No. 24-118

In the Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Petitioner,
v.
ALAN MCCLAIN, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE ARKANSAS INSURANCE DEPARTMENT, ET AL.
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF IN OPPOSITION OF RESPONDENTS COMMUNITY HEALTH CENTERS OF ARKANSAS AND PIGGOTT COMMUNITY HOSPITAL

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QUESTION PRESENTED

The Eighth Circuit held that Arkansas Act 1103 is not preempted by the 340B Drug Pricing Program ("340B Program") because Act 1103 operates in an area wholly within its traditional state powers—distribution of drugs—which falls outside the purview of the federal 340B Program. The federal 340B Program is a voluntary drug discount program that allows drug companies to obtain coverage for their products by Medicare Part B and Medicaid in exchange for selling "covered outpatient drugs" at a discount to certain health care providers. Numerous drug companies, including Petitioner's members, restrict shipments of 340B-discounted drugs to pharmacies under contract with providers that participate in the 340B Program. Arkansas enacted Act 1103, which forbids drug companies from blocking shipments of 340B-priced drugs to pharmacies. The D.C. Circuit and the Third Circuit both held that the text of the 340B statute is "silent about delivery" of 340B drugs. In *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), this Court held that health care providers that participate in the 340B Program are not third-party beneficiaries of contracts between the U.S. Department of Health and Human Services and drug companies.

The question presented is:

Whether the Eighth Circuit correctly held—consistent with rulings of this Court and other circuits—that the 340B statute's silence on drug distribution preserves a State's traditional police power to regulate drug distribution.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondents, Community Health Centers of Arkansas and Piggott Community Hospital, by and through their undersigned counsel, state that they are not-for-profit corporations that do not have parent corporations and do not issue stock. Accordingly, no publicly held corporation owns 10% or more stock of either Community Health Centers of Arkansas or Piggott Community Hospital.

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SUMMARY OF THE ARGUMENT

This Court should deny the petition for certiorari by the Pharmaceutical Research and Manufacturers of America ("PhRMA") because there is no circuit split and the Eighth Circuit's decision is consistent with the Court's precedents. Several similar cases brought by PhRMA and drug companies are pending in the Fourth and Fifth Circuits and in district courts in several states. These cases may be decided consistently with the Eighth Circuit's opinion, or one of these cases may produce a circuit split. But this Court's intervention now is at best premature.

This case is one battle of a multifront war waged by drug companies seeking to dismantle the 340B drug discount program ("340B Program") that aids not-for-profit, safety-net health care providers that receive federal financial support. Drug companies have sought to eviscerate the 340B Program by halting shipments of discounted drugs to pharmacies under contract with health care providers, known as "covered entities." To address the harms that drug companies are inflicting on covered entities and their patients, Arkansas enacted Act 1103, which requires drug companies to ship discounted drugs to pharmacies under contract with covered entities.

The Eighth Circuit correctly held that Act 1103 is not preempted by the 340B statute because the federal and state laws operate in separate fields: the 340B statute regulates pricing, while Act 1103 regulates distribution. The Eighth Circuit's ruling

aligns with holdings of the D.C. Circuit and the Third Circuit. In litigation against the federal government, drug companies successfully argued that the 340B statute, 42 U.S.C. § 256b, is silent on drug distribution. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460-61 (D.C. Cir. 2024); *Sanofi Aventis U.S. v. HHS*, 58 F.4th 696, 703-04 (3d Cir. 2023). The 340B statute's silence on distribution also permits states to regulate 340B drug distribution, which is within their traditional police powers. The Eighth Circuit found that this statutory silence allowed Arkansas to enact Act 1103, which governs distribution of 340B discounted drugs. App. 11a.

The Eighth Circuit did not disturb this Court's precedents. This Court has issued a decision on the 340B Program only once—in *Astra USA, Inc. v. Santa Clara County*—and that decision focused on the narrow issue of whether covered entities may sue drug companies as third-party beneficiaries of contracts between drug companies and the U.S. Department of Health and Human Services ("HHS") to provide discounts under the 340B Program. The Court held that covered entities may not sue as third-party beneficiaries, and the 340B statute gives HHS exclusive enforcement authority to adjudicate *pricing* disputes between health care providers and drug companies. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113, 121-22 (2011). The decision did not extend into state regulation of drug *distribution*, which is precisely the issue addressed by the Eighth Circuit.

Similarly, this Court's opinion in *Arizona v. United States*, 567 U.S. 387 (2012), is wholly

distinguishable from this case. *Arizona* considered preemption of a state law setting new requirements for immigrants, an area in which the federal government has "broad, undoubted power," Congress had unquestionably occupied the field, and the state law penalized the same conduct regulated under federal law. *Id.* at 393, 394, 400-01. The facts of *Arizona* are clearly distinguishable from those presented here.

Intervention by the Court is unwarranted. States act within their traditional police power to regulate the health and safety of their citizens when enacting laws governing the distribution of drugs, even if the state regulation is limited to drugs that are priced by federal law. This governance in no way encroaches upon, or interferes with, the limited operational and enforcement scheme Congress established for the 340B Program. The petition should be denied.

STATEMENT OF THE CASE

I. 340B Program

The 340B Program is named for Section 340B of the Public Health Service Act ("PHSA"), which was enacted as part of the Veterans Health Care Act of 1992 ("VHCA"). Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (codified as amended at 42 U.S.C. § 256b). The 340B Program is voluntary. If drug companies want Medicaid and Medicare Part B to cover their drugs, the 340B statute requires drug companies to offer discounts on covered outpatient drugs to covered

entities. App. 39a (42 U.S.C. §§ 256b(a)(1)); 42 U.S.C. § 1396r-8(a)(1). As a condition of coverage, a drug company is required to enter into a 340B pharmaceutical pricing agreement ("PPA") with HHS. App. 39a (*id.* § 256b(a)(1)). PPAs require that drug companies "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*

Each category of 340B covered entity receives some form of federal assistance to treat the nation's most vulnerable patients. Covered entities range from federally qualified health centers ("FQHCs"), tribal & urban Indian health centers, Ryan White HIV/AIDS clinics, certain hospitals (including children's and rural hospitals), and specialized clinics (e.g., black lung and tuberculosis clinics), among others. App. 41a-44a (*id.* § 256b(a)(4)). These covered entities provide health care and other critical services to the country's neediest individuals regardless of their ability to pay.

The genesis of the 340B Program can be traced to 1990 when Congress established the Medicaid Drug Rebate Program ("MDRP") to combat rising drug costs to state Medicaid programs. 42 U.S.C. § 1396r-8. The MDRP requires drug companies to provide rebates to state Medicaid programs on outpatient drugs. For brand name drugs, those rebates were calculated based on the difference between a given drug's average price and its lowest price, or "best price," in the U.S. marketplace, subject to certain narrow exceptions and a minimum difference of at least 12.5 percent. *Id*. § 1396r-8(c)(1).

In response to the MDRP, drug companies "deleted numbers of drugs" available to federal purchasers and raised their "best prices" on covered outpatient drugs for preferred customers, including the Department of Veterans Affairs ("VA") and non-profit safety-net providers like FQHCs and public hospitals. H.R. Rep. No. 102-384, pt. 2, at 10 (1992). Congress noted that "[h]ospital costs for the drugs . . . increased, on average, by 32 percent, far in excess of the historical 5 to 9 percent annual increases in drug prices experienced by public hospitals." *Id.* These drastic price increases "reduced the level of services and the number of individuals" that safety-net providers were "able to provide with the same level of resources." *Id.* at 11.

Congress intended the VHCA "to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs" that they purchased. *Id*. at 7; Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943. Section 602 of the VHCA established the 340B Program. § 602, 106 Stat. at 4967-71. Thus, the 340B Program was not enacted to correct "unintended consequences" of the MDRP as PhRMA contends. Pet. Writ Cert. ("Pet.") 5. Rather, Congress sought to remedy drug companies' predatory price increases to safety-net providers that minimized rebates to Medicaid at the expense of the nation's safety net. H.R. Rep. No. 102-384, pt. 2, at 9-10.

The 340B Program helps relieve the financial burden covered entities bear when they provide care at no or reduced costs. 340B discounts result in covered entities losing less money on the services that

they provide to uninsured and underinsured patients. By mitigating these losses, they can reduce or waive pharmacy copayments or provide additional vital health care services. Covered entities also reduce their dependence on taxpayer support because the 340B Program helps generate revenue. If a patient has prescription drug coverage, the difference between the insurer's payment and the discounted drug price is income to the covered entity that supplements federal funds, "enable[ing] these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" as Congress intended. *Id.* at 12; *see also Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 316 (D.S.C. 2023) ("[T]he purpose of the 340B program was to provide a means to make 340B entities profitable in order for those 340B entities to 'stretch scarce Federal resources as far as possible.'" (citing H.R. Rep. No. 102-384, pt. 2, at 12)).

As a condition for participation in the 340B Program, a covered entity may not seek a 340B discount for a drug subject to a Medicaid rebate or "resell or otherwise transfer the drug to a person who is not a patient of the entity." App. 44a (42 U.S.C. § 256b(a)(5)(A)(i), (a)(5)(B)). These restrictions are commonly known as the "duplicate discount" and "diversion" prohibitions, respectively.

To adjudicate 340B pricing disputes—including allegations by manufacturers that covered entities violated the duplicate discount or diversion prohibitions—Congress provided manufacturers and covered entities with an alternative dispute resolution ("ADR") process. App. 53a-55a (42 U.S.C. §

256b(d)(3)). A drug company that suspects a violation of the prohibition on duplicate discounts or diversion is entitled to audit the covered entity and file an ADR petition. App. 44a-45a, 54a (*id.* § 256b(a)(5)(C), (d)(3)(B)(iv)); 42 C.F.R. § 10.21(a)(2).

II. Contract Pharmacies

Most illnesses and injuries cannot be treated or managed adequately without the patient taking one or more medications. That means a provider of health care—whether a doctor, clinic, or hospital—must ensure that patients have access to a pharmacy to fill their prescriptions. For this reason, many providers own and operate their own pharmacies, commonly referred to as in-house pharmacies.

However, many 340B covered entities cannot afford to "expend precious resources to develop their own in-house pharmacies" because constructing and managing a pharmacy is expensive and requires special expertise. 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) ("1996 Guidance"). Instead, these covered entities contract with independent retail pharmacies to dispense drugs. Covered entities with large service areas contract with pharmacies that are accessible to patients. In addition, some medications require special storage and handling and can only be dispensed by specialty pharmacies,[1] through a mail

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[1] *See Specialty Pharmacy*, Am. Pharmacists Ass'n, https://www.pharmacist.com/Practice/Patient-Care-Services/Specialty.

order program, or are subject to a manufacturer-imposed "limited distribution network."[2] These various arrangements are established by contract between covered entities and pharmacies, so they are called "contract pharmacies."

Contract pharmacies help fulfill the 340B Program's purposes by enabling covered entities to participate in the program and by making drugs accessible to patients. Contrary to PhRMA's characterization, Pet. 9-11, contract pharmacy arrangements are not an abuse but a necessary means of serving patients and fulfilling the 340B Program's purpose to stretch scarce resources.

HHS has long permitted covered entities to order 340B drugs for shipment directly to contract pharmacies. 1996 Guidance, 61 Fed. Reg. at 43,550. In 2010, HHS published guidance clarifying that covered entities may use an unlimited number of contract pharmacies. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) ("2010 Guidance").

Contract pharmacies are not permitted to purchase 340B drugs. Typically, a covered entity creates a 340B purchasing account with a drug wholesaler. The wholesaler then creates a "ship to, bill to" arrangement under which the drugs are billed

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[2] *Limited Distribution Drugs 101*, Clarivate (Sept. 27, 2019), https://clarivate.com/blog/limited-distribution-drugs-101/ ("Under a limited distribution network, a manufacturer contracts with one or a few specialty pharmacies to dispense high-maintenance medications.").

to the covered entity and shipped to the contract pharmacy. 2010 Guidance, 75 Fed. Reg. at 10,277.[3] The contract pharmacy dispenses the drugs to the covered entity's patients, collects reimbursement for the drugs from both the patient and the patient's third-party payer (if any), and remits the collected reimbursement to the covered entity. The covered entity, in turn, pays the pharmacy a fee for dispensing and billing drugs on the covered entity's behalf.

III. Drug Companies Unilaterally Restrict Contract Pharmacy Shipments and HHS and Federal Courts Respond

For twenty-four years, every drug company participating in the 340B Program, including PhRMA's members, honored contract pharmacy arrangements. In July 2020, manufacturers began fully eliminating or significantly restricting distribution of 340B drugs ordered through contract pharmacy arrangements. *See, e.g.*, AstraZeneca, 340B Contract Pharmacy Pricing (Aug. 17, 2020).[4] As of the date of this opposition, thirty-seven manufacturers have unilaterally imposed restrictions on shipping 340B drugs to contract pharmacies under the guise of preventing diversion and duplicate discounts. These restrictions deprive covered entities of crucial revenue and savings Congress intended for the 340B Program to provide.

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[3] *See also FAQs*, HRSA, https://www.hrsa.gov/opa/faqs ("What is a 'ship to bill to' arrangement?").

[4] https://www.340bhealth.org/files/AstraZeneca_Retail_Communication_-_340B_-_Final.pdf?_zs=Ccipc1&_zl=DaI27.

To protect covered entities from these devastating policies, HHS sent letters to several manufacturers informing them that their policies violated the 340B statute and demanding that manufacturers rescind the policies. *See Novartis*, 102 F.4th at 458-59; *Sanofi*, 58 F.4th at 701. Drug companies sued HHS to thwart its enforcement. The Third Circuit held that the contract pharmacy restrictions imposed by Sanofi, Novo Nordisk, Inc., and AstraZeneca are lawful under federal law and not subject to enforcement actions by HHS. *Sanofi*, 58 F.4th at 707. The *Sanofi* court concluded that the 340B statute's "text is silent about delivery" and that the "purchased by" language in the statute "says nothing about delivery." *Id.* at 703-04. The D.C. Circuit held in favor of Novartis and United Therapeutics. *Novartis*, 102 F.4th at 459. The D.C. Circuit also acknowledged that "Section 340B is . . . silent about delivery conditions." *Id.* at 456, 460-61.

The U.S. District Court for the Southern District of Indiana considered whether restrictions imposed by Eli Lilly & Co. are lawful and held that "the [340B] statute, correctly construed, does not permit drug manufacturers, such as Lilly, to impose unilateral extra-statutory restrictions on its offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements." *Eli Lilly & Co. v. HHS*, No. 1:21-cv-00081, 2021 WL 5039566, at *24 (S.D. Ind. Oct. 29, 2021). Lilly appealed to the Seventh Circuit, and the government cross-appealed the district court's remand to HHS. The Seventh Circuit held oral arguments on October 31, 2022, and

has not yet issued a decision. *Eli Lilly & Co. v. HHS*, No. 21-3128 (7th Cir. argued Oct. 31, 2022).

IV. Arkansas and Other States Pass Laws Protecting Covered Entities

In May 2021, Arkansas enacted Act 1103. App. 56a-59a (Ark. Code Ann. §§ 23-92-601–606 (2024)). PhRMA challenges provisions of Act 1103 that prohibit drug companies from refusing to ship drugs to pharmacies under contract with 340B covered entities or otherwise interfering with contracts between covered entities and pharmacies. The provisions at issue state that a drug company shall not:

> (1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or
>
> (2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

App. 59a. (Ark. Code Ann. § 23-93-604(c) (2024)).

Seven states subsequently passed similar laws to protect delivery of 340B priced drugs to contract pharmacies. *See* S.B. 28, 2023-2024 Leg., Reg. Sess. (Kan. 2024); H.B. 548, 2023 Leg., Reg. Sess. (La. 2023); H.B. 1056, 2024 Gen. Assemb., 446th Sess. (Md. 2024); H.F. 4991, 93rd Leg., Reg. Sess. (Minn. 2024); H.B. 728, 2024 Leg., Reg. Sess. (Miss. 2024); S.B. 751, 102nd Gen. Assemb., 2nd Reg. Sess. (Mo. 2024); S.B. 325, 86th Leg., Reg. Sess. (W. Va. 2024).

Drug companies and PhRMA have sued each of these states. *PhRMA v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024)[5]; Order, *Novartis Pharms. Corp. v. Brown,* No. 1:24-cv-01557 (D. Md. Sept. 5, 2024), *appeal docketed*, No. 24-1949 (4th Cir. Oct. 2, 2024); Order, *PhRMA v. Brown*, No. 1:24-cv-01631 (D. Md. Sept. 5, 2024), *appeal docketed*, No. 24-1978 (4th Cir. Oct. 8, 2024); Order, *AbbVie, Inc. v. Brown*, No. 1:24-cv-01816 (D. Md. Sept. 5, 2024), *appeal docketed*, No. 24-1939 (4th Cir. Sept. 26, 2024); Order, *AstraZeneca Pharms. LP v. Brown*, No. 1:24-cv-01868 (D. Md. Sept. 5, 2024); *PhRMA v. Fitch*, No. 1:24-cv-00160, 2024 WL 3277365 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); Order, *Novartis Pharms. Corp. v. Fitch*, No. 1:24-CV-00164, 2024 WL 3276407 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024); Order, *AbbVie, Inc. v. Fitch*, No. 1:24-cv-00184,

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[5] The Western District of Louisiana issued one memorandum opinion in favor of the state for three related cases brought by separate plaintiffs: *PhRMA v. Murrill*, No. 6:23-cv-00997 (W.D. La filed July 27, 2023), *AstraZeneca Pharms. LP v. Murrill*, No. 6:23-cv-01042 (W.D. La filed Aug. 4, 2023), and *AbbVie, Inc. v. Murrill*, No. 6:23-cv-01307 (W.D. La filed Sept. 21, 2023).

2024 WL 3503965 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024); *AbbVie, Inc. v. Ellison*, No. 0:24-cv-02605 (D. Minn. filed July 1, 2024); *AstraZeneca Pharms. LP v. Ellison*, No. 0:24-cv-02621 (D. Minn. filed July 2, 2024); *Novartis Pharms. Corp. v. Morrisey*, No. 2:24-cv-00272 (S.D. W. Va. filed May 31, 2024); *PhRMA v. Morrisey*, No. 2:24-cv-00271 (S.D. W. Va. filed May 31, 2024); *AstraZeneca Pharms. LP v. Morrisey*, No. 2:24-cv-00290 (S.D. W. Va. filed June 13, 2024); *AbbVie, Inc. v. Morrisey*, No. 2:24-cv-00298 (S.D. W. Va. filed June 18, 2024); *Novartis Pharms. Corp. v. Kobach*, No. 5:24-cv-04068 (D. Kan. filed July 30, 2024); *AbbVie, Inc. v. Kobach*, No. 6:24-cv-01111 (D. Kan. filed July 1, 2024); *AstraZeneca Pharms. LP v. Kobach*, No. 6:24-cv-01112 (D. Kan. filed July 2, 2024); *Novartis Pharms. Corp. v. Kobach*, No. 5:24-cv-04068 (D. Kan. filed July 30, 2024); *PhRMA v. Kobach*, No. 6:24-cv-01132 (D. Kan. filed Aug. 5, 2024); *AstraZeneca Pharms. LP v. Bailey*, No. 2:24-cv-04143 (W.D. Mo. filed Aug. 21, 2024); *PhRMA v. Bailey*, No. 2:24-cv-04144 (W.D. Mo. filed Aug. 22, 2024); *Novartis Pharms Corp. v. Bailey*, No. 2:24-cv-04131 (W.D. Mo. filed Aug. 2, 2024); *AstraZeneca Pharms. LP v. McClain*, No. 4:24-cv-00268 (E.D. Ark. filed Mar. 25, 2024).

V. Procedural History

On September 29, 2021, PhRMA sued the Commissioner of the Arkansas Insurance Department ("AID"), which enforces Act 1103, seeking to invalidate Act 1103 under the Supremacy Clause of the United States Constitution. App. 20a (citing U.S. Const. art. VI, cl. 2). PhRMA argued that

Act 1103 was impliedly preempted by the 340B statute under the field and obstacle preemption doctrines. App. 20a. PhRMA also claimed that Act 1103 was preempted by the Risk Evaluation and Mitigation Strategy ("REMS") provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), codified at 23 U.S.C. § 355-1.

On May 3, 2022, Respondents Community Health Centers of Arkansas ("CHCA") and Piggot Community Hospital ("PCH") intervened on behalf of the Defendant—Alan McClain, the AID Commissioner. Order Granting Mot. Intervene, *PhRMA v. McClain*, 645 F. Supp. 3d 890 (E.D. Ark. 2022) (No. 4:21-cv-00864). The Medicare Program categorizes PCH as a critical access hospital, which is a type of small rural hospital. *See generally* 42 C.F.R. §§ 485.601-485.647. CHCA is a non-profit organization comprised of eleven Arkansas-based FQHCs that provide primary health services. CHCA members and PCH rely on contract pharmacies to fill prescriptions for their patients.

On December 12, 2022, the Eastern District of Arkansas granted the motion for summary judgment of CHCA and PCH and denied PhRMA's motion for summary judgment. The court held that the 340B Program does not preempt Act 1103. App. 28a, 31a, 33a-34a. As to field preemption, the court responded to PhRMA's reliance on *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011) ("*Astra*"), by stating that it was "not convinced that the Supreme Court's narrow holding concerning third-party lawsuits in *Astra* makes the 340B Program a solely federal scheme immune from any type of state

regulation." App. 30a. The district court further held that Act 1103 was not an obstacle to the 340B Program's purpose because "the effects of [Act 1103] are limited to the distribution of and access to the discounted drugs," and PhRMA "provided no evidence that Act 1103 interferes with PPA agreements . . . or, in effect, adds contract pharmacies to the covered entities list." App. 34a. Finally, the court held that Act 1103 in no way "interferes with the 340B Program's enforcement mechanism" because "the penalties that may be assessed for violations of Act 1103 relate to activities outside the scope of the 340(B) Program's enforcement procedures which are focused on overcharging covered entities." App. 33a-34a. The court also rejected PhRMA's argument that Act 1103 is preempted by the FFDCA. App. 36a.

On March 12, 2024, the Eighth Circuit affirmed the district court on all counts, finding that Act 1103 was lawful and "not preempted by federal law under any theory." App. 2a. Under field preemption, the court found that "the text of 340B is 'silent about delivery' of drugs," in contrast to the "340B[] provisions that directly address distribution by third-party wholesalers." App. 11a (quoting *Sanofi*, 58 F.4th at 703). It further reasoned that Congress was aware of the role of pharmacies and state pharmacy law and that Congress's "silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." App. 12a.

Further, the Eighth Circuit stated that Act 1103 "assists in fulfilling the purpose of 340B." App. 14a. In response to PhRMA's contention that Act

1103's enforcement mechanisms conflict with those under section 340B, the court stated that PhRMA "conflates the two statutes" because Act 1103 focuses on providing relief "if manufacturers deny 340B drugs to covered entities' contract pharmacies" while the 340B statute focuses on "disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion." App. 13a. The court emphasized that pharmacies are traditionally regulated at the state level and that a court "must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *Id.* Congress made no such strong showing.

On May 2, 2024, the Eighth Circuit denied PhRMA's petition for rehearing en banc or panel rehearing. App. 37a.

REASONS FOR DENYING THE WRIT

PhRMA premises its petition on a circuit split that does not exist. Several similar cases brought by PhRMA and drug companies are pending in the Fourth and Fifth Circuits and in district courts in several states. These may *eventually* result in a circuit split, but this is not certain and is not the case now. The Third Circuit's decision in *Sanofi Aventis U.S. v. HHS*, 58 F.4th 696, 706 (3d Cir. 2023) and the D.C. Circuit's decision in *Novartis Pharmaceuticals Corp. v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024) concerned HHS's enforcement authority under the 340B Statute, while the Eighth Circuit addressed the entirely separate question of whether the federal 340B statute preempts Arkansas Act 1103. *Sanofi*

and *Novartis* held that the 340B statute is silent on delivery, thus supporting the Eighth Circuit's conclusion that Congress permitted the states to regulate delivery of 340B-priced drugs.

Further, the Eighth Circuit's decision is consistent with this Court's precedents in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 122 (2011) and *Arizona v. United States*, 567 U.S. 387 (2012). *Astra* held that the 340B statute gives HHS exclusive enforcement authority to adjudicate *pricing* disputes between health care providers and drug companies. This decision does not extend to state regulation of drug *distribution*. In *Arizona*, Congress had unquestionably occupied the field of immigration. Congress has not, however, occupied the field of drug distribution. Rather, such questions typically fall under states' traditional police power to regulate the health and safety of their citizens.

For these reasons, the Court should deny PhRMA's petition.

I. The Eighth Circuit's Decision Does Not Create a Circuit Split

Intervention by the Court is unwarranted because there is no split in circuit court decisions. *See* Sup. Ct. R. 10(a). Numerous similar cases are pending in the Fourth and Fifth Circuits and in district courts within the Eighth and Tenth Circuits. One of these cases may or may not result in a circuit split, but no split exists now. The Eighth Circuit's decision is wholly consistent with district and circuit court holdings that the 340B statute is silent on delivery

and distribution. *See Sanofi*, 58 F.4th at 703; *Novartis*, 102 F.4th at 460; *Eli Lilly & Co.*, 2021 WL 5039566, at *17. Congressional silence in this area in no way precludes states from enacting laws to protect the health and safety of their citizens.

A. Similar Cases Are Pending in the Fourth and Fifth Circuits and in Several District Courts

Lawsuits challenging state laws very similar to Act 1103 are currently pending in in the Fourth and Fifth Circuits and in federal district courts within the Eighth and Tenth Circuits. PhRMA is an appellant in cases in the Fourth and Fifth Circuits. *PhRMA v. Brown*, No. 1:24-cv-01631 (D. Md. filed June 5, 2024), *appeal docketed*, No. 24-1978 (4th Cir. Oct. 8, 2024); *PhRMA v. Morrisey*, No. 2:24-cv-00271 (S.D. W. Va. filed May 31, 2024); *PhRMA v. Fitch*, No. 1:24-cv-00160, 2024 WL 3277365 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); *PhRMA v. Murrill*, No. 6:23-cv-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024), *appeal docketed*, No. 24-30673 (5th Cir. Oct. 21, 2024). One of these cases may produce a circuit split that would warrant the Court's review. The lower courts currently are unanimously in line with the Eighth Circuit. *See PhRMA v. Murrill*, No. 6:23-cv-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024) (the court issued one opinion for all three cases in the Western District of Louisiana); Order, *Novartis Pharms. Corp. v. Brown*, No. 1:24-cv-01557 (D. Md. Sept. 5, 2024); Order, *PhRMA v. Brown*, No. 1:24-cv-01631 (D. Md. Sept. 5, 2024); Order, *AbbVie, Inc. v. Brown*, No. 1:24-cv-01816 (D. Md. Sept. 5, 2024); Order, *AstraZeneca*

Pharms. LP v. Brown, No. 1:24-cv-01868 (D. Md. Sept. 5, 2024); *PhRMA v. Fitch*, No. 1:24-cv-00160, 2024 WL 3277365 (S.D. Miss. July 1, 2024); Order, *Novartis Pharms. Corp. v. Fitch*, No. 1:24-cv-164, 2024 WL 3276407 (S.D. Miss. July 1, 2024); Order, *AbbVie, Inc. v. Fitch*, No. 1:24-cv-00184, 2024 WL 3503965 (S.D. Miss. July 22, 2024).

The District Court of Maryland, part of the Fourth Circuit, denied motions by PhRMA, AbbVie, Inc. ("AbbVie"), AstraZeneca Pharmaceuticals, LP ("AstraZeneca"), and Novartis Pharmaceuticals Corp. ("Novartis") to enjoin Maryland H.B. 1056, which, like Arkansas Act 1103, requires drug companies to ship discounted drugs to contract pharmacies. Order, *Novartis Pharms. Corp. v. Brown,* No. 1:24-cv-01557 (D. Md. Sept. 5, 2024); Order, *PhRMA v. Brown*, No. 1:24-cv-01631 (D. Md. Sept. 5, 2024); Order, *AbbVie, Inc. v. Brown*, No. 1:24-cv-01816 (D. Md. Sept. 5, 2024); Order, *AstraZeneca Pharms. LP v. Brown*, No. 1:24-cv-01868 (D. Md. Sept. 5, 2024).[6] In a decision from the bench, the district court denied the plaintiffs' motions for preliminary injunctions because they were not likely to succeed on the merits of their cases. All plaintiffs appealed to the Fourth Circuit, which consolidated the appeals. Opening briefs are due November 18, 2024. Briefing Order, *AbbVie, Inc. v. Brown*, No. 24-1939 (4th Cir. Oct. 8, 2024), ECF No. 9.

In the Fifth Circuit, six cases are pending, three challenging a Louisiana law (Act 358) similar to Act 1103 and three challenging Mississippi's similar

[6] The court published one identical order for all four cases.

law (H.B. 728). Louisiana Act 358 was challenged by PhRMA, AstraZeneca, and AbbVie. On September 30, 2024, the district court granted the defendants' motions for summary judgment and denied the plaintiffs' motions, holding that Act 358 is not preempted by the 340B statute and also rejecting the plaintiffs' takings, vagueness, and Contracts Clause claims. Each plaintiff appealed to the Fifth Circuit. Briefing has not yet begun.

Mississippi H.B. 728 was challenged by PhRMA, AbbVie, AstraZeneca, and Novartis. *PhRMA v. Fitch*, No. 1:24-cv-00160, 2024 WL 3277365 (S.D. Miss. filed May 30, 2024); *Novartis Pharms. Corp. v. Fitch*, No. 1:24-cv-00164 (S.D. Miss. filed June 3, 2024); *AbbVie, Inc. v. Fitch*, No. 1:24-cv-00184 (S.D. Miss. filed June 18, 2024); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-00196 (S.D. Miss. filed June 26, 2024). All four plaintiffs moved to enjoin implementation of the law. Like the Maryland cases, the district court denied three of the motions for preliminary injunction,[7] holding that the plaintiffs were unlikely to succeed on the merits of their preemption, takings, vagueness, and extraterritorial regulation claims. Order, *PhRMA v. Fitch*, 2024 WL 3277365, at *16, *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); Order, *Novartis Pharms. Corp. v. Fitch*, 2024 WL 3276407, at *10, *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024); Order, *AbbVie, Inc. v. Fitch*, 2024 WL 3503965, at *21, *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024). All three

[7] Briefing is ongoing for the fourth motion for a preliminary injunction filed by AstraZeneca. *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-00196 (S.D. Miss.).

plaintiffs appealed to the Fifth Circuit. Briefing is ongoing.

Similar cases are pending in district courts in Minnesota, West Virginia, Kansas, Arkansas, and Missouri. *AbbVie, Inc. v. Ellison*, No. 0:24-cv-02605-DSD-TNL (D. Minn. filed July 1, 2024); *AstraZeneca Pharms. LP v. Ellison*, No. 0:24-cv-02621 (D. Minn. filed July 2, 2024); *Novartis Pharms. Corp. v. Morrisey*, No. 2:24-cv-00272 (S.D. W. Va. filed May 31, 2024); *PhRMA v. Morrisey*, No. 2:24-cv-00271 (S.D. W. Va. filed May 31, 2024); *AstraZeneca Pharms. LP v. Morrisey*, No. 2:24-cv-00290 (S.D. W. Va. filed June 13, 2024); *AbbVie, Inc. v. Morrisey*, No. 2:24-cv-00298 (S.D. W. Va. filed June 18, 2024); *AbbVie, Inc. v. Kobach*, No. 6:24-cv-01111 (D. Kan. filed July 1, 2024); *AstraZeneca Pharms. LP v. Kobach*, 6:24-cv-01112 (D. Kan. filed July 2, 2024); *Novartis Pharms. Corp. v. Kobach*, No. 5:24-cv-04068 (D. Kan. filed July 30, 2024); *PhRMA v. Kobach*, No. 6:24-cv-01132 (D. Kan. filed Aug. 5, 2024); *AstraZeneca Pharms. LP v. McClain*, No. 4:24-cv-00268 (E.D. Ark. filed Mar. 25, 2024); *Sanofi-Aventis U.S. LLC v. McClain*, No. 4:24-cv-00609 (E.D. Ark. filed July 23, 2024); *AstraZeneca Pharms. LP v. Bailey*, No. 2:24-cv-04143 (W.D. Mo. filed Aug. 21, 2024); *PhRMA v. Bailey*, No. 2:24-cv-04144 (W.D. Mo. filed Aug. 22, 2024); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131 (W.D. Mo. filed Aug. 2, 2024); *AbbVie, Inc. v. Bailey*, No. 4:24-cv-00996 (E.D. Mo. filed July 22, 2024). These plaintiffs allege that state laws similar to Act 1103 are unlawful for a plethora of reasons, and all but AstraZeneca's Arkansas suit include allegations that the state laws are preempted by the 340B statute. Eventually, the

Minnesota cases will likely be appealed to the Eighth Circuit, the West Virginia cases to the Fourth Circuit, and the Kansas cases to the Tenth Circuit.

The Court should deny PhRMA's petition for writ of certiorari because circuits other than the Eighth Circuit will weigh in on the preemptive effects, if any, the 340B statute has on state laws governing drug distribution. Other circuit opinions will provide the Court with a clearer view on whether there is a circuit split on this *precise issue* and a more robust record for any review of that future case. Until such a record is fully developed, the "nature and timing of this case counsel caution." *Arizona*, 567 U.S. at 415.

B. The Eighth Circuit's Decision Is Consistent With the *Novartis* and *Sanofi* Holdings

PhRMA is incorrect that the Eighth Circuit's decision conflicts with *Novartis* and *Sanofi*, Pet. 24-28, which dealt with narrow issues that were not presented in the Eighth Circuit case. In *Novartis*, the D.C. Circuit considered whether HHS could punish drug companies (Novartis and United Therapeutics Corp.) for implementing restrictions on contract pharmacy arrangements. The court held that the 340B statute did not preclude the contract pharmacy restrictions of Novartis and United Therapeutics and, therefore, HHS could not sanction those manufacturers. *Novartis Pharms. Corp.*, 102 F.4th at 459. The court acknowledged that, since the 340B Program's inception, Congress restricted the program in three significant ways. First, the statute limits the healthcare providers who qualify as covered entities.

Id. at 456 (citing 42 U.S.C. § 256b(a)(4)). Second, it prohibits covered entities from engaging in diversion. *Id.* (citing 42 U.S.C. § 256b(a)(5)(B)). Third, it prohibits covered entities from receiving duplicate discounts. *Id.* (citing 42 U.S.C. § 256b(a)(5)(A)(i)). The court held that the 340B statute only requires drug companies to "'offer each covered entity covered outpatient drugs for purchase' at or below a specified ceiling 'price.'" *Id.* at 460 (quoting 42 U.S.C. § 256b(a)(1)). Considering the text of these requirements, the court concluded that "Section 340B is thus silent about delivery conditions." *Id.* at 460.

In *Sanofi*, the Third Circuit reviewed the legality of HHS's enforcement action against drug companies, Sanofi, Novo Nordisk and AstraZeneca, regarding their restrictive contract pharmacy policies. The court enjoined HHS's enforcement. *Sanofi Aventis U.S.*, 58 F.4th at 706. Like the D.C. Circuit, the Third Circuit found that the 340B "text is silent about delivery." *Id.* at 703. It reasoned that the 340B statute's "shall offer" provision, 42 U.S.C. § 256b(a)(1), "nowhere" mentions contract pharmacies. *Id.* The court found the statute's "'purchased by' language likewise says nothing about delivery." *Id.* at 704 (citing 42 U.S.C. § 256b(a)(1)).

The Eighth Circuit's holding is consistent with *Novartis* and *Sanofi*. Both of these decisions explicitly state that the 340B statute is silent about drug distribution and delivery mechanisms. *Novartis*, 102 F.4th 450; *Sanofi*, 58 F.4th at 703-04. Relying on *Sanofi* and *Novartis*, the Eighth Circuit found the same: "the text of 340B is silent about delivery of drugs to patients." App. 11a (cleaned up). The silence

on distribution contrasts with "340B's provisions that directly address distribution by third-party wholesalers." *Id.* (citing 42 U.S.C. § 256b(a)(8)). While "[p]harmacies have always been an essential part of the 340B Program," Congress has time and again chosen "not to legislate the issue of pharmacy distribution." *Id.*

PhRMA is mistaken that *Sanofi*'s and *Novartis*'s acknowledgement of 340B's silence somehow preserves drug company "authority," Pet. 26, to limit distribution of 340B drugs at the expense of a sovereign state's authority to oversee the health and safety of its citizens through laws addressing drug distribution. *Novartis*, 102 F.4th at 459. The same statutory silence that limits HHS's authority to take enforcement actions related to contact pharmacy restrictions permits Arkansas to regulate drug distribution.

II. The Eighth Circuit's Decision Comports With Supreme Court Precedent

The Eighth Circuit's decision does not conflict with the Court's holdings in either *Astra* or *Arizona*. PhRMA's attempt to stretch these rulings beyond their limited facts is unpersuasive.

A. The Eighth Circuit's Opinion Is Consistent With *Astra USA, Inc. v. Santa Clara County*

Astra was a narrow decision focused solely on whether 340B covered entities are third-party beneficiaries of drug company contracts with HHS.

Astra did not hold, as PhRMA asserts, that the federal government "alone controls 340B." Pet. 28. In that case, a covered entity contended that AstraZeneca and other drug companies had overcharged for drugs that should have been provided at the 340B price. *Astra USA, Inc.*, 563 U.S. at 116. The Court found that the 340B statute does not permit covered entities to bring lawsuits against drug companies to "enforce ceiling-price contracts" (i.e., PPAs) in which the manufacturer agreed to charge covered entities no more than the 340B-discounted price. *Id.* at 113. The Court held that PPAs recite the terms of the 340B statute's text and that a lawsuit to enforce a PPA is a "suit to enforce the statute itself." *Id.* at 118. The Court also held that the 340B ADR process was the proper means to address a dispute regarding manufacturer overcharges. *Id.* at 121. *Astra* did not address the distribution of 340B-priced drugs, nor did it consider the role of state laws regulating contract pharmacy distribution arrangements.

The Eighth Circuit's decision comports with the Court's narrow holding. The Eighth Circuit correctly found that the boundaries of the 340B Program do not wade into the traditional police powers of sovereign states. App. 10a-14a; *see also Novartis Pharms. Corp. v. Fitch*, 2024 WL 3276407, at *9 ("Supreme Court's rejection of a right of action for covered entities under PPAs [in *Astra*] has minimal bearing on whether Section 340B preempts state law about the delivery of 340B drugs."); *AbbVie, Inc. v. Fitch*, 2024 WL 3503965, at *16 (same); *PhRMA v. Fitch*, 2024 WL 3277365, at *12 (same).

The issues that the Court analyzed in *Astra* do not support PhRMA's broad reading in its attempt to create a conflict with the Eighth Circuit. *Astra* rejected the use of private enforcement actions to resolve *pricing* disputes, while Act 1103 addresses *distribution* and "assists in fulfilling the purpose of 340B." App. 14a. "Act 1103 does not require manufacturers to provide 340B pricing discounts to contract pharmacies" or "set or enforce discount pricing." *Id.*; *see also PhRMA v. Fitch*, 2024 WL 3277365, at *9 (a state law similar to Act 1103 "does not require pharmaceutical manufacturers to offer 340B drugs below applicable ceiling prices, expand the definition of what a 340B healthcare provider is, or expand the remedies available to a covered entity when a manufacturer overcharges it for 340B drugs"). The legality of Act 1103 does not "mirror" the concerns that the *Astra* case presented, which dealt with agreements reciting the responsibilities imposed by the text of the 340B statute. Pet. 29.

PhRMA is wrong that the Eighth Circuit failed to properly consider *Astra*. Pet. 16. The Eighth Circuit fully affirmed the Eastern District's decision, which recognized that this case is wholly distinguishable from *Astra*. The Eighth Circuit cited *Astra* numerous times, App. 6a-7a, demonstrating that it agreed with the district court's conclusion that "the Supreme Court's narrow holding concerning third-party lawsuits in *Astra*" does not "make[] the 340B Program a solely federal scheme immune from any type of state regulation." *PhRMA*, 645 F. Supp. 3d at 899, *aff'd*, 95 F.4th 1136 (8th Cir. 2024).

Other cases cited by PhRMA are inapplicable.[8] In *NLRB v. Nash-Finch Co.*, the Court considered whether a federal agency could enjoin state actions regulating "peaceful picketing governed by the federal agency." 404 U.S. 138, 139-40 (1971). As PhRMA concedes, this case held that the state's actions were preempted because it sought to regulate "certain activity covered by the [federal] statute." Pet. 29. Additionally, the NLRB was the "sole protector of the national interest," which was "defined with particularity in the [federal National Labor Relations Act.]" *Nash-Finch Co.*, 404 U.S. at 145. "The exclusiveness of the federal domain [was] clear." *Id.* at 147. Here, the Eighth Circuit correctly concluded that Act 1103 regulates "activity that falls outside the purview of 340B." App. 14a. Distribution is not covered by the 340B statute. *See supra* Section I.B. The 340B statute does not carve out a clear, exclusive federal domain. App. 12a; *see also Novartis Pharms. Corp. v. Fitch*, 2024 WL 3276407, at *9 ("Merely because Section 340B is sufficiently comprehensive to meet the need identified by Congress does not mean that States and localities are barred from identifying additional needs or imposing further requirements in the field.") (citing *Hillsborough County v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 717 (1985) (cleaned up))).

PhRMA's reliance on *Buckman* is similarly misplaced. The *Buckman* Court found that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001)

[8] *Arizona v. United States* is discussed in Section II.B below.

(quotation omitted). Unlike the fraud-on-the-FDA claims in *Buckman*, the Eighth Circuit found that pharmacy is a field that "has traditionally been regulated at the state level." App. 12a-13a; *see also Novartis Pharms. Corp. v. Fitch*, 2024 WL 3276407, at *6 (a state law similar to Act 1103 "plainly falls under the umbrella of a health and safety regulation" and is "within a state's traditional police powers"). Also, unlike the statute at issue in *Buckman*, Congress has not provided clear evidence that it intended federal authorities to have exclusive authority to oversee any activity related to the 340B Program. App. 14a; *see also Novartis Pharms. Corp. v. Fitch*, 2024 WL 3276407, at *9 ("While federal law comprehensively regulates the determination of ceiling prices on Section 340B drugs and provides robust enforcement mechanisms that ensure covered entities and manufacturers comply with the statute's requirements . . . Congress has not precluded [a state] from enacting its own policy governing delivery.").

In its final attempt to attack the Eighth Circuit's decision, PhRMA exaggerates the effects of the court's holding. To implement Act 1103, neither AID nor the state will be forced to "immerse" themselves in the adjudication of federal questions. Pet. 29-30. First, Act 1103 presumes that manufacturers *are complying* with the 340B statute by offering drugs at 340B discounts. Second, the questions PhRMA poses, Pet. 30, are easily resolved by review of HHS's Office of Pharmacy Affairs Information System ("OPAIS"), which is available to the public. OPAIS lists each participating 340B covered entity, its eligibility status, and each covered

entity's contract pharmacies. *340B Office of Pharmacy Affairs Information System*, HRSA (May 2024).[9] Regarding PhRMA's fourth question, drug companies know which drugs they manufacturer and thus which drugs are eligible for 340B pricing. Finally, Act 1103 operates "outside the purview of 340B," App. 14a, presenting no "risk of conflicting adjudications." *Astra*, 563 U.S. at 120, and the Eighth Circuit's decision leaves the 340B Program's enforcement scheme uninterrupted. *See PhRMA v. Fitch*, 2024 WL 3277365, at *11 (holding that a law similar to act 1103 "addresses delivery and Section 340B does not, so adjudications under [the law] will not interfere with federal enforcement of Section 340B's compliance mechanisms").

The Court should deny PhRMA's petition because it asks the Court to "immerse" itself in an inquiry into the tensions between federal and state objectives, and an "[i]mplied preemption analysis does not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives'; such an endeavor 'would undercut the principle that it is Congress rather than the courts that pre-empts state law.'" *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 111 (1992)).

[9] https://www.hrsa.gov/opa/340b-opais.

B. The Eighth Circuit's Decision Is Consistent With *Arizona v. United States*

The Eighth Circuit's decision fully comports with the holding in *Arizona* as well. *Arizona*'s particular facts and holding presented preemption concerns which starkly contrast with the issues reviewed by the Eighth Circuit.

In *Arizona*, the Court considered whether a state law relating to immigrants was preempted by federal law. 567 U.S. at 393-94. This case is distinguishable for several reasons. First, *Arizona* dealt with a subject in which the federal government has "broad, undoubted power": immigration and the status of foreign nationals. *Id.* at 394. The federal government is also granted explicit constitutional power to "establish a uniform Rule of Naturalization." U.S. Const. art. I, § 8, cl. 4. Governance of immigration policy is "well settled," "fundamental," "extensive and complex," and "one of the most important and delicate" powers the federal government holds. *Arizona*, 567 U.S. at 395. In *Arizona*, Congress irrefutably occupied the field of foreign national registration. *Id.* at 401.

In contrast, the 340B statute does not occupy the field of 340B drug distribution and it is not an area for which the federal government has "broad, undoubted power." *Id.* at 394. HHS and several federal courts have confirmed that the 340B statute is not a comprehensive and exclusive scheme and is silent about drug delivery and distribution. *See e.g.*, App. 11a ("[T]he text of 340B is silent about delivery

of drugs to patients.") (quotations omitted); 1996 Guidance, 61 Fed. Reg. at 43,549 ("The [340B] statute is silent as to permissible drug distribution systems.").

Second, *Arizona* dealt with state penalties for conduct that was already regulated under federal law. 567 U.S. at 401. The 340B statute and Act 1103 regulate different conduct, pricing and distribution, respectively. App. 14a; *PhRMA v. Fitch*, 2024 WL 3277365, at *11. Enforcement of Act 1103 against a drug company would result in penalties for restricting distribution, conduct that the 340B statute does not reach.

That Act 1103 and the 340B statute provide for different remedies (for different conduct) also does not create any conflict between the two regimes. As PhRMA's petition concedes, HHS can order refunds and issue civil monetary penalties to manufacturers "for any *overcharges*" or "knowing and intentional *overcharges*." Pet. 32 (emphasis added). These are pricing penalties. Act 1103 cannot—and does not—penalize drug manufacturers for overcharges. As the Eighth Circuit held, "Act 1103's penalties are aimed at activity that falls outside the purview of 340B."[10] App. 14a; *see also PhRMA v. Fitch*, 2024 WL 3277365, at *11.

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[10] PhRMA cites a recent West Virginia law's penalty provision as further evidence of conflicting remedies. Pet. 32. That too falls "outside the purview of 340B" because it similarly regulates "[*d*]*istribution* of drugs to safety net providers and contract pharmacies." App. 14a; W. Va. Code § 60A-8-6a(b) (emphasis added).

PhRMA's reliance on *Teltech Systems, Inc. v. Bryant*, is also misplaced. The Eighth Circuit's decision does not conflict with *Teltech Systems,* 702 F.3d 232 (5th Cir. 2012). *Teltech* concerned a federal law prohibiting only harmful "spoofing" (providing inaccurate telephone caller identification information) and a state law that prohibited both harmful and non-harmful spoofing. *Id.* at 234. Because "Congress' intent is the ultimate touchstone" of any preemption theory, the court looked to Congress's actions and statements when passing the federal law. *Id.* at 236 (quoting *Elam v. Kan. City S. Ry.*, 635 F.3d 796, 803 (5th Cir. 2011)). *Teltech* found "compelling evidence" of congressional intent to protect non-harmful spoofing. *Id.* at 239. The "considered regulatory choices" that PhRMA cites, Pet. 33 n.8, were House members stating, "*expressly* their intent to protect-non harmful spoofing." *Teltech*, 702 F.3d at 238 (emphasis added).

There is no such compelling evidence that Congress intended to preclude state drug distribution laws. The 340B statute's history demonstrates quite the opposite. In 2010, against an eighteen-year backdrop of contract pharmacy arrangements, Congress enacted extensive amendments to the 340B statute and did not enact any law to govern, much less preempt, state laws that regulate the distribution of 340B-priced drugs to contract pharmacies. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101-03, 124 Stat. 119, 821-28 (2010) (codified at 42 U.S.C. § 256b). It added five categories of hospitals as covered entities, program integrity

measures, and ADR. *Id.* § 7101(a), 124 Stat. 821-822; 42 U.S.C. § 256b(a)(4)(M)-(O).

Rather than usurp power from states to regulate distribution of 340B-priced drugs, Congress remained silent on state laws related to distribution systems for 340B-priced drugs and the use of contract pharmacy arrangements in the 340B Program. As the Eighth Circuit correctly pointed out, "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." App. 11a. And "absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." App. 13a. Congress has not demonstrated any intent similar to its statements in *Teltech*.

Thus, the Court should follow its longstanding practice and "enjoin seeking out conflicts between state and federal regulation where none clearly exists." *Huron Portland Cement Co. v. Detroit,* 362 U.S. 440, 446 (1960); *Fox v. Washington,* 236 U.S. 273, 277 (1915) ("So far as statutes fairly may be construed in such a way as to avoid doubtful constitutional questions they should be so construed; and it is to be presumed that state laws will be construed in that way by the state courts." (citation omitted)); *Hillsborough Cnty.*, 471 U.S. at 715.

C. The Eighth Circuit's Decision Was Correctly Decided

The Eighth Circuit's decision was correctly decided on the merits and comports with the Court's

precedents and other circuit decisions. In enacting 340B, Congress expressed no clear intent to preclude states from passing their own laws regulating the distribution of drugs, and the Eighth Circuit's decision preserves this traditional state right and creates no conflict with, or obstacle to, federal law. *See Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015); *Wyeth v. Levine*, 555 U.S. 555, 565, 578-79 (2009); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Further, Arkansas' enforcement of distribution is valid because it regulates a different subject and thus fall outside the purview of the 340B Program's delineated enforcement scheme. *Rice*, 331 U.S. at 230; *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021). Finally, Arkansas' law lawfully regulates drug distribution because Congress has not occupied the field of either 340B's operation or its enforcement mechanisms. *See Oneok, Inc.*, 575 U.S. at 377; *English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990).[11]

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[11] The longstanding presumption against federal preemption of state law is fully applicable, despite PhRMA's assertions. Pet. 34 n.9. Under this principle, courts presume that Congress supersedes state police powers only if it expresses a "clear and manifest" purpose to do so. *Hillsborough Cnty.*, 471 U.S. at 715 (quotation omitted); *see also Wyeth*, 555 U.S. at 565; *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146-47 (1963) (courts should not "conclude that Congress legislated the ouster of [a] [State] statute . . . in the absence of an unambiguous congressional mandate").

PhRMA argues that its alleged "direct conflicts with federal law" in this case overcome the presumption. Pet. 34 n.9. As explained above, the Eighth Circuit's decision creates no conflict. Act 1103 addresses drug distribution and directly impacts the health of Arkansas residents, which courts have

D. PhRMA's Allegations of "Abuse" Lack Merit and Should Be Directed at Federal ADR Proceedings

PhRMA repeatedly paints the 340B Program as riddled with abuse and criticizes the use of contract pharmacies, the replenishment model, and the efficacy of the program in providing charity care to the populations the 340B Program serves. Pet. 3, 9, 10, 11, 21, 26. PhRMA's claims are wrong, but, more importantly, PhRMA's complaints are irrelevant to the issue the Eighth Circuit considered: the 340B Program's preemptive effects on state laws governing distribution.

First, PhRMA's concerns should be addressed in a federal ADR proceeding. PhRMA cites GAO and OIG reports with concerns about contract pharmacies and the replenishment model. However, these claims center around the same alleged abuse: diversion. Pet. 10 ("This black-box [replenishment] system . . . creates even more opportunities for diversion of 340B-priced drugs."); *id.* 9-10 (alleging that "contract pharmacies accounted for nearly two-thirds of the violations for unlawful diversion"). If drug companies really believe that the replenishment model results in diversion, they should file ADR petitions with HHS. *See Astra*, 563 U.S. 110, 117, 121-22; *see also* App. 8a ("When payment, pricing, diversion, or discount disputes arise between manufacturers and covered

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long recognized as a historic area of a state's police power. *See Hillsborough Cnty.*, 471 U.S. at 719 ("[R]egulation of health and safety matters is primarily, and historically, a matter of local concern.").

entities, 340B mandates parties first go through HHS's dispute resolution process to resolve the issue."). Moreover, a court has already found that the replenishment model does not result in diversion of 340B drugs. *AbbVie, Inc. v. Fitch*, 2024 WL 3503965, at *14 ("[T]he Court does not find that the replenishment model constitutes illegal diversion" because "pharmaceuticals distribution often relies on pharmaceuticals' fungibility to facilitate efficiency.").

Second, PhRMA again "conflates" the 340B statute and Act 1103. App. 13a. In *AbbVie, Inc. v. Fitch*, a drug company challenged a similar Mississippi law and alleged that it was preempted by the 340B Program. *AbbVie, Inc. v. Fitch*, No. 1:24-cv-00184, 2024 WL 3503965 (S.D. Miss. June 22, 2024). It too offered studies to argue that contract pharmacy use did not correlate to more charity care under the 340B Program. *Id.* at *11. But, such allegations, even if true, were not deemed relevant by the court. The court stated that "criticism of Section 340B's effectiveness in achieving its *own* purposes cannot give rise to a conflict-preemption claim when the state statute is not inconsistent with Section 340B's terms." *Id.* The same is true here.

Third, many of the industry studies and reports cited by PhRMA are self-serving and should be viewed skeptically. For example, PhRMA relies on a Berkeley Research Group article as support for one of its criticisms of contract pharmacy use. *See* Aaron Vandervelde, et al., *For-Profit Pharmacy Participation in the 340B Program*, Berkeley Rsch.

Grp. (Oct. 2020).[12] This 2020 "study" is not credible because it concedes that it was "funded by the Pharmaceutical Research and Manufacturers of America." *Id.*

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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[12] https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/.