No. 22-3675

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellant,

v.

ALAN MCCLAIN, in his official capacity as Commissioner of the Arkansas Insurance Department,

Defendant-Appellee,

COMMUNITY HEALTH CENTERS OF ARKANSAS; PIGGOTT COMMUNITY HOSPITAL,

Intervenors-Appellees.

On Appeal from the United States District Court
for the Eastern District of Arkansas

Civil Action No: 4:21-cv-864-BRW

BRIEF OF INTERVENORS-APPELLEES

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SUMMARY OF THE CASE

Arkansas Act 1103 governs distribution of drugs discounted under 42 U.S.C. § 256b (the "340B Program") to pharmacies within Arkansas. The district court correctly held that the federal and state statutes operate in separate spheres—42 U.S.C. § 256b governs pricing, and Act 1103 governs distribution, and, therefore, Act 1103 is not preempted by the federal statute. Several federal courts have held that § 256b is silent on drug distribution. Indeed, Appellant, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), has numerous members that sued the U.S. Department of Health and Human Services ("HHS"), arguing that § 256b does not govern distribution. HHS, which administers the 340B Program, has consistently interpreted § 256b as deferring to state distribution laws. PhRMA has not overcome the strong presumption against preemption of state health laws. *Hillsborough Cnty. v. Automated Med. Lab'ys., Inc.*, 471 U.S. 707, 718 (1985). PhRMA mischaracterizes § 256b and Act 1103. Act 1103 does not add contract pharmacies to the list of health care providers ("covered entities") permitted to participate in the 340B Program because covered entities must order and retain title to 340B drugs. Act 1103 sanctions distribution violations and does not conflict with the 340B Program enforcement scheme, which resolves pricing disputes.

Intervenors-Appellees contend that oral argument is warranted and that each side should be given 15 minutes.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Eighth Circuit Rule 26.1A, Intervenors–Appellees Community Health Centers of Arkansas ("CHCA") 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 of either Intervenors-Appellees' stock. CHCA's members are also not-for-profit corporations that do not issue stock.

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ADR	Alternative dispute resolution
AID	Arkansas Insurance Department, Appellee
CAH	Critical access hospital
CHCA	Community Health Centers of Arkansas, Intervenor-Appellee
CMP	Civil monetary penalty
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FQHC	Federally qualified health center
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration, a subcomponent of HHS
MDRP	Medicaid Drug Rebate Program
PBM	Pharmacy benefit manager
PCH	Piggott Community Hospital, Intervenor-Appellee
PhRMA	Pharmaceutical Research and Manufacturers of America, Appellant
PHSA	Public Health Service Act
PPA	Pharmaceutical pricing agreement
REMS	Risk Evaluation and Mitigation Strategies
VA	U.S. Department of Veterans Affairs
VHCA	Veterans Health Care Act of 1992
WAC	Wholesale acquisition cost

INTRODUCTION

This case is one battle of a multifront war waged by drug companies against not-for-profit, safety-net health care providers that participate in the 340B drug discount program ("340B Program"). Appellant, Pharmaceutical Research and Manufacturers of America ("PhRMA"), and its drug-company members attempt to create villains of commercial pharmacies that provide vital services to 340B providers, known as "covered entities," but the real goal is to deprive covered entities of most 340B discounts they have received for over two decades, discounts they either pass on to low-income patients or use to provide expanded services to vulnerable patients. PhRMA's members have filed multiple suits in three other circuits, with mixed results, against the federal agency responsible for administering the 340B Program, arguing that 42 U.S.C. § 256b does not obligate drug companies to ship 340B-discounted drugs to contract pharmacies. In this lawsuit, PhRMA attempts to invade the traditional state domain of overseeing drug distribution, arguing that Arkansas Act 1103 is preempted by federal law. The district court correctly rejected PhRMA's attempt to undermine Arkansas's power to regulate drug distribution within its borders.

Arkansas Act 1103 is not preempted by 42 U.S.C. § 256b. Ark. Code Ann. §§ 23-92-601–606. Act 1103 is presumed to be valid because it is designed to foster public health and pursues "common purposes" with section 340B of

enabling covered entities to treat more patients and provide more services. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) ("*PhRMA*"); *Hillsborough Cnty. v. Automated Med. Lab'ys., Inc.,* 471 U.S. 707, 719 (1985). PhRMA mischaracterizes Act 1103, the 340B Program at 42 U.S.C. § 256b, and contract pharmacy arrangements that permit Arkansas health care providers that participate in the 340B Program ("covered entities") to dispense drugs to their patients. Act 1103 and the 340B Program regulate different areas: Act 1103 governs drug distribution within the state of Arkansas, while the 340B Program governs drug pricing. The 340B Program has not occupied the field of drug distribution, which Congress has traditionally left to the states. Likewise, no conflict exists between Act 1103 and the 340B Program because Act 1103 does not add new participants to the 340B Program and does not impede federal oversight of 340B pricing. Act 1103 simply requires drug companies to permit Arkansas covered entities to dispense discounted drugs to their patients at community pharmacies. Act 1103 also does not conflict with federal Risk Evaluation and Mitigation Strategies ("REMS") because Act 1103 does not require manufacturers to ship to pharmacies unless authorized under REMS.

Act 1103 regulates 340B drug *distribution* arrangements in two ways. First, the law prohibits a manufacturer from "denying [an Arkansas pharmacy] access" to drugs purchased by a covered entity. Ark. Code Ann. § 23-92-604(c)(1). Second,

the law proscribes a manufacturer from restricting the acquisition and receipt of 340B-priced drugs purchased by a covered entity under a 340B contract pharmacy arrangement with an Arkansas pharmacy. *Id*. § 23-92-604(c)(2). Act 1103 does not regulate whether a manufacturer has overcharged a covered entity for drugs purchased by the covered entity. Act 1103, therefore, does not intrude into the field of 340B drug pricing.

Protecting distribution of 340B-priced drugs to Arkansas contract pharmacies is squarely within Arkansas's police power to regulate the public health and safety of its citizens. Arkansas safety-net providers rely on contract pharmacy distribution arrangements to obtain 340B-priced drugs. Without contract pharmacies, many Arkansas safety-net healthcare providers would be unable to dispense 340B-priced drugs to their vulnerable patients to treat often life-threatening conditions. By preserving the right of Arkansas safety-net providers to dispense drugs to patients at community pharmacies, Act 1103 protects the public health and safety of Arkansans from the restrictive and detrimental distribution policies of drug companies.

In contrast to Act 1103, the federal 340B Program is a pricing program and does not regulate drug distribution. Under the 340B Program, drug companies agree to sell outpatient drugs at a discount to statutorily defined covered entities, which include community health centers, clinics that receive federal grants, and

certain hospitals that treat large numbers of uninsured and underinsured patients. As a condition of having a drug company's products covered by Medicaid and Medicare Part B, the 340B statute specifies the prices of drugs subject to discounts and the entities that may participate and says nothing about how drugs travel from manufacturers to patients, which is the subject of Act 1103. Several federal courts have affirmed that the 340B statute is silent on distribution. *See, e.g.*, *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023) ("The text [of 340B] is silent about delivery."). Indeed, Congress has traditionally left the regulation of drug distribution to the states, and Congress did the same in the 340B statute. Therefore, no conflict exists between Act 1103 and the 340B Program. Each operates in separate spheres, distribution and pricing.

PhRMA makes a limited preemption argument that Act 1103 conflicts with the Federal Food, Drug, and Cosmetic Act ("FDCA") to the extent that Act 1103 requires shipments to pharmacies not authorized by federal REMS. Act 1103 also does not conflict with REMS because Act 1103 does not require shipments in violation of the FDCA. The REMS program is established at 21 U.S.C. § 355-1 to ensure the safe use of potentially risky pharmaceutical products. The statute addresses how certain REMS-regulated drugs are transported, stored, and administered. Specialty pharmacies can and do serve simultaneously as REMS-authorized participants and as covered entities' 340B contract pharmacies. Act

1103 does not force a manufacturer to distribute REMS drugs to a pharmacy that is not permitted to dispense such drugs regardless of whether the pharmacy is a contract pharmacy.

Accordingly, this Court should affirm the district court's summary judgment in favor of Intervenors-Appellees, Community Health Centers of Arkansas and Piggott Community Hospital (the "Covered Entities"). Nothing in the 340B statute precludes a state from regulating the distribution of 340B drugs, including protecting 340B contract pharmacy arrangements, and Act 1103 does not conflict with the 340B Program or REMS.

JURISDICTIONAL STATEMENT

The district court had jurisdiction pursuant to 28 U.S.C. § 1331. The district court entered final judgment on PhRMA's preemption claim on December 29, 2022. PhRMA timely appealed on December 29, 2022. This court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF ISSUES

1. Whether the district court correctly held that Act 1103 is not preempted by 42 U.S.C. § 256b. U.S. Const. art. VI, cl. 2; 42 U.S.C. § 256b; Ark. Code Ann. § 23-92-604(c); *Wyeth v. Levine*, 555 U.S. 555 (2009); *Hillsborough Cnty. v. Automated Med. Lab'ys., Inc.*, 471 U.S. 707 (1985); *Lefaivre v. KV*

Pharm. Co., 636 F.3d 935 (8th Cir. 2011); *Pharm. Care Mgmt. Ass'n v. Wehbi,* 18 F.4th 956 (8th Cir. 2021).

2. Whether the district court correctly held that Act 1103 is not preempted by the FDCA. U.S. Const. art. VI, cl. 2; 21 U.S.C. § 355-1(a); Ark. Code Ann. § 23-92-604(c); *Wyeth v. Levine*, 555 U.S. 555 (2009); *Hillsborough Cnty. v. Automated Med. Lab'ys., Inc.*, 471 U.S. 707 (1985); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935 (8th Cir. 2011); *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956 (8th Cir. 2021).

STATEMENT OF THE CASE

PhRMA's preemption arguments are premised on mischaracterizations of the 340B Program and contract pharmacy arrangements. The 340B Program was enacted to curb dramatic price increases in pharmaceutical products—increases that were harming safety-net providers and their patients. The program was not enacted, as PhRMA contends, to correct the "unintended side effect[s]" of the Medicaid rebate statute but rather to address drug companies' intentional response to the Medicaid rebate statute, which was to raise prices for safety-net providers. PhRMA also misrepresents the role of contract pharmacies, which did not "barge" into the 340B Program as PhRMA repeatedly alleges and do not purchase 340B drugs. Rather, contract pharmacies enable covered entities to dispense drugs where the covered entity's patients reside. The covered entity retains title to the

drugs, and the contract pharmacy dispenses those drugs to patients of the covered entity. Of course, a covered entity compensates the pharmacy for its work providing dispensing services. A covered entity's payment of a dispensing fee for contract pharmacy services does not transform the pharmacy into a 340B covered entity as PhRMA argues.

I. The 340B Drug Pricing 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") and requires drug companies to offer discounts on covered outpatient drugs to specified safety-net health care providers as a condition of the manufacturers' drugs being reimbursed by Medicaid and Medicare Part B.[1] 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1). As a condition of covering their drugs under Medicaid and Medicare Part B, drug companies must execute a 340B pharmaceutical pricing agreement ("PPA") with HHS that requires "that the manufacturer 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." 42 U.S.C. § 256b(a)(1).

[1] Medicare Part B covers physician, hospital outpatient, and certain other non-hospital services. 42 U.S.C. § 1395k.

Safety-net hospitals and clinics that participate in the 340B Program—referred to as "covered entities" in the 340B statute—provide health care and other critical services to the neediest individuals, regardless of their ability to pay. Covered entities must meet strict eligibility criteria specified in the 340B statute to enroll in the 340B Program. *Id*. § 256b(a)(4). Each category of covered entity receives some form of federal assistance to treat the nation's most vulnerable patients. The 340B Program is administered by the Health Resources and Services Administration ("HRSA"), which is a subcomponent of the federal Department of Health and Human Services ("HHS"). 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." 42 U.S.C. § 256b(a)(5)(A)(i), (a)(5)(B). These restrictions are commonly known as "duplicate discounts" and "diversion," respectively.

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. *Id*. § 1396r-8. The MDRP requires pharmaceutical manufacturers to provide rebates to state Medicaid programs on outpatient drugs and biological products furnished to Medicaid beneficiaries. 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). Manufacturers responded to passage of the MDRP statute by raising their "best prices" on covered outpatient drugs for preferred customers, including large governmental purchasers like the Department of Veterans Affairs ("VA") and non-profit safety-net providers like federally qualified health centers ("FQHCs") and public hospitals. H.R. Rep. No. 102-384, pt. 2, at 9 (1992). Manufacturers "promptly cancelled discount contracts, terminated special-price practices, and raised the prices they charged" to safety-net providers. *Id*. at 10. 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.*

Concerned about rising "[p]rices paid for outpatient drugs by the [VA], and some Federally-funded clinics and public hospitals," Congress enacted the VHCA "to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs" that they purchase. *Id*. at 7, 11; Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943 (1992). Section 602 of the VHCA established the 340B Program. Thus, the 340B Program was not enacted to correct "unintended side effect[s]" of the MDRP as PhRMA contends. Opening Brief of Appellant Pharmaceutical Research and Manufacturers of America ("PhRMA Br.") at 7. Rather, Congress intended to remedy manufacturer

gaming following enactment of the original MDRP, in which manufacturers increased prices to safety-net providers in order to minimize rebates to Medicaid. H.R. Rep. No. 102-384, pt. 2, at 9.

Congress enacted the 340B Program to make drugs more affordable for covered entities. *Id.* at 12. "In giving these 'covered entities' access to price reductions," Congress intended "to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." *Id.*

Covered entities provide significant levels of uncompensated care, and 340B discounts help relieve this financial burden. Covered entities essentially lose less money on their uninsured and underinsured patients because of the prescription drug discounts under the 340B Program. And by mitigating these losses, they can be more generous with reducing or waiving patient pharmacy copayments or by providing other necessary health care services. The 340B Program also generates revenue for covered entities so that they are less dependent on taxpayer support. If a covered entity patient has prescription drug coverage, the difference between the insurer's payment and the discounted price is income to the covered entity that supplements federal funds, thus allowing the covered entity to stretch its scarce resources to treat more patients and to provide more services. *Id.*

Congress provided manufacturers and covered entities with an alternative dispute resolution ("ADR") process to adjudicate 340B pricing disputes, including allegations by manufacturers that covered entities violated the duplicate discount or diversion prohibitions. 42 U.S.C. § 256b(d)(3). A manufacturer that suspects violations is entitled to audit the covered entity and file an ADR petition. *Id.* § 256b(a)(5)(C), (d)(3)(B)(iv); 42 C.F.R. § 10.21(c)(2). The Covered Entities are aware of no ADR proceeding in which a manufacturer challenged the use of contract pharmacy arrangements.

Congress also authorized HHS to assess civil monetary penalties ("CMPs") against manufacturers that knowingly and intentionally charge covered entities more than the 340B ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi). Congress required HHS to issue CMP regulations, *id.* § 256b(d)(1)(B)(vi)(I), which HHS promulgated at 42 C.F.R. §§ 10.1–10.24. An HHS regulation defines a manufacturer overcharge under the 340B Program as any "order for a covered outpatient drug which results in a covered entity paying more than the [340B] ceiling price," 42 C.F.R. § 10.11(b), which "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.* § 10.11(b)(1).

II. 340B Contract Pharmacy Arrangements

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.

Most drugs are not sent directly from manufacturers to pharmacies. *See* HHS OIG, *Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information*, OEI-05-14-00640, 4 (Sept. 2019)[2]; Kaiser Family Foundation, *Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, 3-4, 8-10 (Mar. 2005) ("*Follow the Pill*").[3] Rather, pharmacies contract with wholesalers that purchase the manufacturer's drugs. *Follow the Pill*, 10. A pharmacy or health care provider then purchases drugs from the third-party wholesaler. *Id.* at 10, 18. If the pharmacy or health care provider is entitled to a discount from the manufacturer, the initial transaction with the wholesaler is at wholesale acquisition cost ("WAC"), and the wholesaler subsequently initiates a "charge back": "the wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then

[2] https://oig.hhs.gov/reports-and-publications/oei/d.asp.
[3] https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

'charges back' the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler's cost of goods (WAC)." *Id.* at 19.

Because the construction and management of a pharmacy is expensive and requires special expertise, many 340B covered entities, including the Covered Entities, cannot afford to "expend precious resources to develop their own in-house pharmacies." 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"). They rely instead on independent retail pharmacies to dispense drugs, typically oral medications, on their behalf. Providers with large service areas also contract with independent pharmacies that are accessible where the provider's patients reside. In addition, some medications require special storage and handling and can only be dispensed by a specialty pharmacy,[4] through a mail order program, or subject to a limited distribution network.[5] These arrangements are established by contract between covered entities and pharmacies, so they are often called "contract pharmacy arrangements," and the pharmacies are generally referred to as "contract pharmacies."

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

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

From the early years of the 340B Program, HRSA permitted covered entities to order discounted drugs for shipment directly to contract pharmacies. *Id.* In 2010 guidance, HRSA clarified that covered entities may use an unlimited number of contract pharmacies. 75 Fed. Reg. 10,272 (Mar. 5, 2010). The 2010 guidance expanded the existing program, which included the requirement that contract pharmacies act as agents of the covered entity. 61 Fed. Reg. at 43,550 ("The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy."). HRSA emphasized repeatedly that a covered entity that uses contract pharmacies "has and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity, and to prevent situations in which a drug is subject to both the 340B discount and a Medicaid rebate claim." Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. at 10,273 (Mar. 5, 2010). HRSA determined that "pharmacy and inventory management processes are available that make utilization of more than one pharmacy readily feasible for many covered entities without increasing the risk of diversion." *Id.* Multiple drug companies argued that HRSA should permit them to audit covered entities that use contract pharmacies. *Id.* HRSA pointed out that manufacturers

could already audit covered entities, *id.* at 10,274, and, less than two weeks after publication of the 2010 guidance, Congress granted manufacturers an additional right to audit. Patient Protection and Affordable Care Act § 7102(a), Pub. L. No. 111-148, 124 Stat. 823 (2010), codified at 42 U.S.C. § 256b(d)(3)(B)(iv).

Contract pharmacies are not permitted to purchase 340B drugs. Wholesalers do not establish 340B accounts for contract pharmacies, which are not eligible for these discounts. A covered entity establishes a 340B account with the wholesaler, enabling the covered entity to purchase 340B-discounted drugs. The wholesaler creates a "ship to, bill to" arrangement under which the drugs are billed to the covered entity and shipped to the contract pharmacy. 75 Fed. Reg. at 10,277.[6] A covered entity must "purchase the drug, maintain title to the drug and assume responsibility for establishing its price." *Id.* 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 providing the service of dispensing and billing drugs on the covered entity's behalf.

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

Contract pharmacy arrangements are built on the well-established commercial practice of one party purchasing and taking title to a product and a second party taking possession of the product on the first party's behalf. Contract pharmacy distribution arrangements are commonly used within the U.S. drug distribution system and are not unique to the 340B Program. *See, e.g.*, Fed. Trade Comm'n, University of Michigan Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010)[7]; 134 Cong. Rec. H6971-02 (1988) (statement of Rep. Charlie Rose) ("[H]ealth centers often include onsite pharmacies, or agreements with community pharmacists to ensure that the medicines needed to treat or control these chronic conditions are available."); *Social Security and Welfare Proposals, Hearing Before the H. Comm. on Ways and Means*, 91st Cong. 2129 (1969) (statement of Jacob W. Miller, Chairman, Comm. Pub. Affs., Am. Pharm. Ass'n) ("As I am sure you are aware, many health care facilities do not maintain their own onsite pharmaceutical services … [r]ather, they look to the community pharmacies to provide such service on a contract basis.").

Contract pharmacies therefore help fulfill the 340B Program's purposes. Covered entities that lack in-house pharmacies can only participate in the 340B Program by contracting with outside pharmacies. Some covered entities,

[7] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

particularly in rural areas, serve patients living hundreds of miles away. Caitlin Ostroff, *Millions of Americans Live Nowhere Near a Hospital, Jeopardizing Their Lives*, CNN (Aug. 3, 2017).[8] Covered entities, therefore, contract with pharmacies that are not located nearby to meet the needs of these patients. Contrary to PhRMA's characterization, this is not an abuse but a necessary means of serving all patients. *See* PhRMA Br. 13. In other instances, drugs may only be available from specialty pharmacies designated by the drug company, which may be located on the opposite side of the country from the covered entity. *See Limited Distribution Drugs 101*, Clarivate (Sept. 27, 2019)[9]; PhRMA Br. 12 n.3.

For 26 years, every drug company participating in the 340B Program, including PhRMA's members, honored contract pharmacy arrangements. Beginning in July 2020, one manufacturer after another either fully eliminated or significantly restricted distribution of 340B drugs ordered through contract pharmacy arrangements. *See, e.g.,* Sanofi, *Sanofi Policy* (Feb. 1, 2021).[10] As of the date of filing this brief, twenty-one manufacturers have unilaterally imposed restrictions on shipping 340B drugs to contract pharmacies. These restrictions have deprived covered entities of the revenue and savings that Congress intended under the 340B Program, which reduces the resources available to covered entities

[8] https://www.cnn.com/2017/08/03/health/hospital-deserts/index.html.
[9] https://clarivate.com/blog/limited-distribution-drugs-101/.
[10] sanofi-policy-2022-04-15.pdf (340besp.com).

to meet the needs of their vulnerable patients, including the need for affordable and accessible prescription drugs.

In response to these policies, HHS sent letters dated May 17, 2021, to several manufacturers informing them that their policies are contrary to the 340B statute and demanding that they modify or rescind the policies. In response, several manufacturers sued the federal government. On January 30, 2023, the Third Circuit issued a decision that the contract pharmacy restrictions imposed by Sanofi, Novo Nordisk, Inc., and AstraZeneca are lawful and not subject to enforcement actions by HHS. *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696, 707 (3d Cir. 2023). The court granted HHS's motion for an extension to April 17, 2023, to request rehearing en banc. Text Order, *Sanofi Aventis U.S., LLC v. HHS*, Case No. 21-3167 (3d Cir. Feb. 28, 2023), ECF No. 82.

The U.S. District Court for the District of Columbia disagreed with the government's interpretation of the 340B statute, partially finding in favor of Novartis and United Therapeutics. The government appealed the decision to the D.C. Circuit, which held oral arguments on October 24, 2022. The parties await a decision.

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 companies, 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). The court remanded the May 17, 2021, letter to HRSA to address HRSA's change in position regarding its authority to enforce contract pharmacy arrangements. Lilly appealed, and the government cross-appealed, to the Seventh Circuit. The Seventh Circuit held oral arguments on October 31, 2022, and the parties await a decision.

III. The Importance of Contract Pharmacies in Arkansas

Arkansas has historically supported and protected the two constituencies that advocated for passage of Act 1103—safety-net providers and independently owned retail pharmacies. *See, e.g.*, Ark. Code Ann. § 23-61-1002; Act 1497, S.B. 1020, 89th Gen. Assemb., Reg. Sess. (Ark. 2013); Act 1498, S.B. 1143, 89th Gen. Assemb., Reg. Sess. (Ark. 2013). Arkansas has passed an even longer list of legislation for the benefit of independent pharmacies, including a 2017 pharmacy practice act, a 2018 pharmacy benefit manager ("PBM") licensure law, and several other pieces of legislation. Ark. Code Ann. § 17-92-101 *et seq.* (Pharmacy Practice Act); Ark. Code Ann. § 23-92-501 *et seq.* (Pharmacy Benefits Manager Licensure Act); Ark. Code Ann. § 23-79-1801, *et seq.* (requiring PBMs to disclose if the plan is self-funded or fully insured on benefit cards).

Arkansas's support for independent pharmacies is one reason 340B contract pharmacies are so important in Arkansas. Under Arkansas Code Section 17-92-607(a), non-profit, tax exempt, and governmentally funded hospitals are prohibited from holding a license as a retail pharmacy. As a result, most 340B hospitals in Arkansas have no way to fill retail prescriptions with 340B drugs except through contract pharmacies. FQHCs are not legally barred from owning their own retail pharmacies, but most of them dispense 340B drugs through contract pharmacies due to the cost and resource demands of establishing and operating an in-house pharmacy.

IV. Arkansas Act 1103

In May 2021, the Arkansas legislature passed Act 1103, which prohibits discriminatory conduct against covered entities that has the practical effect of denying Arkansas covered entities the benefit of the 340B Program. Ark. Code Ann. §§ 23-92-601–606. Among those benefits is the right of covered entities and their contract pharmacy partners to enter into bill-to/ship-to arrangements for the distribution of 340B drugs. The legislative history of Act 1103 is clear that the Arkansas legislature understood the importance of contract pharmacies for both Arkansas safety-net providers and Arkansas independent pharmacies and that such arrangements need protection from drug company restrictions. *To Establish the 340B Drug Pricing Nondiscrimination Act, Hearing on H.B. 1881 Before the Ark.*

House of Representatives, 93d Gen. Assembly Regular Session (Ark. 2021) (statement of Rep. Michelle Gray that "[l]ast year one manufacturer . . . decided that they would no longer ship . . . medications to the contract pharmacy," that the manufacturer said that "[i]f Hospital does contract with a pharmacy . . . we are no longer going to send medications there because we are trying to limit the amount of drugs that we send at a reduced price," and that Act 1103 is aimed to protect Arkansas "patients, our pharmacies, [and] our hospitals.").

Most provisions of Act 1103 regulate PBMs and other third-party payers. *See, e.g.*, Ark. Code Ann. § 23-92-604(a)(3), (a)(9). Neither PhRMA nor any other entity has challenged these payer-related provisions.

PhRMA's lawsuit focuses exclusively on the two provisions in Act 1103 that protect the use of contract pharmacy arrangements to distribute 340B drugs within the state of Arkansas: These provisions state that a pharmaceutical manufacturer 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.

Id. § 23-92-604(c). The first provision prohibits a drug company from interfering with contractual relationships between contract pharmacies and covered entities.

Id. § 23-92-604(c)(1). The second provision prohibits a manufacturer from preventing a contract pharmacy from receiving 340B-priced drugs on behalf of a covered entity. *Id.* § 23-92-604(c)(2).

Act 1103 requires the Arkansas Insurance Department ("AID") to "promulgate rules to implement" its provisions. Ark. Code Ann. § 23-92-606. In Final Rule 123, AID promulgated 340B drug program nondiscrimination requirements, including those for third parties and drug companies. Final Rule 123 clarifies that Act 1103 regulates the "acquisition and delivery" of drugs already subject to a manufacturer's 340B-price. AID Rule 123: 340B Drug Program Nondiscrimination Requirements II(7) (defining "340B-drug pricing").

V. The FDCA and REMS Program

The FDCA's REMS program was created to ensure the safe use of potentially high-risk products that might otherwise not be approved for use. 21 U.S.C. § 355-1. The Food and Drug Administration ("FDA") imposes REMS requirements if "necessary to ensure that the benefits of the drug outweigh the risks of the drug." *Id*. § 355-1(a)(1); *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary*, FDA (Apr. 2019). REMS requirements may include restrictions for those who prescribe, dispense, or use the drug. 21 U.S.C. § 355-1(e). FDA explains, "[c]ertain REMS may also require pharmacies or other healthcare settings to become certified to dispense the REMS medication."

Roles of Different Participants in REMS, FDA (Mar. 24, 2020).[11] The FDA considers whether the REMS requirements are "unduly burdensome on patient access to the drug," whether they "minimize the burden on the health care delivery system," and whether, to the extent practicable, the REMS program is "compatible with established distribution, procurement, and dispensing systems for drugs." 21 U.S.C. § 355-1(f)(2)(C), (D)(ii).

VI. Intervenors-Appellees

Piggott Community Hospital ("PCH") and the FQHC members of Community Health Centers of Arkansas ("CHCA") rely on the 340B Program to support their missions of caring for low-income and other vulnerable patients. They cannot effectively participate in the 340B Program for self-administered drugs in the absence of a contract pharmacy to dispense 340B drugs.

PCH is located in Piggott, Arkansas and is designated under the Medicare program as a critical access hospital ("CAH"). App. 523; R. Doc. 37, at 9 ¶ 48.[12] PCH is owned and operated by the City of Piggott and participates in the 340B Program based on its governmental ownership and CAH status. 42 U.S.C. §§ 256b(a)(4)(N), 1395i-4(c)(2); 42 C.F.R. §§ 485.601-485.647; App. 581; R. Doc.

[11] https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems.

[12] CAHs are small rural hospitals that receive favorable Medicare reimbursement to ensure their financial viability and hence access to health care in rural areas. 42 C.F.R. §§ 485.601–485.647.

48, at 2. As a requirement of its CAH designation, PCH is located in an area that serves residents who would otherwise have to travel long distances to receive inpatient medical care. *See* 42 U.S.C. § 1395i-4(c)(2)(B)(i)(I); 42 C.F.R. § 485.610(c); App. 523; R. Doc. 37, at 9 ¶ 48. As an Arkansas governmentally funded hospital, PCH is prohibited from owning an on-site retail pharmacy. *See* Ark. Code Ann. §§ 17-92-605(d), 17-92-607; App. 523; R. Doc. 37, at 9 ¶ 48. Therefore, PCH relies exclusively on independently-owned contract pharmacies to fill prescriptions with 340B drugs for its patients, many of whom are uninsured and low income. *Id.*

CHCA is a non-profit membership organization comprised of eleven community health centers located in Arkansas that provide primary health services in over 120 service locations. App. 523; R. Doc. 37, at 9 ¶ 49. CHCA members treat large numbers of uninsured and underinsured, low-income Arkansans as a condition of community health center status. All of CHCA's members participate in the 340B Program by virtue of their receipt of FQHC funding under Section 330 of the PHSA. 42 U.S.C. §§ 254b, 256b(a)(4)(A), 1396d(l); App. 523; R. Doc. 37, at 9 ¶ 49. Importantly, Section 330 requires health centers to offer "pharmaceutical services as may be appropriate" and to provide care regardless of a patient's ability to pay. 42 U.S.C. §§ 254b(b)(1)(A)(i)(I), 254b(k)(3)(G)(iii). The majority of CHCA's eleven health centers do not own their own pharmacies. App. 523; R.

Doc. 37, at 9 ¶49. Instead, they rely on outside, community-based retail pharmacies to order, receive, and dispense 340B self-administered medications on behalf of their patients. *Id.*

VII. Procedural History

On September 29, 2021, PhRMA filed suit challenging certain contract pharmacy provisions of Act 1103 arguing that the Arkansas law is 1) preempted by the 340B statute and 2) unlawful under the dormant Commerce Clause's extraterritoriality principle. App. 29-42; R. Doc. 1, at 21-34 ¶¶ 66-104. The Commerce Clause challenge was initially stayed pending the outcome of PhRMA's preemption challenge and later stayed pending the Supreme Court's upcoming decision in *National Pork Producers Council v. Ross*, No. 21-468. App. 5; R. Doc. 28; App. 7; R. Doc. 55. On May 3, 2022, the Covered Entities intervened as defendants. App. 99-106; R. Doc. 22. Following cross motions for summary judgement on the preemption challenge, the district court granted the Covered Entities' motion for summary judgment. App. 126-27; R. Doc. 24; App. 511-13; R. Doc. 35; App. 580-96; R. Doc. 48. The district court held that neither the 340B Program nor the FDCA preempt Act 1103. *Id.*

The district court held that "Act 1103 is not subject to field preemption under the 340(B) Program." App. 591; R. Doc. 48, at 12 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Responding to PhRMA's reliance on

Astra USA, Inc. v. Santa Clara County, 563 U.S. 110 (2011) ("*Astra*"), the district court 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. 590; R. Doc. 48, at 11. The court concluded that "[t]he 340B Program is not 'so pervasive as to make reasonable the inference that Congress left no room for States' to protect their specific drug distribution systems" and that 340B is not "a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws." App. 591; R. Doc. 48, at 12 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

Regarding impossibility preemption, the district court held that "Act 1103 does not require illegal conduct under the 340(B) Program and is not preempted." App. 593; R. Doc. 48, at 14. Characterizing contract pharmacy arrangements "as transfers or resales to non-patients" is "not a reasonable construction of the statute." App. 592; R. Doc. 48, at 13. In any case, even if this characterization were reasonable, the district court explained that "Congress mandated that any concerns regarding diversion be addressed first through ADR procedures, not in federal court." App. 593; R. Doc. 48, at 14.

The district court further held that "Act 1103 is not an obstacle to the purpose and objective of the 340(B) Program" under the obstacle preemption

doctrine. App. 594; R. Doc. 48, at 15. The district court stated that "the effects of [Act 1103] are limited to the distribution of and access to the discounted drugs." App. 593; R. Doc. 48, at 14. PhRMA "provided no evidence that Act 1103 interferes with PPA agreements between covered entities and HHS, or, in effect, adds contract pharmacies to the covered entities list." App. 593-94; R. Doc. 48, at 14-15. Further, 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." *Id.*

Finally, the district court held that the FDCA does not preempt Act 1103 because "Act 1103 and the FDCA regulate completely different subject matter and activities." App. 595; R. Doc. 48, at 16. While the FDCA focuses on safety, "Act 1103 does not regulate drug safety." *Id.* The district court explained that that "the FDCA does not include any statement preempting state laws governing distribution of prescription drugs," and "[n]othing in Act 1103 prevents manufacturers from limiting the pharmacies that may dispense drugs as required under a REMS." *Id.* (citing *Wyeth v. Levine*, 555 U.S. 555, 567 (2009); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 941 (8th Cir. 2011)).

SUMMARY OF THE ARGUMENT

The district court correctly held that "Act 1103 is not preempted by either the 340(B) Program or the FDCA" under the field, impossibility, or obstacle doctrines. App. 595; R. Doc. 48, at 16. Act 1103 does not intrude into the federal 340B scheme because the 340B statute governs pricing of drugs, and Act 1103 solely governs distribution of 340B-priced drugs to Arkansas pharmacies. The 340B statute establishes the 340B ceiling price and the entities eligible to purchase drugs at that price. 42 U.S.C. § 256b(a)(1), (4). The 340B statute does not regulate how 340B drugs are acquired and distributed, in large part because such matters are generally addressed under state law. Indeed, the Third Circuit recently concluded that "[t]he text [of 340B] is silent about delivery." *Sanofi*, 58 F.4th at 703. When enacting the 340B statute, Congress considered and rejected limitations on drug distribution, and Congress has been aware of 340B contract pharmacy arrangements for decades and has never addressed these distribution schemes in subsequent amendments to the statute. HHS, several federal courts, and PhRMA's own members have acknowledged that the 340B statute does not regulate drug distribution.

Act 1103 also does not create any direct conflicts with the 340B statute. Act 1103 does not add contract pharmacies as participants to the 340B Program, as PhRMA contends, because contract pharmacies do not take title to 340B drugs.

Ownership remains with the covered entity, and the pharmacy is merely the mechanism for dispensing the covered entity's drugs to its patients. Act 1103 also does not conflict with HHS's enforcement mechanisms, because both the ADR procedures and CMPs are focused on pricing, not distribution.

Act 1103 does not conflict with REMS. A pharmacy would not be permitted to contract with a covered entity to receive drugs that the pharmacy is not authorized to receive under REMS. Act 1103 does not require otherwise.

ARGUMENT

I. The District Court Correctly Held that Act 1103 Is Not Preempted by Section 340B

Courts have long presumed that Congress does not cavalierly preempt state laws because States are independent sovereigns in the U.S. federal system. *Hillsborough,* 471 U.S. at 715; *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Pracs. Litig*., 621 F.3d 781, 794 (8th Cir. 2010) ("There is a presumption against preemption in areas of traditional state regulation."). The presumption against federal preemption of a state statute designed to foster public health has special force when a state and the federal government are pursuing "common purposes." *PhRMA*, 538 U.S. at 666; *Hillsborough Cnty.*, 471 U.S. at 715–718; *New York State Dept. of Soc. Servs. v. Dublino*, 413 U.S. 405, 421 (1973). Under the presumption against preemption, courts assume that the historic police powers of states are not superseded by federal law unless Congress expresses a "'clear and

manifest'" purpose to do so. *Hillsborough Cnty.*, 471 U.S. at 715 (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)); *see also Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

Congress expressed no such clear and manifest purpose in Section 340B to preempt state distribution laws. Indeed, in numerous other health care laws, Congress has expressly preempted state laws. *See, e.g.*, 42 U.S.C. §§ 234(c), 238q(c)(1)(B), 247d-6d(b)(8), 300aa-22(e), 300gg-23(b)(1), 1395w–26(b)(3), 1395dd(f), 1395w-104(e)(5). Congress did not expressly preempt state distribution laws in Section 340B.

Act 1103 is not impliedly preempted because it governs drug distribution, not federal 340B pricing. Act 1103 references the federal 340B statute merely to describe the drugs subject to the Act's distribution requirements, drugs that are already discounted in accordance with the 340B statute. Act 1103's focus on drug distribution is clear from its legislative history. PhRMA's preemption arguments are also directly contrary to AID's authoritative interpretation that Act 1103 regulates drug distribution, not pricing.

A. The District Court Correctly Held that Act 1103 Is Not Subject to Field Preemption Under the 340B Program

The District Court properly rejected PhRMA's claim that "the 340B Program is a solely federal scheme" and finding that "Act 1103 is not subject to field preemption under the 340(B) Program." App. 589-91; R. Doc. 48, at 10, 12.

The District Court reasoned that PhRMA's reliance on *Astra USA, Inc. v. Santa Clara County* was misplaced and that the 340B Program is completely silent as to the role of contract pharmacies. Indeed, the Third Circuit recently confirmed that 340B is wholly silent on drug distribution, which is the sole focus of the challenged provisions of Act 1103. The district court also correctly rejected PhRMA's argument that Act 1103 transforms contract pharmacies into covered entities. Act 1103 does nothing of the sort because HRSA's longstanding policy is that covered entities must purchase and retain title to drugs shipped to contract pharmacies. Act 1103 does not alter this federal requirement. Because contract pharmacies do not take title to 340B drugs, they are not covered entities.

1. Act 1103 Governs Distribution Within Arkansas

The district court explained that "[e]ven though the title of Act 1103 includes pricing in its name, the effects of the disputed provisions are limited to the distribution of and access to the discounted drugs." App. 593; R. Doc. 48, at 14. Subsection (c)(1) forbids drug companies from "denying access" to the manufacturer's 340B-priced drugs. Ark. Code. Ann. § 23-92-604(c)(1). Subsection (c)(2) focuses on a contract pharmacy "that *receives* drugs purchased under a 340B drug pricing contract pharmacy arrangement." *Id.* § 23-92-604(c)(2) (emphasis added). Both provisions regulate distribution, not pricing, and govern

distribution of drugs that have already been purchased at the 340B price under federal law.

a. The Text of Act 1103 Focuses on Distribution and Does Not Regulate Pricing

Section 23-92-604(c) of Act 1103 has two subparagraphs, neither of which intrude on the 340B Program. The first subparagraph forbids a manufacturer from prohibiting pharmacies from "contracting or participating" with a covered entity by "denying access" to the manufacturer's 340B-priced drugs. Ark Stat. Ann. § 23-92-604(c)(1). This provision focuses on the relationship between a pharmacy and a covered entity and the covered entity's access to a manufacturer's drugs, which is governed under state contract law. *See* 1996 Guidance, 61 Fed. Reg. at 43,550. Arkansas has traditionally governed access to a manufacturer's drugs by addressing a party's ability to order and receive drugs and other aspects of the drug delivery system. *See, e.g.*, Ark. Code Ann. §§ 20-64-505 (wholesale distribution of prescription drugs), 20-64-506 (drug shipment).

Likewise, the second subparagraph of Act 1103 does not intrude on the 340B Program. That paragraph prohibits a manufacturer from "deny[ing] or prohibit[ing] 340B drug pricing for an Arkansas-based community pharmacy." Ark. Code Ann. § 23-92-604(c)(2). PhRMA contends that this provision is an attempt to qualify contract pharmacies as covered entities under the 340B statute. PhRMA Br. 4, 35. PhRMA ignores the remainder of that subparagraph, however,

which clarifies that the contract pharmacy "receives" the drugs at issue, which have already been "purchased" through the 340B Program by "an entity authorized to participate in 340B drug pricing." Ark. Code Ann. § 23-92-604(c)(2). The term "purchased" is used in the past tense, demonstrating that Act 1103 regulates distribution of drugs that are already subject to a 340B price. *Id.* The Arkansas contract pharmacy "receives," not purchases, the 340B drugs, meaning the contract pharmacy receives *possession* of drugs already subject to federal 340B prices. *Id.* Thus, Act 1103 does not transform contract pharmacies into covered entities because the statute plainly applies to drugs already purchased by covered entities.

In enacting Act 1103, the Arkansas General Assembly recognized that numerous drug companies have expressly restricted *distribution* of 340B-priced drugs, which damages Arkansas' health care safety net. *See, e.g.*, Lilly Notice (entitled "*Limited Distribution Plan* Notice for Eli Lilly and Company Products," stating "Lilly is *limiting distribution* of all 340B ceiling priced product directly to covered entities and their child sites only") (emphasis added) (undated).[13] To

[13] Lilly is a member of PhRMA, and other PhRMA members similarly stress that they are restricting distribution. *See* Novo Nordisk, "Notice Regarding Limitation on Hospital Contract Pharmacy Distribution," (Jan. 24, 2022), Novo-Nordisk_Contract_Pharmacy_Policy_Update_1.24.2022.pdf (alinea-group.com); Johnson & Johnson, Notice to 340B and Non-340B End Customers Regarding Bill To/Ship To Orders (Mar. 21, 2022), Microsoft Word - JJHCS Notice to End Customers Regarding Updates to 340B Delivery Limitations.docx (340besp.com) (340bhealth.org); Bausch Health US, LLC (July 1, 2022),

protect the health and safety of individuals within its borders, the Arkansas General Assembly passed Act 1103 to require manufacturers to "actually ship[] medications" subject to 340B-prices to legally authorized Arkansas pharmacies. *To Establish the 340B Drug Pricing Nondiscrimination Act: Hearing on H.B. 1881 Before the Ark. H.R.*, 93d Gen. Assemb., Reg. Sess. (Ark. 2021) (statement of Rep. Michelle Gray).[14] Representative Gray stated to the Arkansas House of Representatives immediately prior to its vote on Act 1103 that it was intended to curb these predatory distribution limitations. *Id.* Representative Gray emphasized that "nowhere [in Act 1103] are we setting a price." *Id.*

Leo Hauser, testifying on behalf of PhRMA to the Arkansas Senate Insurance and Commerce Committee, acknowledged that "the real sense of [Act 1103] is, the bill would require manufacturers to ship" 340B drugs. *To Establish the 340B Drug Pricing Nondiscrimination Act*: *Hearing on H.B. 1881 Before the S.*

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https://340breport.com/wp-content/uploads/2022/07/BHC-340B-Policy_CE.pdf; Bristol Myers Squibb, 340B Distribution Practice Fact Sheet (undated), https://www.bms.com/assets/bms/us/en-us/pdf/340B-distribution-practice-factsheet.pdf; GlaxoSmithKline, Notice to 340B Covered Entities- Update to GSK's 340B Contract Pharmacy Policy (Mar. 31, 2023), a2870f8d-382c-43fb-a22d-e0fe0d572e97.pdf (340breport.com).

[14] https://sg001-harmony.sliq.net/00284/Harmony/en/PowerBrowser/PowerBrowserV2/20221024/-1/21626# (Representative Gray's testimony begins at 1:46 pm, and her quoted statements begin at 1:50:40 pm).

Comm. on Ins. & Com. (Ark. 2021) (statement of Leo Hauser, PhRMA Rep.).[15] Mr. Hauser never asserted that Act 1103 would regulate drug pricing. *Id.*

Thus, the Arkansas legislature intended Act 1103 to address drug distribution. Act 1103 does not authorize contract pharmacies to purchase 340B drugs, and, therefore, it does not "expand the list of entities entitled to receive 340B-discounted drugs." PhRMA Br. 49. Under a plain reading of Act 1103, the manufacturer prohibitions do not become applicable until after a 340B price has been established for a covered "entity authorized" to receive those prices. Ark. Code Ann. § 23-92-604(c)(2).

b. AID's Authoritative Interpretation of Act 1103 in Rule 123 Confirms that Act 1103 Is a Distribution Statute

In Final Rule 123, AID clarifies that Act 1103 regulates the "delivery and acquisition" of drugs already subject to a manufacturer's 340B-price. Code Ark. R. 003.22.123-I (defining "340B-drug pricing"). Act 1103 specifically mandates AID to "promulgate rules to implement" its provisions. Ark. Code Ann. § 23-92-606. AID's interpretation of Act 1103, therefore, is entitled to deference. *Ark. Health Servs. Comm'n v. Reg'l Care Facilities, Inc.*, 93 S.W.3d 672, 676 (Ark.

[15] https://sg001-harmony.sliq.net/00284/Harmony/en/PowerBrowser/PowerBrowserV2/20210426/-1/21667?viewMode=1#info. (Mr. Hauser's testimony begins at 9:31 am, and the referenced statement is made at 9:34 am).

2002) ("When considering the validity of a regulation, the court must give the regulation the same presumption of validity as it would a statute.").

AID promulgated Final Rule 123 under the Arkansas Administrative Code, and it carries the force and effect of Arkansas law. Ark. Code Ann. § 25-15-202(9) ("'Rule' means an agency statement of general applicability and future effect that implements, interprets, or prescribes law or policy…."). AID's well-informed definition of "340B drug pricing" is entitled to deference. *Reg'l Care Facilities, Inc.*, 93 S.W.3d at 676. Arkansas courts will overturn an agency's regulation only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *Id*. An Arkansas "court will not attempt to substitute its judgment for that of the administrative agency." *Id.*

Thus, when analyzing the meaning of a statute, Arkansas courts defer to the expertise of the state agency that is responsible for administering that statute because the agency is better equipped by specialization, insight, and experience to analyze legal issues affecting statutory programs that they administer. Likewise, this Court should defer to AID's interpretation of "340B drug pricing" as meaning the "acquisition and delivery" of drugs. AID's regulatory interpretation, which was properly promulgated under Rule 123, is that Act 1103 encompasses only the distribution of drugs that have already been discounted and purchased by covered entities under the 340B Program.

2. Section 340B Is Not a Comprehensive Drug Distribution Statute

PhRMA argues that 340B is a "comprehensive scheme" and a "closed system," PhRMA Br. 28-34, while ignoring the Third Circuit's recent opinion to the contrary: "The text [of 340B] is silent about delivery." *Sanofi*, 58 F.4th 696 at 703. The Third Circuit emphasized that "[s]ection 340B's 'purchased by' language likewise says nothing about delivery." *Id.* at 704. The court pointed out that "Congress also knew how to impose delivery-related requirements" in 340B because it created a prime vendor program obligating manufacturers to "'be responsible for the costs of distribution'" while not regulating distribution more generally. *Id.* (quoting 42 U.S.C. § 256b(a)(8)). Thus, "when Congress's words run out, [PhRMA] may not pick up the pen," *id.*, and transform 340B into a drug distribution statute.

Sanofi was issued after the district court's decision in this case, but, consistent with *Sanofi*, the district court held that 340B does not regulate distribution or pharmacies. App. 592; R. Doc. 48, at 13 (citing *Sanofi-Aventis U.S., LLC v. U.S. Dep't Health & Hum. Servs.*, 570 F. Supp. 3d 129, 193 (D.N.J. 2021)); *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 59 (D. Del. 2021)). As the district court recognized, several other federal courts have also stated that the 340B statute does not regulate the distribution of 340B-priced drugs. *Sanofi*, 570 F. Supp. 3d at 193 ("§ 340B is silent as to permissible drug distribution

systems.") (internal citations and quotation marks omitted); *NovartisPharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL 5161783 at *6 (D.D.C. Nov. 5, 2021) ("HRSA has long recognized that '[t]he [340B] statute is silent as to permissible drug distribution systems.'"); *Eli Lilly & Co.*, 2021 WL 5039566 at *17 ("[T]he 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' delivery obligations.").

The District Court also correctly found that HHS guidance supports that the 340B Program is not a solely federal scheme. The District Court cited HHS's 1996 Guidance that the 340B Program "'is silent as to permissible drug distribution systems' and contains 'many gaps.'" App. 591; R. Doc. 48, at 12 (citing 61 Fed. Reg. at 43,549). HRSA's 1996 Guidance stated that contract pharmacies are not "an unauthorized expansion of the [340B] program" because "[t]he statute is silent as to permissible drug *distribution* systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." 1996 Guidance, 61 Fed. Reg. at 43,549 (emphasis added). HRSA emphasized that contract pharmacy distribution arrangements were "simply recognizing an existing right that covered entities enjoy *under State law*." *Id.* at 43,550 (emphasis added). Moreover, HRSA stated that "the covered entity will adhere to all Federal, *State and local laws and requirements*" relating to contract pharmacy distribution arrangements. *Id*. at 43,551 (emphasis added). HRSA

explained that "if State X permits a covered entity to use contract pharmacy services to purchase drugs on its behalf, the entity could presumably use this mechanism"; and "[t]o the extent the [1996] guidelines may be inconsistent with a State's distributor licensing requirements, this same reasoning would apply." *Id.* Thus, HRSA has recognized since 1996 that 340B contract pharmacy distribution arrangements were governed by state law and that participants of the 340B Program are subject to state law distribution requirements, such as Act 1103.

Moreover, the district court noted that "the practice of pharmacy is an area traditionally left to state regulation." App. 591; R. Doc. 48, at 12 (citing *Pharm. Care Mgmt. Ass'n*, 18 F.4th at 972). States have traditionally shared authority with the federal government over the licensing and conduct of drug companies and wholesale drug distributors. The federal government has long regarded state law "as a complementary form of drug regulation" that "offers an additional, and important, layer of consumer protection." *Lefaivre*, 636 F.3d at 941; *see Pharm. Care Mgmt. Ass'n,* 18 F.4th at 972 (HHS has a "general position of deferring to States for regulating the practice of pharmacy"). For example, in all states within the Eighth Circuit, wholesalers must meet qualifications to satisfy registration requirements. Ark. Code Ann. § 20-64-505; Ark. Code Ann. § 20-64-501 *et seq.* (grounds for pharmacies to receive and possess legend and controlled drugs); Iowa Code Ann. § 657-17.3(155A); Minn. Stat. § 151.47; Minn. R. 6800.1400; Mo.

Rev. Stat. § 338.333; Neb. Rev. Stat. § 71-7447; N.D. Admin. Code 61-10-01-05 to 61-10-01-06; S.D. Admin. R. 20:67:02. To allow the distribution of controlled substances, all seven states require that distributors be registered in their states and meet certain recordkeeping requirements. Code Ark. R. 007.39.8-08-01-0002; Iowa Code Ann. § 657-10.14(124); Minn. Stat. § 152.101; Mo. Rev. Stat. § 195.050; Neb. Rev. Stat. § 28-411, 414.03; N.D. Cent. Code § 19-03.1-20; S.D. Codified Laws § 34-20B-29, 39. Act 1103 is a perfect example of a state exercising its police power to support public health and merely complements existing laws in Arkansas regulating drug distribution.

PhRMA's reliance on *National Meat Association v. Harris* and *Engine Manufacturers Association v. South Coast Air Quality Management District* is misplaced. PhRMA Br. 40-41. Those cases are inapplicable because the federal statutes in those cases included express preemption provisions, and the 340B statute does not include such a provision. R. Doc. 47, at 10; *Nat'l Meat Ass'n v. Harris*, 541 U.S. 246, 248-49, 252-55 (2004); *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 248-49, 252-55 (2004). In addition, unlike *National Meat Association*, Act 1103 does not "substitute[] a new regulatory scheme" for the 340B Program, nor does it have an "inevitable effect" on manufacturer conduct, because a violation of Act 1103 requires that the 340B-price

is already established *prior to* the manufacturer foreclosing distribution to contract pharmacies. 541 U.S. at 464; *see* R. Doc. 47, at 4, 7, 10, 11.

The reality is that the 340B statute governs the purchasing and pricing of 340B drugs and to whom 340B drugs may be sold and resold, but is completely silent on contract pharmacies and how 340B drugs make their way through the supply chain from manufacturer to patient. 42 U.S.C. § 256b(a)(1), (a)(4), (a)(5)(B). Thus, the 340B statute regulates the beginning and end of a drug's journey from manufacturer to patient, but not the journey itself. Act 1103 appropriately regulates a drug's journey within Arkansas.

3. Act 1103 Is Substantively and Procedurally Valid

The district court correctly held that Act 1103 does not place "contract pharmacies on the 340(B) Program's covered entities list." App. 593; R. Doc. 48, at 14. Participation in the 340B Program is reserved for covered entities, not contract pharmacies, and nothing in Act 1103 confers covered entity status to contract pharmacies. The district court explained that "[e]ven though the title of Act 1103 includes pricing in its name, the effects of the disputed provisions are limited to the distribution of and access to the discounted drugs." *Id.* Act 1103 does not add contract pharmacies as a type of covered entity as PhRMA contends. PhRMA Br. 4.

Act 1103 does not transform contract pharmacies into covered entities because the Act does not intrude on the federal scheme requiring that the statutorily enumerated covered entities purchase and maintain title to all drugs shipped to contract pharmacies. HRSA's policy clearly states that a covered entity registered with HRSA must "purchase the drug, maintain title to the drug and assume responsibility for establishing its price . . . ." 75 Fed. Reg. at 10,277. [16] The covered entity must use "[a] 'ship to, bill to' procedure … in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy." *Id.* If a drug company believes that a covered entity engages in unlawful diversion by transferring title to the contract pharmacy, the company may audit the covered entity. 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv). PhRMA has identified no instance in which a contract pharmacy has actually taken title to a 340B-priced drug.

Furthermore, the district court pointed out that the "drug-ceiling price has already been set at the point Act 1103 becomes applicable to any specific drug shipment." App. 594; R. Doc. 48, at 15. On the one hand, the 340B statute establishes the 340B ceiling price and the entities eligible to purchase drugs at that

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

price. 42 U.S.C. § 256b(a)(1), (4). Act 1103, on the other hand, prohibits a drug company from (1) interfering with contractual relationships between contract pharmacies and covered entities and (2) prohibits a manufacturer from preventing a contract pharmacy from receiving 340B-priced drugs on behalf of a covered entity. Ark. Code Ann. § 23-92-604(c)(1)-(2). Neither of these provisions change the drug-ceiling price facially or as a practical matter. Therefore, the district court held that "Act 1103 has no bearing on setting the ceiling price." App. 594; R. Doc. 48, at 15.

Lastly, the district court found that PhRMA "provided no evidence that Act 1103 interferes with PPA agreements between covered entities and HHS, or, in effect, adds contract pharmacies to the covered entities list." App. 593-94; R. Doc. 48, at 14-15. Indeed, all evidence points to the contrary. Contract pharmacies do not purchase or take title to 340B drugs. Decl. of Krista M. Pedley ¶¶ 7, 8, 9, ECF No. 24-1, Ex. 1-E ("Pedley Decl."); Decl. of Dr. Lanita S. White, Chief Executive Officer of Community Health Centers of Arkansas ¶ 8, ECF No. 17, Ex. 1 ("CHCA Decl.") (CHCA's "community health centers purchase and take title to the 340B medications, but the drugs are shipped to and dispensed by contract pharmacies"). Rather, the contract pharmacy obtains possession of the drugs on behalf of the covered entity to dispense the drugs to the covered entity's patients. *Id*. It is a well-recognized precept of the 340B Program that only covered entities

may purchase 340B drugs from wholesalers and manufacturers. Pedley Decl. ¶¶ 7, 8, 9; CHCA Decl. ¶ 8. Moreover, only covered entities may establish 340B accounts with wholesale distributors. Pedley Decl. ¶ 9; CHCA Decl. ¶ 8. PhRMA's own exhibit in district court—from Rear Admiral Krista Pedley—states that covered entities, not contract pharmacies, purchase 340B drugs. Pedley Decl. ¶¶ 7, 8, 9.

The 340B statute requires drug companies to enter into a PPA that requires "that the manufacturer 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." 42 U.S.C. § 256b(a)(1) (emphasis added). This mandate does not require covered entities to take physical possession of 340B drugs, nor does it govern the distribution channels or delivery location of the 340B-priced drug. The statute merely says that covered entities may purchase drugs at a statutorily determined price.

The prevailing understanding of the term "purchase" in 1992 when Congress enacted Section 340B was to obtain title by paying a price, rather than to obtain possession. In 1992, as now, the meaning of the term "purchase" was "to obtain (as merchandise) by paying money or its equivalent." *Purchase,* WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY UNABRIDGED (1992). The term did not, and does not, require a purchaser to obtain physical possession of a good. In

contrast, distribution is a concept that is entirely focused on possession and delivery of the drug. *See* 21 U.S.C. § 802(11) ("The term 'distribute' means to deliver (other than by administering or dispensing)" a drug).

Because contract pharmacies do not purchase 340B drugs, Act 1103 does not expand the scope of the 340B statute by "add[ing] contract pharmacies to the covered entities list." App. 594; R. Doc. 48, at 15; *see Eli Lilly & Co.*, 2021 WL 5039566 at *3 ("The 1996 Guidance therefore explicitly provided that permitting the use of contract pharmacies does not constitute an unauthorized expansion of the 340B Program because '[t]he statute is silent as to permissible drug distribution systems,' and contains 'no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself.'"); 1996 Guidance, 61 Fed. Reg. at 43,549. Participation in the 340B Program, which confers the right to purchase 340B drugs, but not distribute 340B drugs, is reserved for covered entities and nothing in Act 1103 elevates the status of contract pharmacies to covered entities or authorizes them to purchase 340B drugs. While Congress enumerated the entities that may purchase 340B-priced drugs, it was silent on the entities authorized to possess and dispense those drugs throughout the distribution pathway, including pharmacies that receive 340B-priced drugs under contract pharmacy distribution arrangements. 42 U.S.C. § 256b(a)(1), (4); *see supra* Section I.A.2; *Bills to Amend the Public Health Service Act and the Social Security*

Act to Establish Limits on Certain Drug Prices, Hearing on H.R. 2890, H.R. 3405 and H.R. 5614 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce, 102d Cong. 77-82 (1992). Because Act 1103 does not expand the scope of the 340B statute, it does not interfere with the purpose or objectives of the 340B Program.

Act 1103 is also procedurally valid because AID enforcement is limited to violations of state law distribution requirements and does not tread into federal enforcement. PhRMA's procedural arguments stem from the same faulty premise that contract pharmacies take title to 340B-priced drugs. Any penalties against drug companies arising from Act 1103 would be limited to distribution violations in which a drug company denies a covered entity access to 340B drugs by refusing to ship discounted drugs to the covered entity's designated contract pharmacy. Ark. Code Ann. § 23-92-604(c).

The district court recognized that the issue presented in this case is wholly distinguishable from the issue in *Astra*, contrary to PhRMA's characterization. The district court 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. 590; R. Doc. 48, at 11. The district court was correct. In *Astra,* the Supreme Court analyzed whether covered entities have a private right of action against manufacturers as third-party

beneficiaries of PPAs between manufacturers and HHS. *Astra USA*, 563 U.S. at 113; *see also* App. 589-90; R. Doc. 48, at 10-11. Those PPAs are strictly based on the text of the 340B statute, limiting the focus of the *Astra* dispute to *covered entity purchases*. *Astra,* 563 U.S. at 113.

Astra in no way addressed distribution of 340B-priced drugs, nor did it analyze the primacy of state laws regulating contract pharmacy distribution arrangements. Rather, *Astra* focused on a much different issue—whether the ADR process was the proper adjudicatory framework to remedy "covered entities complaining of 'overcharges'" on purchases of 340B drugs. *Id.* at 122; *see also* App. 590; R. Doc. 48, at 11. The *Astra* decision does not suggest that HHS's authority extends outside the 340B statute to drug distribution. *Astra*, 563 U.S. at 114 ("Congress placed the Secretary (acting through her designate, HRSA) in control of §340B's drug-price prescriptions."); *see also* App. 590; R. Doc. 48, at 11. Instead, that decision addressed only HHS's limited enforcement role over 340B-drug pricing, rather than the distribution of 340B-priced drugs.

The district court correctly held that the 340B statute does not regulate distribution. Because "[t]he 340B Program is not 'so pervasive as to make reasonable the inference that Congress left no room for States' to protect their specific drug distribution systems" and because this is not "a field in which the federal interest is so dominant that the federal system will be assumed to preclude

enforcement of state laws," "Act 1103 is not subject to field preemption under the 340(B) Program." App. 591; R. Doc. 48, at 12 (quoting *Rice*, 331 U.S. at 230).

B. Act 1103 Does Not Conflict with Section 340B

The District Court correctly held that Act 1103 does not conflict with the federal 340B Program. A distribution violation under Act 1103 could only occur if a drug company violated 340B pricing rules. Act 1103 also does not conflict with the federal 340B pricing scheme because those two enforcement mechanisms focus on different areas, pricing for 340B and distribution for Act 1103. Therefore, Act 1103 is not preempted by the 340B Program. App. 593; R. Doc. 48, at 14.

1. The District Court Correctly Held That Act 1103 Is Not an Obstacle to the Purpose and Objective of the 340B Program

PhRMA rehashes its meritless arguments that 340B is a "closed system" and that Act 1103 adds contract pharmacies as covered entities. PhRMA Br. 43-44. As the Covered Entities have explained, 340B does not regulate drug distribution, and Act 1103 does not add pharmacies as covered entities. The district court opinion was well reasoned in finding that "Act 1103 is not obstacle to the purpose and objective of the 340(B) Program" and thus not preempted under the obstacle doctrine. App. 593; R. Doc. 48, at 15.

PhRMA relies on the Third Circuit's statement in *Sanofi* that the 340B statute "suggests that" Congress "had in mind one-on-one transactions between a covered entity and a drug maker," PhRMA Br. 44 (quoting *Sanofi*, 58 F.4th at

704), but the Third Circuit did not consider 340B regulations, which were promulgated pursuant to notice and comment rulemaking as required by the Administrative Procedure Act, 5 U.S.C. § 553, and the 340B statute, 42 U.S.C. § 256b(d)(1)(B)(vi)(I). 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,644 (Dec. 14, 2020). Those regulations define a manufacturer overcharge under the 340B Program as any "order for a covered outpatient drug which results in a covered entity paying more than the [340B] ceiling price," 42 C.F.R. § 10.11(b), which "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or *agent*." *Id.* § 10.11(b)(1) (emphasis added). As explained above, contract pharmacies have served as agents of covered entities since 1996. 61 Fed. Reg. at 43,550 ("As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients."). Act 1103 simply regulates distribution within Arkansas of drugs priced at the 340B discount when ordered by agents as permitted under federal law.

The Third Circuit expressly declined to apply the highly deferential *Chevron* standard of review because it believed that "HHS lacks rulemaking authority." *Sanofi*, 58 F.4th at 703 (citing *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000)). The Third Circuit was only partially correct. HHS lacks rulemaking authority over many aspects of the 340B Program, but Congress expressly

authorized HHS to issue 340B Program regulations to address manufacturer overcharges to covered entities. 42 U.S.C. § 256b(d)(1)(B)(vi)(I). The Third Circuit should have deferred to HHS's properly promulgated regulation defining a manufacturer overcharge as including overcharges on orders placed by agents of covered entities, which includes contract pharmacies. *See Chevron U.S.A., Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837, 843-33 (1984).

PhRMA's analogy to a car sale is off base because Act 1103 does not force manufacturers to sell drugs at a particular price (a car for $1 in PhRMA's analogy). PhRMA Br. 50. The price is set by the 340B Program. A more apt analogy describes manufacturer conduct that Act 1103 seeks to remedy: "I am required to sell you a discounted car, but I will only deliver it where you cannot drive it." The 340B Program sets the statutory price for drugs, but manufacturers have established onerous distribution restrictions that prevent Arkansas covered entities from actually obtaining and dispensing those drugs. Act 1103 appropriately regulates distribution, ensuring that 340B priced drugs are delivered where they can be dispensed to patients (*cf.*, a car delivered to a paved road).

PhRMA also complains that Act 1103 does not prescribe detailed standards for contracts between covered entities and contract pharmacies. *Id.* at 44. As AID pointed out at the district court, a "340B drug pricing contract" would be governed by HRSA guidance. R. Doc. 24-1, at 2, 10. On the federal side, the contract

pharmacy agreement ensures compliance with 340B pricing. On the state side, Arkansas would look to the same agreement when enforcing intrastate distribution requirements.

2. Act 1103 Does Not Interfere with the 340B Program's Enforcement Mechanisms

The district court also found that Act 1103 does not "interfere[] with the 340B Program's enforcement mechanism." App. 593; R. Doc. 48, at 14. The court reasoned that "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 overcharging covered entities." App. 594; R. Doc. 48, at 15. Indeed, Act 1103 does not co-opt federal enforcement authority to police manufacturers' compliance with the 340B statute's mandate that they offer 340B-priced drugs for purchase by covered entities. That is because the 340B ADR process is the sole mechanism for adjudicating covered entity complaints of manufacturer overcharges. Act 1103 has an entirely different purpose: to protect the right of Arkansas covered entities and pharmacies to dispense drugs through contract pharmacy arrangements.

The statutory language creating the ADR process and investing HHS with authority to impose CMPs undermines PhRMA's contention that Act 1103 usurps those federal enforcement powers. 42 U.S.C. § 256b(d)(1)(B)(vi), (d)(3)(A). Congress was careful to use the terms "for drugs purchased" and "purchased by"

covered entities in these portions of the 340B statute. *Id*. § 256b(d)(3)(A). In fact, PhRMA conceded this point in district court: "Congress . . . vested unitary authority in HHS to ensure *compliance* with the Program's requirements via resolution of disputes *between participants*." R. Doc. 26, at 20 (emphasis added). And as discussed above, contract pharmacies and other parties in the distribution supply chain are not "participants" in the 340B Program. Congress simply never endeavored to regulate comprehensively or create a unitary dispute resolution system addressing distribution of 340B-priced drugs.

Furthermore, this Court should not infer broad obstacle preemption if there is no evidence of congressional intent to promote uniform federal regulation of conduct governed by state law. *See, e.g.*, *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146–47 (1963) (the intent to preempt state law under obstacle preemption will not lightly be implied from an ambiguous statute); *Harris v. Great Dane Trailers, Inc.*, 234 F.3d 398, 402 (8th Cir. 2000) ("Only when federal regulators determine that uniformity is needed to promote the predominant legislative purpose of [the conduct regulated by the federal law] will uniformity itself justify broad conflict preemption.").

Moreover, Act 1103 is not preempted because, as discussed *supra*, Section I.A.2, Congress disclaimed interest in regulating conduct governed by state law. *See Silkwood v. Kerr-McGee Corp*., 464 U.S. 238, 256 (1984); *Pac. Gas & Elec.*

Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983); *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 487-88 (2008) (rejecting obstacle preemption claim and "find[ing] it too hard to conclude that a statute expressly geared to protecting 'water,' 'shorelines,' and 'natural resources' was intended to eliminate *sub silentio* oil companies" common law duties to refrain from injuring the bodies and livelihoods of private individuals); *see also Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 352 (2001); *supra* Section I.A.2.

As shown by Final Rule 123, Act 1103 focuses on protecting the "acquisition and delivery" of 340B-priced drugs by Arkansas pharmacies, not the drugs' purchase price. Code Ark. R. 003.22.123-I. Act 1103 is therefore focused on distribution and prohibits a manufacturer from engaging in any conduct that encumbers distribution of 340B drugs among Arkansas covered entities and pharmacies. *See supra* Section IV; *To Establish the 340B Drug Pricing Nondiscrimination Act*: *Hearing on H.B. 1881 Before the Ark. H.R.*, 93d Gen. Assemb., Reg. Sess. (Ark. 2021) (statement of Rep. Michelle Gray) (the [Arkansas] 340B Drug Pricing Nondiscrimination Act "is not price setting," and it is intended to require manufacturers to "actually ship[] medications to the state of Arkansas"); Code Ark. R. 003.22.123-I.

II. The District Court Correctly Held that the FDCA Does Not Preempt Act 1103

PhRMA presents a more limited FDCA preemption claim, arguing that Act 1103 should be enjoined only "with respect to drugs subject to REMS." PhRMA Br. 52-53. The district court correctly held that the FDCA does not preempt Act 1103 because "Act 1103 and the FDCA regulate completely different subject matter and activities." App. 595; R. Doc. 48, at 16. This Court should reject PhRMA's attempt to read preemption into the FDCA and to ignore AID's express statement that Act 1103 will not be implemented in conflict with REMS. No matter how PhRMA attempts to construe Act 1103, no actual conflict exists between Act 1103 and the FDCA REMS requirements or any other sections of the FDCA.

The district court rightfully dismissed PhRMA's contention that Act 1103 forced manufacturers to "choose between either violating federal law or state law" because "Act 1103 requires manufacturers to provide contract pharmacies the 340(B) Program's discounted drugs regardless of whether the drug is subject to the REMS program." App. 595; R. Doc. 48, at 16. PhRMA's interpretation of the statute is overly broad and would result in absurd consequences not intended by AID or the General Assembly. *See Friedman v. United States*, 374 F.2d 363, 367 (8th Cir. 1967); *First State Bank v. City of Elkins*, 546 S.W.3d 477, 481 (Ark. 2018). A correct interpretation would "seek[] to reconcile statutory provisions to

make them consistent, harmonious, and sensible." *JPMorgan Chase Bank, N.A. v. Johnson,* 719 F.3d 1010, 1015 (8th Cir. 2013) (quoting *Mamo Transp., Inc. v. Williams*, 289 S.W.3d 79, 83 (Ark. 2008)).

With the vast number of federal and state laws and regulations that govern the safe handling, storage and dispensing of drugs, the General Assembly could not expressly include an exception for every federal requirement that could potentially overlap with Act 1103. *See Hurd v. Arkansas Oil & Gas Comm'n*, 601 S.W.3d 100, 105 (Ark. 2020) ("[I]t would be impracticable for statutes to cover every possible situation that an agency may encounter when carrying out its statutory duties."). Act 1103's silence on REMS does not suggest that it forces manufacturers to violate REMS.

A REMS plan often limits the drugs that may be purchased by covered entities and which pharmacies are authorized to dispense those drugs. Nothing in Act 1103 forces a manufacturer to distribute REMS drugs in contradiction of REMS requirements, whether or not that pharmacy is a contract pharmacy. For example, Bristol Myers Squibb manufactures three drugs that are subject to REMS. *Commitment to Safety and Patients: Risk Evaluation and Mitigation Strategies (REMS)*, Bristol Myers Squibb, (July 2022).[17] If a REMS program restricts the

[17] https://www.bms.com/patient-and-caregivers/risk-evaluation-and-migration-strategies-rems.html.

pharmacies that can dispense a drug, a wholesaler will ship the drug only to those pharmacies. A covered entity that prescribes a REMS-limited drug would need a contract pharmacy arrangement with one of those REMS-authorized pharmacies for 340B-priced drugs to be shipped to that pharmacy. If the covered entity does not have a contract pharmacy arrangement with an authorized pharmacy, Act 1103 would not be implicated.

The district court was also correct that "the FDCA does not include any statement preempting state laws governing distribution of prescription drugs." App. 595; R. Doc. 48, at 16. Indeed, Congress did not intend state laws that govern drug distribution to be preempted by the FDCA to the extent they vary in even the slightest degree. *Wyeth*, 555 U.S. at 571. The statute, congressional intent, and the practical effect of the REMS requirements all demonstrate that a manufacturer can comply with both REMS and Act 1103.[18]

If Congress thought a state might pose "an obstacle to its objectives [under the FDCA], it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Id.* at 574. Congress did not do so. *Id.* at 567 (noting that Congress declined to enact an express preemption provision for prescription drugs under the FDCA); *Lefaivre*, 636 F.3d at 941. In fact, the FDCA requires the FDA to consider whether the REMS requirements are not "unduly

[18] PhRMA cites no case addressing the preemptive effect of the REMS program.

burdensome on patient access to the drug" and also "minimize the burden on the health care delivery system." 21 U.S.C. §§ 355-1(f)(2)(C), (D)(ii). Act 1103 is a complementary drug distribution statute that requires manufacturers to ship 340B drugs that are subject to the REMS statute to those contract pharmacies that are authorized to handle and dispense REMS drugs. Thus, the REMS requirements are intended to be compatible with state drug distribution laws, such as Act 1103. Act 1103 does not conflict with the purpose of REMS to ensure access to safe and effective medication.

Additionally, the district court noted that "[n]othing in Act 1103 prevents manufacturers from limiting the pharmacies that may dispense drugs as required under a REMS." App. 595; R. Doc. 48, at 16 (citing *Wyeth*, 555 U.S. at 567; *Lefaivre*, 636 F.3d at 941). Indeed, AID—which is charged with administering Act 1103—stated in its brief before the district court that AID "does not interpret Ark. Code Ann. § 23-92-604(c) as a means to circumvent, or avoid, any separate or additional state or federal laws governing the health and safety of the drugs, civil or criminal in nature, or separate FDCA laws limiting the transfer of the drugs themselves." R. Doc. 30, at 11. AID's interpretation of Act 1103 should be given deference. *Wilson v. Commodity Futures Trading Comm'n*, 322 F.3d 555, 559 (8th Cir. 2003). Therefore, as a practical matter, the boogeyman that PhRMA invents—requiring manufacturers to ship REMS drugs to pharmacies that are not

approved to accept the REMS drugs—is non-existent. As the District Court stated, "Act 1103 does not regulate drug safety." App. 595; R. Doc. 48, at 16 (emphasis in original).

CONCLUSION

For the foregoing reasons, the district court's decision on PhRMA's preemption claims should be affirmed.

Dated: April 7, 2023

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a) AND LOCAL RULE 28A(h)

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Pursuant to Eighth Circuit Rule 28(A)(h), I further certify that Intervenors-Appellees' brief have been converted to Adobe PDF format by printing to Adobe PDF from the original word processing file, and has been provided to the Court and counsel for Appellants. The brief has been scanned for viruses using a commercial virus scanning program, which confirms that the brief is virus free.

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CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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