No. 24-60340

UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff-Appellant*,

v.

Lynn Fitch, in her official capacity as Attorney General of Mississippi, *Defendant-Appellee*,

> On Appeal from the United States District Court for the Southern District of Mississippi Case No. 1:24-cv-164-HSO-BWR

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MISSISSIPPI HOSPITAL ASSOCIATION, RURAL HOSPITAL ALLIANCE, AND AMERICAN SOCIETY FOR HEALTH-SYSTEM PHARMACISTS AS AMICI CURIAE IN SUPPORT OF DEFENDANT-APPELLEE

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Counsel for Amici Curiae

Pursuant to Federal Rule of Appellate Procedure 29(a)(3) and Fifth Circuit Rule 29.1, movants American Hospital Association, 340B Health, Mississippi Hospital Association, Rural Hospital Alliance, and American Society of Health-System Pharmacists respectfully move the Court for leave to file a brief as *amici curiae* in support of Defendant-Appellant. Defendant-Appellee consents to and Plaintiff-Appellant does not oppose the filing of this *amicus* brief in this litigation. A copy of the proposed brief is attached as Exhibit A.

I. <u>INTEREST OF MOVANTS</u>

Movants include four hospital associations with members in Mississippi that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists, many who are located in Mississippi, who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings, many of which benefit from the 340B program. Movants 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. The discounts provided by the 340B program are essential to achieving this goal. Movants therefore have a strong interest in the success of Mississippi's legislative efforts to protect the 340B program.

II. MOVANTS' BRIEF WILL BE USEFUL TO THE COURT'S CONSIDERATION OF THIS APPEAL.

"Courts enjoy broad discretion to grant or deny leave to *amici* under Rule 29." *Lefebure v. D'Aquilla*, 15 F.4th 670, 673 (5th Cir. 2021). This Court has construed this guidance to mean that it "would be 'well advised to grant motions for leave to file amicus briefs unless it is obvious that the proposed briefs do not meet Rule 29's criteria as broadly interpreted." *Id.* at 676 (quoting *Neonatology Assocs., P.A. v. C.I.R.*, 293 F.3d 128, 132 (3d Cir. 2002)).

Movants' brief complies with Federal Rule 29 and Fifth Circuit Rule 29.1 and contains valuable insight to inform the Court's consideration of the merits of this appeal. As representatives of 340B covered entities and pharmacists serving patients, movants are uniquely positioned to explain the critical role of contract pharmacies, which have been used by covered entities since the beginning of the 340B program. Movants are also qualified to explain how the onerous contract pharmacy restrictions that drug companies began to impose in 2020 resulted in significant harms to patients and 340B providers, which operate on razor-thin margins to provide care to individuals with low incomes. Further, movants' brief explains why the challenged Mississippi statute, which requires drug companies to honor the contract pharmacy relationships of Mississippi covered entities, is an essential healthcare regulation within the State's historic police powers to promote public health.

III. <u>CONCLUSION</u>

Based on the foregoing, movants respectfully request that the Court grant this motion for leave to file a brief as *amici curiae* in support of Defendant-Appellant and accept for filing the *amici curiae* brief submitted contemporaneously with this motion.

Date: November 15, 2024 Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on November 15, 2024, the foregoing Unopposed Motion for

Leave to File Brief of American Hospital Association, 340B Health, Mississippi

Hospital Association, Rural Hospital Alliance, and American Society of Health-

System Pharmacists as Amici Curiae in Support of Defendant-Appellee was filed

electronically and has been served via the Court's ECF filing system in compliance

with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered

counsel of record.

/s/ William B. Schultz

Counsel for Amici Curiae

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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Rule of

Appellate Procedure 27(d)(2) because it contains 472 words, as counted by

Microsoft Word, excluding the parts of the motion excluded by Federal Rule of

Appellate Procedure 32(f). This motion complies with the typeface requirements of

Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of

Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using

Microsoft Word in 14-point Times New Roman font.

/s/ William B. Schultz Counsel for Amici Curiae

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EXHIBIT A

No. 24-60340

UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff-Appellant*,

v.

Lynn Fitch, in her official capacity as Attorney General of Mississippi, *Defendant-Appellee*,

On Appeal from the United States District Court for the Southern District of Mississippi Case No. 1:24-cv-160-HSO-BWR

BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MISSISSIPPI HOSPITAL ASSOCIATION, RURAL HOSPITAL ALLIANCE, AND AMERICAN SOCIETY FOR HEALTH-SYSTEM PHARMACISTS, AS AMICI CURIAE IN SUPPORT OF DEFENDANT-APPELLEE

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

Pharmaceutical Research and Manufacturers of America v. Fitch, No. 24-60340

In addition to the persons and entities listed in Plaintiff-Appellant's Certificate of Interested Persons, undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Amici Curiae

American Hospital Association

340B Health

Mississippi Hospital Association

Rural Hospital Alliance

American Society for Health-System Pharmacists

Amici are all non-profit organizations, none of which has a parent corporation nor issues stock.

Attorneys for Amici Curiae

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Date: November 15, 2024 /s/ William B. Schultz
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Attorney of Record for Amici Curiae

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Allen Dobson et al., The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients (July 10, 2020)	.6
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INTEREST OF AMICI CURIAE¹

Amici include four hospital associations with members in Mississippi that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists, many who are located in Mississippi, who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings, many of which benefit from the 340B program. 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. The discounts provided by the 340B program are essential to achieving this goal. Amici therefore have a strong interest in the success of Mississippi's 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 promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

Pursuant to Federal Rule of Appellate Procedure 29, undersigned counsel for *Amici* certify

that: no party's counsel authored this *amicus* brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this *amicus* brief; and no person or entity, other than *Amici* or their counsel, contributed money intended to fund the preparation or submission of this *amicus* brief. Defendant-Appellee consents and Plaintiff-Appellant does not oppose the filing of this *amicus* brief in this litigation.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,500 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Mississippi Hospital Association** (MHA) represents approximately 75 hospital members, many of which participate in the 340B program and are impacted by efforts of drug companies to limit access to 340B-discounted drugs. Among its many services, MHA develops and improves healthcare policy through legislative, regulatory, and judicial processes.

The **Rural Hospital Alliance** (RHA) represents the interests of Mississippi rural hospitals. Its mission includes assisting rural hospitals with their unique and often challenging issues, including through advocacy for federal and state legislation to maintain and improve rural healthcare. Many RHA members participate in the 340B program and are impacted by the efforts of drug companies to reduce distribution of 340B-acquired drugs.

The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice;

advanced education and professional development; and served as a steadfast advocate for members and patients.

BACKGROUND

Beginning four years ago, amid a devastating pandemic, multiple drug companies broke with decades of precedent and devised a plan to undermine the 340B drug discount program. Under that program, drug companies that participate in Medicaid and Medicare Part B must provide discounts on drugs sold to patients of certain nonprofit or public hospitals and community health centers. See 42 U.S.C. § 256b(a)(1)(4). Before 2020, drug companies had provided drug pricing discounts to eligible hospitals for drugs dispensed both through in-house pharmacies and community pharmacies with which the hospitals had contracts. See Pharm. Rsch. & Mfrs. of Am. v. McClain, 95 F.4th 1136, 1139 (8th Cir. 2024) (PhRMA v. McClain) ("For 25 years, drug manufacturers . . . distributed 340B drugs to covered entities' contract pharmacies."). But in July 2020, one drug company suddenly refused to provide these discounts for one of its drugs if dispensed to 340B patients at community pharmacies (or contract pharmacies), later expanding this new policy to cover essentially all its drugs.² Recognizing an opportunity to boost their own bottom lines, 38 other major drug companies—many of which are members of Plaintiff-

² See 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.

Appellant Pharmaceutical Research and Manufacturers of America (PhRMA)—quickly followed suit.³

The contract pharmacy arrangements that drug companies honored for almost 30 years helped sustain hospitals and their patients. Prior to the implementation of contract pharmacy restrictions, discounts on drugs dispensed at community and specialty contract pharmacies made up about one-quarter of overall 340B savings for hospitals participating in 340B. For rural Critical Access Hospitals, savings from partnerships with these pharmacies represented an average of 52% of overall 340B savings. Of the 61 Mississippi hospitals participating in the 340B drug discount program, 55 contract with at least one community pharmacy to dispense drugs to patients.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.⁶ This is why, contrary to

Collectively, 19 of these companies made more than \$660 billion in profits in 2021. *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/.

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 Health Res. & Servs. Admin, Off. of Pharmacy Affairs, 340 OPAIS, https://340bopais.hrsa.gov/coveredentitysearch.

⁶ 340B Health, *Drugmakers Pulling \$8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* 2, https://www.340bhealth.org/files/Cont ract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

PhRMA's claim, PhRMA Br. 13, 340B covered entities have relied on contract pharmacies since the beginning of the program.⁷ Even fewer 340B hospitals—only one in five—have in-house "specialty" pharmacies, which many payors require for the dispensing of "specialty" drugs. These drugs are typically used to treat chronic, serious, or life-threatening conditions, and are generally priced much higher than non-specialty drugs.⁸ Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy to receive the 340B discount for their patients' high-priced specialty drugs. ⁹ In fact, for seven of the 21 drug companies with restrictive contract pharmacy policies as of June 1, 2023, specialty drugs make up more than threequarters of the savings associated with restricted drugs. 10 Denied these and other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services, and some patients have been denied discounts on their drugs.¹¹

⁷ 60 Fed. Reg. 55,586 (Nov. 1, 1995).

⁸ Adam J. Fein, *Insurers* + *PBMs* + *Specialty Pharmacies* + *Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels Institute (Dec. 12, 2019), https://www.drugchannels.net/2020/05/insurers-pbms-specialty-pharmacies.html; U.S. Dep't of Health & Human Servs. Off. of Inspector Gen., *Specialty Drug Coverage and Reimbursement in Medicaid*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

⁹ 340B Health, *supra* note 6, at 7 (citing Adam J. Fein, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2022).

¹⁰ *Id.* at 6.

¹¹ *Id.* at 1.

Savings from contract pharmacy relationships are especially important for another reason: the fragile state of hospital finances. In stark contrast to the drug industry, 340B hospitals typically operate with razor-thin (and often negative) margins. The reason why is not surprising: 340B hospitals provide a disproportionate amount of uncompensated care, community health services, and other services to the country's most vulnerable patients. Savings from the 340B program help to offset the cost of providing uncompensated health care services to underserved populations. As the Supreme Court has recognized, "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*, 596 U.S. 724, 738 (2022).

The drug company restrictions at issue here have substantially reduced the intended savings from the 340B program. This is devastating for 340B hospitals in Mississippi, which provide 82% of all hospital care that is provided to Medicaid

Devna Bose, A Quarter of Mississippi's Rural Hospitals Could Close Within Three Years, Report Shows, Mississippi Today (Apr. 25, 2023), https://mississippitoday.org/2023/04/25/mississippi-hospital-crisis-rural-closures/; see also Am. Hosp. Ass'n, 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_R eport_7.10.2020_FINAL_.pdf.

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; Am. Hosp. Ass'n, supra note 12, at 2; Dobson et al., supra note 12, at 13–17.

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patients in the state. 14 And of course this means that patients lose critical health care services—and sometimes even savings that hospitals directly pass on to them. For example, St. Dominic – Jackson Memorial reports that the contract pharmacy restrictions have cut its 340B savings by 50%. The same is true for Choctaw Regional Medical Center, which uses 340B savings, among other things, to continue to provide healthcare services to patients in underserved areas, including providing free care for indigent patients and providing cash cards for indigent patients.

The patients of other Mississippi 340B hospitals, like **Southwest Mississippi** Regional Medical Center (SMRMC), suffered serious harm from these cuts. SMRMC is a disproportionate share hospital that serves a large rural population. Patients often must travel an hour or more to receive medical care. 15 Prior to the drug company restrictions on 340B discounts for drugs dispensed by community pharmacies, SMRMC planned to use some of its 340B discount savings to expand behavioral health services, offer more direct patient financial assistance and charity care, and establish more preventative screening and medication management service

¹⁴ Dobson DaVanzo Health Economics Consulting, Mississippi 340B Hospitals Serve More Patients With Low Incomes and Provide the Majority of Hospital Care to Medicaid Patients, https://www.340bhealth.org/files/MS-340B-Low-Income15022.pdf.

³⁴⁰B Health, Faces of 340B: Tiffany Poole, Director of Pharmacy at Southwest Mississippi Center, Mississippi, https://www.340bhealth.org/newsroom/faces-of-Regional Medical 340b/tiffany-poole.

to reduce hospital readmissions.¹⁶ Instead, some patients were left to forgo their medications or to use them sparingly. Some families have been forced, for instance, to buy a single EpiPen for multiple family members.¹⁷

Likewise, Magnolia Regional Health Center (Magnolia) is a community hospital located in Corinth, Mississippi. Approximately 24% of Magnolia's patients are uninsured or underinsured. Magnolia relies on the 340B program to give patients direct discounts on 340B drugs and to otherwise offset some of the losses it incurs in caring for these low-income patients. As a result of these drug company restrictions, patients who cannot afford to pay full prices will not be able to receive discounts and will thus be forced to miss necessary medications. What's more, many of Magnolia's patients are not be able to drive long distances to the "permitted" non-contract pharmacy. They, too, will have a harder time getting the medicine they need.

Faced with the drug industry's unprecedented assault on Mississippi's health care safety net, the Mississippi legislature responded. By an overwhelming bipartisan 132-33 vote, it passed the "Defending Affordable Prescription Drug Costs Act." *See* Miss. Code H.B. 728, Section 4.¹⁸ This law prohibits 340B manufacturers from directly or indirectly denying, restricting, prohibiting, discriminating against,

¹⁶ *Id*.

¹⁷ *Id*.

The text of the statute can be found at https://legiscan.com/MS/text/HB728/2024.

or otherwise limiting the acquisition or delivery of 340B drugs by pharmacies that are authorized by covered entities to receive 340B drugs on their behalf, unless such limitation is required under 21 U.S.C. § 355-1, which permits the Food and Drug Administration to limit the distribution of certain drugs. Any violation of this provision is considered an unfair, abusive, or deceptive trade practice, subject to enforcement and penalties under the Mississippi Consumer Protection Act. H.B. 728, Section 5.

ARGUMENT

The district court's ruling should be affirmed because PhRMA cannot demonstrate that it is likely to succeed on the merits. "[T]here is authority" in this Circuit that likelihood of success "is the most important of the preliminary injunction factors." *Mock v. Garland*, 75 F.4th 563, 587 n.60 (5th Cir. 2023). Here, PhRMA has no chance of success.²⁰

First, Mississippi's law is not preempted because Congress did not create or occupy any field through its 340B legislation, nor does it conflict with the 340B statute. At bottom, PhRMA takes the position that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. PhRMA's

¹⁹ *Id*.

²⁰ PhRMA also fails to meet any of the other three factors required for injunctive relief, as explained by Defendant-Appellee in her brief. *See* Def.-App. Br. 51–55.

argument is especially inapplicable here because "[p]harmacy has traditionally been regulated at the state level, and [courts] must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *PhRMA v. McClain*, 95 F.4th at 1144 (citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)); *see MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023 (5th Cir. 1994). For this reason, *every court* that has considered the issue has rejected PhRMA's preemption claims regarding materially similar state laws. *See PhRMA v. McClain*, 95 F.4th at 1143–45; *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 6:23-cv-0997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024), *appeal docketed*, No. 24-30673 (5th Cir. Oct. 21, 2024); *Novartis Pharms. Corp. v. Brown*, No. 24-cv-1557-MJM, ECF No. 57 (Sept. 5, 2024).

Second, PhRMA's argument that the Mississippi statute violates the dormant Commerce Clause ignores the Supreme Court's decision in *National Pork Producers*Council v. Ross, 598 U.S. 356 (2023), which eviscerates its dormant Commerce Clause claim.

Third, H.B. 728 is not unconstitutionally vague. PhRMA cannot credibly argue that it does not know which conduct falls within the scope of the statute. The term "interference," as used in the Mississippi law, can undoubtedly be understood by a "person[] of common intelligence." *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 421 (5th Cir. 2001).

I. H.B. 728 IS NOT PREEMPTED BY THE 340B STATUTE.

"In determining a federal statute's preemptive reach, congressional purpose is 'the ultimate touchstone." *United Motorcoach Ass'n, Inc. v. City of Austin*, 851 F.3d 489, 492 (5th Cir. 2017) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which the States have traditionally occupied," *Medtronic*, 518 U.S. at 485 (citation omitted), courts "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," *United Motorcoach*, 851 F.3d at 492 (quoting *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432 (2002)). PhRMA has the burden to show that Congress intended to preempt H.B. 728. *See Planned Parenthood of Houston & S.E. Tex v. Sanchez*, 403 F.3d 324, 336 (5th Cir. 2005).

PhRMA does not claim that H.B. 728 is expressly preempted. Nor does it deny that States have police power over public health policy, *see* PhRMA Br. 50 n.4, including the regulation of healthcare. *See, e.g., N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (recognizing the regulation of healthcare as a "field[] of traditional state regulation"); *Ass'n of Taxicab Operators USA v. City of Dallas*, 720 F.3d 534, 538 (5th Cir. 2013) (same regarding public safety). Thus, unlike state laws that intrude into uniquely federal

areas such as immigration and foreign relations that PhRMA has cited during this litigation, H.B. 728 is presumptively *not* preempted.²¹ PhRMA therefore must demonstrate Congress's "clear and manifest purpose" to supersede Mississippi's historic authority to regulate in the public health arena, *Medtronic*, 518 U.S. at 485 (citation omitted), which it cannot do.

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

"Field preemption of state law is disfavored." *Nat'l Press Photographers*Ass'n v. McCraw, 84 F.4th 632, 657 (5th Cir. 2023). In rare instances, it "occurs when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation." *Murphy v. Nat'l Collegiate Athletic*Ass'n, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[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 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.

²¹ See, e.g., Arizona v. United States, 567 U.S. 387 (2012) (immigration); Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363 (2000) (national security); Hines v. Davidowitz, 312 U.S. 52 (1941) (immigration).

Co., 496 U.S. 72, 87 (1990). With the 340B program, "a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent." *Dublino*, 413 U.S. at 415.

Ignoring this well-established precedent, PhRMA relies on what it describes as Congress's intention to "provide a comprehensive and exclusive plan for delivering a unique federal benefit" to support its argument that the federal government intended to occupy a field with the 340B program. *See* PhRMA Br. 22. But PhRMA fails to cite any authority—from the statute, governing regulations, or legislative history—for its assertions about Congress's *intent* to create (or occupy) this purported 340B "field." In fact, recent authority from a sister Circuit holds precisely the opposite—namely, that "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." *PhRMA v. McClain*, 95 F.4th at 1143.

In addition to repeatedly (and wrongly) asserting that Congress created a comprehensive federal scheme through the 340B program, PhRMA relies primarily on *Astra USA*, *Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011), an inapposite precedent. *Astra* addressed *only* whether covered entities could use a third-party beneficiary theory to enforce the 340B statute's federal requirements, not whether the 340B program preempts state law. *See Astra*, 563 U.S. at 113. The only mention

of preemption in *Astra* is in a footnote concerning a different federal program, the Medicaid Drug Rebate Program. *Id.* at 120 n.5.

PhRMA nevertheless asserts that Astra's discussion of the 340B program's centralized enforcement scheme proves the statute's preemptive effect. PhRMA Br. 23–25. 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. Moreover, PhRMA's reliance on Astra is further undermined by the federal government's decades-old recognition of State authority over contract pharmacy arrangements.²² Thus, the Astra Court's hesitance to allow "potentially thousands of covered entities" to sue to correct "errors in manufacturers' price calculations" has no bearing on whether *States* can legislate as Mississippi did here to restore contract pharmacies as an outlet for 340B drugs. Even if Congress had created a "340B field," PhRMA would have to further demonstrate that H.B. 728 intrudes into that field, which it has failed to do.

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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").

PhRMA also claims that "H.B. 728 invades the federal field procedurally by creating its own scheme of oversight and enforcement to penalize manufacturers for not supplying 340B-priced drugs to contract pharmacies." PhRMA Br. 28. But this again mischaracterizes H.B. 728, which does not authorize the Attorney General to enforce any restrictions or requirements in the federal 340B statute. "HHS has jurisdiction over different disputes: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs." *PhRMA v. McClain*, 95 F.4th at 1144. H.B. 728 allows the Mississippi Attorney General *only* to enforce H.B. 728's state-law requirement that drug manufacturers not deny the 340B discount to covered entities that dispense 340B drugs to their patients at contract pharmacies or otherwise interfere with contract pharmacy arrangements.

B. H.B. 728 Does Not Conflict with the 340B Statute.

PhRMA also claims that H.B. 728 is preempted because it conflicts with the federal 340B statute. But PhRMA is not able to identify any actual conflict between H.B. 728 and the 340B statute, particularly because H.B. 728 only requires drug companies to continue a practice (*i.e.*, recognition of multiple contract pharmacy arrangements) that had been in place since 2010. No one, including PhRMA, disputes that 340B hospitals are entitled to discounts under the 340B statute if the 340B drugs are dispensed at a hospital pharmacy. The Mississippi law simply allows

340B hospitals to prescribe discounted drugs to eligible patients to be dispensed at pharmacies with which they have contractual relationships. H.B. 728 does not change the prices that PhRMA may charge for these drugs. Nor does H.B. 728 change the character of the contract pharmacies. Contrary to PhRMA's claims, the contract pharmacies are *not* covered entities. They instead function as the hospitals' pharmacies. *See PhRMA v. McClain*, 95 F.4th at 1139 ("Since the beginning, covered entities have contracted with outside pharmacies, referred to as 'contract pharmacies,' for the distribution and dispensation of 340B drugs."). Consequently, PhRMA cannot 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).

PhRMA next contends that H.B. 728 conflicts with federal 340B law by "impermissibly expand[ing] the scope of manufacturers' obligations" under 340B. PhRMA Br. 32. Relying on decisions made in connection with claims that there is a *federal* statutory requirement to honor contract pharmacies, PhRMA asserts that the omission of a contract pharmacy requirement reflects a deliberate choice by Congress to confer the pricing benefit on a narrow class of covered entities while minimizing the reciprocal burden on manufacturers. PhRMA Mem. at 34–35 (citing *Sanofi Aventis v. U.S. Dept. of Health & Human Servs.*, 58 F.4th 696 (3d Cir. 2023); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024)).

But PhRMA distorts those decisions. Contrary to PhRMA's argument, the *Sanofi* court found that the 340B statute's "text is silent about delivery," and accordingly, HHS lacked authority under the statute to require drug companies to honor contract pharmacy arrangements. *Sanofi*, 58 F.4th at 703, 707. The Third Circuit said absolutely nothing about what *States* may do in the face of the federal law's "silence." PhRMA cannot spin this statutory silence into preemptive substance. *See PhRMA v. McClain*, 645 F. Supp. 3d. 890, 899 (E.D. Ark 2022), *affirmed*, 95 F.4th 1136 (8th Cir. 2024) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *see also Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1143 (9th Cir. 2015); *Frank Bros., Inc. v. Wis. Dep't of Transp.*, 409 F.3d 880, 891 (7th Cir. 2005).

PhRMA also tries to sidestep the well-established high bar for field preemption by arguing that the Supreme Court's decision in *Arizona v. United States*—a case evaluating preemption in the context of a state immigration statute—dictates the outcome of this case. *See* PhRMA Br. 39 (citing 567 U.S. 387 (2012)). That contention ignores how the unique context of immigration shaped the Court's analysis in that case. There, the Court concluded that federal law preempted an Arizona statute imposing criminal penalties for violations of federal immigration registration requirements. 567 U.S. at 393–94. The Court did *not* find preemption merely because of the comprehensive nature of the federal law. Rather, as the Court

emphasized, "[t]he federal power to determine immigration policy is well settled," in part because "[i]t is fundamental that foreign countries concerned about the status, safety, and security of their nationals in the United States must be able to confer and communicate on this subject with one national sovereign, not the 50 separate States." Id. at 395; see id. at 394–95 (citations omitted) ("The Government of the United States has broad, undoubted power over the subject of immigration and the status of aliens. This authority rests, in part, on the National Government's constitutional power to 'establish a uniform Rule of Naturalization,' and its inherent power as sovereign to control and conduct relations with foreign nations."). In stark contrast to immigration regulation, the 340B program and H.B. 728 address matters of public health and safety—matters that are squarely within the historic police powers of the States. N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. at 655.

At bottom, PhRMA's conflict preemption arguments miss the forest for the trees. The 340B program was designed 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., Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (quoting same), *rev'd on other grounds sub nom. Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022). 340B providers and their patients benefit greatly from the use of contract

pharmacies, which allow hospitals to provide more comprehensive services. H.B. 728, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer improved and expanded health care to their patients. Therefore, not only does H.B. 728 not interfere with Congress's 340B scheme; it "furthers" it. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 82 (1987); *PhRMA v. McClain*, 95 F.4th at 1144–45 ("[Arkansas' similar 340B law] does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: Act 1103 assists in fulfilling the purpose of 340B.).

II. H.B. 728 DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

PhRMA argues that H.B. 728 violates the dormant Commerce Clause because it regulates conduct outside of Mississippi. PhRMA Br. 50. But that contention is squarely foreclosed by *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023).

As a factual matter, H.B. 728 applies *only* to 340B drugs dispensed to patients of *Mississippi* 340B hospitals pursuant to contract pharmacy arrangements. Even to the extent H.B. 728, like "many (maybe most) state laws," may *indirectly* impact "extraterritorial behavior" for drug companies that are headquartered outside of Mississippi, *see Nat'l Pork Producers*, 598 U.S. at 374, H.B. 728 itself in no way targets "transactions by those with *no* connection' to Mississippi." PhRMA Br. 52 (quoting *Nat'l Pork Producers*, 598 U.S. at 376 n.1). To the contrary, H.B. 728 is

focused entirely on drug distribution to patients of Mississippi hospitals. Thus, even if PhRMA had a valid legal theory about extraterritorial effects, it would not apply to H.B. 728 on the facts. *See Nat'l Pork Producers*, 598 U.S. at 375 (quoting *Hoyt v. Sprague*, 103 U. S. 613, 630 (1881)) ("[T]his Court has recognized the usual "legislative power of a State to act upon persons and property within the limits of its own territory.").

But PhRMA has no valid legal theory. *National Pork Producers* flatly rejected the kind of "almost per se" extraterritoriality rule that PhRMA seeks here, holding that the dormant Commerce Clause does not forbid "enforcement of state laws that have the practical effect of controlling commerce outside the State." Nat'l Pork Producers, 598 U.S. at 371 (internal quotation marks omitted). Instead, National Pork Producers explained that the "very core" of its dormant Commerce Clause jurisprudence is the "antidiscrimination principle," i.e., prohibiting States from engaging in "economic protectionism" by privileging in-state competitors over outof-state competitors. Id. at 369. Here, PhRMA does not claim that Mississippi's state law is in some way discriminatory against out-of-state manufacturers. Nor could it. The law treats in-state and out-of-state manufacturers the same. PhRMA should not be permitted to revive this "extraterritoriality doctrine" just one year after the Supreme Court rejected it. *Id.* at 371.

III. H.B. 728 IS NOT UNCONSTITUTIONALLY VAGUE.

An economic regulation is invalid "only if it commands compliance in terms 'so vague and indefinite as really to be no rule or standard at all'... or if it is 'substantially incomprehensible." *Ford Motor Co. v. Tex. Dep't Transp.*, 264 F.3d 493, 507 (5th Cir. 2001) (citing *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122 n. 2 (5th Cir. 1991)). That is not the case here.

H.B. 728 is not unconstitutionally vague because it does not include a definition of "interference." Drug "manufacturer[s] or distributor[s]"—the only entities subject to the provisions' prohibitions—can readily assess what conduct is prohibited by the term "interfere." Countless criminal and civil statutes prohibit "interference" without expressly defining the term. The Supreme Court of Mississippi, for example, has upheld the application of a state law that used the term "interfere" without providing a statutory definition based on the "the oft-cited (and statutorily mandated) rule of statutory interpretation that nontechnical [w]ords contained in statutes are to be interpreted 'according to their common and ordinary acceptation and meaning." *Rex Distrib. Co., Inc. v. Anheuser-Busch, LLC*, 271 So. 3d 445, 455 (Miss. 2019) (cleaned up) (quoting Miss. Code Ann. § 1-3-65 (Rev.

Black's Law Dictionary defines "interference" as "[t]he act of meddling in another's affairs" or "[a]n obstruction or hindrance." *Interference*, Black's Law Dictionary (10th ed. 2014). Merriam-Webster defines "interfere" as "to enter into or take a part in the concerns of others," "to interpose in a way that hinders or impedes," or "to act reciprocally so as to augment, diminish, or otherwise affect one another." *Interfere*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/interfering.

2005)). And there are numerous examples in the U.S. Code. See, e.g., 15 U.S.C. § 77kk(c) ("[I]t shall be unlawful for [specified entity] . . . to do any act directly or indirectly which would interfere with or obstruct or hinder or which might be calculated to obstruct, hinder, or interfere with the policy or policies of the said Department of State or the Government of the United States . . . "); 18 U.S.C. § 245(b) ("Whoever . . . by force or threat of force willfully injures, intimidates or interferes with, or attempts to injure, intimidate or interfere with [specified persons] shall be fined . . . or imprisoned . . . "); 29 U.S.C. § 158(a) ("It shall be an unfair labor practice for an employer [] to interfere with, restrain, or coerce employees in the exercise of the rights . . . [or] to dominate or interfere with the formation or administration of any labor organization . . . "); 29 U.S.C. § 2615(a)(1) ("It shall be unlawful for any employer to interfere with, restrain, or deny the exercise of or the attempt to exercise, any right..."); 42 U.S.C. § 3617 ("It shall be unlawful to coerce, intimidate, threaten, or interfere with any person in the exercise or enjoyment of ..."); 47 U.S.C. § 333 ("No person shall willfully or maliciously interfere with or cause interference to any radio communications . . . "). Thus, finding the term "interfere" to render H.B. 728 unconstitutionally vague would have vast repercussions throughout the various civil and criminal codes of Mississippi and the nation.

In any event, it is disingenuous for PhRMA to argue that its members do not understand what is meant by "interference." Mississippi and the six other states that have passed these laws are specifically responding to the drug companies' efforts, since 2020, to restrict the use of contract pharmacies. The drug companies know exactly what the law is aimed at preventing. Courts must "interpret the relevant words not in a vacuum, but with reference to the statutory context, 'structure, history, and purpose." Abramski v. United States, 573 U.S. 169, 179 (2014) (citation omitted). And if there is any doubt, the Mississippi courts recognize the "doctrine of 'noscitur a sociis,' the philosophy of which is that the meaning of a doubtful word may be ascertained by reference to words associated with it," meaning that the term "interference" can be considered in the context of the surrounding words "deny," "restrict," and "prohibit." State Farm Ins. Co. v. Gay, 526 So.2d 534, 537 (Miss. 1988).

CONCLUSION

For the foregoing reasons, and those outlined in Defendant-Appellee's Brief, *Amici* respectfully request that the Court affirm the judgment below.

Date: November 15, 2024 Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on November 15, 2024, the foregoing Brief of American Hospital Association, 340B Health, Mississippi Hospital Association, Rural Hospital Alliance, and American Society of Health-System Pharmacists as *Amici Curiae* in Support of Defendant-Appellee was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

/s/ William B. Schultz Counsel for Amici Curiae

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This brief complies with the type-volume limitation of Federal Rule of

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/s/ William B. Schultz Counsel for Amici Curiae

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