No. 22-3675

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellant,

v.

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

Defendant-Appellee,

COMMUNITY HEALTH CENTERS OF ARKANSAS *and* PIGGOTT COMMUNITY HOSPITAL,

Intervenors-Appellees.

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

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

BRIEF OF AMERICAN HOSPITAL ASSOCIATION, ARKANSAS HOSPITAL ASSOCIATION, AND 340B HEALTH AS *AMICI CURIAE* IN SUPPORT OF APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(a)(4)(A), *Amici Curiae* American Hospital Association, Arkansas Hospital Association, and 340B Health state that they are not-for-profit organizations. None of the *Amici* has a parent company, and no publicly held company holds more than a ten percent interest in any of the *Amici*.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

INTERESTS OF *AMICI CURIAE* 1

INTRODUCTION 3

ARGUMENT 8

I. Act 1103 Is Not Field Preempted. 9

A. Congress Did Not Create or Occupy a Field When It Enacted the 340B Program. 9

B. Act 1103 Does Not Intrude into PhRMA's Purported 340B "Field." 14

II. Act 1103 does Not Conflict with the 340B Program. 18

III. Act 1103 Does Not Conflict with the FDCA. 25

CONCLUSION 28

TABLE OF AUTHORITIES

CASES

Abbott Labs. v. Portland Retail Druggist Ass'n, Inc.,
425 U.S. 1 (1976) 22

Am. Hosp. Ass'n v. Azar,
967 F.3d 818 (D.C. Cir. 2020) 24

Am. Hosp. Ass'n v. Becerra,
142 S. Ct. 1896 (2022) 6, 24

Arizona v. United States,
567 U.S. 387 (2012) 18

Astra USA, Inc. v. Santa Clara County,
563 U.S. 110 (2011) 11, 12, 13

Chamber of Com. of U.S. v. Whiting,
563 U.S. 582 (2011) 18

Crosby v. Nat'l Foreign Trade Council,
530 U.S. 363 (2000) 24

CTS Corp. v. Dynamics Corp. of Am.,
481 U.S. 69 (1987). 24

Eli Lilly & Co. v. HHS,
No. 1:21-cv-00081-SEB-MJD,
2021 WL 5039566 (S.D. Ind. Oct. 29, 2021).....23

English v. Gen. Elec. Co.,
496 U.S. 72 (1990) 9, 10-11, 12, 14

Granite Re, Inc. v. Nat'l Credit Union Admin. Bd.,
956 F.3d 1041 (8th Cir. 2020).....20-21

Harris v. Great Dane Trailers, Inc.,
234 F.3d 398 (8th Cir. 2000)..... 12, 20

Hillsborough Cnty. v. Automated Med. Labs., Inc.,
471 U.S. 707 (1985) 11, 13, 17, 18

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996) 8, 9, 13, 20

Mo. Bd. of Examiners for Hearing Instrument Specialists v. Hearing Help Express, Inc.,
447 F.3d 1033 (8th Cir. 2006) 24-25

Murphy v. NCAA,
138 S. Ct. 1461 (2018) 9

N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,
514 U.S. 645 (1995) 8

N.Y. State Dep't of Soc. Servs. v. Dublino,
413 U.S. 405 (1973) 9, 10, 20

Nordgren v. Burlington N. R.R. Co.,
101 F.3d 1246 (8th Cir. 1996) 14

O'Melveny & Myers v. FDIC,
512 U.S. 79 (1994) 14

Parten v. Consol. Freightways Corp. of Del.,
923 F.2d 580 (8th Cir. 1991) 9, 20

Pharm. Care Mgmt. Ass'n v. Wehbi,
18 F.4th 956 (8th Cir. 2021) 8

R.J. Reynolds Tobacco Co. v. City of Edina,
60 F.4th 1170 (8th Cir. 2023) 8

Rice v. Norman Williams Co.,
458 U.S. 654 (1982) 20

Sanofi Aventis U.S. LLC v. HHS,
58 F.4th 696 (3d Cir. 2023) 22

Wuebker v. Wilbur-Ellis Co.,
418 F.3d 883 (8th Cir. 2005) 8, 16

Wyeth v. Levine,
555 U.S. 555(2009) 8

STATUTES

42 U.S.C. § 256b 15

Ark. Code Ann. § 17-92-607 4

Ark. Code Ann. § 23-92-604 ..... 6, 25, 26

Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (2010). 15

OTHER AUTHORITIES

340B Health, *Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients* 28

340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 4

340B Informed, *Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021* (updated Jan. 13, 2023) 3

Am. Hosp. Ass'n, *Setting the Record Straight on 340B: Fact vs. Fiction* (Mar. 2021) 5, 6

Apexus, *340B Split-Billing Software Key Attributes* (Jan. 17, 2023) 22

Allen Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* (July 10, 2020) 5, 6

Dale Ellis, *Arkansas Insurance Department hears opposition to state drug pricing rules*, Arkansas Democrat-Gazette (Apr. 15, 2022) 7

Food & Drug Admin., *Roles of Different Participants in REMS* 28

Maya Goldman, *Hospital groups worry as more drugmakers limit 340B discounts*, Modern Healthcare (Mar. 25, 2022) 3

Health Res. & Servs. Admin., *340B Drug Pricing Program* (Mar. 2023) 24

Health Res. & Servs. Admin., *Program Integrity: FY19 Audit Results* 23

Health Res. & Servs. Admin., *Program Integrity: FY20 Audit Results* 23

Health Res. & Servs. Admin., *Program Integrity: FY21 Audit Results* 23

Health Res. & Servs. Admin., *Program Integrity: FY22 Audit Results* 23

H.R. Rep. No. 102-384(II) (1992) 7, 24

L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* (Mar. 12, 2018) 6

Letter from Markus H. Meier, Assistant Dir., Fed. Trade Comm'n, to Kathleen A. Reed (Apr. 9, 2010) 22

Specialty Drug Coverage and Reimbursement in Medicaid, HHS Office of Inspector Gen.....27

REGULATIONS

Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) 12, 15

Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010) 15, 27

INTERESTS OF *AMICI CURIAE*[1]

Amici are three hospital associations whose members receive 340B discounts for drugs dispensed through contract pharmacies. *Amici* and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care, and the 340B program is essential to achieving this goal. *Amici* therefore have a strong interest in the success and viability of Arkansas' legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. The AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are considered in formulating health policy. One way in which the AHA promotes the interests of its members is by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

[1] Appellant and Appellees consent to the filing of this brief. Undersigned counsel for *amici curiae* certify that this brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for the brief; and no one other than *Amici* and their counsel contributed money for this brief.

The **Arkansas Hospital Association** has worked for the betterment of Arkansas hospitals for more than 90 years. It represents more than 100 Arkansas hospitals, including many that participate in the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate on behalf of 340B hospitals, which are a vital part of the nation's healthcare safety net. 340B Health represents more than 1,400 public and private nonprofit hospitals and health systems that participate in the 340B program.

INTRODUCTION

Three years ago, in the midst of a devastating pandemic, drug companies broke with decades of precedent and adopted a plan to undermine the 340B program. Previously, Appellant Pharmaceutical Research and Manufacturers of America's (PhRMA's) members had provided drug pricing discounts to eligible hospitals no matter where their drugs were dispensed, whether through in-house or contract pharmacies. But in July 2020, one of PhRMA's members suddenly refused to provide 340B discounts for one of its drugs if dispensed to patients at contract pharmacies, later expanding its policy to cover essentially all of its drugs.[2] Recognizing an opportunity to pad their profits, 20 other major drug companies soon followed suit.[3]

While drug companies have watched their profits grow, the contract pharmacy arrangements PhRMA's members honored for almost 30 years have helped sustain 340B providers and their patients. Today, a quarter of hospitals' 340B benefit comes

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[2] *See, e.g.*, Maya Goldman, *Hospital groups worry as more drugmakers limit 340B discounts*, Modern Healthcare (Mar. 25, 2022), https://www.modernhealthcare.com/safety-net-hospitals/hospitals-worry-more-drugmakers-limit-340b-discounts.

[3] Collectively, 19 of these companies made more than $660 billion in profits in 2021, the year the Arkansas Legislature enacted the statute at issue in this case. *See* 340B Informed, *Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021* (updated Jan. 13, 2023), https://340binformed.org/2023/01/updated-drugmakers-cutting-340b-discounts-reported-record-revenues-in-2021/.

from drugs dispensed through contract pharmacies.[4] In Arkansas, *more than three-quarters* of some hospitals' 340B benefit comes from drugs dispensed using contract pharmacies.[5]

Contract pharmacy arrangements are particularly important in Arkansas because state law bars virtually all hospitals from having their own in-house pharmacy. *See* Ark. Code Ann. § 17-92-607. Dispensing drugs at contract pharmacies allows Arkansas's 340B providers to meet their patients where they are, rather than forcing them to travel long and costly distances to pick up prescriptions.[6] Patients further benefit from contract pharmacy arrangements either by having to

[4] 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

[5] For example, more than 90 percent of Ozarks Community Hospital of Gravette's and Dallas County Medical Center's 340B benefit comes from drugs sold at contract pharmacies, while 78 percent of Lawrence Memorial Hospital's 340B benefit is made possible through its contract pharmacy arrangements.

[6] Because covered entities often serve rural communities, their patients may live more than 100 miles from the provider. This is true, for example, for 340B providers like St. Bernards Medical Center in Jonesboro, Arkansas, and Jefferson Regional Medical Center in Pine Bluff, Arkansas.

pay less for their medicine (many Arkansas hospitals pass the 340B discount directly to patients[7]) or by the increased services the 340B benefit makes possible.[8]

In stark contrast to PhRMA's members, the principal targets of their contract pharmacy restrictions—340B hospitals—often operate with substantially lower operating margins than those of non-340B hospitals—and in fact, often *negative* operating margins.[9] Some Arkansas hospitals, such as Ozarks Community Hospital of Gravette and St. Bernards CrossRidge Community Hospital, report that drug manufacturers' refusal to provide 340B discounts on drugs dispensed through contract pharmacies threatens their ability to keep their doors open.

The reason why 340B hospitals struggle financially is not surprising: these hospitals provide a disproportionate amount of uncompensated care, community

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[7] This includes, for example, Ozarks Community Hospital, Jefferson Regional Medical Center, and Arkansas Children's Hospital.

[8] For instance, Baxter Regional Medical Center in Mountain Home, Arkansas recently used the 340B benefit it received from drugs dispensed via contract pharmacies to hire an infectious disease physician and to expand care to patients with hepatitis C. Without the 340B benefit it derives from contract pharmacy arrangements, St. Bernards Medical Center in Jonesboro, Arkansas would have to discontinue some combination of its medical oncology, radiation oncology, or neurosurgery services, despite being the only provider offering head coverage, heart surgery, neonatal intensive care, and mental health crisis stabilization services to residents of Northeast Arkansas and Southeast Missouri.

[9] *See* AHA, *Setting the Record Straight on 340B: Fact vs. Fiction* 2 (Mar. 2021), https://www.aha.org/system/files/2018-02/340BFactvsFiction.pdf; Allen Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 12-13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

health services, and other specialized services to America's most vulnerable patients.[10] Savings from the 340B program help to offset the cost of providing uncompensated health care services to underserved populations. As the Supreme Court recently affirmed, "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, 1905-06 (2022).

Faced with the drug industry's unprecedented assault on Arkansas's health care safety net, the General Assembly acted. In 2021, a bipartisan majority enacted Act 1103, the "340B Drug Pricing Nondiscrimination Act," which prohibits drug companies from denying Arkansas hospitals the same 340B discounts for drugs dispensed at community pharmacies as would be provided if the drugs were dispensed at an in-house pharmacy. Ark. Code Ann. § 23-92-604(c). Stating that the tactics being used against independent pharmacies "are as much like a mafia shakedown as you'll find," one sponsor explained that the law was "an attempt to

[10] *See* L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf; AHA, *supra* note 9, at 2; Dobson et al., *supra* note 9, at 13-17.

stave off . . . unfair trade practices that are squeezing independent contract pharmacies out of the 340B program."[11]

PhRMA quickly challenged Arkansas's exercise of its historic power to protect public health and safety. That challenge should be rejected, just as it was in the district court. PhRMA cannot demonstrate that Congress intended to create (and occupy) any field through its 340B legislation. Likewise, although PhRMA's conflict preemption arguments largely recycle its erroneous field preemption contentions, Act 1103 does not conflict with federal law. Rather, Act 1103 furthers Congress's goal in enacting the 340B program: to enable hospitals to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). The fact that Act 1103 incorporates the 340B statute's definition of entities eligible for these discounts, or that it uses the federally dictated 340B price as a reference point, does not displace Arkansas's traditional state authority to regulate pharmaceutical sales at Arkansas pharmacies. There is also no conflict with the Federal Food, Drug, and Cosmetic Act's (FDCA's) provisions limiting which pharmacies may sell certain drugs.

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[11] Dale Ellis, *Arkansas Insurance Department hears opposition to state drug pricing rules*, Arkansas Democrat-Gazette (Apr. 15, 2022), https://www.arkansasonline.com/news/2022/apr/15/arkansas-insurance-department-hears-opposition-to/ (statement of State Senator Jason Rapert).

Put simply, Act 1103 does not interfere with or intrude upon Congress's scheme—"it operates within it." *R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170, 1178 (8th Cir. 2023). It therefore is not preempted.

ARGUMENT

"Congressional intent is the touchstone for determining the preemptive effect of a statute." *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 886 (8th Cir. 2005). "In all pre-emption cases, and particularly in those in which Congress has 'legislated in a field which the States have traditionally occupied,' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (ellipsis and citations omitted). PhRMA has the burden of showing that Congress intended to preempt Act 1103. *See R.J. Reynolds*, 60 F.4th at 1175.

PhRMA does not argue that Act 1103 is expressly preempted. Nor does it deny that "[s]tate governments historically possess police power to protect public health," *id.* at 1176, including the regulation of healthcare,[12] "the practice of pharmacy,"[13] and the regulation of drugs.[14] Thus, Act 1103 is presumptively *not*

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

[13] *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021).

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

preempted, and PhRMA fails to demonstrate Congress's "clear and manifest purpose" to supersede Arkansas's authority to regulate in the public health arena. *Medtronic*, 518 U.S. at 485 (citation omitted).

I. ACT 1103 IS NOT FIELD PREEMPTED.

A. Congress Did Not Create or Occupy a Field When It Enacted the 340B Program.

"Field preemption occurs when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. NCAA*, 138 S. Ct. 1461, 1480 (2018) (citation omitted). However, as the Supreme Court has explained, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has expressly rejected "the contention that pre-emption is to be inferred merely from the comprehensive character" of federal provisions. *Id.*; *see also English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990) ("Ordinarily, the mere existence of a federal regulatory or enforcement scheme, even one as detailed as § 210 [of the Energy Restoration Act of 1974], does not by itself imply pre-emption of state remedies."); *Parten v. Consol. Freightways Corp. of Del.*, 923 F.2d 580, 582 (8th Cir. 1991) (similar). With the 340B program, just as with the federal program at issue in *Dublino*, "a detailed statutory scheme

was both likely and appropriate, completely apart from any questions of pre-emptive intent." 413 U.S. at 415.

To support its contention that Congress intended to occupy a field with the 340B program, PhRMA relies exclusively on the "comprehensive" character of the federal scheme and the "dominant federal interest" in maintaining the program. *See* Opening Br. PhRMA (App. Br.), Doc. 5248308, at 27, 28-29. But PhRMA cites no authority—from the statute, governing regulations, or legislative history—for its assertions about Congress' *intent* to create or occupy this purported 340B "field." Instead, PhRMA relies on a recitation of the 340B program's statutory components as proof of Congress's intent. Specifically, PhRMA lists the 340B program's "carefully enumerat[ed] . . . intended beneficiaries," *id.* at 29; its limitations on "further distribution of drugs purchased at the 340B price," *id.* at 30; and its "multi-faceted administrative enforcement scheme," *id.*

But the fact that Congress limited which hospitals and health systems can participate in the 340B program, prohibited duplicate discounts and diversion of 340B drugs, and developed federal enforcement mechanisms does not show that Congress intended to create (and occupy) a field. If it did, *every time* Congress created a federal program, it would create an exclusively federal field into which States cannot intrude. That cannot be. *See English*, 496 U.S. at 89 ("Absent some *specific suggestion* in the text or legislative history of § 210 [of the Energy

Restoration Act of 1974], which we are unable to find, we cannot conclude that Congress intended to pre-empt all state actions that permit the recovery of exemplary damages.") (emphasis added); *cf. Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985) ("To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence."). And it especially cannot be when the field PhRMA insists Congress created is one that collides with the States' traditional police powers.

Astra USA, Inc. v. Santa Clara County, 563 U.S. 110 (2011), on which PhRMA relies, does not support a contrary conclusion. Although PhRMA contends that *Astra* is "materially indistinguishable" from this case, App. Br. 36, the *Astra* Court *never* addressed whether the 340B program preempts state law. Instead, the Court addressed *only* whether covered entities could employ a third-party-beneficiary theory to overcome Congress's decision not to authorize a private right of action to enforce the 340B statute's requirements. *See Astra*, 563 U.S. at 113. The Court's ruling that the 340B statute did not authorize *all* 340B providers to sue to enforce the 340B statute's requirements has no bearing on whether Congress preempted the *States* from legislating in any purported 340B "field." Significantly,

the only *mention* of preemption in *Astra* is in a footnote concerning a different, related federal program, the Medicaid Drug Rebate Program. And there, the Court expressly "t[ook] *no position*" regarding the correctness of the United States' position that "the statute establishing [that program] *does not preempt* States from maintaining state-law fraud claims based on fraudulent reporting of 'best prices' to [the Department of Health and Human Services (HHS)]." *Id.* at 120 n.5 (emphasis added).

PhRMA nevertheless argues that *Astra*'s discussion of the 340B program's centralized enforcement scheme demonstrates the statute's preemptive effect. But nothing about *Astra* displaced the Supreme Court's well-established principle that "the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply pre-emption of state remedies.'" *English*, 496 U.S. at 87; *cf. also Harris v. Great Dane Trailers, Inc.*, 234 F.3d 398, 402 (8th Cir. 2000) ("Only when federal regulators determine that uniformity is needed to promote the predominant legislative purpose of [the federal act] will uniformity itself justify broad conflict preemption."). PhRMA's reliance on the reference to uniformity in *Astra*, *see* App. Br. 37-38, is further undermined by the federal government's own recognition of State authority over contract pharmacy arrangements. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) (noting that "[a]s a matter of State

law, . . . covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs," and that, "[b]y issuing guidelines in this area, [the federal agency] is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law"). All in all, the *Astra* Court's hesitance to allow "potentially thousands of covered entities" to sue to enforce the federal 340B statute has no bearing on whether *States* can legislate as Arkansas did here, because upholding Arkansas's authority to act would not "spawn a multitude of dispersed and uncoordinated lawsuits." 563 U.S. at 114, 120.

Finally, PhRMA's arguments concerning the importance of the federal interest in the 340B program similarly fail to show field preemption. "Undoubtedly, every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law." *Hillsborough*, 471 U.S. at 719. And critically, the Supreme Court has expressly contrasted "the regulation of health and safety matters[, which] is primarily, and historically, a matter of local concern," with, "[f]or example, . . . the dominance of the federal interest in foreign affairs." *Id.* Giving the 340B statute the preemptive effect that PhRMA seeks here would undermine the very "federalism concerns" that underlie preemption questions and "the historic primacy of state regulation of matters of health and safety." *Medtronic*, 518 U.S. at 485.

B. Act 1103 Does Not Intrude into PhRMA's Purported 340B "Field."

Even if PhRMA were correct that Congress intended to create an exclusively federal field with the 340B program, States are free to legislate outside of that field. *See, e.g.*, *O'Melveny & Myers v. FDIC*, 512 U.S. 79, 85 (1994) ("[M]atters left unaddressed in such a [federal] scheme are presumably left subject to the disposition provided by state law."); *English*, 496 U.S. at 83 (finding "no basis for respondent's contention that all state-law claims arising from conduct covered by the [federal law] section are necessarily included in the pre-empted field"); *Nordgren v. Burlington N. R.R. Co*., 101 F.3d 1246, 1252 (8th Cir. 1996) (holding that "[p]roperty damage claims fall outside of th[e] preempted field" of "recovery for personal injuries to railroad employees incurred in the course of employment"). Here, Act 1103 does not address the 340B program's requirements and prohibitions—which entities qualify as covered entities, what those covered entities must or cannot do within the 340B program, the prices drug companies may charge covered entities, or federal enforcement within the 340B program—and thus is not preempted.

PhRMA's two arguments to the contrary depend on a mischaracterization of the 340B statute and Act 1103. *First*, PhRMA contends that Act 1103 "effectively adds contract pharmacies to the list of" 340B covered entities. App. Br. 4; *see also id.* at 35. But contract pharmacies do not become covered entities simply by receiving and dispensing 340B-discounted drugs. No matter how many times

PhRMA repeats the phrase "closed system,"[15] nothing about contract pharmacy arrangements adds contract pharmacies to the statutory list of covered entities eligible for 340B discounts.[16] Rather, under the contract pharmacy arrangements 340B providers have used since the beginning of the 340B program, the provider purchases the drugs, which are shipped to a pharmacy where the provider's patients have access—an arrangement that HHS has consistently endorsed.[17] Moreover, PhRMA's members' current policies, which all allow covered entities to use at least one contract pharmacy under certain circumstances, completely undermine PhRMA's argument that using contract pharmacies somehow transforms them into covered entities.

Second, PhRMA argues that Act 1103 "creat[es] its own scheme of oversight and enforcement to penalize manufacturers for not supplying that 340B price." App. Br. 35. But this mischaracterizes Act 1103, which does not "interject[] [the Arkansas Insurance Department (AID)] as an additional enforcer" of *federal* 340B obligations or as "an additional arbiter of appropriate penalties" for violations of the *federal*

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[15] *See* App. Br. 2, 23, 29, 34, 35, 43, 51.

[16] *See* 42 U.S.C. § 256b(a)(4).

[17] *See, e.g.*, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010); 61 Fed. Reg. 43,549. When Congress expanded the 340B program in 2010, it gave no indication that it had any issue with contract pharmacy arrangements. *See* Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (2010) (codified at 42 U.S.C. § 256b).

statute. *Id.* Act 1103 and its implementing regulations allow AID to enforce *only* Act 1103's requirement that drug manufacturers not deny the 340B discount to covered entities that dispense 340B drugs to their patients at contract pharmacies. AID has no authority to enforce any restrictions or requirements in the 340B statute itself—*i.e.*, the ceiling price for 340B drugs, duplicate discounts or diversion, or compliance with the federal statute.

Importantly, Act 1103's references to the federal 340B drug pricing program do not support PhRMA's argument that Act 1103 intrudes on the federal program. PhRMA argues that by "requiring the delivery of *340B-discounted drugs* to contract pharmacies, Arkansas is necessarily imposing a pricing term in addition to a delivery requirement." *Id.* at 50. But as an initial matter, even if PhRMA's characterization of Act 1103 as a pricing statute were correct, the 340B statute does not preclude States from imposing their own indirect pricing conditions. There is nothing in the 340B statute that "indicates whether [Congress] meant for it to be a regulatory floor or ceiling." *Wuebker*, 418 F.3d at 888. Arkansas clearly has the authority to regulate various aspects of drug pricing (for example, through taxes on manufacturers or sales taxes on pharmaceutical drugs), which PhRMA makes no effort to dispute. And here, Congress expressed no view on whether States can supplement federal pricing standards through separate regulatory requirements that may indirectly impact drug

pricing. Consequently, "the presumption against preemption obliges [this Court] to conclude that [the 340B program] does not preempt [Act 1103]." *Id.*

Moreover, Act 1103 does not directly regulate drug pricing.[18] Act 1103 is an independent statutory scheme that complements the 340B program. Critically, Arkansas could have adopted substantively the same scheme by drafting Act 1103 to condition the grant of permits to drug manufacturers[19] on those manufacturers selling drugs to the nonprofit hospitals and other covered entities identified in the federal 340B statute at specified prices, regardless of how the drugs are dispensed. That hypothetical permitting statute could have referenced the 340B program merely to incorporate the covered entities and ceiling prices it establishes. *Cf. Hillsborough*, 471 U.S. at 710 (local ordinance not preempted despite fact that "[t]he ordinance incorporates by reference the [Food and Drug Administration's (FDA's)] blood plasma regulations"). PhRMA's arguments against such a version of Act 1103 would be equally wrong in this substantively indistinguishable scenario.

In short, Arkansas is free to enact its own drug-pricing program for contract pharmacies, and it is free to incorporate by reference (and for the sake of efficiency) prices the federal government sets. To borrow from PhRMA's car analogy, *see* App.

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[18] *See also* Br. Intervenors-Appellees, Doc. 5263448, at 33-35 (citing, *inter alia*, Act 1103's legislative history).

[19] *See* Ark. Code Ann. § 20-64-505 (permitting statute).

Br. 50, if the federal government creates a program prohibiting the sale of blue cars above a certain price point, Arkansas is free to create its own program prohibiting the sale of *red* cars above that same price point, incorporating aspects of the federal program regarding the sale of blue cars by reference. Such legislation would not be preempted just because Congress created a comprehensive federal blue-car-pricing scheme. *See Hillsborough*, 471 U.S. at 717 ("[M]erely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field."). PhRMA thus fails to show that Act 1103 intrudes on the federal 340B program such that it is preempted.

II. ACT 1103 DOES NOT CONFLICT WITH THE 340B PROGRAM.

PhRMA next argues that Act 1103 is preempted because it conflicts with the federal 340B regime. Notably, PhRMA does not contend that compliance with both Act 1103 and the 340B statute is a "physical impossibility." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citation omitted). Instead, PhRMA argues that Act 1103 is preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citation omitted); *see also* App. Br. 42. But PhRMA fails to meet the "high threshold [that] must be met if a state law is to be preempted for conflicting with the purposes of a federal Act." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citation omitted).

For starters, most of PhRMA's conflict preemption arguments merely rehash its field preemption arguments. Throughout the section of its brief arguing that Act 1103 conflicts with the 340B program, PhRMA expressly relies on the arguments it made regarding field preemption. *See, e.g.*, App. Br. 43 ("As discussed at length . . .") (citing *id.* at 30); *id.* at 45 ("As discussed . . .") (citing *id.* at 31-34); *id.* at 46 ("As explained . . .") (citing *id.* at 36-38). To take one example, PhRMA's conflict preemption arguments with respect to oversight and enforcement are the same as its field preemption arguments, simply dressed in different clothing. *Compare id.* at 43 ("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."), *with id.* at 34-35 (arguing that "Act 1103 impermissibly intrudes into the exclusive field Congress designed by wading into the federal 340B program's closed system substantively and procedurally," including "by creating its own scheme of oversight and enforcement"). Thus, PhRMA's repackaged arguments fail for the same reasons discussed above.

Moreover, that Arkansas imposes additional, different penalties on drug companies that violate Act 1103 does not, by itself, create a conflict with the

penalties that Section 340B provides for diversion, duplicate discounts, or overcharging. *See, e.g.*, *Medtronic*, 518 U.S. at 495 (holding that the presence of a state-law damages remedy tied to violations of FDA requirements does not impose a conflicting requirement upon medical device manufacturers); *Dublino*, 413 U.S. at 422 ("[T]he [federal] Act allows for complementary state . . . programs and procedures incident thereto . . . . Such programs and procedures are not necessarily invalid, any more than other supplementary regulations promulgated within the legitimate sphere of state administration."). Indeed, Act 1103's limited regulation of contract pharmacy arrangements does not "interfere[] with" any purported "uniformity of a national remedial scheme" because "the state remedy is a complementary remedy which does not conflict with section [340B]." *Parten*, 923 F.2d at 583; *see also Great Dane Trailers*, 234 F.3d at 402.

In any event, there is no basis for invalidating Act 1103 based on *potential* enforcement or oversight conflicts. *See* App. Br. 46 ("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.") (emphasis added). Until there is an *actual* conflict, this Court should heed the Supreme Court's admonition that "[t]he existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982); *see also Granite Re, Inc. v. Nat'l Credit Union Admin. Bd.*,

956 F.3d 1041, 1048 (8th Cir. 2020) ("Until it is clear that Granite's recovery under [the local ordinance] exceeds the limits of [the federal statute], we need not address whether there is an actual conflict between the two for purposes of preemption.").

Apart from its rehash of its field preemption arguments, the only conflict preemption argument PhRMA makes is that Act 1103 conflicts with the 340B statute because "many contract pharmacies in Arkansas use the replenishment model" and therefore necessarily engage in diversion, which the 340B statute prohibits. App. Br. 44-45. This misunderstands the reality of drug purchasing and dispensing, as well as the meaning of "diversion" under the 340B statute.

A bit of background on how pharmacies stock drugs is necessary. When a 340B provider uses a contract pharmacy, the provider orders and pays for the drugs, which are shipped directly to the pharmacy to be dispensed (or to replenish drugs that have been dispensed) to the provider's patients. Some providers use a "separate inventory" model, where the provider purchases 340B drugs, which are kept in stock at the pharmacy, separate from non-340B drugs, and dispensed to the provider's patients. Most providers, however, use a "replenishment" model, where the pharmacy uses its own stock, and the provider purchases replacement drugs at the discounted 340B price to replenish the pharmacy's stock. The pharmacy then remits to the 340B provider the payments the pharmacy received, minus a dispensing fee, thus ensuring that the provider receives the benefit of the 340B discount as Congress

intended. This model typically involves a computerized tracking system following rules designed to ensure that only eligible patients of 340B providers receive drugs for which the provider receives the 340B discount.[20]

Under either arrangement, *it is the 340B provider* that purchases the 340B discounted drug—not the contract pharmacy.[21] The Supreme Court and the Federal Trade Commission have endorsed accounting systems like those used under the replenishment model as an appropriate way to distinguish drugs that qualify for a discount from those that do not.[22] Nothing about this stocking mechanism "circumvent[s] the limitations Congress built into its 340B program," App. Br. 45, or otherwise frustrates the federal regime.

Nor does this stocking model constitute diversion, as PhRMA contends. *See id.* at 44-45. As the district court rightly recognized,

> to the extent that contract pharmacy arrangements can be characterized as transfers or resales to non-patients, [PhRMA's] position is not a reasonable construction of the

[20] *See, e.g.*, Apexus, *340B Split-Billing Software Key Attributes* (Jan. 17, 2023), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-key-attributes.docx.

[21] *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 700 (3d Cir. 2023) ("Covered entities using contract pharmacies would still order and pay for the drugs, but they would be shipped directly to the pharmacies."). It is thus incorrect to state, as PhRMA does, that contract pharmacies "purchase" 340B drugs. App. Br. 10-11.

[22] *See Abbott Labs. v. Portland Retail Druggist Ass'n, Inc.*, 425 U.S. 1, 20 n.11 (1976); Letter from Markus H. Meier, Assistant Dir., Fed. Trade Comm'n, to Kathleen A. Reed 1 (Apr. 9, 2010), https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

> statute. The 340B Program's non-transfer/resale provision refers to situations where medications are given to individuals who are not receiving health care services from covered entities or are receiving services inconsistent with the type of services for which the covered entity qualified for 340B status.[23]

The fact that contract pharmacies step into the shoes of covered entities to distribute drugs to those entities' patients is manifestly not diversion. Proof of this comes from PhRMA's members' own contract pharmacy policies, which *allow* for the use of contract pharmacies—without distinguishing between the replenishment or separate inventory model. Either the replenishment model constitutes diversion, or it does not. (It does not.)[24]

Finally, and perhaps most important, PhRMA's conflict preemption arguments miss the forest for the trees. In determining whether PhRMA can satisfy

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[23] Order, R. Doc. 48, at 13. Other courts have similarly rejected PhRMA's diversion argument. *See, e.g.*, *Eli Lilly & Co. v. HHS*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *20 (S.D. Ind. Oct. 29, 2021).

[24] Similarly, PhRMA's assertions that 340B providers' use of contract pharmacies has been accompanied by "rampant diversion" are unfounded. *See, e.g.*, App. Br. 16. In fiscal years 2019 through 2022, the federal government conducted more than 600 audits of 340B hospitals, and almost 95 percent of those audits did not identify any instances of diversion related to contract pharmacies. *See* Health Res. & Servs. Admin., *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results; *Program Integrity: FY20 Audit Results*, https://www.hrsa.gov/opa/program-integrity/fy-20-audit-results; *Program Integrity: FY21 Audit Results*, https://www.hrsa.gov/opa/program-integrity/fy-21-audit-results; *Program Integrity: FY22 Audit Results,* https://www.hrsa.gov/opa/program-integrity/audit-results/fy-22-results.

its high burden to establish conflict preemption, the core inquiry is "a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). Here, it is universally recognized—including by all three branches of government—that Congress's purpose in enacting the 340B program was to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also, e.g.*, *AHA v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (quoting same), *rev'd on other grounds sub nom. AHA v. Becerra*, 142 S. Ct. 1896 (2022); Health Res. & Servs. Admin., *340B Drug Pricing Program* (Mar. 2023), https://www.hrsa.gov/opa (quoting same). 340B providers and their patients benefit greatly from the use of contract pharmacies, which allow providers to reap more 340B benefits, and thereby provide more comprehensive services, and allow patients to access more affordable drugs by allowing them to pick up their medicines more conveniently, at their local pharmacies. Act 1103, in turn, enables 340B providers to reach more patients and to provide more comprehensive services. Therefore, Act 1103 does not interfere with Congress's 340B scheme—it "furthers" it. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 82 (1987).

In the end, this Court has recognized that "[i]mplied preemption is . . . rarely found." *Mo. Bd. of Examiners for Hearing Instrument Specialists v. Hearing Help*

Express, Inc., 447 F.3d 1033, 1035 (8th Cir. 2006). Because Act 1103 does not frustrate Congress's purpose in enacting the 340B program—and instead advances it—it is not conflict preempted.

III. ACT 1103 DOES NOT CONFLICT WITH THE FDCA.

PhRMA's argument that Congress intended the FDCA to preempt Act 1103 also fails. Simply put, Act 1103 does not interfere with federal limitations "on how and by whom drugs may be sold." App. Br. 51.

PhRMA argues that, "[o]n its face," Act 1103 conflicts with the FDCA because 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." *Id.* at 52. But Act 1103 requires no such thing. PhRMA spills much ink explaining the importance of properly interpreting statutory text, *see id.* at 53-54, but never actually engages with the text of Act 1103.

Two provisions of Act 1103 are at issue. *First*, section 23-92-604(c)(1) makes it unlawful for a "pharmaceutical manufacturer [to] [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." This language prohibits manufacturers from interfering with a contract pharmacy's sale of 340B-discounted drugs to 340B patients. It says nothing about federal prohibitions or restrictions on the sale of certain drugs. Thus,

pharmacies not authorized under federal law to dispense certain drugs would consequently not be authorized to enter into contracts with 340B providers to dispense those drugs, and Act 1103 would not require drug companies to deliver such drugs to those pharmacies. There is no conflict.

Second, section 23-92-604(c)(2) of Act 1103 makes it unlawful for a "pharmaceutical manufacturer [to] [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." This language prohibits manufacturers from denying the 340B discount to covered entities that use contract pharmacies to deliver the 340B-discounted drugs to their patients. Nothing in this provision authorizes (or requires) contract pharmacies to dispense drugs if they are restricted by federal law or regulations from doing so. A contract pharmacy not authorized to dispense certain drugs would simply not dispense those drugs.

Indeed, this is exactly how the 340B program has operated for years: covered entities purchase drugs at the 340B discount from drug manufacturers and have the drugs delivered to contract pharmacies that are permitted to dispense them. Covered entities do not direct drug companies (and drug companies are not required) to deliver drugs to contract pharmacies not authorized to dispense them. When HHS issued guidance in 2010 regarding the 340B program and the use of contract

pharmacies, it stated that "compliance with 340B requirements and guidelines does not excuse individual providers, covered entities, pharmacies, wholesale distributors or manufacturers from adherence to all other local, State or Federal requirements."[25] If the use of contract pharmacies within the 340B program caused no conflict with the FDCA thirteen years ago, then there is no reason why Act 1103 creates a conflict now.

As a final note, PhRMA's argument underscores why protecting contract pharmacy arrangements is so important. Specifically, drug companies are using their restrictive contract pharmacy policies to avoid providing 340B discounts on particularly expensive "specialty" drugs, which are typically used to treat chronic, serious, or life-threatening conditions,[26] are generally priced much higher than traditional drugs, and often may be dispensed *only* at what are called "specialty" pharmacies. Indeed, in order to assure drug safety, in its Risk Evaluation and Mitigation Strategies (REMS) discussed in PhRMA's brief,[27] the FDA often requires

[25] 75 Fed. Reg. at 10,273.

[26] *See Specialty Drug Coverage and Reimbursement in Medicaid*, HHS Office of Inspector Gen., https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp ("There is no standard definition for specialty drugs. They may be expensive; be difficult to handle, monitor or administer; or treat rare, complex or chronic conditions.").

[27] *See* App. Br. 51-53.

that a drug only be dispensed using specialty pharmacies.[28] The vast majority of 340B hospitals, however, do not have specialty pharmacies, which are generally mail-order and may be located hundreds of miles from the hospital.[29] To access specialty drugs at the 340B price, 340B hospitals therefore *must* enter into contract pharmacy arrangements.

Act 1103 thus does not conflict with the FDCA or the 340B program, but instead furthers Congress's intent to support 340B providers and the vulnerable patients and communities they serve.

CONCLUSION

For the foregoing reasons, and those outlined in the Defendant-Appellee's and Intervenors-Appellees' briefs, the district court's judgment should be affirmed.

Dated: April 14, 2023

Respectfully submitted,

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[28] *See* FDA, *Roles of Different Participants in REMS* (Jan. 23, 2023), https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems ("For [certain] REMS, you will need to send the prescription to a specialty pharmacy to have the prescription dispensed, or complete a separate prescription ordering form.").

[29] 340B Health, *Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients* 4, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf.

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COMBINED CERTIFICATIONS

I hereby certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because this brief contains 6,339 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

I further certify that this brief complies with the typeface requirements of Federal Rule Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word with 14-point Times New Roman font.

I further certify, pursuant to Local Rule 28A(h) that the electronic version of this brief was scanned using virus-detection software—namely with Cylance Smart Antivirus—and no virus was detected.

/s/ William B. Schultz
William B. Schultz

CERTIFICATE OF SERVICE

I certify that on April 14, 2023, I caused a copy of this Brief of American Hospital Association, Arkansas Hospital Association, and 340B Health as *Amici Curiae* in Support of Appellees to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices. Within five days of receipt of notice that the brief has been filed, a paper copy will be served on each party separately represented, and 10 paper copies of the brief will be transmitted to the clerk of the court.

/s/ William B. Schultz
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