Summ. J., ECF No. 28-1 (AbbVie Mem.), at 21; *see PhRMA*, ECF No. 56 (*PhRMA* Br.), at 9–13; *AstraZeneca*, ECF No. 55 (*AZ* Br.), at 9–13. *Amici* focus this brief on new or distinct issues AbbVie raises in its motion for summary judgment.

BACKGROUND

In an effort to defeat Louisiana's lawful effort to preserve its public health safety net, AbbVie tries to paint a picture of profit-hungry hospitals joining forces with profit-hungry pharmacies, all at the expense of patients and drug companies just trying to eke by. To do so, AbbVie mischaracterizes the 340B program, contract pharmacy arrangements, and Act 358. The Court should reject AbbVie's efforts.

First, AbbVie incorrectly describes the 340B program's purpose, which is not limited to ensuring patients get access to discounted drugs. Even the authority AbbVie cites does not support its proposition that "[t]he 340B program aims to help uninsured, low-income patients by providing them with better access to prescription medications at deeply discounted prices." AbbVie Mem. 12 (citing Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015)). Rather, as the note explains, the 340B program is "a statutory scheme designed to reduce pharmaceutical costs *for safety-net medical providers* and the indigent populations they serve." Baer, *Drugs for the Indigent*, at 638 (emphasis added) (footnote omitted); *see also id.* at 641 ("Congress enacted the 340B drug discount program . . . to help *certain safety-net medical service providers* 'stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'") (emphasis added) (quoting H.R. Rep. No. 102-384(II), at 12 (1992)).

AbbVie's limited view of the 340B program's purpose allows it to ignore—particularly with its repeated accusations of "profit-making arbitrage," AbbVie Mem. 10—that, as recounted more fully in *Amici*'s earlier briefs,[2] Louisiana's 340B hospitals use the 340B benefit to fund much-needed patient services they otherwise could not afford to offer. (Many of the hospitals also pass the 340B discount directly onto their patients, though they are not required to do so.) Unlike massive pharmaceutical companies like AbbVie—which raked in $4.86 billion of profit in 2023[3]—340B hospitals typically operate with razor-thin (and often negative) margins.[4] The 340B benefit

[2] *PhRMA* Br.11–12; *AZ* Br. 11–12.

[3] Associated Press, *AbbVie: Q4 Earnings Snapshot* (Feb. 2, 2024), https://www.ctinsider.com/business/article/abbvie-q4-earnings-snapshot-18644002.php.

[4] *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),

these hospitals receive, including through the use of contract pharmacies, is a lifeline Congress *intended* would help them "reach[] more eligible patients and provid[e] more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). That is precisely what Louisiana's 340B hospitals are doing.

Doubling down on its effort to paint *non-profit* 340B hospitals as profit-hungry manipulators, contrasted against neutral drug companies, AbbVie repeatedly bemoans that "[m]any mandatory 340B ceiling prices are as little as *one penny* per unit of drug—effectively a giveaway." AbbVie Mem. 13; *see id.* at 46, 50, 52. However, AbbVie conveniently omits *why* certain ceiling prices are so low. Drug manufacturers may charge 340B providers no more than the statutorily defined "ceiling price" for 340B covered drugs, which is calculated by subtracting the unit rebate amount (generally 23.1 percent) from the "average manufacturer price." *See* 42 U.S.C. § 256b(a); 42 C.F.R. § 10.10. Congress also provided for a larger rebate when drug companies increase drug prices *faster than the inflation rate*. 42 U.S.C. § 1396r-8(c)(2)(A). This inflation-based penalty could have resulted in negative prices for 340B covered drugs, but the Department of Health and Human Services (HHS) has adopted a policy that, when the calculated ceiling price for a drug is zero or less, drug companies may charge one penny for the drug. 42 C.F.R. § 10.10(b). Research demonstrates that this inflationary penalty slows price increases for drugs sold to all purchasers, not just 340B providers.[5]

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https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

[5] Sean Dickson, *Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases*, JAMA (Sept. 11, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770540; *see also* Sean Dickson & Ian Reynolds, *Estimated Changes in Manufacturer and Health Care Organization Revenue Following List Price Reductions for Hepatitis C Treatments*, JAMA (July 5, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2737308.

AbbVie and the other drug companies are using restrictive contract pharmacy policies to avoid having to pay these congressionally imposed penalties they otherwise would face. For example, the price of AbbVie's Humira®—until recently the most-sold drug worldwide—increased almost *four-fold* between 2007 and 2019, from $17,689 to $69,850 for a year of treatment—well outpacing inflation.[6] As a result, Humira® became penny-priced under the 340B program. And it is not alone: the U.S. government recently reported that between January 2022 and January 2023, drug companies raised prices faster than inflation for almost 2,000 drugs (averaging a 15.2 percent increase).[7] By placing restrictions on contract pharmacy arrangements to evade 340B pricing, AbbVie and other drug companies can charge tens of thousands of dollars more than they otherwise would under Congress's inflation-control measures.

AbbVie next mischaracterizes the nature of contract pharmacy arrangements. 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) 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."); Statement of Material Facts, Ex. 2 (Decl. of Krista M. Pedley, Director of the Office of Pharmacy Affairs, Health Resources and Services Administration), ECF No. 28-5 (Pedley Decl.), ¶¶ 4–13. The covered entity pays a fee to the

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[6] Alvaro San-Juan-Rodriguez et al., *Trends in list prices, net prices, and discounts of self-administered injectable tumor necrosis factor inhibitors*, 27 J. Managed Care + Specialty Pharmacy 112 (Jan. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7788267/pdf/jmcp.2021.27.1.112.pdf.

[7] Assistant Secretary for Planning and Evaluation, Office of Health Policy, *Changes in the List Prices of Prescription Drugs, 2017-2023* 1 (Oct. 6, 2023), https://aspe.hhs.gov/sites/default/files/documents/0cdd88059165eef3bed1fc587a0fd68a/aspe-drug-price-tracking-brief.pdf.

pharmacy—as it would for any drugs the pharmacy dispenses on the provider's behalf—which is generally a flat fee ranging between $6 and $15 per prescription, though it can be as low as $0 and occasionally higher for more expensive drugs; a fee based on percentage of revenue; or a combination.[8]

The replenishment model does not render the dispensing of 340B drugs to 340B patients "a fiction," and the contract pharmacy does not simply "later determine[] how much of its stock it *thinks* it has dispensed to customers who might have at one time been patients of a covered entity." AbbVie Mem. 17. Rather, as a declaration AbbVie submitted confirms, "340B-tailored software programs" ensure that the 340B discount attaches *only* to drugs dispensed to 340B patients. Pedley Decl. ¶ 6. HHS performs regular audits of these sales, and "the covered entity has to provide auditable records that show each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient." *Id.*; *see also id.* ¶¶ 12, 13. Importantly, 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.[9]

Finally, AbbVie seeks to mask its own profiteering at the expense of needy patients by asserting that it and other drug companies enacted restrictive contract pharmacy policies—while the COVID-19 pandemic raged—"to restore the [340B] program's integrity" after watching "abuses spiral out of control." AbbVie Mem. 20. AbbVie cites to reports from 2011, 2014, and

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[8] *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* GAO-18-480, Report to Congressional Requesters 24–27 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf.

[9] *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.

2018 (analyzing fiscal years 2012 to 2017), which noted concerns of increased *risk* of diversion. *See id.* at 19. But AbbVie omits the more recent data for fiscal years 2019 through 2022, when the federal government conducted more than 600 audits of 340B hospitals and thus fails to disclose that almost 95 percent of those audits did not identify any instances of diversion related to contract pharmacies.[10] And to the extent AbbVie has concerns about diversion (or duplicate discounts), the 340B statute provides for audits and enforcement. *See, e.g.*, *id.* at 14 (citing 42 U.S.C. § 256b(d)(2)(A)). Act 358 does not impact the federal integrity measures at all.

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, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). 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)). AbbVie has 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).

[10] *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.

Like PhRMA and AstraZeneca, AbbVie does not claim that Act 358 is expressly preempted. Nor does it deny that States have police power over public health policy, including the regulation of healthcare,[11] "the practice of pharmacy,"[12] and the regulation of drugs.[13] Thus, unlike state laws that intrude into uniquely federal areas such as immigration and foreign relations,[14] Act 358 is presumptively *not* preempted, and AbbVie has 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.

As *Amici* explained before, "[f]ield preemption of state law is disfavored." *Nat'l Press Photographers Ass'n v. McCraw*, 84 F.4th 632, 657 (5th Cir. 2023).[15] 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.*

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

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

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

[14] *See, e.g.*, *Arizona v. United States*, 567 U.S. 387 (2012) (immigration); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000) (national security); *Hines v. Davidowitz*, 312 U.S. 52 (1941) (immigration).

[15] *See PhRMA* Br. 15; *AZ* Br. 15.

Notwithstanding this well-established precedent, AbbVie relies on the "comprehensive" character of the federal scheme to support its contention that Congress intended to occupy a field with the 340B program. *See* AbbVie Mem. 28. But as with AstraZeneca and PhRMA, AbbVie cites no authority—from the statute, governing regulations, or legislative history—for its assertions about Congress's *intent* to create (or occupy) this purported 340B "field." Instead, AbbVie relies on (i) the federal nature of the 340B program and (ii) a recitation of the 340B program's statutory components. Neither contention supports AbbVie's argument that Congress created a "340B field" in which States cannot act.

First, AbbVie states that "Congress created the federal 340B program, rendering it a purely federal creature," and even "doubly federal" because "participating in the 340B program is a condition of participation in *other* federal drug programs." *Id.* But not all federal programs necessarily preempt state action, so AbbVie is left to grasp at the Supreme Court's remark in *Astra USA, Inc. v. Santa Clara County* that the 340B program and Medicaid Drug Rebate Program are "interdependent." 563 U.S. 110, 120 (2011). AbbVie claims that this means that "[m]aintaining a harmonious balance between the two programs is a dominant federal interest." AbbVie Mem. 29.

AbbVie's argument ignores the Court's analysis, however, which does not apply to AbbVie's preemption argument. In reality, the Court noted the need for the federal government to "balance the competing interests" that may arise between *States* and *covered entities* with respect to "average" drug prices, from which the 340B program's "ceiling prices" are derived. *Astra*, 563 U.S. at 120 & n.6 (citation omitted). This is because, "[t]ypically, the lower the 'average' price, the lower a product's price to a 340B entity[,] [b]ut the higher the 'average' price, the more a State Medicaid agency typically receives in rebates from the manufacturers." *Id.* (citation omitted).

AbbVie ignores the fact that no such potential problem exists here, as Act 358 does not alter 340B prices, and it certainly does not affect the rebates that Louisiana or any State receives under Medicaid; it only affects whether 340B hospitals may receive the 340B discount for drugs dispensed to their patients at contract pharmacies, which AbbVie allowed until 2023. Thus, *Astra* does not support a "dominant federal interest" in the 340B program sufficient to show that Congress intended to prevent Louisiana from enacting Act 358. AbbVie Mem. 29; *see also PhRMA* Br. 18–19 (explaining why *Astra* is inapposite and does not support field preemption here); *AZ* Br. 18–19 (same).

Second, AbbVie list components of the federal scheme as proof of Congress's intent to create an exclusively federal field. Specifically, AbbVie notes that Congress (i) "enumerated fifteen types of organizations that can qualify as 'covered entities'"; (ii) "created a set of rules those entities must abide by"; (iii) "instructed manufacturers that they 'shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price'"; and (iv) "established a comprehensive, carefully balanced, and exclusive remedial scheme." AbbVie Mem. 29–30 (alteration adopted) (citations omitted). As *Amici* explained before, *PhRMA* Br. 17; *AZ* Br. 17, the fact that Congress included these provisions in the 340B statute does not show that Congress intended to create (or occupy) a field. If Congress's creation of a federal program alone were enough to preempt state action, as AbbVie maintains, then *every time* Congress created a federal program, it would create an exclusively federal field into which States cannot intrude. That is not the law. *See id.*

In the same vein, AbbVie's suggestion that because the contractual arrangements authorizing community pharmacies to dispense covered entities' 340B drugs would not exist but for the 340B program, Congress must have meant to create a federal field encompassing "the realm

of 'contract pharmacies,'" AbbVie Mem. 30, is misplaced. *First*, the Third Circuit case on which AbbVie heavily relies throughout its motion belies this position. As that court made clear, the 340B statute's "text is *silent* about delivery." *Sanofi*, 58 F.4th at 703 (emphasis added). AbbVie fails to explain how Congress expressed clear intent to preempt state regulation of contract pharmacy arrangements without even mentioning contract pharmacies. *Second*, the 340B statute's legislative history further undercuts AbbVie's position, since Congress specifically rejected a version of the bill that would have required 340B discounts *only* for on-site pharmacy services (either operated by the 340B provider or under a contractual arrangement). *See PhRMA* Br. 25 (quoting S. Rep. No. 102-259, at 2 (1992)); *AZ* Br. 25 (same).[16]

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

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

First, AbbVie asserts that because Act 358 "refers to the federal 340B program thirty-eight times," its "purpose is to augment, and modify, [drug] manufacturers' obligations *under the federal 340B* program." AbbVie Mem. 31–32. But while Act 358 certainly does refer to the 340B program, AbbVie fails to demonstrate that Act 358 has any effect on drug manufacturers' obligations under federal law. If AbbVie sticks with its restrictive contract pharmacy policy in Louisiana, it will violate Act 358, but there will be *no effect* under the federal 340B program. The single out-of-

[16] Dispensing by contract pharmacies is fully consistent with the 340B program, since at the time the bill was passed, *fewer than five percent* of 340B providers had on-site dispensing services. *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); *see also id.* ("It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program."). This means that had Congress truly "deliberately excluded such pharmacies from participating in the 340B program," as AbbVie asserts, AbbVie Mem. 10, it would have deliberately chosen to exclude *nearly all* the providers for which it created the program.

circuit district court case AbbVie cites offers no additional support. Here, in contrast to that case, there is no federal project, nor federal funds. *Id.* at 32 (citing *United States v. Certain Land Situated in City of Detroit, Wayne Cnty., Mich.*, 43 F. Supp. 2d 762, 772 (E.D. Mich. 1999)). Simply put, Act 358 has no effect on "federal spending programs." *See id.*

Still, AbbVie asserts that "Act 358 is aimed at the heart" of the 340B program: "what below-market sale offers manufacturers must make and which entities are entitled to access manufacturers' drugs at the federally discounted 340B price." *Id.* But Act 358 affects neither: it has no impact on which prescription drugs are subject to 340B discounts or which entities are entitled to those discounts. Act 358 instead steps in to preserve what had been the status quo until 2020 across all drug companies and until 2023 with AbbVie, specifically: after making the federally required offer to sell drugs at 340B prices to covered entities, drug companies may not, in Louisiana, deny *delivery* to contract pharmacies.

AbbVie maintains that because Louisiana's Attorney General used the term "overcharge" when answering AbbVie's complaint, it means "that Act 358's objective is to reverse the Third Circuit's decision and expand manufacturers' 340B obligations," because "whether covered entities have been overcharged for 340B drugs is exclusively a question of federal law." *Id.* at 32–33 (alterations adopted). But Louisiana can hold the position that its hospitals are being overcharged for particular 340B drugs sold at contract pharmacies without holding the position that *as a matter of federal law*, they are being overcharged. AbbVie demonstrates how, like AstraZeneca and PhRMA's other members, it wants to have its cake and eat it too: according to AbbVie, because Congress said nothing about contract pharmacies, Congress *did not intend* to require drug companies to honor contract pharmacy arrangements, but because Congress said nothing, Congress *did intend* to prevent States from acting in any way with respect to contract

pharmacies. This heads-I-win-tails-you-lose argument has no basis in law. *See, 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); *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.") (citing *Hillsborough Cnty. v. Automated Med. Labs.*, 471 U.S. 707, 718 (1985); *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 616 (1997) (Thomas, J., dissenting)); *cf. Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1747 (2020) ("Nor is there any such thing as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception.").

Second, AbbVie claims that "Act 358 is aimed at interfering with the exclusive authority of the federal [administrative dispute resolution (ADR)] tribunals." AbbVie Mem. 34. But this again mischaracterizes Act 358, which does not authorize the Louisiana Attorney General to enforce any restrictions or requirements in the 340B statute itself. Instead, Act 358 allows the Attorney General *only* to enforce Act 358's state-law requirements 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.

Astra does not support a contrary conclusion. AbbVie points out that the Supreme Court "held that because Congress intended to 'centralize enforcement in the government,' 'spreading the enforcement burden' beyond the ADR process would frustrate Congress's purpose." AbbVie Mem. 35 (alteration adopted) (quoting *Astra*, 563 U.S. at 119). But as *Amici* have explained, *PhRMA* Br. 18–19; *AZ* Br. 18–19, Act 358 does not seek to enforce the 340B statute, the issue of

whether the 340B program preempts state law was never presented to the Court, and the Court never addressed it. 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.

Nor does the "logic" of the Supreme Court's decision in *Arizona v. United States*, 567 U.S. 387, lend AbbVie support. AbbVie Mem. 36. The Court did not find preemption merely because of the comprehensive nature of the federal law, *i.e.*, "because it specified which categories of immigrants may be admitted to the United States, created federal offenses . . . , required registrations . . . , and provided powers to States to deny noncitizens a range of public benefits." *Id.* Rather, as the Court emphasized, "[t]he Government of the United States has broad, undoubted power over the subject of immigration and the status of aliens. This authority rests, in part, on the National Government's constitutional power to 'establish a uniform Rule of Naturalization,' and its inherent power as sovereign to control and conduct relations with foreign nations." *Arizona*, 567 U.S. at 394–95 (citations omitted). Unlike with public health, which underlies the 340B program and Act 358, "[t]he federal power to determine immigration policy is well settled," in part because "[i]t is fundamental that foreign countries concerned about the status, safety, and security of their nationals in the United States must be able to confer and communicate on this subject with one national sovereign, not the 50 separate States." *Id.* at 395; *see also Hines*, 312 U.S. at 62–63.

Beneficial National Bank v. Anderson, 539 U.S. 1 (2003), similarly fails to support AbbVie's position. The Supreme Court explained that "[w]hen the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law." *Id.* at 8. As the Court explained, because of the recognized, special nature of *federally chartered banks*, "[u]niform rules

limiting the liability of national banks and prescribing exclusive remedies for their overcharges are an integral part of a banking system that needed protection from 'possible unfriendly State legislation.'" *Id.* (citation omitted). Act 358 does not seek to enforce a state law cause of action against 340B overcharges; it does not seek to re-define the ceiling price for 340B drugs; and there is nothing uniquely federal about hospitals, drugs, pharmacies, or patients.

In the end, Act 358 does not change the conditions for participation in the 340B program, or Medicaid or Medicare Part B. If AbbVie refuses to deliver Louisiana's covered entities' 340B drugs to contract pharmacies, then AbbVie can continue to participate in the 340B program, in Medicaid, and in Medicare. Act 358 has no effect on AbbVie's participation in those programs and would not intrude into any "340B field," even if one existed.

II. ACT 358 IS NOT CONFLICT PREEMPTED.

AbbVie next claims that Act 358 is preempted because it conflicts with the federal 340B statute by "stand[ing] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." AbbVie Mem. 40 (quoting *Crosby*, 530 U.S. at 372–73). But AbbVie fails to identify any actual conflict between Act 358 and the 340B statute, particularly since Act 358 only requires AbbVie to continue a practice it had for at least 13 years. Consequently, AbbVie fails to 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, AbbVie insists that "Act 358 conflicts with Congress's design of the 340B program," relying on the Third Circuit's decision in *Sanofi*. AbbVie Mem. 40. But as *Amici* explained before, *PhRMA* Br. 24; *AZ* Br. 24, AbbVie distorts that decision. In reality, the Third Circuit made clear that the 340B statute's "text is silent about delivery." *Sanofi*, 58 F.4th at 703. AbbVie cannot

transform this statutory silence into preemptive substance. *See PhRMA v. McClain*, 645 F. Supp. 3d 890, 899 (E.D. Ark. 2022) ("[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."). Trying to create substance out of this statutory silence, AbbVie insists that "Congress 'intentionally' omitted any obligation on manufacturers to transfer their drugs at 340B discounted prices to contract pharmacies." AbbVie Mem. 40 (quoting *Sanofi*, 58 F.4th at 704). But this is mistaken.

AbbVie ignores that HHS first recognized the role of contract pharmacies in the 340B program in 1996,[17] and in 2010 it finalized guidance (which it had proposed in 2007) allowing multiple contract pharmacies, shortly before Congress amended the 340B statute as part of the Affordable Care Act (significantly expanding the program to include an additional five types of covered entities).[18] And for at least ten years, drug companies like AbbVie, AstraZeneca, and PhRMA's other members honored unlimited contract pharmacy arrangements, and Congress never stepped in. Even now, contract pharmacies continue to have a role in the 340B program, including under AbbVie's and the other drug companies' restrictive contract pharmacy policies. *See, e.g.*, Statement of Material Facts, ECF No. 28-2, ¶¶ 56–57; AbbVie Mem. 21 ("Federal grantees are excepted from this policy.").

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[17] *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.").

[18] *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)).

Second, AbbVie asserts another false conflict, claiming that "Act 358 contravenes Congress's decision to vest exclusive authority for enforcing the 340B statute in [the Health Resources and Services Administration] and its ADR tribunals." AbbVie Mem. 41. But as explained before, *PhRMA* Br. 26; *AZ* Br. 26, 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; *Dublino*, 413 U.S. at 422.

Crosby, 530 U.S. 363, is not to the contrary. Act 358 regulates separate conduct than the 340B statute does, unlike in *Crosby*, where Congress had "placed the President in a position with as much discretion to exercise economic leverage against Burma, with an eye toward national security, as our law will admit," and the State sought to impose additional economic leverage against Burma. *Id.* at 375–76. There the Court found that "[c]onflict is imminent," *id.* at 380, but that is not the case here since AbbVie's obligations under 340B and Act 358 are entirely different. Thus, Louisiana does not seek to regulate or enforce ceiling prices, which drugs are subject to those prices, which entities are entitled to purchase drugs at those prices, the 340B statute's prohibitions on diversion and duplicate discounts, or any other provision of the federal statute. Indeed, federal ADR tribunals "adjudicate claims that covered entities have been 'overcharged' by manufacturers that failed to afford them the 340B ceiling price when they were supposed to," AbbVie Mem. 42; Louisiana does not.

CONCLUSION

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

Respectfully submitted,

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