No. 24-60342

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,
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

William B. Schultz
Margaret M. Dotzel
Alyssa Howard Card
Zuckerman Spaeder LLP
1800 M Street NW, Suite 1000
Washington, D.C.
(202) 778-1800
wschultz@zuckerman.com

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. INTEREST OF MOVANTS

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. CONCLUSION

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,

/s/ William B. Schultz
William B. Schultz
Margaret M. Dotzel
Alyssa Howard Card
Zuckerman Spaeder LLP
1800 M Street NW, Suite 1000
Washington, D.C.
(202) 778-1800
wschultz@zuckerman.com

Counsel for Amici Curiae

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

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

EXHIBIT A

No. 24-60342

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,
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

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

William B. Schultz
Margaret M. Dotzel
Alyssa Howard Card
Zuckerman Spaeder LLP
1800 M Street NW, Suite 1000
Washington, D.C.
(202) 778-1800
wschultz@zuckerman.com

Counsel for Amici Curiae

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

***Novartis Pharmaceuticals Corporation v. Fitch*, No. 24-60342**

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*

William B. Schultz
Margaret M. Dotzel
Alyssa Howard Card
Zuckerman Spaeder LLP
1800 M Street NW, Suite 1000
Washington, D.C. 20036

Date: November 15, 2024

/s/ William B. Schultz
William B. Schultz

Attorney of Record for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

RULES

REGULATIONS

INTEREST OF *AMICI CURIAE*[1]

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.

[1] 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

"Section 340B, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to offer discounted drugs to covered entities for purchase. It is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies." *Novartis Pharms. Corp. v. Johnson*, No. 21-5229, Novartis Br. 4, Doc. No. 1949831 (June 8, 2022) (Novartis D.C. Cir. Br.). Plaintiff-Appellant Novartis Pharmaceuticals Corporation (Novartis) submitted these exact words to the United States Court of Appeals for the D.C. Circuit only two years ago when faced with the federal government's attempt to penalize the company's harsh restrictions on contract pharmacy arrangements. The D.C. Circuit adopted Novartis's position, holding that Section 340B is "silent about delivery conditions" and contract pharmacy arrangements. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). After banking that win, Novartis has abruptly switched course in this litigation, now arguing that Mississippi also lacks the authority to fill that federal statutory hole. Seeking to avoid all accountability for its rapacious contract pharmacy restrictions, be it from the federal government or the States, this whiplash-inducing, heads-I-win-tails-you-lose argument is contrary to law for the many reasons explained below. But it is—regrettably—entirely consistent with Novartis and the drug industry's pattern of

behavior in connection with the 340B program, contract pharmacy arrangements, and their desire to pad their profits at the expense of hospitals and the patients they serve.

Four years ago, amid a devastating pandemic, Novartis and 38 other drug manufacturers 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, Novartis and other major drug companies 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.[4] 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.[5]

---

[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.

[3] 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.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[6] This is why, contrary to Novartis's claim, Novartis Br. 6, 340B covered entities have relied on contract pharmacies since *the beginning* of the program.[7] Even fewer—only one in five 340B hospitals—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 three-quarters of the savings associated with restricted drugs.[10] Denied these and other 340B savings associated with contract pharmacies, 340B hospitals have been forced

---

[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/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[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.

to cut critical programs and services, and some patients have been denied discounts on their drugs.[11]

Savings from contract pharmacy relationships are especially important for another reason: the fragile state of hospital finances. In stark contrast to the pharmaceutical industry, 340B hospitals typically operate with razor-thin (and often negative) margins.[12] 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.[13] 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).

---

[11] *Id.* at 1.

[12] 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* 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.

[13] *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.

The restrictions at issue here by drug companies like Novartis 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 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

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

[15] 340B Health, *Faces of 340B: Tiffany Poole, Director of Pharmacy at Southwest Mississippi Regional Medical Center, Mississippi*, https://www.340bhealth.org/newsroom/faces-of-340b/tiffany-poole.

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 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

[16] *Id.*

[17] *Id.*

Act." *See* Miss. Code H.B. 728, Section 4.[18] This law prohibits 340B manufacturers from directly or indirectly denying, restricting, prohibiting, discriminating against, 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.[19] 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 Novartis 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).

And here, Novartis has no chance of success.[20] 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, Novartis takes the

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

[19] *Id.*

[20] Novartis 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. 39–43.

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. Novartis's argument is especially inapplicable here because "[p]harmacy has traditionally been regulated at the state level, and we 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 Novartis's preemption claims regarding materially similar state laws. *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).

"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, 485 (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)). Novartis 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).

Novartis does not claim that H.B. 728 is expressly preempted. Nor does it deny that States have police power over public health policy, 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 Novartis has cited during this litigation, H.B. 728 is presumptively *not* preempted.[21] Novartis 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.

[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).

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. 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, Novartis relies on what it describes as "the thorough and comprehensive reach" of 340B to support its argument that the federal government intended to occupy a field with the 340B program. *See* Novartis Br. 25. But Novartis 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, Novartis 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.

Novartis nevertheless asserts that *Astra*'s discussion of the 340B program's centralized enforcement scheme proves the statute's preemptive effect. Novartis Br. 26. 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, Novartis'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," Novartis would have to further demonstrate that H.B. 728 intrudes into that field, which it has failed to do.

Relying on decisions made in connection with claims that there is a *federal* statutory requirement to honor contract pharmacies, Novartis also asserts that the omission of a contract pharmacy requirement in the 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. Novartis Br. 28–29 (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)). It is rich that Novartis, after arguing in the D.C. Circuit that statutory silence does not prohibit manufacturers from adopting limitations on sales to covered entities that dispense 340B drugs through contract pharmacies, *see* Novartis D.C. Cir. Br. 4, is now

[22] *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").

arguing that that same statutory silence precludes state action. Novartis Br. 28–29. Novartis cannot have it both ways.

Contrary to Novartis's current argument, the Third Circuit and D.C. Circuit both 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; *Novartis v. Johnson*, 102 F.4th at 469. Neither court said anything about what *States* may do in the face of the federal law's "silence." And as other courts have held, Novartis 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).

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

Novartis also claims that H.B. 728 is preempted because it conflicts with the federal 340B statute. But Novartis 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 Novartis, 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 Novartis may charge for these drugs.

Nor does H.B. 728 change the character of the contract pharmacies, which function as the covered entities' pharmacies, not covered entities themselves. *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, Novartis 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).

At bottom, Novartis'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.).

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,

/s/ William B. Schultz
William B. Schultz
Margaret M. Dotzel
Alyssa Howard Card
Zuckerman Spaeder LLP
1800 M Street NW, Suite 1000
Washington, D.C.
(202) 778-1800
wschultz@zuckerman.com

Counsel for Amici Curiae

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

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 4,104 words, as counted by Microsoft Word, excluding the parts of the brief excluded by Federal Rule of Appellate Procedure 32(f). This brief 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.

I further certify that (1) any required privacy redactions have been made, 5th Cir. R. 25.2.13; and (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1.

/s/ William B. Schultz
Counsel for Amici Curiae