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

REPLY BRIEF OF APPELLANT PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

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INTRODUCTION

Congress did not intend for the 340B Drug Pricing Program, 42 U.S.C. § 256b ("340B"), to operate as a general price control regime or a windfall generator for for-profit interests. 340B is a carefully tailored drug discount program that obligates drug manufacturers to offer a substantial discount on their drugs to specified qualifying healthcare facilities as a condition of having their drugs reimbursed under other federal healthcare programs (Medicaid and Medicare Part B). It is a delicate bargain struck by statute: 340B is designed to stretch federal resources to provide accessible healthcare to poor or uninsured patients through private funding. But it is also designed to not become so onerous that drug manufacturers are incentivized to withdraw from participation in Medicaid and Medicare Part B. Given the stakes, it is unsurprising the Supreme Court has already concluded in materially indistinguishable circumstances that Congress intended 340B to operate "on a uniform, nationwide basis" with HHS "hold[ing] the control rein." *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 119-20 (2011).

Dissatisfied with the balance struck by Congress concerning the scope of manufacturers' obligations under 340B, Arkansas attempted to implement its own vision of what 340B should require through Act 1103. Act 1103's intrusion into this federal scheme runs headlong into the Supremacy Clause.

Defendant Arkansas Insurance Department's ("AID") and Intervenors' principal defense of Act 1103 against field preemption boils down to this: 340B is concerned solely with drug pricing, not distribution, and Act 1103 deals solely with drug distribution, not pricing. But their artificial distinction does not save Act 1103. The exclusive federal field is broad: The 340B statute, in fact, speaks quite clearly to drug distribution by creating a closed system intended to limit the availability of 340B-discounted drugs to a narrow list of specified entities who can only distribute to their patients, capping the burden on manufacturers to prevent adverse collateral consequences to other federal programs. The entirety of 340B, including its remedial and enforcement scheme, is designed around that purpose. Act 1103, or the "340B Drug Pricing Nondiscrimination Act," Ark. Code Ann. § 23-92-601, focuses on its face on "[p]ricing" and barges into that exclusive federal field by regulating who is entitled to (and must) receive the 340B-discounted price and imposing its own state enforcement scheme for failing to provide that price to Arkansas pharmacies. The idea that Act 1103 imposes only a delivery requirement divorced from pricing is illogical—after all, Arkansas is not mandating delivery of drugs to contract pharmacies in general, it is requiring manufacturers to provide *340B-discounted drugs* to pharmacies.

Act 1103 is also conflict preempted because it interferes with Congress's closed system (by requiring the provision of 340B-discounted drugs to contract

pharmacies, despite the absence of contract pharmacies from the federal statute) and the exclusive remedial scheme that Congress established (by imposing AID as an additional arbiter of obligations and levying differing and additional penalties on manufacturers). AID's principal response is that it intends to "defer" to the Federal Government on key issues where a conflict might arise. But how? AID had originally proposed requiring covered entities to go through the federal administrative dispute resolution process before filing a complaint with AID but abandoned that proposal at the request of certain interest groups. So Act 1103, as it operates today, contemplates no deference to federal law.

Other provisions of federal law also preempt Act 1103. AID essentially admits that Act 1103 is in conflict with the restrictions imposed by the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act's ("FDCA") Risk Evaluation and Mitigation Strategies ("REMS") provision. *See* 21 U.S.C. § 355-1. Rightfully so: Act 1103's text requires manufacturers to deliver 340B-discounted drugs to *any* Arkansas-based contract pharmacy, without exception, even when that delivery would be prohibited by a REMS. That is a textbook case of impossibility preemption.

Finally, the so-called "presumption against preemption" does not apply here. Act 1103 does not act in an area of traditional state regulation, *and* it implicates an

area of unique federal concern, either of which is sufficient to bring Act 1103 outside the ambit of any such presumption.

ARGUMENT

I. ACT 1103 IS PREEMPTED BY 340B

A. Act 1103 Impermissibly Intrudes On The Federal Field Of The Operation Of 340B

As PhRMA explained in its opening brief (at 27-33), Congress designed 340B to provide a comprehensive and exclusive plan for delivering a unique federal benefit. To push drug manufacturers to provide desired discounts, Congress conditioned Medicaid and Medicare Part B coverage 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, by circumscribing who is entitled to the discount (specifically enumerated "covered entities") and what can be done with the discounted drugs (transferred only to the covered entity's patients), and by creating a carefully calibrated enforcement scheme within the Federal Government. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 120 (2011). These limits sought to avoid deterring manufacturers from participating in 340B and, accordingly, being incentivized to withdraw from participating in Medicaid and Medicare Part B. Congress therefore made 340B a tightly controlled, closed system, with unique remedial and enforcement mechanisms centralized in HHS. *See id.* Given the

comprehensive scheme and the dominant federal interest at stake, Congress has occupied the field with respect to the operation of this federal program.

Act 1103, however, intrudes into the federal field both substantively and procedurally. It intrudes substantively by barging into Congress's closed system and by attempting to define the scope of manufacturers' 340B obligations within Arkansas. *See* Opening Br. 28-30, 35. It then invades that closed system procedurally by creating its own scheme of oversight and enforcement to penalize manufacturers for not supplying the 340B price to contract pharmacies. *Id.* at 30-32, 35-36.

Appellees acknowledge there is at least *some* exclusively federal field surrounding 340B, so the primary question before the Court is the breadth of that field. In Appellees' view, that field is limited to 340B drug "pricing" and does not cover state laws that regulate the distribution of drugs sold at the 340B price. AID Br. 14; Intervenors Br. 37, 41, 45. But as PhRMA explained in its opening brief (at 27-42), the exclusive federal field is far broader. 340B is a closed system that is carefully balanced to achieve specific federal aims. State laws like Act 1103 that target and insert themselves into that closed system trespass on the federal field and thus are preempted, regardless of whether they are characterized as distribution or pricing rules.

1. The exclusive federal field sweeps broadly to maintain Congress's carefully balanced scheme and contains no carve-out for state 340B-specific distribution rules.

Appellees' principal argument is that the federal field concerns pricing, not distribution, and Act 1103 escapes field preemption because, rather than regulate drug pricing, it regulates the distribution of drugs sold at 340B-discounted prices. But Appellees' arguments focus on semantics rather than actual impact. *See Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 636 (2013) (explaining that "[p]re-emption is not a matter of semantics," but of "the statute's intended operation and effect").

340B's field cannot be sliced-and-diced in the way Appellees urge. As PhRMA explained in its opening brief, 340B was designed to help manage the federal fisc by enabling primarily "*Federally-funded clinics* to obtain lower prices on the drugs they provide to their patients" and "enabl[ing] these entities to stretch scarce *Federal resources* as far as possible" in order to help poor or uninsured patients. H.R. Rep. No. 102-384, pt. 2, at 7, 12 (1992) (emphasis added); *see also* 76 Fed. Reg. 29,183, 29,183 (May 20, 2011). But rather than provide the subsidy directly, Congress decided its costs would be borne by drug manufacturers as a condition of their participation in other federal programs—likely because simply requiring manufacturers to give away drugs at steep discounts would raise significant constitutional concerns. 42 U.S.C. § 1396r-8(a)(1), (5); *see infra* at 15-16 (discussing possible constitutional concerns were Arkansas to enact such a

scheme). Critical to the operation of this integrated scheme is ensuring manufacturers are not burdened to the point where they would need to leave 340B and thereby be forced to withdraw from participating in Medicaid and Medicare Part B. *Cf. Astra*, 563 U.S. at 118, 120; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001). That is why the Supreme Court held in *Astra* that 340B is a delicate balance, given that 340B and the Medicaid Drug Rebate Program are "'interdependent,'" and Congress intended 340B to operate "on a uniform, nationwide basis" with HHS "control[ling]" the "rein[s]" of the Program. 563 U.S. at 114, 120 (citation omitted).

Contrary to the thrust of Appellees' arguments, Congress did not leave any "gap" for States to fill regarding 340B drug "distribution." To begin, that claim is descriptively false. Congress explicitly spoke to distribution throughout the short statute, most prominently by dictating who is eligible to receive 340B-discounted drugs in the first place. *See* 42 U.S.C. § 256b(a)(1) (discount required only as to drugs "purchased by a covered entity"); *see also id.* (requiring manufacturers only to offer 340B-discounted drugs to covered entities); *id* § 256b(a)(9) (requiring Federal Government to notify manufacturers "of the identities of covered entities" that are no longer eligible to participate in 340B).

It spoke again on distribution by explaining that discounted drugs would flow to covered entities either from manufacturers (who "shall be responsible for the costs

of distribution") or through a "distribution" program of "prime vendors" HHS "shall establish." 42 U.S.C. § 256b(a)(8). And Congress *again* spoke to distribution when it explained how discounted drugs could be further distributed by covered entities: only to the covered entities' patients. *Id.* § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.").

Appellees' distinction between preempted "pricing" issues and non-preempted "distribution" also makes no sense in the context of this statutory scheme. Arkansas, after all, has not simply required manufacturers to provide *drugs*: it has required manufacturers to provide *340B-discounted drugs*. Where a statutory scheme requires that manufacturers sell drugs at a *particular price* to *particular entities*, the scope of distribution (*who is entitled to receive the discounted drugs*) and the price are inextricably intertwined. AID's hypothetical regarding the imposition of penalties (at 31-32) reinforces its folly in trying to separate the two concepts: There, the manufacturer delivers drugs to a contract pharmacy but simply charges its normal price rather than the 340B-discounted price. Yet AID correctly asserts a manufacturer would be subject to penalties under Act 1103. That is because Act 1103 is imposing a particular price on the sale. And no matter how creative AID gets in using regulatory definitions to redefine Act 1103's repeated references to

"pricing," Arkansas cannot escape the obvious effect of the Act and the obligations it imposes on manufacturers.

By purporting to dictate that entities not eligible under federal law must be granted access to the federal 340B discount, Arkansas is changing the fundamental cost-benefit balance struck by Congress.[1] The same is true even if Appellees' proposed distribution carve-out is viewed even more narrowly, as they sometimes describe it, as a "delivery" carve-out. Under Appellees' interpretation, Arkansas could apparently require manufacturers to hand deliver 340B-discounted drugs directly to patients in Arkansas at manufacturers' expense. That type of purported "delivery" requirement would dramatically increase the cost of 340B participation and fundamentally skew the incentive structure Congress established. And if Arkansas is free to require that, what would stop other States from coming up with even more creative delivery obligations, subjecting manufacturers to state-by-state

[1] Intervenors' argument (at 44) that the pharmaceutical pricing agreements ("PPAs") entered into between the Federal Government and manufacturers do not govern distribution channels or delivery location fails for a similar reason. As noted, the statute itself cannot be segmented between pricing and distribution. *See* App.185, R.Doc.24-1, Ex. 1-B § 1 (sample PPA providing that all terms in the agreement have the meaning set forth in the 340B statute). And the use of PPAs, which are exclusively federal in nature, reinforces (rather than detracts from) the broad and exclusive nature of the federal field here. *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).

variation in their 340B obligations?[2] That is certainly *a* way Congress could have designed 340B, but it is not the "uniform" "nationwide" Program the Supreme Court described in *Astra.*

2. Appellees' other attempts to escape field preemption fail.

AID (at 34-35) and Intervenors (at 47) attempt to distinguish *Astra* on the basis that it involved claims by covered entities and did not address preemption of state laws. But *Astra* is in all relevant respects materially indistinguishable from this case. Had *Astra* happened to involve state-law-based claims (as it initially did before the case was removed to federal court), the reasoning of the Supreme Court would have yielded the same result under preemption doctrine. *Astra* asked whether Congress intended to authorize a separate way for covered entities to enforce 340B's requirements outside the statutory enforcement process—specifically, a cause of action for covered entities to sue drug manufacturers as third-party beneficiaries to the PPAs. 563 U.S. at 117. The Court concluded that, given the detailed remedial scheme set forth in the statute, Congress clearly would not have also intended for third parties to the PPA to be able use the contract as a backdoor to address disputes about 340B obligations and sow dissonance in the system. *Id.* The inquiry here is

[2] Other States are currently considering legislation similar to Act 1103. *See, e.g.*, H.B. 548, 49th Leg., Reg. Sess. (La. 2023); S.B. 236, 2023 Leg. (Kan. 2023); H.B. 198, 102nd Gen. Assemb., 1st Reg. Sess. (Mo. 2023); S.B. 26, 102nd Gen. Assemb., 1st Reg. Sess. (Mo. 2023); H.B. 6669, File No. 453, 2023 Gen Assemb., Jan. Sess. (Conn. 2023).

fundamentally the same: Would Congress have intended for state regulators like AID to insert themselves into 340B to resolve disputes about obligations outside of the established remedial scheme? *See, e.g.*, *Arizona v. United States*, 567 U.S. 397, 399 (2012) (asking whether Congress intended to preclude States from enforcing additional regulations in the field). *Astra* provides the answer: No.

AID (at 43-44) and Intervenors (at 37-38) attempt to take refuge in the Third Circuit's recent decision in *Sanofi Aventis U.S., LLC v. United States Department of HHS*, noting that the court held the 340B statute is silent on the issue of whether "drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies." 58 F.4th 696, 707 (3d Cir. 2023). According to Appellees, "silence" equals "permission" for state legislation. But Appellees misunderstand that case, and the others like it, that *have rejected* HRSA's argument that the 340B statute compels manufacturers to deliver to all contract pharmacies of a covered entity's choosing. *Id.* at 703-04. The Third Circuit noted that, by definition, the statute cannot compel manufacturers to deal with contract pharmacies without limitation when the statute does not even mention contract pharmacies. *Id.* That "silence" does not mean, as Appellees contend, that Act 1103 is free to impose the obligation that Congress itself omitted from federal law. When Congress creates an exclusively federal field, the statute need not speak directly to a specific issue to have preemptive effect. *See Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306-

09 (1988) (recognizing that, while a federal statute did not provide a federal agency with the "explicit authority to regulate the issuance of securities of natural gas companies," the agency's extensive federal authority in the area precluded such state regulation); *see also NLRB v. Nash-Finch Co.*, 404 U.S. 138, 144 (1971).[3]

For example, in *Hines v. Davidowitz*, the Supreme Court held that a Pennsylvania statute, which required aliens to register with the Commonwealth and carry a registration card at all times, was preempted by a federal law that required federal registration but imposed no requirement that a card be carried. 312 U.S. 52, 59-60, 72-74 (1941); *see also Arizona*, 567 U.S. at 403 (recognizing *Hines* as a field preemption case). Although the federal statute did not speak directly on the issue of whether registrants should be required to carry a registration card, the Court nonetheless held that the state requirement was barred because the Federal Government had occupied the field in a "harmonious" fashion and had chosen, through silence on the issue, to impose no such requirement. *Hines*, 312 U.S. at 59-61, 72-74.

Similarly, in *Arizona*, the Supreme Court addressed whether a state authority could "enact[] a state criminal prohibition where no federal counterpart exists." 567

[3] Intervenors note (at 42) that HRSA has at times permitted use of contract pharmacies in its guidance. But the Third Circuit has already made clear that HRSA's view of 340B's requirements is flawed and contrary to law.

U.S. at 403. The Court concluded that provision was field preempted, even though the federal statute was silent on criminal penalties for the offense, because "[t]he correct instruction to draw from the text, structure, and history of [the federal statute] is that Congress decided it would be inappropriate to impose criminal penalties." *Id.*; *see also Puerto Rico Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988) ("Where a comprehensive federal scheme intentionally leaves a portion of the regulated field without controls, *then* the preemptive inference can be drawn—not from federal inaction alone, but from inaction joined with action."). The same is true here. The 340B statute may not directly reference contract pharmacies, but it does create a comprehensive and unitary federal regime that displaces state intrusion.

Intervenors assert (at 49-50) that Act 1103 simply enforces a preexisting federal obligation. But that flies in the face of multiple federal court decisions, including the Third Circuit's, holding that manufacturers are *not* required to provide 340B-discounted drugs to contract pharmacies without limitation—the very same requirement Act 1103 purports to impose here. *Sanofi Aventis*, 58 F.4th at 704; *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58-59 (D. Del. 2021); *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *5 (D.D.C. Nov. 5, 2021); *see supra* at 11. As the Third Circuit rightly noted, Congress

"had in mind one-to-one transactions between a covered entity and drug maker"—not "contract pharmacies." *Sanofi Aventis*, 58 F.4th at 704.[4]

It also does not matter, as Intervenors assert (at 32-33, 42, 45-46), that Act 1103 literally "does not transform contract pharmacies into covered entities." That misses the point. All parties agree that Congress has explicitly defined (in great detail) who qualifies as a covered entity eligible to receive 340B-discounted drugs, and contract pharmacies are not on that list. 42 U.S.C. § 256b(a)(4). That detail and precision, along with the other limitations, requirements, and mechanisms Congress created, are what set the broad federal field. PhRMA's point is not that Act 1103 literally makes a contract pharmacy into a covered entity, it is that Congress's careful delineation of who may receive discounted drugs and what they may do with them shows Congress did not intend for States to add additional actors into the closed

[4] Intervenors seem to suggest that the Third Circuit erred by failing to defer to HRSA's interpretation of the 340B statute. Not so. Intervenors incorrectly assert (at 49-50) that HHS has rulemaking authority because "Congress expressly authorized HHS to issue 340B Program regulations to address manufacturer overcharges to covered entities." But, as HHS itself recognized, HHS does not have general rulemaking authority. U.S. Br. 47, *Sanofi Aventis U.S., LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023) (No. 21-3167), ECF No. 32. Instead, its rulemaking authority as it relates to overcharges is limited to "regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section." 42 U.S.C. § 256b(a)(3)(A). That only applies to establishing the administrative dispute resolution *process*, not to substantive requirements for manufacturers and as such, the Third Circuit appropriately declined to apply *Chevron* deference to HHS's interpretation. *Sanofi Aventis*, 58 F.4th at 703.

system. *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.").

Finally, *Amici* take the remarkable position that even if Act 1103 directly regulates 340B drug pricing (thus triggering preemption under even Appellees' cramped view of the federal field), Act 1103 would remain valid because "Arkansas could have adopted substantively the same scheme" absent reference to 340B. Amici Br. 17. In other words, according to *Amici,* the Court can simply treat Act 1103 as a state law price control statute divorced from 340B. Tellingly, AID has not made that argument. AID Br. 20 (explicitly disclaiming that Act 1103 is a pricing statute). There is a reason why: Multiple federal courts have held that state drug pricing statutes are preempted by the Patent Act to the extent they regulate the price of patented drugs. *See Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007); *Se. Penn. Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015). Also, given that the upshot of any such regulation would be the transfer of private goods (discounted drugs) from one private entity (drug manufacturers) to another private entity (contract pharmacies) for the second private entity's benefit, any such scheme would run headlong into the Takings Clause of the Fifth Amendment. *See Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798). And even if Arkansas tried to condition the pricing obligation as part

of a permitting requirement, as *Amici* suggest, it would have a significant problem under the Dormant Commerce Clause. *See, e.g.*, *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935); *North Dakota v. Heydinger*, 825 F.3d 912, 921-22 (8th Cir. 2016).

The 340B statute does *not* require manufacturers to provide 340B-discounted drugs to contract pharmacies without condition, *Sanofi Aventis*, 58 F.4th at 707, and Arkansas may not wade into the federal field.

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

Even if 340B does not preempt the field, for similar reasons Act 1103 fails under obstacle preemption principles. As PhRMA explained in its opening brief (at 43-45), Act 1103 conflicts with the closed system that Congress established, which was designed to deliver a pricing benefit to a limited class of covered entities while also limiting the burden that pricing obligation imposes on manufacturers. Act 1103 impermissibly conflicts with that closed system by requiring manufacturers to provide 340B-discounted drugs to entities other than covered entities, so long as they have a "340B drug pricing contract pharmacy arrangement" with a covered entity. Ark. Code. Ann. § 23-92-604(c); *see Sanofi Aventis*, 58 F.4th at 704. Act 1103 fails to provide any limitations or guideposts with respect to the purported agreements between covered entities and contract pharmacies that would trigger a manufacturer's obligation to provide Arkansas pharmacies 340B-discounted drugs,

notwithstanding the federal prohibition on transfers of 340B-discounted drugs. Thus, Act 1103 forces manufacturers to provide discounted drugs in circumstances beyond those mandated by federal law, and in circumstances that might very well violate federal law. *See infra* at 21 n.7 (discussing how the replenishment model and contract pharmacy arrangements attempt to circumvent federal requirements).

Act 1103 also conflicts with Congress's chosen scheme of exclusive federal oversight. *See Astra*, 563 U.S. at 113; *see also Buckman*, 531 U.S. at 349-50 (where federal statute provided agency with a plethora of enforcement options, state-law tort claims would "inevitably conflict"). Congress provided very precise mechanisms within 340B for oversight, enforcement, and dispute resolution. Opening Br. 31-34. Notwithstanding that exclusive federal remedial scheme, Arkansas now seeks to introduce its Insurance Department as a separate adjudicator of 340B obligations and to enforce state-law requirements that go beyond the federal statute.

Appellees have no genuine answers to either conflict.

1. AID's promise to defer to federal law does not ameliorate the conflicts.

In an effort to dodge the conflicts created by Act 1103, AID asserts it will defer to federal law. For example, AID claims (at 33) that the Act's mandate is consistent with federal law because federal law will determine the validity of the

"340B 'drug pricing contract[s]'" needed to trigger an obligation under Act 1103.[5] But that is not what Act 1103 actually says. Act 1103 requires manufacturers to provide 340B-discounted drugs *whenever* there is a "340B drug pricing contract"—period. There is no reference to federal law, and even if there were, AID's argument does not make sense because contract pharmacies (much less "340B drug pricing contracts" with contract pharmacies) are not contemplated by federal law, as multiple federal courts have now confirmed.[6] *See supra* at 13-14.

But even assuming that federal law determines the validity of a "340B drug pricing contract"—and thus whether and in what circumstances Act 1103's pricing mandate applies—what would that mean for enforcement of Act 1103? AID originally proposed an exhaustion requirement that would have required a federal 340B administrative dispute resolution determination prior to enforcement of Act 1103, but later abandoned that proposal. *See* App.454, R.Doc.24-1, Ex. 1-K § VIII. Enforcement Policy; App. 462-63, R.Doc. 24-1, Ex.1-M at 1-2. Thus, AID seems

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[5] AID also says (at 29) it will "defer[] to HRSA and HHS about the current legality of whether contract pharmacies are or are not receiving diversions."

[6] To the extent AID seeks to rely on agency guidance rather than the federal statute itself, that also fails. While AID notes that HRSA has in the past approved the use of contract pharmacies, the Third Circuit has made clear that HRSA's prior positions on contract pharmacy use are contrary to the statute. *See supra* at 11. In any event, Act 1103 does not purport to incorporate the enumerated conditions that HRSA has said should be present in a contract between a covered entity and a pharmacy. *See* 61 Fed. Reg. 43,549, 43,555-56 (Aug. 23, 1996).

to be saying that it will itself adjudicate these issues of purported federal law (all the while disclaiming the ability to itself investigate those contracts, AID Br. 25). But that would usurp the Federal Government's authority because Congress authorized only HHS—not a state agency—to make "final" and "binding" decisions on the scope of obligations under 340B (subject to judicial review). 42 U.S.C. § 256b(d)(3)(B), (C). And should AID attempt to exercise concurrent authority with HHS over questions of federal 340B law, inconsistent results are inevitable—something the Supreme Court already made clear in *Astra* was unacceptable. 563 U.S. at 119.

The problems run deeper with Act 1103 than just the potential for conflict over what constitutes a genuine "340B 'drug pricing contract.'" Arkansas cannot, in fact, enforce Act 1103 without determining whether an entity is "authorized to participate in 340B drug pricing"—an issue determined exclusively by the federal 340B statute. *See* Ark. Code Ann. § 23-92-604(c); 42 U.S.C. § 256b(a)(4). And, critically, under federal law, the definition of a "covered entity" excludes any entity that fails to meet the statute's requirements for covered entity status. *See* 42 U.S.C. § 256b(a)(4) ("'[C]overed entity' means an entity that meets the requirements described in paragraph (5) . . . ."). This includes compliance with the statute's anti-transfer provision, compliance with the provision allowing manufacturers to audit the entity's records, and compliance with the prohibition on seeking duplicate

rebates. *See id.* § 256b(a)(5)(A), (B), (C). In other words, a so-called "covered entity" is not actually a covered entity—and thus is not "authorized" to participate in the 340B Program—if it has violated these important statutory commands. In any enforcement action brought by AID, AID will be required to assess the purported covered entity's compliance with these provisions to determine whether or not Act 1103 even applies. Because Act 1103 as implemented contains no deference to federal authorities' decisions or a requirement to utilize the federal enforcement scheme, it is difficult to see how AID could enforce Act 1103 without also addressing contested and potentially sensitive issues of federal law on which federal authorities might well disagree.

Arkansas is on a collision course with the Federal Government and Congress's exclusive federal remedial scheme.

2. Appellees' other arguments fail to address the conflicts.

Appellees' other rebuttal points are similarly unavailing.

AID first argues (at 28-30) that Act 1103 poses no conflict with 340B's closed system because transfers to contract pharmacies are not barred by the 340B statute's anti-transfer provision. The anti-transfer provision provides that "a covered entity shall not resell or *otherwise transfer* the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). No Appellee grapples with the language of that provision. As Intervenors point out (at 42), Act 1103 does not

turn a "contract pharmac[y]" into a "covered entit[y]," and a "contract pharmacy" is also not a "patient." But for present purposes it suffices to observe that a state law that orders a 340B drug to be sent to someone other than a "covered entity" or "patient" is, at a minimum, in deep tension with Congress's statutory design. *See Mainstream Mktg. Servs., Inc. v. FTC*, 284 F. Supp. 2d 1266, 1277 (D. Colo. 2003) (recognizing "substantial body of case law to the effect that a person enjoined cannot do indirectly through another what it is prohibited from doing directly"); *see also City of Eugene v. FCC*, 998 F.3d 701, 711 (6th Cir. 2021) (regulated entities "[may] not "end-run" [an] [a]ct's limitations by using other . . . entities or other sources of authority to accomplish indirectly what [they] are prohibited from doing directly" (first alteration in original) (citation omitted)).

And while AID attempts to skirt responsibility for what a contract pharmacy might do with the discounted drug after receiving it pursuant to Act 1103's mandate by claiming that the pharmacy would itself be subject to enforcement by the Federal Government for violating the federal anti-transfer provision, AID conveniently ignores that none of the federal remedial and enforcement schemes Congress included in the statute address contract pharmacies—again, because contract pharmacies are not contemplated by the federal statute at all.[7]

[7] Covered entities and contract pharmacies attempt to avoid the plain language of the anti-transfer provision, in a variety of ways, including by claiming that the

Intervenors (at 20) and *Amici* (at 4-6) argue that contract pharmacies are particularly important in Arkansas due to a separate state law that bars some covered entities from operating their own in-house retail pharmacies. But as the Arkansas Attorney General has observed, that state prohibition appears to be protectionist legislation aimed at furthering the financial interests of Arkansas's commercial-pharmacy industry by eliminating "anticompetitive retail sales of drugs purchased at discount by nonprofit hospitals." Ark. Op. Att'y Gen. No. 2003-353 at 3 (Jan. 20, 2004), https://ag-opinions.s3.amazonaws.com/uploads/2003-353.pdf (citing *Arkansas Hosp. Ass'n v. Arkansas State Bd. of Pharm.*, 763 S.W.2d 73 (Ark. 1989)). Arkansas's decision to limit indirectly some covered entities' participation in 340B

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pharmacies are operating as "agents" of covered entities and that the covered entities retain "title" to the drugs held at contract pharmacies. *See* AID Br. 28-30; Intervenors Br. 42-43, 49; Amici Br. 22. If the contract pharmacy never holds title, or is simply an agent of the covered entity, they argue, covered entities have not "transferred" the drugs to the contract pharmacy. But it does not make sense as a legal matter that a covered entity would retain title to a drug that, pursuant to the replenishment model, is being added to a contract pharmacy's general inventory to be dispensed to any patient that walks in the door. App.318-19, R.Doc.24-1, Ex. 1-E ¶¶ 10-11. Unsurprisingly then, a dispute between an Arkansas covered entity and contract pharmacy has recently made public an agreement showing that, there, the contract pharmacy was operating as an "independent contractor" with respect to the covered entity—not an agent—and that the pharmacy did in fact take title to 340B drugs. Complaint Ex. 1 § 12, *Jefferson Hosp. Ass'n v. Whitehall Pharm. LLC*, No. 35cv-23-357 (Ark. Cir. Ct. May 5, 2023) (noting that the parties were in an "independent contractor[]" relationship); *id.* § 4(a)(3) (but also noting that the "[*p*]*harmacy* shall be deemed to own the replenished 340B Drugs" (emphasis added)).

for the benefit of its commercial-pharmacy industry may raise interesting preemption questions of its own, but provides no justification for distorting manufacturers' obligations under 340B through Act 1103.[8]

Nor do Appellees have any real answers for the differences between the federal and state enforcement schemes. As PhRMA explained (at 43) in its opening brief, Congress carefully circumscribed when penalties could be imposed and the amounts of those penalties to avoid over deterring program participation. Yet Act 1103 disrupts that calibration by omitting any scienter requirement and imposing its own penalty amounts. Ark. Code Ann. §§ 23-66-210, -211. The divergent scienter requirements, which AID does not address in its response, mean that manufacturers could be penalized for less culpable conduct under Act 1103 compared to the federal scheme. And its only answer (at 32) with respect to the fact its penalties are approximately double that of the federal regime is that it imposes a penalty in the same amount on other entities and that pharmaceutical companies have "assets and capital" to pay the increased penalty. AID does not grapple with the fact that the amount of its penalty is approximately double that permitted under the federal scheme. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 379-80

[8] Arkansas law expressly permits all hospitals to obtain a permit for the operation of a *non*-retail pharmacy for dispensing drugs to patients who are being discharged. *See* Ark. Code Ann. § 17-92-605(d).

(2000) ("The fact of a common end hardly neutralizes conflicting means" when the "state Act" is "at odds with achievement of the federal decision about the right degree of pressure to employ.").

For their part, Intervenors appear to argue that additional enforcement mechanisms are not preempted because the federal system and Act 1103 are pursuing the same objective. But the Supreme Court has made clear "conflicts are not rendered irrelevant by the State's argument that there is no real conflict between the statutes because they share the same goals." *Id.* at 379. *Amici*'s argument (at 19-20) that the remedies are "complementary" fails for a similar reason. *Arizona*, 567 U.S. at 406 (recognizing "that a '[c]onflict in technique'"—such as a conflict in the method of enforcement—"can be fully as disruptive to the system Congress erected as conflict in overt policy" (alteration in original) (citation omitted)); *see also Wis. Dep't of Indus., Labor, & Human Relations v. Gould Inc.*, 475 U.S. 282, 286 (1986). Unlike in the cases cited by *Amici* (*Medtronic, Inc v. Lohr*, 518 U.S. 470 (1996); *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973)), here Congress is vested with authority to maintain a program that requires delicate balancing, including of the correct level "of pressure to employ." *Cf. Buckman*, 531 U.S. at 343, 349-50.[9] That was absent in both *Medtronic* (no carefully drawn federal

[9] AID attempts (at 35-36) to distinguish *Buckman* on the basis that here, unlike in *Buckman*, Act 1103 will not increase burdens on the Federal Government. That

scheme that required balancing) and *Dublino* (involved a program that States and the Federal Government co-administered). *Medtronic*, 518 U.S. at 487-97; *Dublino*, 413 U.S. at 413 (describing program at issue there "as a scheme of cooperative federalism" (citation omitted)).

Finally, *Amici*, for their part, make an argument, not advanced by either AID or Intervenors, that there is no need to address conflict preemption until there is an "*actual* conflict." Amici Br. 20-21 (citing *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982), and *Granite Re, Inc. v. Nat'l Credit Union Admin. Bd.*, 956 F.3d 1041, 1048 (8th Cir. 2020)). But neither case supports *Amici*'s position. Here, conflict is inevitable (not merely hypothetical) because, as Appellees have no answer for, Act 1103 expressly mandates inclusion of an outside actor (contract pharmacies) into 340B's closed system and the state and federal scienter requirements and penalty amounts conflict on their face. *See supra* at 16-17 (explaining how Act 1103 conflicts with the closed system); *supra* at 17 (discussing Act 1103's imposition of a conflicting enforcement scheme). Where conflict is inevitable, not hypothetical, review is appropriate now. *See Rice*, 458 U.S. at 660 (explaining that a conflict arises when a state statute authorizes conduct that would necessarily conflict with

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misses the mark: The point was not regulatory burden, but that state laws would upend Congress's detailed enforcement scheme, which was designed to ensure that the Federal Government could maintain an appropriate balance. The same is true here.

federal law); *Granite*, 956 F.3d at 1048 (noting that conflict was merely potential where state statute recovery *could* exceed federal but was not guaranteed to do so like in this case).

Act 1103 seeks to impose a requirement that the Third Circuit has held even the Federal Government cannot levy on manufacturers—that manufacturers must provide 340B-discounted drugs to all contract pharmacies in Arkansas. *See Sanofi Aventis*, 58 F.4th at 704. It also upsets the careful balance struck by Congress in 340B's exclusive remedial scheme. Act 1103 is accordingly conflict preempted.

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

Act 1103 also directly conflicts with federal law governing the distribution of certain drugs—most relevantly, the FDCA's REMS provision. *See* 21 U.S.C. § 355-1. AID essentially admits as much: It explains that "[u]nder Act 1103, a drug manufacturer *must deliver* 340B drugs to contract pharmacies for covered entities." AID Br. 42 (emphasis added). It then explains that "there may exist other federal or state laws, such as FDA restrictions, which may *impinge upon such distributions*." *Id.* (emphasis added). It is difficult to see how AID can interpret those statements as anything other than textbook impossibility preemption: state law requires one thing ("a drug manufacturer must deliver 340B drugs") that federal law ("FDA restrictions," or the FDCA's REMS provision administered by FDA) simultaneously prohibits ("impinge upon such distributions"). *See PLIVA, Inc. v. Mensing*, 564 U.S.

604, 617-18 (2011) (finding impossibility preemption where "[i]t was not lawful under federal law for the Manufacturers to do what state law required of them"). As the Third Circuit recognized, mandating that manufacturers ship drugs to contract pharmacies would "put drug makers in a legal bind" as it would be incompatible with their REMS restrictions. *Sanofi Aventis*, 58 F.4th at 705. Arkansas has brought the Third Circuit's concern to life in Act 1103.

It does not matter, as both AID (at 41) and Intervenors (at 56) point out, that the REMS provisions have no express preemption provision. Impossibility and express preemption are analytically distinct: "Even in the absence of an express pre-emption provision, . . . [a] state law [is] impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).

That is the case here. Although both AID (at 40-42) and Intervenors (at 54-58) argue that federal and state law can coexist, neither party grapples with the actual language of Act 1103. Under Ark. Code Ann. § 23-92-604(c)(1), a manufacturer cannot "prohibit a pharmacy from contracting or participating with" a covered entity "in 340B drug pricing by denying access to drugs." Ark. Code Ann. § 23-92-604(c)(1). In other words, a manufacturer cannot "deny" *any* "pharmacy" from receiving 340B-discounted drugs as long as they have "contract[ed] . . . with" a

covered entity. So too with Ark. Code Ann. § 23-92-604(c)(2): under that provision, a manufacturer cannot "[d]eny or prohibit 340B drug pricing" to an Arkansas pharmacy "that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with" a covered entity. *Id.* § 23-92-604(c)(2). The plain language of both provisions prevents drug manufacturers from denying any 340B-discounted drug to an Arkansas-based pharmacy, provided that pharmacy contracts with a covered entity to receive the discounted drug.

As AID admits, there is no exception in the statute to these requirements for drugs subject to federal distribution restrictions, like those under the FDCA's REMS program. AID Br. 41 (Act 1103 "does not specifically and expressly carve out any FDCA controlled drug safety provisions.").[10] So AID and Intervenors instead argue that such an exception should be implied. But federal courts cannot add language to an Arkansas statute to preserve its constitutionality. *See Willson v. City of Bel-Nor*, 924 F.3d 995, 1004 (8th Cir. 2019); *McMillan v. Live Nation Ent., Inc.*, 401 S.W.3d 473, 476 (Ark. 2012).

[10] *Amici* (at 26-27) try to address the text, arguing that because Act 1103 does not authorize or require contract pharmacies to dispense drugs, Act 1103 does not compel the violation of REMS requirements. But that argument ignores the fact that manufacturers violate their REMS obligations upon delivery to a pharmacy, whether or not that pharmacy eventually dispenses the drug. *See, e.g.*, App.465, 469, R.Doc.24-1, Ex. 1-N at 1, 5 (Jynarque®'s manufacturer "must ensure that . . . wholesale-distributors . . . [d]istribute only to certified pharmacies.").

That remains true notwithstanding Intervenors' claim (at 54-55) that it would "result in absurd consequences not intended by AID or the General Assembly" to read Act 1103 according to its plain terms.[11] The essence of Intervenors' arguments is that because the Arkansas Legislature could not possibly have intended to pass a law that was preempted by the FDCA, the Court must distort Act 1103 to save it from preemption. But States pass preempted laws all the time. Extending the absurdity canon as Intervenors suggest would license federal courts to take the pen in every case where a state law is preempted, no matter how clearly the state legislature has spoken. *Cf. Willson*, 924 F.3d at 1004. That is not the role of the federal courts in our federalist system.[12]

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[11] Intervenors suggest (at 55) that if Act 1103 is read literally, it may violate a host of other federal drug safety laws. PhRMA does not disagree. But the state statute says what it says, and Arkansas knows how to write exceptions for federal law into its laws when it wants to do so. *See, e.g.*, Ark. Code Ann. § 20-76-115 ("Unless required by federal law . . . ."); *id.* § 20-3-109(c)(1) ("Unless prohibited by federal law . . . ."); *id.* § 9-27-341(b)(3)(B)(v)(b) ("unless required by federal law or federal regulations"). Whatever defects Act 1103 may have do not justify reading Act 1103 atextually here.

[12] Intervenors (at 55-56) and *Amici* (at 25-26) argue that, practically speaking, contract pharmacies are unlikely to acquire drugs they cannot legally dispense. But that is cold comfort for manufacturers, who are the ones at risk of significant federal penalties. *See* 21 U.S.C. § 333(f)(4) (holding the "responsible person," that is, the drug manufacturer, responsible for violations of the REMS statute); *id.* § 352(y) (explaining that a drug is "misbranded" and therefore in violation of the law if the "responsible person" fails to comply with a REMS requirement under 21 U.S.C. § 355-1(f), for example, by failing to ensure that only specially certified pharmacies dispense the drugs).

Finally, Intervenors—but, tellingly, not AID—ask the Court to "defer" to AID's statement to the district court that Act 1103 is not "'a means to circumvent, or avoid . . . separate FDCA laws limiting the transfer of the drugs themselves.'" Intervenors Br. 57 (citation omitted). There is a reason AID is not invoking any kind of deference: three years ago, the Arkansas Supreme Court explained that courts are to give *no* deference to even authoritative agency interpretations of Arkansas statutes. *Myers v. Yamato Kogyo Co.*, 597 S.W.3d 613, 617 (Ark. 2020).

Act 1103 requires manufacturers to do what federal law prohibits. The district court should have found Act 1103 preempted as applied to drugs subject to federal REMS distribution limitations.

III. ACT 1103 IS NOT ENTITLED TO A PRESUMPTION AGAINST PREEMPTION

Both AID (at 37-40) and Intervenors (at 29-30) ask this Court to apply a presumption against preemption to save Act 1103. But no presumption should apply here.[13] Some courts apply a presumption against preemption in cases where the state law acts "in a field" of "traditional[]" state regulation, but only if the law does not also implicate an area of "unique federal concern." *Boyle v. United Techs. Corp.*, 487 U.S. 500, 507-08 (1988); *United States v. Alabama*, 691 F.3d 1269, 1295-96 (11th Cir. 2012) (because a state law addressing "matter[s] of traditional state

[13] The presumption's validity and origins are questionable at best. *See, e.g.*, *Bell v. Blue Cross & Blue Shield of Okla.*, 823 F.3d 1198, 1201 (8th Cir. 2016).

concern . . . impinge[d] on an area of core federal concern," it was entitled to no presumption against preemption). Act 1103 is not entitled to a presumption under either prong of the test.

As explained in detail above, *see supra* at 4-5, 340B is a uniquely federal program that was designed to stretch scarce federal resources by providing a special drug price subsidy to certain, specifically enumerated healthcare providers for eligible patients through private funding. Act 1103 admits by its express terms that its object is 340B. Ark. Code Ann. §§ 23-92-601, -602(5), -604(c). Said another way, Act 1103 would mean nothing without 340B. By acting directly in this area of unique federal concern, Act 1103 removes itself from the ambit of the presumption against preemption. *See Boyle*, 487 U.S. at 507-08; *Alabama*, 691 F.3d at 1295-96.

But even if Act 1103 did not implicate a "unique federal concern," it would still not qualify for the presumption because it also does not implicate a "field of traditional state regulation." AID (at 37-39) claims that Act 1103 operates in the traditional state fields of medicine and "pharmacy." While it is certainly true that States have traditionally had a prominent role in the training and licensure of medical professionals, Act 1103 on its face is not that kind of occupational licensing regulation. This is clear because it imposes its obligations not on doctors or pharmacists, but on out-of-state *manufacturers*.

None of the cases cited by Intervenors (at 29-30) demonstrate that Act 1103 acts in a field of traditional state regulation, or that it does not implicate an area of "unique federal concern." Most of those cases involve the interaction of state tort-law claims—which do not have as their object a federal program—and federal laws regarding product labeling. *See Wyeth v. Levine*, 555 U.S. 555, 568-73 (2009) (failure to warn); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 941-42 (8th Cir. 2011) (breach of implied warranty); *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Pracs. Litig.*, 621 F.3d 781, 798-99 (8th Cir. 2010) (consumer protection). And in their final case, *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714-16 (1985), FDA had already disclaimed that its regulations preempted state and local laws, which has not happened here.

Because Act 1103 acts directly on 340B, Act 1103 is entitled to no presumption against preemption.

CONCLUSION

The district court's summary judgment ruling should be reversed, and summary judgment should instead be granted in PhRMA's favor.

Dated: May 15, 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 Reply Brief of Appellant complies with the type-volume limitations of this Court's order dated April 18, 2023 because the brief contains 7,940 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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 365 in 14-point Times New Roman font.

Pursuant to Eighth Circuit Rule 28A(h), I further certify that the Reply Brief of Appellant has 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 has been scanned for viruses using a commercial virus scanning program, which reports the brief to be virus free.

s/ *Philip J. Perry*
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Dated: May 15, 2023

CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2023, pursuant to Fed. R. App. P. 25(a)(2)(A)(ii), I caused the foregoing Reply Brief of Appellant 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 the Reply Brief of Appellant 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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