**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

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| NOVARTIS PHARMACEUTICALS CORPORATION,<br><br>*Plaintiff*,<br><br>*v.*<br><br>PATRICK MORRISEY, in his official capacity as ATTORNEY GENERAL OF THE STATE OF WEST VIRGINIA, et al.,<br><br>*Defendant*. | Case No. 2:24-cv-00272 |

**BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AND WEST VIRGINIA HOSPITAL ASSOCIATION IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

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## INTERESTS OF *AMICI CURIAE*[1]

*Amici* are three 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 West Virginia'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. 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 **West Virginia Hospital Association** (WVHA) is a not-for-profit statewide organization representing hospitals and health systems. Members of WVHA envision a strong healthcare system that supports its members in achieving a strong, healthy West Virginia. Many WVHA members are impacted drug company efforts to limit access to 340B-discounted 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

[1] Pursuant to Fed. R. App. P. 29(a)(4)(A), *Amici Curiae* state that that they are not-for-profit organizations. None of *Amici* has a parent company, and no publicly traded company holds ten percent or more interest in any of *Amici*.

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, now arguing that West Virginia 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 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 drugs if dispensed to 340B patients at community pharmacies (or "contract pharmacies").[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 an average of 52% of overall 340B savings.[5] Of the 37 West Virginia hospitals participating in the 340B drug discount program, 36 contract with at least one community pharmacy.[6]

The drug company restrictions have substantially cut the savings from the 340B program, which is devasting for the very hospitals in West Virginia that provide 86% of all hospital care

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[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* Compl. ¶ 37, ECF No. 1. Novartis initially imposed a 40-mile limitation on a 340B hospital's use of a contract pharmacy. *Id.* Novartis's current policy permits the use of a single contract pharmacy but only by hospitals lacking an in-house pharmacy. *Id.* ¶ 45.

[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/.

[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).

that is provided to Medicaid patients.[7] As one legislator explained, the 340B program "provides a lifeline to rural hospitals and clinics in our state by allowing them to . . . pass that discount on to patients in the form of free or low-cost prescriptions and care for conditions ranging from diabetes to black lung."[8] Several hospitals, including West Virginia University (WVU) Summersville Regional Medical Center, WVU St. Joseph's Hospital, and Boone Memorial Hospital use their 340B savings to provide prescriptions at no cost for those unable to pay.[9]

In addition, hospitals within the WVU system use 340B savings to fund numerous activities, including bedside prescription counseling; a mobile mammography unit; diabetes support groups; and a mobile lung cancer screening unit.[10] But the restrictive drug company policies put these patient-friendly programs at risk. They have caused a whopping $*39 million in annual losses* to the WVU hospital system—threatening the viability of its rural hospitals, which rely on community and specialty pharmacies to provide essential medications to patients. These losses will force the reduction or elimination of services across West Virginia, and rural patients will bear the consequences of drug company greed.

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[7] Dobson DaVanzo Health Economics Consulting, *West Virginia 340B Hospitals Serve More Patients with Low Incomes and Provide the Majority of Hospital Care to Medicaid Patients*, https://www.340bhealth.org/files/WV-340B-Low-Income15040.pdf.

[8] *See* Craig Blair, *'Big Pharma' is Using West Virginia to Scare GOP Supporters of 340B Pharmacies*, WVNews (June 10, 2024), https://www.wvnews.com/opinion/big-pharma-is-using-west-virginia-to-scare-gop-supporters-of-340b-pharmacies/article_f0ca8198-2744-11ef-b7d4-337b8dc01e30.html.

[9] AHA, *The Value of the 340B Program: WVU Medicine St. Joseph's Hospital Case Study* (July 2023), https://www.aha.org/system/files/media/file/2023/07/340B-Case-Study-WVU-St-Josephs-Hospital-West-Virginia.pdf; Boone Memorial Health, *Brighter Futures*, https://www.bmh.org/our-services/brighter-futures.

[10] *The Value of the 340B Program supra* note 8.

Novartis's restrictive policies also threaten hospitals in the Marshall Health Network, like Cabell Huntington Hospital (CHH). As a disproportionate share hospital, CHH predominantly serves low-income patients and provided $149 million in uncompensated care last year—*more than double* its 340B savings. CHH uses 340B savings for critical programs supporting patients who cannot afford their prescriptions; medication adherence; mothers with substance use disorders; and babies of mothers with substance use disorders.[11]

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[12] This is why they have relied on contract pharmacies since the beginning of the program.[13] Even fewer—only one in five—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.[14] Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy to receive the 340B discount for their patients' high-priced specialty

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[11] In this brief, we focus on certain hospitals, but other examples of programs funded by 340B savings are legion. *See, e.g.*, Roane General Hospital, *Prescription For Your Health - Roane General Hospital*, https://roanegeneralhospital.com/services/p4yh/.

[12] 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.

[13] 60 Fed. Reg. 55,586 (Nov. 1, 1995).

[14] 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.

drugs.[15] 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.[16] 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.[17]

In stark contrast to the pharmaceutical industry, 340B hospitals typically operate with razor-thin (and often negative) margins to provide a disproportionate amount of uncompensated care, community health services, and other services to underserved patients.[18] Indeed, "340B hospitals perform valuable 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 West Virginia's health care safety net, the West Virginia legislature responded. By an overwhelming 127/1 vote, it passed a new law, which added a new section to the statute entitled: "Distribution of Safety-Net Drugs to Contract

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[15] 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)).

[16] *Id.* at 6.

[17] *Id.* at 1.

[18] 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; 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.

[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. *See* Novartis Mem. at 7, 27.

Pharmacies; Penalties and Preemption." *See* S.B. 325.[20] This law prohibits manufacturers, wholesale drug distributors, and third-party logistics providers from directly or indirectly denying, restricting, or prohibiting the acquisition or delivery of 340B drugs by/to pharmacies that are authorized by covered entities to receive 340B drugs on their behalf, unless prohibited by the United States Department of Health and Human Services (HHS). *Id.* The act further prohibits manufacturers, wholesale drug distributors, and third-party logistics from requiring 340B entities to submit claims or utilization data, unless required by HHS. *Id.* Any violation of this provision is considered an unfair, abusive, or deceptive trade practice, subject to enforcement and penalties under the West Virginia Consumer Protection Act. *Id.*

Novartis now seeks a preliminary injunction that would halt West Virginia's lawful 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, which just last week the Supreme Court highlighted as the most important factor, even if the equities and harms are equal between movants and the State (and the people it protects)). *Ohio v. EPA*, 603 U.S. ___, slip op. at 11 (2024). 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 at 1143–44; *PhRMA v. Fitch*, No. 1:24-cv-00160-HSO-BWR, Mem. Op. & Order Denying Motion [7] for Preliminary Injunction, ECF No. 21 (S.D. Miss. July 1, 2024); *Novartis v. Fitch*, No. 1:24-cv-00164-HSO-BWR, Mem. Op. & Order Denying Motion [4] for Preliminary Injunction, ECF No. 29 (S.D. Miss. July 1, 2024). Nor does S.B. 325 conflict with the federal 340B statute. *PhRMA v. McClain*, 95 F.4th. at 1144–45. Likewise, the law is not preempted by the Federal Food, Drug,

[20] The text of the statute can be found at https://www.wvlegislature.gov/Bill_Text_HTML/2024_SESSIONS/RS/bills/sb325%20sub2%20enr.pdf.

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; *PhRMA v. Fitch*, slip op. at 19; *Novartis v. Fitch*, slip op. at 14–15; *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir. 1988). 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 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 Henderson for N.L.R.B. v. Bluefield Hosp. Co. LLC*, 902 F.3d 432, 439 (4th Cir. 2018). *Amici* focus on the first factor, which is determinative because Novartis does not come close to meeting it.[21]

### A. S.B. 325 Is Not Preempted By the 340B Statute.

In determining whether a state statute is preempted by federal law, courts are guided first and foremost by the maxim that 'the purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Epps v. JP Morgan Chase Bank, N.A.*, 675 F.3d 315, 322 (4th Cir. 2012) (internal

[21] The Mississippi court determined that there was no need to reach the other preliminary injunction factors but noted that it had considered them and determined that they would not alter the Court's conclusion. *PhRMA v. Fitch*, slip op. at 40; *Novartis v. Fitch*, slip op. at 25.

citation omitted). 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," *S. Blasting Servs., Inc. v. Wilkes Cnty., N.C.*, 288 F.3d 584, 590 (4th Cir. 2002) (quoting *Medtronic*, 518 U.S. at 485). Novartis has the burden to show that Congress intended to preempt S.B. 325. *PhRMA v. Walsh*, 538 U.S. 644, 661–62 (2003). Novartis does not claim that S.B. 325 is expressly preempted or deny that States have police power over public health policy.[22] Thus, S.B. 325 is presumptively *not* preempted, and Novartis must demonstrate Congress's "clear and manifest purpose" to supersede West Virginia's historic authority to regulate in the public health arena. *Medtronic*, 518 U.S. at 485 (citation omitted). It has failed to do so.

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

Courts do not infer field preemption of a State statute in an area traditionally within the scope of States' police powers. *See, e.g.*, *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Instead, field preemption is found only in rare instances, "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,

[22] *See, e.g.*, *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008); *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995).

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*, 496 U.S. at 87.

Ignoring this well-established precedent, Novartis relies on what it describes as 340B's "pervasive" and "comprehensive" character 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." And recent cases, including two decided this week, hold the opposite — "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; *PhRMA v. Fitch*, slip op. at 28; *Novartis v. Fitch*, slip op. at 21.

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. Contrary to Novartis's contention, *see* Novartis Mem. at 15–17, *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) 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. The only *mention* of preemption in *Astra* is in footnote 5 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 16–17. 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 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 to restore contract pharmacies as an outlet for 340B drugs.

Novartis further claims that S.B. 325 "create[s] a separate, state-specific pathway to enforce 340B requirements." Novartis Mem. at 16–17. But this again mischaracterizes S.B. 325, which does not authorize West Virginia 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. By contrast, S.B. 325 allows West Virginia *only* to enforce S.B. 325'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. S.B. 325 Does Not Conflict with the 340B Statute.**

Further, Novartis cannot identify any actual conflict between S.B. 325 and the 340B statute, particularly since S.B. 325 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 Novartis, disputes that 340B hospitals are entitled to discounts under the 340B statute if the 340B drugs are dispensed at a hospital pharmacy. The West Virginia law simply allows 340B hospitals to prescribe

[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").

discounted drugs to eligible patients at contract pharmacies. S.B. 325 does not change the prices that Novartis may charge.

Novartis contends that S.B. 325 conflicts with federal 340B law by purporting to unilaterally expand the universe of sales eligible for the 340B discount. Novartis Mem. at 18. Relying on decisions made in connection with claims that there is a *federal* statutory requirement to honor contract pharmacies, Novartis argues that the lack of a contract pharmacy *requirement* constitutes prohibition. Novartis Mem. at 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 limiting sales of 340B drugs dispensed through contract pharmacies, *see* Novartis D.C. Br. 4, now contends that statutory silence precludes state action. Novartis cannot have it both ways.

In any event, Novartis distorts those decisions and the congressional record. *Sanofi* 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; *PhRMA v. Fitch*, slip op. at 22; *Novartis v. Fitch*, slip op. at 17.

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 18. 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. Compl. ¶ 45.

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 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. The elimination of the phrases "dispensed by" and "on-site pharmacy services" changed the provision to *permit* contract pharmacy relationships.

Novartis asserts another false conflict—that S.B. 325 creates West Virginia's "own enforcement pathway" 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, so "adjudications under [S.B. 325] will not interfere with federal enforcement of Section 340B's compliance mechanism." *PhRMA v. Fitch*, slip op. at 27. The fact that West Virginia may

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[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)).

impose different penalties on companies that violate its statute does not create a conflict with 340B penalties for diversion, duplicate discounts, or overcharging. *See, e.g.*, *Medtronic*, 518 U.S. at 495.

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 patients to access more affordable drugs at their local pharmacies. S.B. 325, in turn, enables 340B providers to reach more patients and to provide more comprehensive services. Therefore, not only does S.B. 325 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."); *PhRMA v. Fitch*, slip op. at 22; *Novartis v. Fitch*, slip op. at 17–18.

**B. S.B. 325 Does Not Regulate Drug Pricing and Would Not Be Preempted Even If It Did.**

Novartis next misconstrues an out-of-Circuit case to argue that S.B. 325 is preempted by federal drug laws governing regulatory exclusivity and patent protection periods. Novartis Mem. at 22–23 (citing *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (*BIO I*)). 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). Here, S.B. 325 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.

*BIO I* also 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."); *see also 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 D.C. penalties for excessive drug prices on patented drugs threatened 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). 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 effect, S.B. 325 addresses the "acquisition" by and "delivery" of prescription drugs to contract pharmacies, not their prices. It only requires drug companies to deliver 340B drugs at congressionally-determined 340B prices to contract pharmacies chosen by West Virginia's 340B hospitals. Far from regulating pricing, S.B. 325 merely "incorporates by reference" the independent federal scheme, which West Virginia 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 S.B. 325 as a pricing statute were correct, federal law still would not preempt West Virginia 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). 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.").

## CONCLUSION

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

Respectfully submitted,

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**pro hac vice* motion forthcoming

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