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

OPENING BRIEF OF APPELLANT PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

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SUMMARY OF THE CASE AND STATEMENT REGARDING ORAL ARGUMENT

Congress enacted the 340B Drug Pricing Program, 42 U.S.C. § 256b, ("340B"), to mandate that drug manufacturers provide significant price discounts to 15 specified types of safety net healthcare providers as a condition of having their drugs reimbursed under Medicare Part B or Medicaid. Congress authorized the Secretary of Health and Human Services ("HHS") to investigate, address, and resolve any alleged manufacturer non-compliance and any disputes that arise between manufacturers and covered entities. In *Astra, USA, Inc. v. Santa Clara County,* 563 U.S. 110 (2011), the Supreme Court rejected Santa Clara County's attempt to supplement these comprehensive statutory enforcement provisions with common-law remedies. Despite that ruling, Arkansas recently passed a law that also purports to supplement the comprehensive federal statutory scheme, by both purporting to define (and expand) the types of entities to which manufacturers must provide 340B-discounted drugs and imposing new state-law procedures and penalties to enforce that requirement. On December 12, 2022, the District Court for the Eastern District of Arkansas granted summary judgment to Intervenor-Defendants as to Pharmaceutical Research and Manufacturers of America's ("PhRMA's") federal preemption claim. This appeal challenges that order.

PhRMA respectfully requests 15 minutes of argument time per side given the complexity of the issues presented and the nature of this Court's review.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Local Rule 26.1A of the United States Court of Appeals for the Eighth Circuit, Appellant Pharmaceutical Research and Manufacturers of America ("PhRMA"), by and through undersigned counsel, certifies that PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock. But PhRMA's membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at https://phrma.org/About#members.

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INTRODUCTION

Congress enacted the 340B Drug Pricing Program, 42 U.S.C. § 256b ("340B"), in 1992 so that specified types of safety net healthcare providers could obtain discounted drugs for their uninsured, underinsured, and low-income patients. 340B forms part of an integrated series of federal programs under which drug manufacturers who want their outpatient drugs to be reimbursed under Medicare Part B or the federal share of Medicaid must, as a condition of participating in those federal programs, offer substantial discounts on certain drugs to 15 types of statutorily enumerated "covered entities." Congress, however, appreciated the need to carefully limit the burdens it was imposing on the manufacturers forced to bear the cost of these subsidies so as not to overly discourage participation in those other federal programs. To achieve that balance, Congress in 340B crafted a comprehensive federal scheme to govern the discounts. Among other provisions in 340B, Congress:

- Specifically enumerated the 15 exclusive categories of healthcare providers that qualify as covered entities with the right to receive discounted drugs;
- Prohibited covered entities from selling or transferring the discounted drugs to anyone other than their patients;
- Established the formula for pricing the discounted drugs;

- Defined how the relevant federal agencies administer 340B (*e.g.*, through contracts between the federal government and manufacturers, known as Pharmaceutical Pricing Agreements ("PPAs"));
- Detailed how 340B was to be enforced by providing specified penalties for noncompliance; and
- Established a federal adjudicative process—Administrative Dispute Resolution ("ADR")—to resolve questions about the applicability of 340B's requirements and 340B's bounds.

With the first two provisions, Congress created a closed system that strictly defined the entities with a right to obtain 340B-discounted drugs and restricted the conveyance of those drugs only to eligible patients of those entities. That closed system limits manufacturers' discounting obligations and ensures that benefits go only to covered entities and their patients. The remaining provisions established an exclusive system of federal management that is designed to be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120. As the Supreme Court has recognized, each aspect of 340B is integral to the functioning of the whole. *See id.* And the centralization of administration and carefully defined enforcement authority within HHS was designed to ensure that manufacturer obligations under 340B did not unduly burden manufacturers, who could potentially leave 340B and be forced to withdraw from

participating in Medicare Part B and Medicaid as well. *See* Br. for the United States as *Amicus Curiae* Supporting Petitioners at *10, *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, No. 09-1273, 2010 WL 4717264 (U.S. Nov. 19, 2010) (federal enforcement scheme "intended to be exclusive").

In the early years of 340B, 340B-discounted drugs were available to covered entities' patients through in-house pharmacies and, for covered entities lacking in-house pharmacies, through a single outside "contract pharmacy" operating under a contract with the covered entity to serve the covered entity's patients. But beginning in 2010, following the issuance of new guidance by HHS's component agency Health Resources and Services Administration ("HRSA"), enterprising commercial pharmacy chains started barging their way into 340B to profit from the discounts intended to benefit covered entities and the vulnerable populations they serve. Contract pharmacy arrangements soon ballooned, with some covered entities entering into contracts with tens or even hundreds of pharmacies scattered throughout the United States. To combat this exploitation of 340B, a number of drug manufacturers adopted policies detailing the conditions under which they would deliver 340B-discounted drugs to contract pharmacies (as opposed to covered entities themselves). Multiple courts, including the Third Circuit in a recently published opinion, have agreed with manufacturers that the 340B program does not require them to extend discounts to as many contract pharmacies as a covered entity

wishes. *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 704 (3d Cir. 2023) (holding that 340B's text "suggests that [Congress] had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies*" (emphasis added)).

Arkansas, however, sought to interfere in the federal scheme and the adjudication by federal courts of what 340B requires. It enacted a new statute of its own, Act 1103, Ark. Code Ann. § 23-92-604, to attempt to dictate as a matter of state law how the federal 340B program should operate, despite having no authority to impose conditions on participation in a uniquely federal program. Act 1103 requires manufacturers to deliver 340B-discounted drugs to any and all contract pharmacies in Arkansas, without limitation. Although the 340B program is entirely a creation of Congress's making, the Act purports to define the scope of the 340B program's obligations and effectively adds contract pharmacies to the list of Congressionally enumerated entities to which manufacturers must provide 340B-discounted drugs as a condition of participating in other federal programs. And in lieu of the federal oversight and enforcement mechanisms established by Congress, Act 1103 imposes its own state-law penalties and other remedies for non-compliance.

The Arkansas Legislature had no authority to define (much less expand) the scope of manufacturers' obligations under 340B. Nor does it have authority to create

alternative state-law enforcement mechanisms for this uniquely *federal* scheme, which already contains detailed and comprehensive oversight and enforcement provisions centralized within HHS. The Supremacy Clause of the U.S. Constitution does not allow States to alter exclusive and comprehensive federal programs at all, much less in ways that threaten program vitality, as Act 1103 does here.

Act 1103 is also preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") and the restrictions the U.S. Food and Drug Administration ("FDA") imposes thereunder. By requiring manufacturers to ship to all contract pharmacies in the State without limitation, Act 1103 separately, but directly, conflicts with federal statutory patient safety limitations, which prohibit distribution of certain drugs to pharmacies lacking specialized expertise and authority. Compliance with both Act 1103 and the FDCA will be impossible, because Act 1103 requires conduct that federal law prohibits. Absent relief, manufacturers will be forced to choose between violating federal law, at the risk of federal civil monetary penalties and criminal liability, or violating Act 1103, at the risk of state-law penalties.

The district court held Act 1103 is not preempted by either 340B or the FDCA because Act 1103 regulates drug distribution as opposed to drug pricing or drug safety. That was error. Regardless of Act 1103's ostensible purpose, Arkansas cannot enforce a state law that intrudes on and reshapes a comprehensive federal statute or directly conflicts with federal mandates.

This Court should therefore reverse and hold that Act 1103's contract pharmacy mandate provisions, codified at Ark. Code Ann. § 23-92-604(c), are preempted by federal law and accordingly invalid under the Supremacy Clause.

JURISDICTIONAL STATEMENT

The district court had jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1343(a)(3). The district court entered a final judgment on December 29, 2022, and PhRMA timely filed a notice of appeal on December 29, 2022. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether Act 1103 is preempted by 340B. U.S. CONST. art. VI, cl. 2; 42 U.S.C. § 256b; Ark. Code Ann. § 23-92-604; *Astra, USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Wisc. Dep't of Indus. v. Gould Inc.*, 475 U.S. 282 (1986).

2. Whether Act 1103 is preempted by the FDCA. U.S. CONST. art. VI, cl. 2; 21 U.S.C. § 355-1(a); Ark. Code Ann. § 23-92-604; *Willson v. City of Bel-Nor*, 924 F.3d 995 (8th Cir. 2019); *McMillan v. Live Nation Ent., Inc.*, 401 S.W.3d 473 (Ark. 2012).

STATEMENT OF THE CASE

A. The Federal 340B Drug Pricing Program

1. The Structure And Purpose Of The 340B Drug Pricing Program

Congress enacted 340B as part of the Veterans Health Care Act of 1992. Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992) (codified as amended at 42 U.S.C. § 256b). 340B requires drug manufacturers who wish to have their "covered outpatient drugs" reimbursed under Medicare Part B or the federal share of Medicaid to provide those drugs at or below a substantially discounted "ceiling price" to specific "covered entities." 42 U.S.C. § 256b(a)(4). These "covered entities" are 15 specifically enumerated types of healthcare providers that treat a disproportionate share of indigent or low-income patients or whose patients are, for the most part, uninsured or underinsured. *Id.*

Prior to 1991, many manufacturers had voluntarily provided discounted drugs to these healthcare providers. App.138-39, R.Doc.24-1, Ex. 1-A at 29-30. But the enactment of the Medicaid Drug Rebate Program ("MDRP") by Congress in 1991, which imposed a mandatory Medicaid rebate on manufacturers, unintentionally made those discounts infeasible because they increased the size of the Medicaid rebates that manufacturers were required to provide. *Cf.* 106 Stat. at 4962. Congress enacted 340B to address this unintended side effect and restore "discounts to these clinics, programs, and hospitals," *i.e.*, "direct clinical care" entities, which had

previously received discounts. *Id.*; *see also* H.R. Rep. No. 102-384, pt. 2, at *11-13 (1992) ("House Report").

At 340B's enactment, Congress thought 340B's scope would be small. It estimated participation by only 90 hospitals, 85 family-planning clinics, 120 AIDS-intervention sites, 54 AIDS-assistance programs, a network of hemophilia treatment centers with 150 facilities, and 2,225 health centers. House Report at 13. As 340B was conceived, these covered entities would buy the covered outpatient drugs at a discount, and then either pass the discounts on to their patients or utilize the savings to provide increased levels of charity care. *See* 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996) (It was expected that covered entities would "pass all or a significant part of the discount to their patients").

To ensure 340B was administered "on a uniform, nationwide basis" and harmoniously with the MDRP, Congress entrusted HHS and HRSA with specific oversight responsibilities. *Astra*, 563 U.S. at 120.

2. Contract Pharmacies Barge Into 340B

A few years after 340B's enactment, HRSA addressed concerns that certain covered entities may not have in-house pharmacies to dispense 340B-discounted drugs. To facilitate participation in 340B by those entities, while also keeping 340B circumscribed, HRSA issued non-binding guidance explaining that a covered entity could enter into a contractual relationship with *one* pharmacy (hence the name

"contract pharmacy") that acted as its agent. *See* 61 Fed. Reg. at 43,555. Under this arrangement, the contract pharmacy would receive drugs on behalf of the covered entity at the 340B-discounted price and dispense those drugs only to patients of the covered entity. *Id.* at 43,550. The requirement of one contract pharmacy per covered entity practically ensured that a covered entity would choose a nearby contract pharmacy (or contract with a third-party pharmacy to operate within its facility) and would maintain close supervision over the contract pharmacy. *Id.* at 43,551, 43,553. HRSA expected, for example, that such a contract pharmacy would verify a patient's 340B eligibility prior to dispensing a discounted drug. *Id.*

Things changed in 2010 when HRSA revised its non-binding guidance to lift its one-contract-pharmacy limit along with the requirement that the pharmacy act as the "agent" of the covered entity. This opened the floodgates for enterprising commercial entities to exploit 340B for private gain. Many sophisticated for-profit pharmacies—including the nation's largest pharmacy chains—recognized that if they could insert themselves into the 340B supply chain, they could sell 340B-discounted drugs at or near full price and pocket a portion of the 340B discount as additional profit, either by receiving a percentage of the prescription sales price or through a flat fee per 340B-discounted prescription.

Under the "replenishment model" now in widespread use in this new generation of contract pharmacies, the pharmacies sell drugs from their general

inventories to all individuals (both 340B covered entity patients and non-340B covered entity patients). Pharmacies sell those drugs at an undiscounted price or a rate negotiated by the patient's insurer that is significantly higher than the 340B-discounted price. Then, after subsequent data analysis using undisclosed algorithms, the contract pharmacies purport to retroactively identify patients with some relationship to a covered entity—patients who were not previously identified as 340B-eligible at the time the drug was dispensed.[1] These black-box algorithms likely result in contract pharmacies claiming discounts where the pharmacies' customers do not qualify for them under 340B. *See* HHS Office of Inspector General ("OIG"), Mem. Report: Contract Pharmacy Arrangements in the 340B Program OEI 05-13-00431, at 16 (Feb. 4, 2014), https://bit.ly/3eWKmBQ.[2]

After identifying the drugs that they have sold to purported patients of a covered entity, the pharmacies then purchase additional drugs at the 340B-

[1] *See, e.g.*, App.201, R.Doc.24-1, Ex. 1-C at 2; *see also* App.278, R.Doc.24-1, Ex. 1-D at 11.

[2] HHS OIG has acknowledged this problem. It discussed the following hypothetical: a physician, who practices part-time at a covered entity hospital, gives a prescription to a patient at his private practice. *See* App.278, R.Doc.24-1, Ex. 1-D at 11. Although this prescription would likely not qualify for 340B, *see* 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015), one contract pharmacy said it would claim a 340B discount because it simply matches the name of the prescriber with those who work at a 340B covered entity *at all* (even if only part time). *See* App.278, R.Doc.24-1, Ex. 1-D at 11. This demonstrates how contract pharmacies can expand the definition of "patient" to cover additional, non-340B prescriptions.

discounted price—nominally in the name of the covered entities—to "replenish" the drugs sold previously to the purported patients. Again, this is done after the fact, without the benefit of data verifying that these newly identified 340B patient prescriptions were actually issued in connection with a patient visit to a covered entity. Once those replenishment drugs are received, the cycle starts anew: the 340B-discounted drugs are again comingled in the pharmacy's general inventory and dispensed to any individual who walks in the door, regardless of covered entity patient status. App.319, R.Doc.24-1, Ex. 1-E ¶ 11 (HRSA Director of Office of Pharmacy Affairs stating that under the replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").

Predictably, widespread use of these aggressive replenishment practices led to an explosion in the number of 340B discounts claimed, without any corresponding increase in the number of patients treated by covered entities. *See* William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program*, at 5, Pioneer Health (Mar. 2022), https://bit.ly/3MShVog. According to the U.S. Government Accountability Office ("GAO"), between 2010 and 2018 the number of contract-pharmacy arrangements increased "more than fifteen-fold, from about 1,300 to approximately 20,000." App.209, R.Doc.24-1, Ex. 1-C at 10. This dramatic expansion was coupled with an increase in the geographical distance

between covered entities and their contract pharmacies. *See* Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program* at 4 & n.5, 7, Berkeley Rsch. Grp. (Oct. 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf (As of 2020, the distance between hospital "covered entities" and their contract pharmacies averaged 334 miles.). Indeed, GAO has noted it is not uncommon for covered entities to contract with for-profit pharmacies located more than 1,000 miles away, App.222, R.Doc.24-1, Ex. 1-C at 23,[3] strongly suggesting 340B-discounted drugs are being diverted to individuals who are not patients of the covered entity. And along with this explosion of contract pharmacy use came an explosion in the number of 340B discounts sought from manufacturers—from about $4 billion per year in 2007-2009 to $38 billion in 2020. App.376, R.Doc.24-1, Ex. 1-I at 5; *see also* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), https://bit.ly/3eq5Fwy (showing the number of claims for 340B discounts nationwide tripled between 2014 and 2019).

[3] One large hospital covered entity located in Florida, for example, listed 499 contract pharmacies, which include pharmacies located in California and Arizona, almost 3,000 miles away. *See* HRSA, HHS, Office of Pharmacy Affairs, 340B OPAIS, https://340bopais.hrsa.gov/cedetails/20962.

These "replenishment" practices now generate extraordinary profits for contract pharmacies. Both CVS and Walgreens have publicly disclosed, for example, that 340B profits are material to their finances. CVS Health Corp., Annual Report (SEC Form 10-K), at 22 (Feb. 8, 2023), https://bit.ly/3Sh3Dl1; Walgreens Boots Alliance, Inc., Annual Report (SEC Form 10-K), at 28 (Oct. 13, 2022), http://bit.ly/3kflVXh; *see also* App.364-70, R.Doc.24-1, Exs. 1-G, 1-H.

Several federal watchdogs, including GAO and HHS's OIG, have warned that the growth of these arrangements exacerbates concerns about abuse and unlawful 340B discounting. *See, e.g.*, App.243, R.Doc.24-1, Ex. 1-C at 44 ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."); App.244, R.Doc.24-1, Ex. 1-C at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts."). Indeed, two-thirds of violations for unlawful diversion of 340B-discounted drugs uncovered by HRSA "involved drugs distributed at contract pharmacies." App.243, R.Doc.24-1, Ex. 1-C at 44.

3. Manufacturers' Efforts To Curb Abuse

The explosive increase in contract pharmacies using the replenishment model and the related massive increase in discount volumes suggesting substantial diversion led certain PhRMA members (and other pharmaceutical manufacturers) to

adopt new policies concerning how they will deal with contract pharmacies. *See, e.g.*, App.410-12, R.Doc.24-1, Ex. 1-J at 17-19. The contours of these policies differ from manufacturer to manufacturer, but each permits every covered entity to continue to purchase an unlimited number of 340B-discounted drugs for delivery directly, while placing reasonable limitations on deliveries to third-party contract pharmacies.

In May 2021, after receiving complaints from covered entities and contract pharmacies, HRSA issued violation determinations to the manufacturers who had implemented contract pharmacy policies and threatened them with penalties. *See, e.g.*, *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *5 (D.D.C. Nov. 5, 2021). Multiple manufacturers—including several PhRMA members—sued HHS and HRSA in federal courts challenging those violation determinations. Three courts so far have rejected HRSA's assertion that manufacturers must supply 340B-discounted drugs to as many contract pharmacies as a covered entity wants—the same requirement Act 1103 purports to impose here.

In a recently published opinion, the Third Circuit rejected the notion that 340B requires manufacturers to provide drugs to a theoretically unlimited number of contract pharmacies. *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 704 (3d Cir. 2023); *id.* at 703 ("Nowhere does Section 340B mention contract pharmacies."). To the contrary, the court noted that "Congress's

use of the singular 'covered entity' in the [statute's] 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies*." *Id.* (emphasis added); *id.* (340B does not "require[] delivery to an unlimited number of contract pharmacies").

The U.S. District Court for the District of Columbia similarly found that nothing in the 340B statute forbids drug manufacturers from imposing reasonable conditions regarding contract pharmacies. *Novartis Pharms*, 2021 WL 5161783, at *7. The court observed that HRSA itself had long acknowledged manufacturers could include provisions in their contracts with covered entities "that address customary business practice, request standard information, or include other appropriate contract provisions." *Id.* (citation omitted). Similarly, the U.S. District Court for the District of Delaware rejected HRSA's argument that the 340B statute affirmatively required manufacturers to provide 340B-discounted drugs to an unlimited number of contract pharmacies. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58-59 (D. Del. 2021).[4]

[4] Two appeals remain pending. *See United Therapeutics Corp. v. Johnson,* No. 21-5304 (D.C. Cir.), *Novartis Pharms. v. Espinosa*, No. 21-5299 (D.C. Cir.) (consolidated); *Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.).

B. The FDCA And The Federal REMS Program

Manufacturers are concerned not only about the rampant diversion of 340B-discounted drugs, but also that their drugs are distributed safely. Manufacturers employ, and in some cases are legally required to employ, various strategies to help mitigate potential safety issues with their drugs, including special labeling restrictions, limiting sales to pharmacies that can properly handle their drugs (in some instances, a single pharmacy with specially trained staff), and requiring safe-use tests to be conducted. The most formal of these mechanisms are Risk Evaluation and Mitigation Strategies ("REMS").

In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (Sept. 27, 2007), which amended the FDCA. In it, Congress explicitly granted FDA authority to require a REMS. *Id.* § 901, 121 Stat. at 926-39 (codified at 21 U.S.C. § 355-1). If FDA makes certain findings, it can require implementation of a REMS, which is proposed by a drug manufacturer and approved by FDA. REMS are designed to regulate the way in which certain drugs may be distributed or dispensed "to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a). FDA tailors each REMS to the particular drug, imposing requirements that help ensure the drug is distributed safely while also limiting burdens on the health care delivery system and patient access. *Id.* § 355-1(f)(2). Among other things, FDA may mandate that

manufacturers require that "pharmacies . . . that dispense [a] drug [covered by a REMS] are specially certified" or that a drug "be dispensed to patients only in certain health care settings." *Id.* § 355-1(f)(3)(B)-(C). As the district court acknowledged below, "[a] manufacturer who violates a REMS is subject to federal civil monetary penalties and potentially criminal liability." App.595, R.Doc.48 at 16; *see also* 21 U.S.C. § 352(y); *id.* § 355(p); *id.* § 333(f)(4) (civil monetary penalties); *id.* § 333(a) (criminal liability).

Manufacturers are required to distribute drugs subject to a REMS in accordance with the REMS regardless of whether the drug is distributed within 340B, and manufacturers are prohibited from providing such drugs to contract pharmacies that do not qualify to receive the drugs under the applicable REMS. 80 Fed. Reg. 52,300, 52,312 (Aug. 28, 2015). Accordingly, HRSA recognizes manufacturers must refuse to distribute 340B-discounted drugs to contract pharmacies that are not authorized to receive them. *See, e.g.,* HRSA, Manufacturer Notices to Covered Entities, https://www.hrsa.gov/opa/manufacturer-notices/index.html (last reviewed Jan. 2023) (listing current and historic limited distribution notices).

For example, PhRMA member Otsuka America markets 340B-discounted drugs it can distribute only to certified pharmacies enrolled in the relevant REMS program. *See* App.465-72, R.Doc.24-1, Ex. 1-N. To qualify to dispense Otsuka's

Jynarque®, for example, outpatient pharmacies must satisfy myriad requirements, including designating a representative to ensure REMS compliance, conducting special training, and contacting the REMS program before distributing Jynarque®. App.467, R.Doc.24-1, Ex. 1-N at 3. As relevant here, "Otsuka . . . must ensure that . . . wholesale-distributors . . . [d]istribute only to [those] certified pharmacies." App.465, 469, R.Doc.24-1, Ex. 1-N at 1, 5.[5]

C. Arkansas's Act 1103

On May 3, 2021, while federal 340B suits were progressing, Arkansas enacted Act 1103, the "340B Drug Pricing Nondiscrimination Act" (formerly known as House Bill 1881). Act 1103 explicitly states that its regulatory object is the operation of the federal 340B program. *See* Ark. Code Ann. § 23-92-601 (title); *id.* § 23-92-602(5) ("'340B drug pricing' means the program established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585."). In doing so, Arkansas made clear its attempt to dictate how manufacturers must treat contract pharmacies within the State.

Act 1103 applies to all 340B-discounted drugs. *See generally* Act 1103. It includes two provisions concerning contract pharmacies. The first instructs "[a]

[5] Other PhRMA members market drugs subject to REMS that contain similar distribution limits. *See*, *e.g.*, Biogen, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Tysabri_2021_12_10_REMS_Document.pdf; Daiichi Sankyo, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Turalio_2020_12_16_REMS_Document.pdf.

pharmaceutical manufacturer shall not . . . [p]rohibit 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." Ark. Code Ann. § 23-92-604(c)(1). The second mandates "[a] pharmaceutical manufacturer shall not . . . [d]eny 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)(2).

Following passage of the Act, the Arkansas Insurance Department ("AID") promulgated regulations implementing Act 1103. On February 22, 2022, AID published a Proposed Rule. App.450-55, R.Doc.24-1, Ex. 1-K ("Original Proposed Rule"). The Original Proposed Rule repeated the prohibitions of Act 1103, but imposed substantial limitations on the applicability or enforcement of those prohibitions. It provided that before a claimant could initiate the hearing and enforcement procedures of Ark. Code Ann. §§ 23-66-209 and 23-66-210, "the complainant's covered entity must first exhaust all available federal arbitration and federal administrative rights for cancellation or limitation on contracting with outside pharmacies through United States Department of Health and Human Services (HRSA) rules." App.454, R.Doc.24-1, Ex. 1-K § VIII. Enforcement Policy. Only if "HRSA determines" as part of its ADR process that the drug

manufacturer has "improperly denied a pharmacy 340B drug pricing" (or HRSA makes certain similar findings) could a complainant seek review of those actions as an "unfair and deceptive act or practice" under Arkansas law. App.454, R.Doc.24-1, Ex. 1-K § VIII. Enforcement Policy. AID admitted that it included this limitation "due to concerns over federal pre-emption . . . claims derived from Act 1103 itself." App.462, R.Doc.24-1, Ex. 1-M at 1.

In response to objections from in-state interests that stand to gain from Act 1103's expansive application, however, AID issued a modified Proposed Rule on May 25, 2022. App.456-60, R.Doc.24-1, Ex. 1-L ("Modified Rule"). The Modified Rule eliminates "any arbitration requirement with HRSA before [AID] begin[s] . . . enforcement." App.463, R.Doc.24-1, Ex. 1-M at 2. AID acknowledged it eliminated the one provision that could mitigate the Act's preemption problem due to "hospital objections." *Id.*

Instead of mitigating Act 1103's preemption problem, the Modified Rule doubled down, specifying the application of state law "penalties and fines [ ] not supplied in Act 1103." *Id.* The rule provides that "[t]he penalties, actions or orders, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule." App.460, R.Doc.24-1, Ex. 1-L § VI. Penalties. Under Ark. Code Ann. § 23-66-210, AID may, following a hearing, issue a cease-and-desist order. If a manufacturer subsequently violates that order, AID may require

"[p]ayment of a monetary penalty of not more than one thousand dollars ($1,000) for each and every act or violation but not to exceed an aggregate penalty of ten thousand dollars ($10,000) unless the person knew or reasonably should have known he or she was in violation." In the latter case, "the penalty shall be not more than five thousand dollars ($5,000) for each and every act or violation" and can be levied up to fifty thousand dollars ($50,000) "in any six-month period." *Id.* § 23-66-210(a)(1). The Modified Rule is now in effect.

D. Procedural History

PhRMA filed this suit on September 29, 2021. App.8-52, R.Doc.1. Its complaint raised two claims concerning Act 1103's contract pharmacy mandate provisions: that they are (1) preempted by federal law and (2) are invalid under the dormant Commerce Clause, U.S. CONST. art. I, § 8, cl. 3, because they will inevitably regulate commerce wholly outside Arkansas's borders. App.29-42, R.Doc.1¶¶ 66-104. Although PhRMA initially brought suit against only state officials, the district court allowed Piggott Community Hospital and the Community Health Centers of Arkansas (together, "Intervenors") to intervene as defendants on May 3, 2022. PhRMA's Commerce Clause claim was stayed pending resolution of motions for summary judgment on PhRMA's preemption claim. App.5, R.Doc.28. PhRMA and Intervenors filed motions for summary judgment on PhRMA's preemption claim. App.126-27, R.Doc.24; App.511-13, R.Doc.35. On December

12, 2022, the district court denied PhRMA's motion and granted Intervenors' Cross-Motion, concluding that Act 1103 was not preempted either by 340B or the FDCA. App.580-96, R.Doc.48.

With respect to preemption by 340B, the district court concluded that field preemption is inapplicable because 340B "is silent on what role (if any) contract pharmacies play in its discount drug scheme." App.590, R.Doc.48 at 11. In the district court's view, 340B drug distribution systems are "not 'a field in which the federal interest is so dominant that that the federal system will be assumed to preclude enforcement of state laws,'" so States are free to compel manufacturers to distribute 340B drugs to contract pharmacies as if they are covered entities. App.590-91, R.Doc.48 at 11-12. The district court gave equally short shrift to obstacle preemption. Even though Act 1103 prohibits drug manufacturers from "deny[ing] . . . 340B drug *pricing*" to contract pharmacies, Ark. Code Ann. § 23-92-604(c)(2) (emphasis added), the court concluded that "the effects of the disputed provisions [of Act 1103] are limited to the distribution of and access to the discounted drugs" and therefore were "not [an] obstacle to the purpose and objective of the 340(B) Program." App.593-94, R.Doc.48 at 14-15. The district court did not address PhRMA's contention that the state-law obligation to deliver 340B-discounted drugs to an unlimited number of pharmacies with no constraints destroys

the closed system Congress painstakingly created to limit manufacturer subsidies to intended beneficiaries.

Last, the district court rejected PhRMA's argument that Act 1103 is preempted by the FDCA. App.594-95, R.Doc.48 at 15-16. The court acknowledged that through use of a REMS and other administrative mechanisms, FDA can require that pharmacies that sell a drug be specially certified and that manufacturers who violate these requirements can be subject to federal penalties, including criminal liability. In contrast, under Act 1103, manufacturers may not prohibit *any* pharmacy from "participating with" a covered entity in 340B drug pricing "by denying access to drugs" or refuse *any* Arkansas-based community pharmacy 340B pricing as long as they contract with a covered entity. Ark. Code Ann. § 23-92-604(c). Despite this unequivocal mandate, the district court held that the state law did not mandate deliveries that federal law prohibits, because "Act 1103 does not regulate drug safety," App.595, R.Doc.48 at 16 (emphasis omitted), and "[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. The court never identified anything in the text or structure of Act 1103 that could support this saving construction.

Following the district court's summary judgment order, the district court granted PhRMA's unopposed motion for entry of judgment under Federal Rule of

Civil Procedure 54(b) or, in the alternative, for certification under 28 U.S.C. § 1292(b), on the preemption claim and this timely appeal followed. App.597-98, R.Doc.52; App.599, R.Doc.56; App.600, R.Doc.57

STANDARD OF REVIEW

This Court reviews *de novo* a district court's summary judgment decisions. *Weitz Co. v. Lloyd's of London*, 574 F.3d 885, 891 (8th Cir. 2009).

SUMMARY OF ARGUMENT

Act 1103 is preempted both by 340B and the FDCA.

I. Act 1103 is preempted by 340B in two distinct and independent ways: it impermissibly intrudes on the exclusively federal field Congress created in the federal 340B program, and it conflicts with 340B by frustrating the realization of 340B's core purposes.

First, the Act impermissibly intrudes on the field surrounding operation of the federal 340B program by purporting to define under state law how manufacturers must fulfill their obligations under this federal program, and by establishing alternative state-law procedures and penalties to enforce those obligations—procedures and penalties that trespass on the exclusive and "centralized" oversight, enforcement, and dispute-resolution scheme that Congress created. *Astra*, 563 U.S. at 119, 120. Act 1103 is in that respect strikingly similar to the common-law enforcement attempt the Supreme Court held was impermissible in *Astra*. By

requiring manufacturers to deliver 340B-discounted drugs to any contract pharmacy designated by a covered entity, Arkansas has impermissibly trespassed on exclusively federal turf. Accordingly, Act 1103 is preempted even aside from its conflicts with federal law.

Second, Act 1103 conflicts with 340B by frustrating the attainment of Congress's objectives. By compelling manufacturers to distribute 340B-discounted drugs to any and all contract pharmacies that request them, the Act undermines Congress's intent—through strict limits on the categories of covered entities and conveyance prohibitions—to cabin the scope of the federal 340B program and the costs imposed on manufacturers. And by creating an alternative state-law enforcement regime, the Act undermines Congress's intent to vest exclusive oversight, enforcement, and (most notably) dispute-resolution authority in HHS, raising the specter of inconsistent results in the competing state and federal systems—a problem AID previously recognized.

II. Act 1103 is also preempted by the FDCA because the Act requires manufacturers to deliver all 340B-discounted drugs to all contract pharmacies who request them, without making any exception for drugs whose distribution is regulated and limited by restrictions imposed by FDA under the FDCA. In this regard, the Act compels conduct that federal law forbids—a textbook case of impossibility preemption. The district court recognized Act 1103 cannot lawfully

compel deliveries in violation of restrictions imposed under the FDCA. But instead of holding the Act is preempted as applied in those circumstances and granting summary judgment to PhRMA, the court erroneously penciled into the Act an exception that appears nowhere in its text and granted summary judgment to the Intervenors.

This Court should reverse the district court's summary judgment and hold that Act 1103 is preempted by 340B as well as the FDCA.

ARGUMENT

The Supremacy Clause provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof," are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. "[E]ven where . . . a statute does not refer expressly to pre-emption, Congress may implicitly pre-empt a state law, rule, or other state action." *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376-77 (2015). Under field preemption, "States are precluded from regulating conduct" in a field where Congress has created a pervasive framework of regulation or where there is a dominant federal interest. *Arizona v. United States*, 567 U.S. 387, 399 (2012). This is true "irrespective of whether state law is consistent or inconsistent with 'federal standards.'" *Oneok, Inc.*, 575 U.S. at 377 (citation omitted). "By contrast, conflict pre-emption exists where 'compliance with both state and federal law is impossible,'

or where 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* (citation and internal quotation mark omitted).

Act 1103 is preempted under both field and conflict preemption principles.

I. ACT 1103 IS PREEMPTED BY THE FEDERAL 340B SCHEME

Act 1103 impermissibly intrudes, substantively and procedurally, into the comprehensive and exclusive field of the operation of the federal 340B program. In so doing, it creates new obligations and an alternative oversight and enforcement process that undermine the intended functioning of 340B, creating a conflict with an entirely federal scheme that imposes federal obligations solely as a condition of participation in other federal programs. States simply have no authority to impose additional conditions or requirements on this kind of federal scheme.

A. Act 1103 Is Preempted Because It Intrudes On The Exclusively Federal Field Of The Operation Of 340B

Field preemption exists where (1) Congress's "framework of regulation [is] 'so pervasive'" that Congress has "left no room for the States to supplement it," or (2) where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona*, 567 U.S. at 399 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Field preemption is especially likely where a state law "'diminish[es] the [Federal Government]'s control over enforcement' and 'detract[s] from the integrated scheme

of regulation' created by Congress." *Id.* at 402 (quoting *Wisc. Dep't of Indus. v. Gould Inc.*, 475 U.S. 282, 288-89 (1986)). As the Supreme Court has already expressly recognized, Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS to safeguard the delicate balance Congress struck. *See Astra*, 563 U.S. 110. There is no room for state supplementation in this field.

1. 340B Is A Comprehensive Scheme That Protects A Dominant Federal Interest

Congress designed 340B to provide a comprehensive and exclusive plan for delivering a unique federal benefit—a substantial drug discount to specific, statutorily defined healthcare providers. 340B works through a carefully calibrated incentive structure. To force drug manufacturers to provide desired discounts, Congress conditioned their ability to receive Medicare and Medicaid reimbursements for their drugs on their participation in 340B. But because continued access to these manufacturers' drugs is crucial to individuals covered by those other programs, Congress limited the scope of 340B obligations and federal enforcement mechanisms to avoid over imposing on manufacturers, who could potentially leave 340B and thus be forced to withdraw from participating in Medicare and Medicaid altogether.[6] Congress also explicitly set out the obligations

[6] The exclusively federal nature of the program is underscored by the constitutional constraints faced by Congress. Congress could not have simply

of all program participants and created a detailed oversight apparatus housed within HHS. Achieving the balance Congress desired is accordingly both delicate and essential, and there is no room for state recalibration and interference. The federal 340B program and the much-larger Medicaid Drug Rebate Program are "interdependent" programs. *Astra*, 563 U.S. at 114, 120. As the Supreme Court explained, "[a]n adjudication of rights under one program must" therefore "proceed with an eye towards any implications for the other." *Id.* at 120. Maintaining that balance—and ensuring that 340B operates harmoniously with Medicare and Medicaid—is a dominant federal interest.

Key to achieving this balance, Congress made 340B a closed system, carefully enumerating its intended beneficiaries. To that end, 340B defines the class of beneficiaries with rights to demand discounted drugs—the covered entities—with a high degree of specificity, providing a finite list of 15 categories of healthcare

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mandated that manufacturers provide covered entities a subsidy: The Takings Clause prohibits Congress from "tak[ing] the property of A for the sole purpose of transferring it to another private party B." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005); *see also Horne v. Dep't of Agric.*, 576 U.S. 350, 365-66 (2015). Congress therefore sought to impose the discounting obligation as a condition of receiving certain federal benefits, which could be constitutional only if the "condition bears an 'essential nexus' and 'rough proportionality'" to legitimate federal interests. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) (quoting *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994)). Congress accordingly strictly limited 340B in an attempt to ensure compliance with those constitutional constraints.

providers. 42 U.S.C. § 256b(a)(1), (4). That level of specificity is significant because it limits the bounds of 340B's beneficiaries to those listed entities. *See AstraZeneca*, 543 F. Supp. 3d at 60 ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.").

Congress reinforced the closed nature of the system by expressly limiting further distribution of drugs purchased at the 340B price. 340B expressly bars covered entities from "resell[ing] or otherwise transfer[ring]" 340B-discounted drugs to anyone who is not a patient of the covered entity. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) ("[A] covered entity shall not resell or otherwise transfer [a 340B-discounted drug] to a person who is not a patient of the entity."). This anti-transfer provision ensures that no one, besides covered entities and their patients, receive the benefit of the 340B discount, and reinforces that Congress intended to limit the subsidy required of manufacturers within carefully crafted bounds.

In addition to strictly delineating the scope of rights and obligations under 340B, Congress created a multi-faceted administrative enforcement scheme centralized within HHS to ensure uniformity, safeguard compliance, and keep the system circumscribed to facilitate manufacturer participation. Importantly, that system includes not only the ordinary tools of agency enforcement, but several other unique features. The Supreme Court has already made clear this scheme is meant to

be exclusive for resolving disputes between covered entities and manufacturers. *Astra*, 563 U.S. at 113 (holding local governments could not bring breach-of-contract claims to enforce manufacturers' 340B obligations).

The first facet of that regime is a unique ADR process that can be used by 340B participants—manufacturers on the one hand, and covered entities on the other—to resolve disputes with each other. *See* 42 U.S.C. § 256b(d)(3)(A); *Astra*, 563 U.S. at 121-22 ("Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers."). Rather than have these participants engage in protracted court battles, the statute directs HHS to designate an official or body within HHS to "review[] and finally resolv[e] claims" by covered entities or manufacturers. 42 U.S.C. § 256b(d)(3)(B), (C).

To that end, the statute requires HHS to establish a set of detailed procedures to govern disputes, including the availability of discovery and audits, and contemplates the possibility of various forms of consolidated or representative proceedings. *See, e.g*, 42 U.S.C. § 256b(d)(3)(B). And covered entities have used this process, including to raise disputes with manufacturers over contract pharmacies' role in 340B.[7] To ensure that HHS retains the "control rein[s]," *Astra*,

[7] *See, e.g.*, Petition for Damages and Equitable Relief, *Open Door Cmty. Health Ctrs. v. AstraZeneca Pharms., LP*, ADR ID: 210112-1 (HHS Jan. 13, 2021), https://pink.pharmaintelligence.informa.com/-/media/supporting-documents/pink-

563 U.S. at 120, Congress specified that the agency's conclusions in the ADR process are binding and final between the parties, "unless invalidated by an order of a court of competent jurisdiction," 42 U.S.C. § 256b(d)(3)(C).

The second facet of the enforcement scheme is an auditing and penalty process administered directly by HHS. As part of this oversight regime, HRSA has auditing authority over both manufacturers and covered entities. Manufacturers can be audited to ensure they are not "overcharging" covered entities (*i.e.*, selling 340B drugs to a covered entity at a price higher than the ceiling price). 42 U.S.C. § 256b(d)(1)(B)(v). HRSA can also audit covered entities to ensure their compliance with 340B limitations. *Id.* § 256b(a)(5)(C). In appropriate circumstances, HHS is empowered to impose civil monetary penalties on covered entities and manufacturers for violations of 340B requirements. *Id.* § 256b(d)(2)(B)(v); *id.* § 256b(d)(1)(B)(ii), (vi). But even in that case, Congress carefully limited HHS's authority to ensure that participants are not overly deterred from participating in 340B. In the case of manufacturers, for example, Congress has imposed a statutory *mens rea* requirement of "knowing[] and intentional[]" for penalties to potentially apply. *See id.* § 256b(d)(1)(B)(vi); 87 Fed. Reg. 15,100,

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15,105 (Mar. 17, 2022); *see also* 42 C.F.R. § 10.11(a).

There is good reason why Congress's design of the federal 340B program leaves no room for state supplementation: As discussed, 340B is intertwined with other major federal healthcare programs such as the Medicaid Drug Rebate Program and Medicare. Obligations under the federal 340B program, and violations of 340B, can have collateral consequences on these other federal programs. *See* 42 U.S.C. § 1396r-8(a)(1), (a)(5), (b)(4)(B)(i). "[A]n adjudication of rights under one program must" therefore "proceed with an eye towards any implications for the other." *Astra*, 563 U.S. at 120. Congress understandably chose to vest HHS and the federal courts—rather than 50 individual States and their own judicial systems—to make carefully considered determinations regarding disputes, enforcement, and penalties. *See* Oral Argument at 0:41-0:49, *United Therapeutics Corp. v. Johnson*, No. 21-5304 (D.C. Cir. argued Oct. 24, 2022) (Government attorney indicating 340B "represents a carefully calibrated scheme that entrusts HHS with oversight over both drug manufacturers and covered entities.").

As the Federal Government has previously argued and the Supreme Court has held, this detailed oversight and enforcement is "intended to be exclusive." Br. for the United States as *Amicus Curiae* Supporting Petitioners at *10, *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, No. 09-1273, 2010 WL 4717264 (U.S. Nov. 19, 2010); *see Astra*, 563 U.S. at 121 ("If Congress meant to leave open the prospect of third-

party beneficiary suits by 340B entities, it likely would not have barred the potential suitors from obtaining the very information necessary to determine whether their asserted rights have been violated."); *see also* Oral Argument at 7:45-7:51, *United Therapeutics Corp.*, No. 21-5304 ("What Congress has done with 340B is place a centralized enforcement mechanism with the federal government."); *cf. Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979) ("[W]here a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it."). In the Federal Government's words, by choosing to centralize oversight, enforcement, and dispute resolution (between manufacturers and covered entities) in HHS, Congress codified its assessment that HHS "is best positioned to determine manufacturers' obligations in the first instance." Brief for the United States as *Amicus Curiae* Supporting Petitioners at *33, *Astra*, 2010 WL 4717264.

For all these reasons, Congress intended the field covered by 340B to be exclusively federal.

2. Act 1103 Impermissibly Intrudes Into This Uniquely Federal Field

Act 1103 impermissibly intrudes into the exclusive field Congress designed by wading into the federal 340B program's closed system substantively and procedurally.

Act 1103 invades the exclusively federal field substantively by purporting to define as a matter of state law the scope of manufacturers' 340B obligations within Arkansas. Neither contract pharmacies nor "community pharmacies" are included in 340B's list of "covered entities" entitled to 340B pricing. 42 U.S.C. § 256b(a)(4). Notwithstanding the closed system created by Congress, Act 1103 nonetheless requires manufacturers to provide these pharmacies the federal 340B discount available only to "covered entities." Ark. Code Ann. § 23-92-604(c).

And Act 1103 then invades the closed system procedurally by creating its own scheme of oversight and enforcement to penalize manufacturers for not supplying that 340B price to contract pharmacies as required by the Act. Act 1103 thus interjects AID as an additional enforcer of 340B obligations and an additional arbiter of appropriate penalties. Notwithstanding the comprehensive enforcement and remedy scheme in 340B, under Act 1103 and its implementing regulations, AID may, following a hearing, issue a cease-and-desist order if a manufacturer refuses to provide 340B pricing to an Arkansas contract pharmacy. *Id.* § 23-66-210(a)(1). If a manufacturer subsequently violates that order, AID can impose "a monetary penalty of not more than one thousand dollars ($1,000) for each and every act or violation" "not to exceed an aggregate penalty of ten thousand dollars ($10,000) unless the person knew or reasonably should have known he or she was in violation." *Id.* In the latter case, "the penalty shall be not more than five thousand dollars

($5,000) for each and every act or violation" and can be levied up to fifty thousand dollars ($50,000) "in any six-month period." *Id.*

Arkansas cannot intrude into an exclusively federal program—indeed, federal field—in this way. This case is materially indistinguishable from *Astra*. Although that case arose in the context of deciding whether to permit common-law claims for 340B violations, its reasoning tracks perfectly the sort of analysis the Supreme Court conducts when evaluating field preemption.[8] There, the Court rejected an attempt by a local government to enforce manufacturers' obligations under the federal 340B program through breach-of-contract lawsuits outside the then-still-developing ADR process. In the Court's view, these private lawsuits were "incompatible with the [340B] statutory regime" because Congress had created 340B as a comprehensive, centralized, and exclusive program. 563 U.S. at 113. The Court reasoned that Congress had made an intentional choice not to create a separate, private right of action within 340B. *Id.* at 117 ("Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities."). The Court also emphasized the importance of balancing the

[8] The Supreme Court did not have occasion in that case to evaluate the issue under preemption principles because the plaintiffs had earlier dismissed their state-law claims after defendants removed the case and the district court held that their state contract claims necessarily raised federal questions because the contracts at issue required application of federal law.

federal objectives in this sensitive area. *Id.* 119-20. And it explained that, in reaction to concerns about lackluster enforcement, Congress had chosen to "strengthen and formalize HRSA's enforcement authority," not to give outsiders private enforcement authority. *Id.* at 121-22 (internal citations omitted). Private enforcement by local governments would therefore "undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 118, 120.

The Court's reasoning in *Astra* should resolve the issue here. Congress directed HHS to create an exclusive and comprehensive remedial scheme "to prevent overcharges and other violations of the discounted pricing requirements" and "to prevent diversion" of 340B discounts via transfer of 340B medications to third parties. 42 U.S.C. § 256b(d)(1)(A), (d)(2)(A), (3); 42 C.F.R. §§ 10.3, 10.20. If 340B is so comprehensive and exclusive as to displace common-law claims by local governments, it is comprehensive enough to create an exclusive field of federal authority into which Arkansas cannot tread merely by codifying its preferred approach. *See, e.g.*, *Arizona*, 567 U.S. at 402-03 (concluding that "state framework of sanctions creates a conflict with the plan Congress put in place" "[e]ven where federal authorities believe prosecution is appropriate"); *Gould Inc.*, 475 U.S. at 288 ("Because Wisconsin's debarment law functions unambiguously as a supplemental sanction for violations of the NLRA, it conflicts with the Board's comprehensive

regulation of industrial relations in precisely the same way as would a state statute preventing repeat labor law violators from doing any business with private parties within the State."); *id.* at 288-89 ("Each additional [State] statute incrementally diminishes the [Federal Government]'s control over enforcement" and "detracts from the 'integrated scheme of regulation' created by Congress.").

It does not matter for these purposes whether Arkansas is right in its belief that manufacturers are required by 340B itself to deliver discounted drugs to any and all contract pharmacies designated by a covered entity, or whether, as the Third Circuit recently held, in striking the balance, Congress left manufacturers participating in the 340B program free to impose reasonable constraints on that practice. That question is solely one controlled by federal law, and by purporting to dictate the result as a matter of state law, Arkansas has impermissibly trespassed on exclusively federal turf. For all of these reasons, this Court should reverse the district court and hold that Act 1103's contract pharmacy mandates are preempted by the exclusive federal field of the operation of 340B.

3. Act 1103's Impermissible Intrusion Into The Exclusive 340B Field Cannot Be Salvaged By Recasting It As A Gap Filling "Pharmacy" Distribution Regulation

In dismissing the possibility of field preemption, the district court incorrectly reasoned that there is a "gap" in 340B concerning contract pharmacies that Arkansas permissibly filled pursuant to its traditional role regulating the practice of pharmacy.

See App.590-91, R.Doc.48 at 11-12 (holding that 340B's "silen[ce] on what role (if any) contract pharmacies play in its discount drug scheme" leaves States free to compel manufacturers to distribute covered drugs to contract pharmacies (or, presumably, to prohibit them from doing so)). As an initial matter, there is no such gap for these purposes: 340B defines the class of entities to which manufacturers must provide discounted drugs, and contract pharmacies are not among them.

But in any event, the district court's reasoning runs directly counter to the entire foundation of field preemption. Where Congress has occupied the field—indeed created the entire federal 340B program and defined its parameters—there is no room for supplemental state legislation within the field, whether or not Congress has directly spoken to the precise question. *See Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 309 (1988) (holding preempted a "state law whose central purpose [wa]s to regulate matters that Congress intended [the Federal Energy Regulatory Commission] to regulate"); *NLRB v. Nash-Finch Co.*, 404 U.S. 138, 144 (1971) (explaining that the requirement of uniform application of federal law implied that States cannot intrude, even if particular activities are unregulated); *cf. U.S. Airways, Inc. v. O'Donnell*, 627 F.3d 1318, 1327 (10th Cir. 2010); *Pohl v. Nat'l Benefits Consultants, Inc.*, 956 F.2d 126, 127-28 (7th Cir. 1992). That is the fundamental attribute of field preemption that differentiates it from conflict preemption.

And while it is true that States also regulate the practice of pharmacy, that has

no bearing on the permissibility of Act 1103's contract pharmacy mandates. To be sure, Arkansas remains free to regulate items like the fee required to operate as a licensed pharmacist in the State, Ark. Code Ann. § 17-92-108; the penalty to be imposed for using the title of "licensed pharmacist" when not conferred, Ark. Code Ann. § 17-92-303; and the training requirements to become licensed as a pharmacist, Ark. Code Ann. § 17-92-307—even when those pharmacists are handling 340B-discounted drugs.

But Act 1103 is not that kind of professional practice regulation. Rather than regulate the practice of pharmacy, Act 1103 instead regulates manufacturers' federal-law obligation to provide steeply discounted 340B drugs to "covered entities" in exchange for the right to have the manufacturers' drugs covered by other federal programs. States have no authority in that space, any more than a State may dictate terms under which a federal contractor participates in a federal contract—even if there are purported third-party beneficiaries (exactly the argument that was rejected in *Astra*).

To the extent the district court thought that Arkansas could avoid preemption by recharacterizing its law as addressing the practice of pharmacy, that is wrong. Tellingly, Act 1103 only applies to manufacturers that participate in the federal 340B program—after all, they are the only entities that have any obligation to provide discounted 340B drugs in the first place—belying the notion that this is some general

background regulation of the practice of pharmacy. In any event, the Supreme Court has repeatedly rejected similar efforts to avoid preemption. Consider, for example, *National Meat Association v. Harris*, 565 U.S. 452 (2012), where the Supreme Court rejected, as a blatant end run around federal law, an attempt by California to avoid preemption by regulating the sale of meat from livestock that had not been inspected, handled, and slaughtered as required under the state's regulations, when federal law preempted state regulations regarding inspecting, handling, and slaughtering. *Id.* at 463-64. The same was true in *Engine Manufacturers Association v. South Coast Air Quality Management District*, 541 U.S. 246, 248-49, 255 (2004). As the Supreme Court has repeatedly made clear, States cannot seek to escape preemption through artful drafting or recharacterization.

Rather, it is the substance of a state law that matters, not the label a State may put on it. *Cent. Mach. Co. v. Ariz. State Tax Comm'n*, 448 U.S. 160, 164 n.3 (1980); *Scott v. Gulf Oil Corp.*, 754 F.2d 1499, 1504 (9th Cir. 1985); *see also Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1919-20 (2019) (Roberts, J., dissenting). And here, Act 1103 regulates to whom manufacturers must provide 340B-discounted drugs, adding to the obligations undertaken to participate in a wholly federal program. *See Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 636 (2013);

Engine Mfrs., 541 U.S. at 255.[9]

Because Act 1103 impermissibly intrudes into this exclusively federal domain, it is preempted by the federal law.

B. Act 1103 Also Conflicts With The Federal Regime Created By Congress

In addition to impermissibly intruding on the exclusively federal field of how 340B operates, Act 1103 is preempted because it frustrates the achievement of core goals of the federal law.

Even if Congress had not occupied the field here, where "state and federal law 'directly conflict,' state law must give way." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617-18 (2011) (quoting *Wyeth v. Levine*, 555 U.S. 555, 583 (2009)). Such a conflict exists where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or "interferes with the methods by

[9] Given the breadth and complexity of many federal healthcare programs, Congress frequently assigns the States significant roles in administering those programs. *See, e.g.*, 42 U.S.C. § 1396a (Medicaid statute providing for state plans); 42 U.S.C. § 18031 (Affordable Care Act establishing states' ability to set up health benefit plan exchanges). But that is not true here. Reflecting 340B's limited scope and purpose, nothing in the 340B statute contemplates any role for the States. Indeed, Congress required that 340B be implemented through uniform federal contracts— known as PPAs—between HHS and drug manufacturers. *Astra,* 563 U.S. at 115, 120. Those agreements in turn all provide that the defined terms in the agreements, including which healthcare providers qualify as a "covered entity," are to "have the meanings specified" in the 340B statute. *See* App.186, R.Doc.24-1, Ex. 1-B § 1(f); *see also Boyle v. United Techs. Corp.*, 487 U.S. 500, 504-05 (1988) (finding preemption because "obligations to and rights of the United States under its contracts" are controlled by federal rather than State law (citations omitted)).

which the federal statute was designed to" achieve those purposes and objectives. *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 492, 494 (1987) (citation omitted).

1. Act 1103 Frustrates The Accomplishment Of Congress's Objectives And Interferes With Congress's Chosen Method Of Oversight

Act 1103 is conflict preempted because it frustrates both Congress's intent to operate the federal 340B program as a closed system with carefully circumscribed benefits and costs, and Congress's intent to supervise the operation of that closed system through a centralized administrative and enforcement process vested in an expert federal administrative agency.

First, Act 1103 undermines Congress's carefully tailored closed system for delivering a pricing benefit to specific kinds of healthcare facilities and their patients, while limiting the collateral consequences of requiring manufacturers to provide such an extraordinary subsidy. As discussed at length, Congress reflected this intent in its careful and limited definition of "covered entity," and its broad limitations on the transfer and resale of discounted medications by covered entities. *See supra* at 30.

Notwithstanding Congress's circumscribed closed system, Act 1103 requires manufacturers to provide 340B-discounted drugs to entities other than covered entities—to any Arkansas pharmacy that happens to have a "340B drug pricing contract pharmacy arrangement" with a covered entity (whatever that ultimately means). Ark. Code Ann. § 23-92-604(c). As its careful design shows, Congress did

not intend for outside actors—including an unlimited number of for-profit pharmacy chains—to insert themselves into the system, siphoning off 340B's benefits and inflating its costs. Indeed, the Third Circuit recently rejected an analogous argument. *Sanofi Aventis*, 696 F.4th at 704; *see id.* ("Congress's use of the singular 'covered entity' in the 'purchased by' language [of the 340B statute] suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies."); *see also Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 326 (2016) (state law that "impose[d] duties that are inconsistent with the central design" of federal law was preempted).

Worse still, Act 1103 imposes no standards or requirements for what must be contained in a "340B drug pricing contract" between a pharmacy and a covered entity that would limit a manufacturer's state-law obligation to provide the 340B discounted drugs—there is no requirement, for example, that the Arkansas pharmacy actually operate as an agent of any Arkansas covered entity for the benefit of that entity's patients. Indeed, Act 1103 imposes no restrictions whatsoever on what a contract pharmacy may do with 340B-discounted drugs once it receives them, notwithstanding the carefully drawn federal prohibition on *covered entities* transferring the discounted drugs to anyone other than their patients. This point is critical, because it is undisputed that many contract pharmacies in Arkansas use the replenishment model, *see supra* at 9-11, under which pharmacies literally provide

the actual drugs purchased at the 340B price to *all* pharmacy customers, regardless of whether a customer is a patient of a covered entity. Act 1103 blows a gaping hole in Congress's closed design by adding an additional actor into the federal 340B program and circumventing the limitations Congress built into its 340B program. *See*, *e.g.*, *Pac. Cap. Bank, N.A. v. Connecticut*, 542 F.3d 341, 352-53 (2d Cir. 2008) (holding that a State cannot seek to avoid preemption "by imposing such a [result] indirectly" that would be directly barred). Indeed, Act 1103 seeks to impose a requirement the Third Circuit has expressly held even the Federal Government *cannot* impose. *See Sanofi Aventis*, 58 F.4th at 704.

Second, Act 1103—like the common-law claims brought by Santa Clara County in *Astra*—conflicts with Congress's federal oversight scheme. 563 U.S. at 113; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 342-43, 349-50 (2001) (holding that because the FDCA provided FDA with "a variety of enforcement options that allow it to make a measured response to suspected fraud upon [it]" greenlighting state-law tort claims would "inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives"). As discussed, in 340B, Congress provided very precise mechanisms for oversight, enforcement, and dispute resolution between covered entities and manufacturers. *See supra* at 31-34. But rather than adhere to the means that Congress has chosen for addressing 340B compliance—a suite of carefully

calibrated tools all overseen by HHS and the federal courts—Arkansas has introduced its Insurance Department as a separate adjudicator of obligations for participating in the federal 340B program, with its own suite of inconsistent state-law remedies and requirements that go beyond the bounds of 340B.

This conflict goes to the core of Congress's concerns in carefully structuring the 340B program. For example, Congress mandated that the federal ADR system would be final and binding between the manufacturers and covered entities (subject to judicial review). *See supra* at 31-32. But Arkansas's entirely separate scheme requires no deference to any "binding" and "final" federal ADR findings. This divergence creates a very real possibility that a federal ADR panel and AID will reach conflicting decisions concerning whether a manufacturer has violated its 340B obligations. *See Astra*, 563 U.S. at 120 ("With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial."). Indeed, the Supreme Court has been particularly sensitive to similar intrusions on federal remedial schemes because they make conflict inevitable. As explained, *see supra* at 36-38, the Supreme Court in *Astra* rejected a nearly identical effort by a municipality to enforce manufacturer obligations under 340B, noting the potential for "conflict." *Astra*, 563 U.S. at 120 at n.6. That potential for conflict was significant because the federal interest at stake is paramount—"Congress made *HHS* administrator of both

the Medicaid Drug Rebate Program and the 340B Program" to ensure "uniformity" in both programs. *Id.* at 120 (emphasis added).

Even Arkansas itself previously recognized this problem. In an earlier version of the Rule implementing Act 1103, AID required covered entities to "first exhaust all available federal arbitration and federal administrative rights for cancellation or limitation on contracting with outside pharmacies through [HRSA] rules" *before* filing a complaint with AID. App.454, R.Doc.24-1, Ex. 1-K § VIII. Enforcement Policy. Although that would not have saved Act 1103 from preemption, it is telling that AID explicitly acknowledged this limitation was included "due to concerns over federal pre-emption." App. 462, R.Doc. 24-1, Ex.1-M at 1. Nevertheless, on May 25, 2022, AID reversed course and deleted this exhaustion requirement from its Rule following objections from certain interest groups. *See* App. 462-63, R.Doc. 24-1, Ex.1-M at 1-2. AID's final Rule now allows AID to act before HHS is given the chance or, worse, to contradict the result HHS has already reached.

This conflict is particularly acute here because, in addition to providing alternative forums, Act 1103 provides different and more drastic penalties for noncompliance, which not only changes the balance Congress struck, but disincentivizes participation in the federal 340B program for manufacturers. Arkansas's law not only nearly doubles the amount of penalties a manufacturers may face ($10,000 per violation vs. 340B's original $5,000), it also eliminates the federal

requirement that such violations be knowing and intentional. *Compare* 42 U.S.C. § 256b(d)(1)(B)(vi) (authorizing civil monetary penalties only where an overcharge by a manufacturer was "knowing[] and intentional[]"), *with* Ark. Code Ann. § 23-66-210, -211 (omitting any scienter requirement for the imposition of state-law penalties). Act 1103 would therefore give state officials the power to impose monetary penalties when they would be barred under 340B. This runs counter to Supreme Court precedent, which establishes that "since remedies form an ingredient of any integrated scheme of regulation, to allow the State to grant a remedy . . . which has been withheld from [a federal agency] only accentuates the danger of conflict." *San Diego Bldg. Trades Council, Millmen's Union, Loc. 2020 v. Garmon*, 359 U.S. 236, 247 (1959); *see also Villas at Parkside Partners v. City of Farmers Branch,* 726 F.3d 524, 529-30 (5th Cir. 2013) (finding conflict where federal law required knowing or intentional conduct for violation while state law governing similar conduct did not).

Those differing and additional penalties would frustrate Congress's carefully balanced system for policing compliance. By limiting the amount of civil monetary penalties and requiring a heightened *mens rea* for imposition of such penalties, Congress sought to ensure that participation in 340B did not become so onerous as to disincentivize manufacturer participation, with all of the attendant detrimental effects for Medicare and Medicaid. Arkansas's imposition of additional penalties

upends that prudently drawn balance.

At bottom, the Supremacy Clause does not permit Arkansas to enforce a regulatory scheme that destroys the uniformity Congress intended and upsets the balance Congress struck in the federal statute. *See Buckman*, 531 U.S. at 350; *see also* Br. for the United States as *Amicus Curiae* Supporting Petitioner at *23, *Buckman Co. v. Plaintiffs' Legal Comm.*, No. 98-1768, 2000 WL 1364441 (U.S. Sept. 13, 2000) ("[F]raud-on-the-FDA claims would permit juries in different States to reach judgments that differ from FDA's concerning whether an entity has actually committed fraud on the FDA."). And, of course, the problem will only intensify if Act 1103 is allowed to stand and pharmacy interest groups persuade other state legislators to impose their own state-specific modifications to 340B. HHS cannot manage the delicate equilibrium required with 50 States separately enforcing their own visions of proper 340B compliance. *See Gould Inc.*, 475 U.S. at 286 ("'[C]onflict is imminent' whenever 'two separate remedies are brought to bear on the same activity.'").

2. The Conflict Between Act 1103 And 340B Cannot Be Resolved By Recasting Act 1103 As A Distribution Requirement

The district court seemed to accept that Arkansas could not directly expand the list of covered entities entitled to receive 340B-discounted drugs under the federal statute. But, at the urging of Arkansas, it concluded Act 1103 was not an obstacle "to the purpose and objective of the 340(B) Program" because Act 1103

purportedly regulates only the "distribution of and access to the discounted drugs," not pricing of the drugs. App.593-94, R.Doc.48 at 14-15. But Act 1103 cannot be saved simply by recasting it as a delivery or distribution requirement. By requiring the delivery of *340B-discounted drugs* to contract pharmacies, Arkansas is necessarily imposing a pricing term in addition to a delivery requirement and is thereby circumventing the statutory limits on who is eligible to receive 340B-discounted drugs and to whom those discounted medications can be transferred, *see supra* at 34-35.

The district court's contrary conclusion is equivalent to saying that "I may not be able to force you to sell me a car for $1.00, but I can force you to deliver to me a car priced at $1.00." That is a distinction without a difference. Arkansas is not merely requiring manufacturers to provide *drugs* to contract pharmacies (a requirement that would not touch on 340B), it is requiring manufacturers to provide *340B-discounted* drugs to those pharmacies. In fact, it seems clear that covered entities and contract pharmacies would not be interested in a law that mandated the former (mere delivery of drugs), rather than the latter (delivery of 340B-discounted drugs), since they would not derive the same profits from that law.

And, even if the district court were correct that Act 1103 regulates distribution of 340B-discounted drugs and not pricing (it does not), that does not matter. As discussed, *see supra* at 43-45, requiring the delivery of the 340B-discounted drugs

to contract pharmacies directly conflicts with the closed system that Congress crafted by imposing additional obligations on manufacturers for choosing to participate in the federal 340B program in the first place. And recasting Act 1103 as a delivery or distribution statute does nothing to address the fact that Act 1103 imposes an additional remedial scheme that frustrates Congress's intent to have HHS supervise 340B through a centralized administrative and enforcement process exclusively invested in the agency, with circumscribed penalties to avoid disincentivizing manufacturer participation. *See supra* at 45-49. In sum, Act 1103 cannot be saved through artful recharacterization.

For those reasons, this Court should reverse the district court and hold that Act 1103 conflicts with, and is therefore preempted by the federal 340B statute.

II. ACT 1103 IS ALSO PREEMPTED BY THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Act 1103 also violates impossibility preemption principles because it requires manufacturers to provide drugs to contract pharmacies that are not permitted to receive them under federal law. As part of the federal drug approval process, a variety of limitations may be placed on how and by whom drugs may be sold. The most formal of these strategies are Risk Evaluation and Mitigation Strategies ("REMS") with "elements to assure safe use," under which FDA may (among other things) require manufacturers to ensure that "pharmacies . . . that dispense a drug [covered by a REMS] are specially certified" or that a drug "be dispensed to patients

only in certain health care settings," which necessarily limits the number of pharmacies that are eligible to dispense the drugs. 21 U.S.C. § 355-1(f)(3)(B)-(C). Act 1103's contract pharmacy mandates contain no exception for drugs subject to such federal requirements. Ark. Code Ann. § 23-92-604(c). On its face, therefore, Act 1103 requires manufacturers to distribute 340B-discounted drugs to *all* contract pharmacies in Arkansas even when they *cannot* legally be sent to or dispensed through those same pharmacies.

PhRMA member Otsuka's drug Jynarque® is a perfect example. *See supra* at 17-18. As discussed above, "Otsuka . . . must ensure that . . . wholesale-distributors . . . [d]istribute only to [those] certified pharmacies." App.465, 469, R.Doc.24-1, Ex. 1-N at 1, 5. Otsuka—understandably—recently expressed concern to the Third Circuit that it was impossible to both ship to contract pharmacies without limitation (as Act 1103 purports to require) and also comply with its REMS obligations to limit which pharmacies receive Jynarque® (as federal law requires). *See* Brief of *Amicus Curiae* Otsuka America Pharmaceutical, Inc. at 23-24, *AstraZeneca Pharms. LP v. Sec'y Dep't of Health & Human Servs.*, No. 22-1676 (3d Cir. July 28, 2022), ECF No. 44. The Third Circuit agreed with that concern. *Sanofi Aventis*, 696 F.4th at 705 (an unlimited-contract-pharmacy requirement would "put drug makers in a legal bind" as it would be incompatible with certain REMS). The contradiction between Act 1103's mandates and the federal REMS

restrictions presents a textbook case of impossibility preemption. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (finding impossibility where "state law penalizes what federal law requires").

The district court appeared to recognize the conflict between Act 1103 and federal law. In its opinion, it said 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; *see also* R.Doc.36 at 48-49. The district court was correct that Act 1103 cannot prevent manufacturers from complying with their FDCA obligations; the state law is preempted in those circumstances. But rather than reaching that conclusion through the correct analysis, the district court faltered. Instead of finding a conflict and enjoining the application of Act 1103 with respect to drugs subject to a REMS, the district court purported to find a drug-safety exception in the state law that could solve the problem. That might have been a sensible exception for the Arkansas Legislature to include in Act 1103, but the district court had no authority to take the drafting pen for itself, even if necessary to save the statute from preemption.

When any federal court is called on to interpret a statute, the court must "predict how the state's highest court would" interpret the statute. *Minn. Supply Co. v. Raymond Corp.*, 472 F.3d 524, 534 (8th Cir. 2006). And as a matter of federalism, federal courts are "without power to adopt a narrowing construction of a state statute

unless such a construction is . . . readily apparent." *Boos v. Barry*, 485 U.S. 312, 330 (1988); *see also Willson v. City of Bel-Nor*, 924 F.3d 995, 1004 (8th Cir. 2019) (Courts cannot "rewrite a law to conform it to constitutional requirements," particularly not a state law.). Consistent with ordinary practice, the Arkansas Supreme Court has explained that "[t]he first rule in considering the meaning and effect of a statute is to construe it just as it reads, giving the words their ordinary and usually accepted meaning in common language." *Yamaha Motor Corp., U.S.A. v. Richard's Honda Yamaha*, 38 S.W.3d 356, 360 (Ark. 2001) (citation omitted). "Where the language of a statute is plain and unambiguous and conveys a clear and definite meaning . . . [a] court has no right to look for or impose another meaning." *City of Little Rock v. Ark. Corp. Comm'n*, 189 S.W.2d 382, 383–84 (Ark. 1945); *see also McMillan v. Live Nation Ent., Inc.*, 401 S.W.3d 473, 476 (Ark. 2012) (Arkansas state courts cannot "add words to a statute to convey a meaning that is not there). After all, the plain language is presumed to "express[] the legislative intention," thus, "such plain and obvious provisions must control." *City of Little Rock*, 189 S.W.2d at 384.[10]

[10] Although AID explained in its briefing below that it would not apply Act 1103 in a situation where a manufacturer refused to deliver because of a FDCA REMS obligation, *see* R.Doc.30 at 11, that is irrelevant. The Arkansas Supreme Court recently held that even formal agency statutory interpretations are to be given no deference, *Myers v. Yamato Kogyo Co., Ltd.*, 597 S.W.3d 613, 617 (Ark. 2020)—and here, we are talking only about a litigating position in a brief. The Supreme Court has instructed that federal courts should give no weight to a state executive's

Act 1103 requires manufacturers to deliver drugs to pharmacies that are under contract with covered entities with no exception. As the Arkansas Legislature chose not to include any exceptions to this rule, a manufacturer would be obligated to provide 340B-discounted drugs to a contract pharmacy *even if* the drug in question is subject to a FDCA restriction obligating the manufacturer to ensure that the pharmacy does not receive the drug. This is textbook impossibility preemption: state law *requires* manufacturers to deliver drugs in all instances and federal law *prohibits* delivery in overlapping instances. *See, e.g.*, *PLIVA*, 564 U.S. at 617-18 (impossibility conflict rendered state law preempted because "[i]t was not lawful under federal law for the Manufacturers to do what state law required of them"); *see also Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143 (1963).

The district court erred by straining to save Act 1103 from preemption by adding a FDCA REMS exception that finds no basis in Act 1103's text. *See Willson*, 924 F.3d at 1004 (federal courts cannot rewrite a law to ensure constitutionality); *McMillan*, 401 S.W.3d at 476 (Arkansas courts cannot add words to statutes that are not there). The court should have found Act 1103 to be preempted and enjoined its

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interpretation of state law if the interpretation "does not bind the state courts." *Stenberg v. Carhart*, 530 U.S. 914, 940 (2000). AID's litigation position should be given no weight as a means of interpreting the statute.

application "to the extent that the [Act] imposes obligations inconsistent with federal law." *Dalton v. Little Rock Fam. Plan. Servs.*, 516 U.S. 474, 478 (1996).

CONCLUSION

The district court's summary judgment on PhRMA's preemption claim in favor of Intervenors should be reversed, and summary judgment should instead be granted in PhRMA's favor.

Dated: February 22, 2023

Respectfully submitted,

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

I hereby certify that this brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) because the brief contains 12,954 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

I also certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because this brief was prepared using Microsoft Word 2016 in 14-point Times New Roman font.

Pursuant to Eighth Circuit Rule 28(A)(h), I further certify that Appellant's Brief and Addendum 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 Appellees. The brief and Addendum have been scanned for viruses using a commercial virus scanning program, which reports the brief and Addendum to be virus free.

s/ *Philip J. Perry*
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Dated: February 22, 2023

CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2023, pursuant to Fed. R. App. P. 25(a)(2)(A)(ii), I caused the foregoing brief to be filed electronically with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit. Within five days of receipt of notice that the foregoing document has been filed, Appellant will serve each party separately represented with a paper copy of the brief.

I further certify that ten paper copies of Appellant's Brief will be provided to the Court within five days after receipt of notice that the foregoing document has been filed pursuant to Rule 28A(d).

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