UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, *v.* LYNN FITCH, in her official capacity as ATTORNEY GENERAL OF THE STATE OF MISSISSIPPI, *Defendant*.	Case No. 1:24-cv-00164-HSO-BWR

AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, THE MISSISSIPPI HOSPITAL ASSOCIATION, AND THE RURAL HOSPITAL ALLIANCE'S UNOPPOSED MOTION TO FILE *AMICUS* BRIEF IN SUPPORT OF DEFENDANT LYNN FITCH'S OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

The American Hospital Association, 340B Health, the Mississippi Hospital Association, and the Rural Hospital Alliance (collectively, the "Proposed *Amici*") move this Court for leave to file the attached *amicus curiae* brief in support of Defendant Lynn Fitch's opposition to Plaintiff Novartis Pharmaceuticals Corporation's Motion for Preliminary Injunction (Exhibit A), as follows:

1. Proposed *Amici* are four hospital associations with members in Mississippi that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies. Proposed *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 340B program is essential to achieving this goal. Proposed *Amici* therefore have a strong interest in the success of Mississippi's legislative efforts to protect the 340B program. The attached

amicus brief provides the Court, for example, information regarding how Proposed *Amici's* members use the 340B discounts they receive for drugs dispensed through contract pharmacies and how Plaintiffs' restrictive contract pharmacy policies negatively impact Proposed *Amici's* members' patients.

2. Because neither the Federal Rules of Civil Procedure nor this Court's local rules address *amicus* briefs in district court, *Amici* have looked to the Federal Rule of Appellate Procedure 29 for guidance concerning the standards for filing an amicus brief. Because we meet the requirements of Fed. R. App. P. 29 and would assist the Court in resolving the issues before it, we urge the Court to grant this motion.

3. Proposed *Amici*'s brief, which is timely filed, provides the Court with a unique perspective and specific information the parties cannot otherwise provide about 340B hospitals in Mississippi and nationwide that can assist the Court's evaluation of the case, and it expounds upon preemption arguments that are directly responsive to the claims set forth in Plaintiff's Memorandum in Support of its Motion for Preliminary Injunction. Additionally, the Court's ruling on Plaintiff's Motion for Preliminary Injunction will directly affect Proposed *Amici's* members, further underlining the value of the *amicus* brief.

4. Proposed *Amici*'s brief is typewritten in 12-point Times New Roman font with 11-point footnotes, and it is 17.5 pages without the table of contents and table of authorities, which is less than half of Defendant's 35-page limit, per S.D. Miss. L.R. 7(b)(5); *see* Fed. R. App. P. 29(a)(5) (providing that an *amicus* brief "may be no more than one-half the maximum length authorized by these rules for a party's principal brief"). Under Fed. R. App. P. 32(f), tables of contents and authorities do not count towards the page limit. However, if, consistent with its June 17, 2024 text-only order, this Court counts *Amici*'s table of contents and table of authorities

towards *Amici*'s page limit, *Amici* seek leave to file an oversize brief of 22.5 pages, which is one-half of the 45 pages that the Court is permitting the parties to file pursuant to that same order. *Amici* would otherwise be unable to provide the Court with all the information that *Amici* believe will be helpful to this Court's deliberations.

5. Proposed *Amici* consulted with counsel for Plaintiff and Defendant and represents that Plaintiff's counsel does not oppose and Defendant's counsel has consented to this Motion.

Accordingly, Proposed *Amici* timely file this motion and respectfully request the Court to grant their motion to file an *amicus* brief in the form attached as Exhibit A.

Dated: June 17, 2024

Respectfully submitted,

/s/ George H. Ritter
George H. Ritter (MSB #5372)
WISE CARTER CHILD & CARAWAY, P.A.
P.O. Box 651
Jackson, MS 39205-0651
401 E Capitol St., 600 Heritage Building
Jackson, MS 39201
Tel.: (601) 968-5526
Fax: (601) 944-7738
ghr@wisecarter.com

Counsel for Proposed Amici Curiae

CERTIFICATE OF SERVICE

I certify that on June 17, 2024, I caused a true and correct copy of American Hospital Association, 340B Health, Mississippi Hospital Association, and Rural Hospital Alliance's Unopposed Motion to File *Amicus* Brief in Support of Defendant Lynn Fitch's opposition to Plaintiff's motion for preliminary injunction to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

/s/ George H. Ritter
George H. Ritter

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, *v.* LYNN FITCH, in her official capacity as ATTORNEY GENERAL OF THE STATE OF MISSISSIPPI, *Defendant*.	Case No. 1:24-cv-00164-HSO-BWR

BRIEF OF *AMICI CURIAE*, AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MISSISSIPPI HOSPITAL ASSOCIATION, AND RURAL HOSPITAL ALLIANCE IN SUPPORT OF DEFENDANT LYNN FITCH'S OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

George H. Ritter
WISE CARTER CHILD & CARAWAY, P.A.
401 East Capitol Street, Suite 600
Jackson, Mississippi 39201
Post Office Box 651
Jackson, Mississippi 39205
(P): 601-968-5500
(F): 601-944-7738
ghr@wisecarter.com
Counsel for Amici Curiae

EXHIBIT
A

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

REGULATIONS

INTERESTS OF *AMICI CURIAE*[1]

Amici are four hospital associations whose members receive 340B discounts for drugs that they purchase, many of which are 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. 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.

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 82 hospital members, many of which participate in the 340B program and are impacted by efforts of drug companies to limit access to reduce 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,

[1] Pursuant to Fed. R. App. P. 29(a)(4)(A), *Amici Curiae* state that that they are nonprofit organizations. None of *Amici* has a parent company, and no publicly traded company holds ten percent or more interest in any of *Amici*.

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.

BACKGROUND AND SUMMARY OF ARGUMENT

"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 Opening Br. at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5229, Doc. No. 1949831 (June 8, 2022) ("Novartis D.C. Br."). Plaintiff 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). Banking that win, Novartis abruptly switches 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's 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.

Almost four years ago, amid a devastating pandemic, Novartis and 35 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 hospitals and community health centers. *See* 42 U.S.C. §§ 256b(a)(1)(4). Before 2020, Novartis and the other 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 PhRMA v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024) ("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 of its drugs.[2] Recognizing an opportunity to boost its own bottom line, Novartis quickly followed suit,[3] as did 34 other major drug companies.[4]

The contract pharmacy arrangements that drug companies like Novartis 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

---

[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] *See Novartis Pharms. Corp. v. Brown*, No. 6:23-cv-1042 (D. Md.), Compl. ¶ 31, 37, ECF No. 1. Novartis initially imposed a 40-mile limitation on a 340B hospital's use of a contract pharmacy. *Id.* ¶ 31. Novartis's current policy permits the use of a single contract pharmacy but only by hospitals lacking an in-house pharmacy. *Id.* ¶ 37.

[4] 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/.

an average of 52% of overall 340B savings.[5] 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.[6]

The drug company restrictions have substantially cut the savings from the 340B program, which is devasting for the very hospitals in Mississippi that provide 82% of all hospital care that is provided to Medicaid patients.[7] And of course this means that patients lose services. St. Dominic – Jackson Memorial in Mississippi 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 to, among other things, continue to provide healthcare services to patients in underserved areas, including providing free care for indigent patients, helping to offset the employee cost of health insurance, and providing cash cards for indigent patients.

Southwest Mississippi Regional Medical Center (SMRMC) is a disproportionate share hospital that serves a significant rural population; patients often must travel an hour or more to receive medical care.[8] Prior to the drug company restrictions on 340B discounts for drugs dispensed by community pharmacies, SMRMC had planned to use some of its 340B discount savings to expand behavioral health services, offer more patient financial assistance, and establish

---

[5] 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.

[6] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, 340 OPAIS, https://340bopais.hrsa.gov/coveredentitysearch (last visited June 15, 2024).

[7] *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.

[8] 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.

more preventative screening and medication management service to reduce hospital readmissions.[9] Instead, now some patients are being forced to forgo their medications or use them sparingly. Some families have even been forced to buy a single EpiPen for multiple family members.[10]

Magnolia Regional Health Center is a community hospital located in Corinth, Mississippi. Approximately 24 percent of Magnolia's patients are uninsured or underinsured. Magnolia utilizes the 340B program to offset some of the losses it incurs in caring for these patients. The restrictions being imposed by drug companies are placing a hardship on patients who may not be able drive to the "permitted" pharmacy and or alternatively may not be able to afford paying full price and so will just miss getting a necessary medication.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[11] This is why, contrary to Novartis's claim (Novartis Mem. Supp. PI Mot at 21, ECF No. 5 ("Novartis Mem.")), 340B covered entities have relied on contract pharmacies since the beginning of the program.[12] Even fewer—only one in five 340B hospitals—have in-house "specialty" pharmacies, which many payers 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.[13] Thus, 340B hospitals typically *must*

---

[9] *Id.*

[10] *Id.*

[11] 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.

[12] 60 Fed. Reg. 55,586 (Nov. 1, 1995).

[13] 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.

contract with at least one specialty pharmacy to receive the 340B discount for their patients' high-priced specialty drugs.[14] 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.[15] Denied these and other 340B savings associated with contract pharmacies, 340B hospitals have been forced to cut critical programs and services, and patients have been denied discounts on their drugs.[16]

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.[17] 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.[18] Savings from the 340B program help to offset the cost of providing uncompensated health care services to underserved populations. As the Supreme Court recognized, "340B hospitals perform valuable

---

[14] 340B Health, *supra* note 5, at 7 (citing Adam J. Fein, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2022).

[15] *Id.* at 6.

[16] *Id.* at 1.

[17] 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.

[18] *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 17, at 2; Dobson et al., *supra* note 17, at 13–17.

services for low-income and rural communities but have to rely on limited federal funding for support." *AHA v. Becerra*, 142 S. Ct. 1896, 1905–06 (2022).[19]

Faced with the drug industry's unprecedented assault on Mississippi's health care safety net, the Mississippi legislature responded. By an overwhelming 132/33 vote, it passed a new law, entitled "Defending Affordable Prescription Drug Costs Act." *See* H.B. 728, Section 4.[20] 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/to 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.[21] 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.

Novartis now seeks a preliminary injunction that would halt Mississippi's exercise of its police power to protect public health and safety. The motion for preliminary injunction should be denied 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. Congress did not create or occupy any field through its 340B legislation. *See PhRMA v. McClain*, 95 F.4th 1136, 1143–44 (8th Cir. 2024). Nor does H.B.728 conflict with the federal 340B statute. *Id.* at 1144–45. Likewise, the law is not preempted by the Federal Food,

---

[19] This finding by the Supreme Court illustrates just how ludicrous it is for Novartis to repeatedly assert that patients are not helped by the 340B program. Novartis Mem. 6, 26.

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

[21] *Id.* 21 U.S.C. § 355-1 is a provision that permits the U.S. Food and Drug Administration to require a drug to have in place a Risk Evaluation and Management Strategy pursuant to which, among other things, the distribution of a drug may be limited. 21 U.S.C. § 355-1.

Drug, and Cosmetic Act. At bottom, Novartis 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. It is especially untrue 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; *see MacDonald v. Monsanto Co*., 27 F.3d 1021, 1023 (5th Cir. 1994). Giving the 340B statute the preemptive effect that Plaintiff seeks would turn upside down the very "federalism concerns" that underlie preemption questions and eviscerate "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

ARGUMENT

To meet the requirements for a preliminary injunction, Novartis must establish (1) that it is likely to succeed on the merits; (2) that it is likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in its favor; and (4) that an injunction is in the public interest. *Winter v. Natural res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also McKinney ex rel. NLRB v. Creative Vision Res. LLC*, 783 F.3d 293, 297 (5th Cir. 2015). Novartis fails to establish that it has met any of these factors. *Amici* focus on the first, third, and fourth factors, on which they believe they can best assist the Court.

I. NOVARTIS'S CLAIM IS UNLIKELY TO PREVAIL ON THE MERITS

A. 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*, 518 U.S. at 485). 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.[22] Thus, H.B. 728 is presumptively *not* preempted, and Novartis 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 has failed to do.

1. 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. NCAA*, 138 S. Ct. 1461, 1480 (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.*

[22] *See, e.g.*, *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995); *Ass'n of Taxicab Operators USA v. City of Dallas*, 720 F.3d 534, 538 (5th Cir. 2013).

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 "pervasive" and "comprehensive" character of the federal scheme to support its contention that Congress intended to occupy a field with the 340B program. *See* Novartis Mem. at 15. 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 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 and pervasive federal scheme through the 340B program, Novartis relies primarily on inapposite precedent. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011). Contrary to Novartis's contention, *see* Novartis Mem. at 16, *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.

Novartis nevertheless asserts that *Astra*'s discussion of the 340B program's centralized enforcement scheme proves the statute's preemptive effect. Novartis Mem. at 16. 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.[23] 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 must further demonstrate that H.B. 728 intrudes into that field. But Novartis fails to do so.

Novartis further claims that H.B. 728 "create[s] a separate, state-specific pathway to enforce 340B requirements." Novartis Mem. at 16. 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.

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

Novartis next 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 since H.B. 728 only requires drug companies to continue a practice (*i.e.*, recognition of multiple contract pharmacies) that had been in place since 2010. No one, including

[23] *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").

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.

The contract pharmacies are not covered entities, as Novartis implies, but instead function as the hospitals' pharmacies. 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).

Novartis contends that H.B. 728 conflicts with federal 340B law by purporting to unilaterally expand the universe of sales eligible for the 340B discount. Novartis Mem. at 17. Relying on decisions made in connection with claims that there is a *federal* statutory requirement to honor contract pharmacies, Novartis 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. Novartis Mem. at 17–18 (relying on *Sanofi Aventis v. U.S. Dept. of Health & Human Servs.*, 58 F.4th at 696, 703 (3d Cir. 2023) and *Novartis* slip op. at 8). 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. Br. 4, is now arguing that that same statutory silence precludes state action. Novartis Mem. at 17–18. Novartis cannot have it both ways.

In any event, Novartis distorts those decisions, and the Congressional record. Contrary to Novartis'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 Aventis*, 58 F.4th at 703, 707. The Third Circuit said nothing about what *States* may do in the face of the federal law's "silence." 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 (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).

Novartis also mischaracterizes the congressional record through its argument that Congress contemplated—and rejected—adding a provision to the 340B statute regarding contract pharmacy arrangements. *See* Novartis Mem. at 17. But this is mistaken for a few reasons. First, HHS has embraced the role of contract pharmacies in the 340B program at least since 1996,[24] and it finalized guidance allowing multiple contract pharmacies shortly before Congress amended the 340B statute in 2010.[25] And contract pharmacies still play a role in the 340B program, even under Novartis and other drug companies' restrictive contract pharmacy policies. *See, e.g.*, Compl. ¶ 28–36.

Moreover, the legislative history cited by Novartis demonstrates that Congress did *not* reject the use of contract pharmacies when it enacted the 340B program. An unenacted, earlier version of the bill addressed how and where 340B drugs must be dispensed, stating that 340B discounts would be required for drugs "purchased *and dispensed by, or under a contract entered*

[24] *See* 61 Fed. Reg. at 43,549–50 ("The statute is silent as to permissible drug distribution systems. … It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities. . . . If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance.").

[25] *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 42 Fed. Reg. 10,272, 10,272 (Mar. 5, 2010); Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (Mar. 21, 2010) (codified at 42 U.S.C. § 256b(a)(1)).

into for on-site pharmacy services with," a covered entity. S. Rep. No. 102-259, at 2 (1992) (emphasis added). If that language had been retained, 340B discounts would have been allowed *only* for drugs dispensed by "on-site" pharmacies. *Id.* The elimination of the phrases "dispensed by" and "on-site pharmacy services" changed the provision to *permit* contract pharmacy relationships.

Novartis further claims another false conflict—that H.B. 728 creates Mississippi's "own enforcement pathways before administrative agencies" for federal 340B requirements. Novartis Mem. at 19. But the state penalties "are aimed at activity that falls outside the purview of 340B." *PhRMA v. McClain*, 95 F.4th at 1145. The fact that Mississippi may impose different penalties on drug companies that violate its state statute does not create a conflict with the federal 340B penalties for diversion, duplicate discounts, or overcharging. *See, e.g.*, *Medtronic*, 518 U.S. at 495; *Dublino*, 413 U.S. at 422.

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.*, *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). 340B providers and their patients benefit greatly from the use of contract pharmacies, which allow hospitals to provide more comprehensive services and allow patients to access more affordable drugs, including by allowing them to pick up their medicines more conveniently at their local pharmacies. H.B. 728, in turn, enables 340B providers to reach more patients and to provide more comprehensive services. 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.).

B. H.B. 728 Does Not Regulate Drug Pricing and Would Not Be Preempted Even if It Did.

Novartis next relies on a misreading of a single, out-of-Circuit case to argue that H.B. 728 is preempted by federal drug laws, including those governing regulatory exclusivity and patent protection periods. Novartis Mem. at 20 (citing *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) ("*BIO I*")). Contrary to Novartis's contention, *BIO I* does not compel the conclusion that H.B. 728 is preempted because states are not permitted to set the price of patented drugs or "'re-balance' the 'rewards and incentives' insofar as it relates to inventive new drugs." Novartis Mem. at 22 (quoting *BIO I*, 496 F.3d at 1374). The Federal Circuit panel explicitly stated that its holding did not apply to state regulation that "did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right." *See Biotech. Indus. Org. v. Dist. of Columbia*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) ("*BIO II*") (Gajarsa, J., concurring in the denial of the petition for rehearing en banc). Unlike the District of Columbia law at issue in that case, H.B. 728 is *not* "targeted at the patent [or exclusivity] right," and it does not "appl[y] only to patented drugs" or drugs subject to market exclusivity. *BIO I*, 496 F.3d at 1374. That distinction alone defeats Novartis's patent/exclusivity preemption argument.

In addition, *BIO I* did not hold that States are barred from enacting laws that touch upon patented drugs. *See BIO II*, 505 F.3d at 1346 n.1 (Gajarsa, J., concurring) ("It is well established that states can generally regulate patented products as part of their general exercise of police powers without preemption, even if this regulation incidentally affects the profits a patentee gains from its patent."). For example, notwithstanding federal patent law, States retain the power to tax

patented products, regulate commercial contracts involving patents, and regulate deceptive practices involving patents. *See, e.g.*, *Webber v. Virginia*, 103 U.S. 344, 347–48 (1880) ("Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted."). Instead, *BIO I* narrowly held that the District of Columbia's penalties for excessive drug prices on patented drugs stood as an obstacle to Congress's determination of the "proper balance between innovators' profit and consumer access to medication." 496 F.3d at 1374; *see also BIO II*, 505 F.3d at 1348 (Gajarsa, J., concurring). Though not at issue in *BIO I*, the same analysis applies to market exclusivity. Here, Congress *already* concluded that 340B pricing appropriately balances "rewards and incentives" for drug companies. *BIO I*, 496 F.3d at 1374.

On its face and in its practical effect, H.B. 728 addresses the "acquisition" by and "delivery" of prescription drugs to contract pharmacies, not the prices paid for them. All it requires is for drug companies like Novartis to deliver 340B drugs, at congressionally-determined 340B prices, to Mississippi's contract pharmacies if a 340B hospital chooses to permit its patients to purchase 340B drugs at contract pharmacies rather than at a hospital pharmacy. Far from regulating pricing, H.B. 728 merely "incorporates by reference" the independent federal scheme, which Mississippi is free to do. *See Hillsborough Cnty. v. Auto. Med. Labs.*, 471 U.S. 707, 710 (1985); *PhRMA v. McClain*, 95 F.4th at 1145.

Even if Novartis's characterization of H.B. 728 as a pricing statute were correct, federal law still would not preempt Mississippi from imposing its own indirect pricing conditions. There is nothing in the 340B statute to indicate that Congress meant for it to be a regulatory ceiling. *See Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 147–48 (1963) (providing that a State statute was not preempted where the relevant federal law "purports only to establish

minimum standards"). In 340B, Congress expressed *no view whatsoever* on whether States can supplement federal pricing standards through separate regulatory requirements that may indirectly impact drug pricing. *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.").

II. THE BALANCE OF EQUITIES AND PUBLIC INTEREST SUPPORT DENYING AN INJUNCTION

In cases where the government is party, the balance of equities and public interest are considered together. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, where the health of the underserved and vulnerable populations is at risk, these factors heavily weigh against an injunction. Specifically, the balance of equities clearly falls in favor of 340B hospitals, which operate on razor-thin margins, and their patients who may otherwise not have access to healthcare, and not in favor of a drug company that reported $14.9 billion in net income in 2023.[26] Novartis' assertion that patients generally do not gain any benefit from the 340B discount, Novartis Mem. at 26, is false and completely refuted by *Amici*'s description of the benefits of the discounts. *See supra* at 2–8. For these reasons, the public interest is better served by ensuring that 340B hospitals continue to serve at-risk populations than by further padding the pockets of an already profitable drug company.

[26] *See Novartis delivers strong full year performance, 10% net sales and 18% core operating income growth (cc[1]), with margin expansion. Continuing innovation momentum with multiple positive Ph3 readouts* 9, Novartis Global Communications (Jan. 31, 2024), https://www.novartis.com/sites/novartis_com/files/q4-2023-media-release-en.pdf.

CONCLUSION

For the foregoing reasons, and those outlined in Defendant's cross-motion, *Amici* respectfully request that the Court deny Novartis's motion for a preliminary injunction.

Respectfully submitted,

/s/ George H. Ritter
George H. Ritter (MSB #5372)
WISE CARTER CHILD & CARAWAY, P.A.
401 East Capitol Street, Suite 600
Jackson, Mississippi 39201
Post Office Box 651
Jackson, Mississippi 39205
(P): 601-968-5500
(F): 601-944-7738
ghr@wisecarter.com

Counsel for Amici Curiae