PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 25-1054

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff – Appellee,

v.

JOHN B. MCCUSKEY, in his official capacity as Attorney General of West Virginia; JOHN BERNABEI, in his official capacity as a member of the West Virginia Board of Pharmacy; JAMES RUCKER, in his official capacity as a member of the West Virginia Board of Pharmacy; JENNA MISITI, in her official capacity as a member of the West Virginia Board of Pharmacy; SAM KAPOURALES, in his official capacity as a member of the West Virginia Board of Pharmacy; DAVID BOWYER, in his official capacity as a member of the West Virginia Board of Pharmacy; DENNIS LEWIS, in his official capacity as a member of the West Virginia Board of Pharmacy; ROBERT DUNCAN, in his official capacity as a member of the West Virginia Board of Pharmacy; ALLAN MCVEY, in his official capacity as Insurance Commissioner,

Defendants – Appellants.

340B HEALTH; AMERICAN HOSPITAL ASSOCIATION; WEST VIRGINIA HOSPITAL ASSOCIATION; WEST VIRGINIA PRIMARY CARE ASSOCIATION,

Amici Supporting Appellants.

No. 25-1055

ABBVIE, INCORPORATED, a Delaware corporation; ALLERGAN, INCORPORATED, a Delaware corporation; DURATA THERAPEUTICS, INC., a Delaware corporation; ABBVIE PRODUCTS LLC, a Georgia limited liability company; APTALIS PHARMA US, INC., a Delaware corporation;

PHARMACYCLICS LLC, a Delaware limited liability company; ALLERGAN SALES, LLC, a Delaware limited liability company,

Plaintiffs – Appellees,

v.

JOHN B. MCCUSKEY, in his official capacity as Attorney General of West Virginia; ALLAN MCVEY, in his official capacity as the West Virginia Insurance Commissioner; JOHN BERNABEI; JAMES RUCKER; JENNA MISITI; SAM KAPOURALES; DAVID BOWYER; DENNIS LEWIS, in his official capacity as Board President of the West Virginia Board of Pharmacy; ROBERT DUNCAN; MICHAEL GOFF, in his official capacity as the Executive Director of the West Virginia Board of Pharmacy,

Defendants – Appellants.

340B HEALTH; AMERICAN HOSPITAL ASSOCIATION; WEST VIRGINIA HOSPITAL ASSOCIATION; WEST VIRGINIA PRIMARY CARE ASSOCIATION,

Amici Supporting Appellants.

and

COMMUNITY ONCOLOGY ALLIANCE, INC.; THE PIONEER INSTITUTE,

Amici Supporting Appellees.

No. 25-1056

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff – Appellee,

v.

JOHN B. MCCUSKEY, in his official capacity as Attorney General of the State of West Virginia; ALLAN MCVEY, in his official capacity as Insurance

Commissioner of West Virginia; JOHN BERNABEI; JAMES RUCKER; JENNA MISITI; SAM KAPOURALES; DAVID BOWYER; DENNIS LEWIS, in his official capacity as Board President of the West Virginia Board of Pharmacy; ROBERT DUNCAN,

Defendants – Appellants.

340B HEALTH; AMERICAN HOSPITAL ASSOCIATION; WEST VIRGINIA HOSPITAL ASSOCIATION; WEST VIRGINIA PRIMARY CARE ASSOCIATION,

Amici Supporting Appellants.

Appeals from the United States District Court for the Southern District of West Virginia, at Charleston. Thomas E. Johnston, District Judge. (2:24-cv-00271; 2:24-cv-00298; 2:24-cv-00272)

Argued: September 9, 2025 Decided: March 31, 2026

Before RICHARDSON, RUSHING, and BENJAMIN, Circuit Judges.

Affirmed by published opinion. Judge Richardson wrote the opinion, in which Judge Rushing joined. Judge Benjamin wrote a dissenting opinion.

ARGUED: Caleb B. David, OFFICE OF THE ATTORNEY GENERAL OF WEST VIRGINIA, Charleston, West Virginia, for Appellants. Philip J. Perry, LATHAM & WATKINS, LLP, Washington, D.C.; Jessica Lynn Ellsworth, HOGAN LOVELLS US LLP, Washington, D.C.; Matthew Scott Owen, KIRKLAND & ELLIS, LLP, Washington, D.C., for Appellees. **ON BRIEF:** John B. McCuskey, Attorney General, Michael R. Williams, Solicitor General, Caleb A. Seckman, Assistant Solicitor General, Spencer J. Davenport, Assistant Solicitor General, OFFICE OF THE ATTORNEY GENERAL OF WEST VIRGINIA, Charleston, West Virginia, for Appellants. Timothy M. Miller, BABST, CALLAND, CLEMENTS, ZOMNIR, P.C., Charleston, West Virginia; Andrew D. Prins, Abid R. Qureshi, LATHAM & WATKINS LLP, Washington, D.C., for Appellee Pharmaceutical Research and Manufacturers of America. Steven R. Ruby, CAREY DOUGLAS KESSLER & RUBY PLLC, Charleston, West Virginia; Meredith M. Pohl,

Lucas H. Funk, KIRKLAND & ELLIS LLP, Washington, D.C., for Appellees AbbVie, Inc.; Allergan, Inc.; Durata Therapeutics, Inc.; AbbVie Products LLC; Aptalis Pharma US, Inc.; Pharmacyclics LLC; and Allergan Sales, LLC. Carte P. Goodwin, Blake N. Humphrey, FROST BROWN TODD, Charleston, West Virginia; Catherine E. Stetson, Susan M. Cook, Aleks Sverdlov, Marlon J. Golden, HOGAN LOVELLS US LLP, Washington, D.C., for Appellee Novartis Pharmaceuticals Corporation. Ronald S. Connelly, POWERS PYLES SUTTER & VERVILLE, PC, Washington, D.C., for Amici West Virginia Hospital Association and West Virginia Primary Care Association. William B. Schultz, Margaret M. Dotzel, Alyssa Howard Card, ZUCKERMAN SPAEDER LLP, Washington, D.C., for Amici American Hospital Association and 340B Health. Matthew J. Modafferi, Jonathan E. Levitt, FRIER & LEVITT, LLC, Pine Brook, New Jersey, for Amicus Community Oncology Alliance, Inc. Robert J. D'Anniballe, Jr., QUINTAIROS, PRIETO, WOOD & BOYER P.A., Charleston, West Virginia, for Amicus The Pioneer Institute.

RICHARDSON, Circuit Judge:

This case is about bargains, in two relevant senses of the term. The first sense is *contractual*, as in an agreement. Congress can make agreements with States or private entities using its spending power. *See Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 370–73 (2025). The 340B program is one such spending-power bargain between the federal government and private drug manufacturers. *See* 42 U.S.C. § 256b. Congress guarantees participating manufacturers access to a large market of prescription drug purchasers: state Medicaid agencies. In exchange, those drug manufacturers agree to give rebates to state Medicaid agencies—and to provide lower drug prices in their offers to select safety-net healthcare providers. The second sense of the term "bargain" is *valuative*, as in cheap or discounted. The 340B program sets the precise discount by formula and limits the discount's availability to select buyers.

Dissatisfied with the scale of drug discounts required by Congress in the 340B program, West Virginia enacted S.B. 325, which imposes additional conditions on drug manufacturers by virtue of their participation in the 340B program. *See* W. Va. Code § 60A-8-6a. The result is that more drugs will be sold at bargain prices. Challenging these impositions, participating manufacturers sued in federal court to enjoin S.B. 325's enforcement.

The district court granted a preliminary injunction after holding that federal law likely preempts the West Virginia statute and that the manufacturers are entitled to equitable relief. *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 446 (S.D. W. Va. 2024). On appeal, West Virginia characterizes S.B. 325 as a classic pharmacy

regulation that does not change the 340B discount or its availability; the drug manufacturers claim that S.B. 325 is preempted because it directly regulates the discounts at the heart of the federal program. These arguments focus too much on the *valuative* bargain. In our view, West Virginia seeks—likely impermissibly—to reshape the *contractual* bargain Congress made with private manufacturers.

Because we agree with the district court's conclusion, we affirm the grant of a preliminary injunction.

I. BACKGROUND

To understand how the 340B program operates, we start by summarizing the series of spending-power bargains that Congress made with States and drug manufacturers to create an integrated system for purchasing prescription drugs through Medicaid.

A. Medicaid And The Drug Rebate Program

Under its so-called spending power, Congress can offer federal funds in exchange for compliance with federally imposed conditions. *Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 216 (2022). Unlike ordinary legislation, which "'imposes congressional policy' on regulated parties 'involuntarily,'" spending-power legislation "operates based on consent." *Cummings*, 596 U.S. at 219 (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 16 (1981)). That is because the spending power, derived from Article I, section eight, clause one, "does not expressly endow Congress with the power to regulate conduct." *Medina*, 606 U.S. at 370. Rather, spending-power legislation operates "in what amounts essentially to a contract between the Government and the

recipient of funds." *Cummings*, 596 U.S. at 219 (quoting *Gebser v. Lago Vista Indep. Sch. Dist.*, 524 U.S. 274, 286 (1998)).

In 1965, Congress created Medicaid. Like other spending-power programs, Medicaid "offers States a bargain." *Medina*, 606 U.S. at 362 (quotation marks omitted). On one side of the bargain, States agree to provide healthcare to those "whose income and resources are insufficient to meet the costs of necessary medical services." *Id.* (quoting 42 U.S.C. § 1396-1). In return, the federal government provides States with funding. Congress's bargain is enticing—all fifty States have accepted the deal. *Id.* As part of the overall bargain, every State has also agreed to provide prescription drug coverage in return for federal funding. This prescription drug coverage constitutes a large portion of Medicaid spending.

To contain this drug spending, Congress created the Medicaid Drug Rebate Program in 1990. § 1396r-8. Simplifying a bit, manufacturers that agreed to this program had to offer rebates on each State's Medicaid drug purchases, such that the State would pay no more than the lowest price available to any other customer. § 1396r-8(c)(1)(A), (c)(1)(C)(i). To entice drug manufacturers to offer these valuable rebates, the rebate program expanded Medicaid's drug coverage to include nearly all of a participating manufacturer's drugs, guaranteeing manufacturers a large and stable base of purchasers. § 1396r-8(d)(4)(B); *see also Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 651–52 (2003).

Unsurprisingly, making Medicaid the participating manufacturers' "most favored customer" had unintended consequences for their other customers. Before the rebate

program's creation, manufacturers routinely gave substantial drug discounts to safety-net hospitals, veterans hospitals, and federally funded clinics. Ryan P. Knox & Ameet Sarpatwari, *The 340B Drug Pricing Program: Administration, Litigation, and Reform*, 77 Okla. L. Rev. 229, 235 (2025). But under the new law, giving hefty discounts to these customers meant extending those same deals to their "most favored customer" too. So, seeking to minimize discounts that would increase their rebate payments to Medicaid, manufacturers "promptly cancelled discount contracts . . . and raised the prices they charged public hospitals," by, on average, 32 percent. *Id.* at 235–36.

Congress quickly returned to the drawing board.

B. The 340B Statute

Just two years later, Congress created the 340B program, tacking on new requirements for the manufacturers that chose to sell their drugs to state Medicaid programs. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71. Now, manufacturers that opted in were also required to "offer" bargain prices on specified outpatient drugs to "covered entities" for "purchase." § 256b(a). These "covered entities" included many of the safety-net healthcare providers from which manufacturers had begun withholding discounts. § 256b(a)(4)(A)–(O).

These bargain prices are fixed by statutory formula. Each drug covered by § 340B has its own "ceiling price," which is known to be "strikingly generous," reaching "as low as a penny per unit." *Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024). But covered entities need not pass these savings on to patients or their insurers. As a result, covered entities can pocket significant sums when they buy drugs at the discounted

340B price but get paid by patients or insurers at much higher prices. *Id.* at 456–57. Congress apparently hoped that the 340B program would provide covered entities with money to reach more patients and improve services.

Still, the statute limits how much covered entities can profit from the 340B program. Covered entities cannot divert—that is, "resell or otherwise transfer"—drugs acquired at the 340B price to nonpatients. § 256b(a)(5)(B). Without a diversion restriction, covered entities could achieve arbitrage at scale, undercutting manufacturers' ability to sell at a profit. Preserving drug manufacturers' ability to sell their drugs at market price to other customers, like private hospitals or pharmacies, is what makes the 340B bargain economically viable. Nor can covered entities request or receive the 340B price on "drugs also subject to a Medicaid rebate." *Novartis*, 102 F.4th at 456; § 256b(a)(5)(A)(i). If a covered entity provides drugs purchased with the 340B discount to Medicaid-insured patients, state Medicaid programs must exclude those providers' claims from their rebate invoices. So manufacturers are protected from giving out "duplicate discounts" for the same drug. In short, these lucrative discounts are not a free-for-all at the manufacturers' expense. Congress struck a balance between supporting covered entities and encouraging manufacturer participation.

The Secretary of Health and Human Services ("HHS") administers the 340B program.[1] To ensure national uniformity in 340B program requirements and harmonious

[1] Agencies within HHS, such as the Health Resources and Services Administration and the Office of Pharmacy Affairs, help administer the 340B program. For simplicity, we refer to them collectively as "HHS."

administration of the program alongside Medicaid, Congress made HHS the sole enforcer of § 340B. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 120 (2011).

As part of its enforcement mandate, HHS requires participating manufacturers to enter into Pharmaceutical Pricing Agreements. § 256b(a)(1). HHS also audits and provides for improvements in compliance by both manufacturers (to prevent overcharges) and covered entities (to prevent diversion and duplicate discounts). § 256b(d). Two improvements HHS made in the last decade are especially important. First, after collecting drug pricing data from manufacturers and calculating 340B ceiling prices, HHS posts these prices on a secure website for covered entity access. *See generally* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 61,563 (Nov. 30, 2018). This price transparency makes it easier for covered entities to identify and report when they are being overcharged. The second improvement involves HHS's supervision of the administrative dispute resolution process for covered entities and manufacturers under § 256b(d)(3). In 2024, HHS updated its dispute resolution requirements and procedures, broadening the definition of "overcharge claims" to include claims that "a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28,643, 28,649 (Apr. 19, 2024) (codified at 42 C.F.R. § 10.21(a)(1)).

The statute's lofty ambitions posed some logistical difficulties for covered entities. Many lacked—and still lack—in-house dispensing pharmacies.[2] Unable to distribute drugs, otherwise-eligible healthcare providers could not financially benefit from acquiring drugs at the discounted price, thus placing § 340B's promise of additional revenue out of reach. *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). So these covered entities sought to contract with outside pharmacies—whether an independent specialty pharmacy or a national chain like CVS—to distribute drugs on their behalf. That way, these covered entities could purchase discounted drugs and sell them to patients through the contract pharmacies, realizing financial benefits. The contract pharmacies were more than happy to help distribute these drugs and charge the covered entities for their services.

Early on, HHS interpreted § 340B to permit covered entities to distribute drugs through contract pharmacies. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). But HHS established some guardrails to prevent 340B program violations. It cautioned that contract pharmacies were not *resellers* of prescription drugs but merely distribution agents. 61 Fed. Reg. at 43,549, 43,550. Title to the drugs stayed with the covered entity. *Id.* at

[2] At the program's inception, fewer than five percent of covered entities had an in-house pharmacy. *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).

43,552. Most importantly, HHS created a "limitation of one pharmacy contractor per entity." *Id.* at 43,555.

In 2010, HHS adopted a different view about contract pharmacies' role in the 340B program, declining to limit the number of contract pharmacies a covered entity could use. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). What was once a modest payday became a jackpot for covered entities. If a covered entity could contract with an unlimited number of pharmacies, it could sell drugs that it acquired at a discount to every patient at full price. Naturally, that would mean more revenues for covered entities, to be split with their contract pharmacies, and reduced revenues for manufacturers. Over the next decade, the use of contract pharmacies "increased twentyfold."[3] *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health and Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023).

This development had little direct effect on covered entities' patients. The 340B program doesn't directly affect the availability of the underlying drugs or the price paid by patients of covered entities. The same underlying drugs can be bought by pharmacies at market price for dispensing to all customers. And the pharmacy doesn't know the customer's status as a covered entity's patient when it fills his prescription. Instead, it

[3] To give an idea of the increase in scale: In the 1990s, there were approximately 1,000 covered entities and 1,000 pharmacies dispensing drugs for covered entities. Knox & Sarpatwari, *supra*, at 232. By the 2020s, there were over 50,000 covered entities and 28,000 contract pharmacies. *Id.* "Approximately 40% of all hospitals in 2015 and 30% of all pharmacies in 2019 in the United States were participating in the 340B Program." *Id.* And by 2021, the 340B program "accounted for almost 15% of the U.S. pharmaceutical market, with approximately ninety-four billion dollars in sales." *Id.* at 232–33.

dispenses a drug from its general inventory and charges the visitor (or his insurance) the market price. Later, the pharmacy conducts a complicated analysis to determine which drugs it dispensed to the covered entity's patients and provides that data to the covered entity so it can submit chargebacks up the distribution chain to the manufacturers. Going forward, the covered entity buys the quantity of drugs needed to replenish its patients' purchases, at the 340B price, for delivery to the pharmacy.

Manufacturers feared the complicated analysis that contract pharmacies used to distinguish covered-entity patients from other visitors was susceptible to duplicate discounting and diversion, meaning manufacturers were giving out more rebates and discounts than required. So in 2020, drug manufacturers began adopting policies to limit the use of contract pharmacies. *Sanofi*, 58 F.4th at 700. Rather than delivering a covered entity's drug purchases to *any* contract pharmacy, manufacturers would frequently offer to deliver a covered entity's 340B purchases to *just one* contract pharmacy. *See id.* at 701. HHS reacted by issuing an Advisory Opinion taking its strongest stance yet—declaring that manufacturers were "obligated to deliver" their drugs to any number of contract pharmacies and to charge the covered entity no more than the 340B price for those drugs. Dep't Health & Hum. Servs., Off. Gen. Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* 1 (Dec. 30, 2020). HHS then sent violation letters to various drug manufacturers that had limited the use of multiple contract pharmacies. *Sanofi*, 58 F.4th at 701. Manufacturers sued to invalidate the Advisory Opinion as inconsistent with the statutory scheme.

The Third Circuit sided with the manufacturers. It held that the statute is "silent about delivery" and contract pharmacies. *Id.* at 703. Zeroing in on the "offer" and "purchased by" language in § 340B, the court applied contract law principles to the statute, noting that an offeror need not deliver goods "wherever and to whomever the buyer demands." *Id.* at 703–04. Instead, the 340B program "impose[d] only a price term for drug sales to covered entities, leaving all other terms blank" for drug manufacturers and covered entities to negotiate. *Id.* at 704. Moreover, "Congress's use of the singular 'covered entity' in the 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *Id.*

A similar challenge reached the D.C. Circuit in 2024, to a similar result. The D.C. Circuit likewise construed the "offer . . . for purchase" language in contract-law terms to "merely require[] manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount." *Novartis*, 102 F.4th at 460. The silence about delivery "preserves—rather than abrogates" manufacturers' ability to impose some delivery conditions. *Id.* Since the statute only fixed the price term, but offers may contain non-price terms, manufacturers could include provisions about the "place or manner of delivery" while being "fully consistent with making an 'offer' at a specified 'price.'" *Id.* Furthermore, for over three decades, HHS had consistently construed the statute "to allow manufacturers to insist on at least some reasonable conditions." *Id.* at 461. Manufacturers, then, were only required to make "at least a bona fide offer." *Id.* at 462.

C. West Virginia's Response

Frustrated with this development, various States passed laws to accomplish what HHS could not: requiring drug manufacturers that opt into the 340B bargain to deliver drugs to an unlimited number of contract pharmacies. They reasoned that if statutory silence meant *HHS* could not require delivery to contract pharmacies, then *States* had room to legislate and require unlimited delivery of drugs purchased through the 340B program. To accomplish this, West Virginia passed S.B. 325 in 2024. W. Va. Code § 60A-8-6a. As relevant here, the statute contains two substantive provisions, which bar manufacturers from attaching certain conditions to offers made under the federal 340B program.

One makes it illegal for a manufacturer to "deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug." § 60A-8-6a(b)(1). Explicitly borrowing from the federal statutory definitions, S.B. 325 defines "340B drug" as a "covered outpatient drug within the meaning of 42 U.S.C. § 256b" that "[h]as been subject to any offer for reduced prices by a manufacturer under 42 U.S.C. § 256b(a)(1)" and "[i]s purchased by a covered entity within the meaning of 42 U.S.C. § 256b." § 60A-8-6a(a)(1). And a "340B entity," under West Virginia's law, "means an entity participating in the federal 340B drug discount program, as described in 42 U.S.C. § 256b" and includes both covered entities and their contract pharmacies. § 33-51-3; *see* § 60A-8-6a(a)(2). The second substantive provision prevents the manufacturer from "requir[ing] a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition . . . or delivery of a 340B drug, to a 340B entity." § 60A-8-6a(b)(2).

Each individual violation of these substantive provisions subjects manufacturers to a $50,000 penalty, along with other civil penalties and restitution. § 60A-8-6a(c). And a separate violation occurs for each package of drugs sold with such delivery or data-sharing conditions. *Id.* The West Virginia attorney general, board of pharmacy, and insurance commissioner may each enforce the substantive provisions. *Id.*

Finally, anticipating the possibility of preemption, S.B. 325 adds that "[n]othing in this section is to be construed or applied to be in conflict with . . . [a]pplicable federal law and related regulations." § 60A-8-6a(d). Similar language is embedded in the second substantive provision. § 60A-8-6a(b)(1) (allowing delivery restrictions where "receipt of the 340B drug is prohibited by [HHS]" and data-sharing requirements when "required by [HHS]"). For these preemption provisions to apply, the text of S.B. 325 must leave room for a construction that would not contradict federal law.

Plaintiff manufacturers greeted S.B. 325 with a lawsuit, seeking to enjoin West Virginia's effort to supplement the 340B bargain. The district court granted their motion for a preliminary injunction.[4] West Virginia timely appealed.

[4] Plaintiffs faced a high bar to obtain the extraordinary remedy of a preliminary injunction. *Am. Fed'n of Tchrs. v. Bessent*, 152 F.4th 162, 169 (4th Cir. 2025). They had to clearly "show (1) that they are likely to succeed on the merits, (2) that they are likely to suffer irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in their favor, and (4) that the injunction is in the public interest." *Id.* at 168–69. While the district court may deny a preliminary injunction based on a single factor, granting a preliminary injunction requires finding that every factor is satisfied. *Id.* at 169. Here, the district court determined that each of the four *Winter* factors was met, and we review that decision for an abuse of discretion. *Id.* at 171.

II. WEST VIRGINIA'S S.B. 325 IS LIKELY PREEMPTED

A. The Analytical Framework

Our Constitution establishes a system of dual sovereigns: the federal government and the States. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 470 (2018). They govern concurrently, often imposing overlapping requirements or restrictions on the same entities. When this happens, the Supremacy Clause bars States from interfering with federal prerogatives, as the Constitution, federal statutes, and treaties constitute "the supreme Law of the Land." U.S. Const. art. VI, cl. 2.

For courts, the difficulty lies in determining what constitutes a legitimate claim of interference. Two principles guide our assessment here. First, the type of interference matters. Second, in the spending-power context, the type of bargain struck by Congress matters.

We begin with the first principle: type of interference. State law may interfere in two ways: (1) by directly regulating or discriminating against the federal government or (2) by conflicting with congressional commands. *North Dakota v. United States*, 495 U.S. 423, 434 (1990). The intergovernmental-immunity and preemption doctrines police each type of interference, though there is no "rigid demarcation between" them. *North Dakota*, 495 U.S. at 452–53 (Brennan, J., concurring in the judgment in part and dissenting in part). Intergovernmental immunity describes the Supremacy Clause's prohibition on "state laws that either regulate the United States directly or discriminate against the Federal Government or *those with whom it deals* (*e.g.*, contractors)." *United States v. Washington*, 596 U.S. 832, 838–39 (2022) (cleaned up) (emphasis added). A state law impermissibly

"discriminates against the Federal Government or its contractors if it singles them out for less favorable treatment . . . or if it regulates them unfavorably on some basis related to their governmental status." *Id.* at 839 (cleaned up); *see also North Dakota*, 495 U.S. at 438 (requiring state regulations to be "imposed on some basis unrelated to the object's status as a Government contractor or supplier, that is, . . . imposed equally on other similarly situated constituents of the State").

Even when the intergovernmental-immunity doctrine doesn't directly apply, a state law may still implicate the preemption doctrine, which provides that federal interests edge out state interests when federal and state law "clash." *North Dakota*, 495 U.S. at 435; *Murphy*, 584 U.S. at 477–79. The common thread is that the more directly the State targets federal functions, the less Congress needs to say for the state law to give way; where a State acts in its ordinary regulatory lane, displacement requires a stronger signal of congressional intent. *See Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 180 (1988); *Boeing Co. v. Movassaghi*, 768 F.3d 832, 840 (9th Cir. 2014). That dynamic is operationalized by the "presumption against pre-emption." *See, e.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). We typically presume that a State's historic powers were not supplanted by federal law unless that was Congress's clear and manifest purpose. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Yet this presumption against preemption applies only when a State legislates in "areas of traditional state regulation," such as health and safety. *Bates*, 544 U.S. at 449. It "is not triggered when the State regulates in an area where there has been a history of significant federal presence." *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 272 (4th Cir. 2025) (quoting *United States v.*

Locke, 529 U.S. 89, 108 (2000)).

S.B. 325 is anything but a traditional health-and-safety regulation. At a high level of generality, the law regulates the pharmaceutical industry—which may sound like a traditional area of state regulation. But the fact that pharmacies stand to receive deliveries of drugs paid for by covered entities under this law does not transform pharmacies, drugs, or healthcare providers into the law's targets. S.B. 325 does not subject the industry to any obligations or restrictions independent of the federal 340B program. Instead, S.B. 325 injects the State into "the relationship between a federal agency and the entity it regulates," which is "inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) (refusing to find a presumption against preemption where a State sought to "polic[e] fraud against federal agencies"). And States have no traditional oversight of federal relationships. *See id.*

A closer look reveals the nature of the interference: S.B. 325 facially "*targets* a federal domain." *GenBioPro*, 144 F.4th at 272 (emphasis in original). S.B. 325 springs obligations on manufacturers specifically by virtue of their participation in a federal program. It does not apply equally to all manufacturers that sell drugs to healthcare providers in West Virginia, but rather singles out those manufacturers that have effectively contracted with the federal government. To be sure, the intergovernmental-immunity doctrine does not control here. A manufacturer that participates in the 340B program is not strictly a federal contractor or supplier, as the Pharmaceutical Pricing Agreements between HHS and manufacturers "are not transactional, bargained-for contracts." *Astra*,

563 U.S. at 113. Nor do the manufacturers supply drugs to the federal government under § 340B. But the same concerns animating the intergovernmental-immunity doctrine counsel skepticism in this analogous scenario. The Pharmaceutical Pricing Agreements *themselves* may not turn manufacturers into federal contractors, but a "contract-law analogy" still appropriately describes the operation of this spending-power legislation. *See Cummings*, 596 U.S. at 219; *Pennhurst*, 451 U.S. at 17.

That brings us to the second structural principle relevant here: Whether state action interferes with spending-power bargains hinges on the bargain's design. Congress frequently leverages its spending-power authority to forge bargains with States, offering federal funds in exchange for compliance with designated conditions. *See Pennhurst*, 451 U.S. at 17 (such legislation is "much in the nature of a contract: in return for federal funds, the States agree to comply with federally imposed conditions"). To safeguard state sovereignty, these bargains must eschew coercion, ensuring States retain a genuine choice to participate. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 577–78 (2012) (plurality opinion). Many spending-power bargains with States preserve state sovereignty by creating a "scheme of cooperative federalism," *inviting* States to supplement federal conditions with state laws that address local variations and fill gaps. *See N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 413 (1973). In these collaborative frameworks, a

State's laws may supplement, rather than interfere with, the federal scheme. As a consenting party, the State's actions fulfill the bargain without disruption.[5]

By contrast, State interventions in spending-power bargains with non-State entities—such as local governments, schools, or private organizations—provoke interference concerns under the Supremacy Clause. *See Lawrence Cnty. v. Lead-Deadwood Sch. Dist. No. 40-1*, 469 U.S. 256, 269–70 (1985). In *Lawrence County*, Congress gave federal funds to local governments to offset revenue losses from tax-exempt federal lands, conditioning the funds' use on "any governmental purpose." *Id.* at 258 (internal quotation marks omitted). South Dakota attempted to change this federal bargain by mandating that counties allocate these funds in the same way as their general tax revenues. The Supreme Court deemed this mandate "substantial interference" with Congress's grant of discretion to the local governments. *Id.* at 269. Since Congress struck the bargain with counties, not the State, the Court invalidated South Dakota's effort to append conditions, emphasizing that a State may not obstruct the federal bargain by adding conditions to it. *Id.* at 270.

Here, the federal government struck one bargain with States to provide medical care to the needy in exchange for funding. It then struck a *separate* bargain with drug manufacturers to provide their products at lower prices in exchange for access to the

[5] Rather than Supremacy Clause interference with a federal-state bargain, a State's actions that conflict with the bargain are analogous to a breach of the bargain, permitting the federal government to withhold funding. *See Medina*, 606 U.S. at 362–63, 365–66; *Pennhurst*, 451 U.S. at 28.

Medicaid market. These bargains, though related, involve different parties and have different characteristics.

In sum, to identify a legitimate claim of state-law interference with federal law, courts must consider the type of interference. And when the state law threatens to interfere with a spending-power bargain, courts must consider characteristics of that bargain. Here, S.B. 325 directly and exclusively targets participants in a federal spending-power program. And in doing so, it seeks to add conditions, uninvited, to a federal spending-power bargain with non-state entities. With these principles in mind, we can examine the preemption claims.

B. S.B. 325 Is Likely Preempted

Preemption is not "based on a freewheeling judicial inquiry into whether a state statute is in tension" with "some brooding federal interest." *Kansas v. Garcia*, 589 U.S. 191, 202 (2020) (citations omitted). Rather, a federal statute must actually clash with state law to "displace" it. *GenBioPro*, 144 F.4th at 270. *How* that "clash" may materialize is outlined in the various preemption theories, which the Supreme Court has labeled "express," "field," and "conflict" preemption.[6] *Id.* If Congress has staked exclusive

[6] The traditional articulation of these preemption categories is as follows: Congress expressly preempts state law when it "withdraw[s] specified powers from the States by enacting a statute containing an express preemption provision." *Arizona*, 567 U.S. at 399. Congress preempts a "field" when its regulatory scheme is "so pervasive" that it leaves "no room for the States to supplement it" or when the federal interest is "so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Finally, Congress preempts state law when there is an operational conflict, either because compliance with both federal and state law is impossible or because the state law stands as a sufficient (Continued)

authority over a subject matter, whether expressly or impliedly, as in "field" preemption, any state law that directly regulates that matter must yield—even if the state law "adopts [the same] substantive standards." *Arizona v. United States*, 567 U.S. 387, 402 (2012). This type of structural clash stems from the State's very assertion of power in a preempted realm. State law can also *operationally* clash with federal law, by imposing a different remedial scheme on the same activity or by creating inconsistencies. *Id.* at 402–3.

It is no surprise then that the preemption categories are not "rigidly distinct." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990); *see also Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 n.6 (2000) (citing scholarship that notes that field preemption "may fall into any of the categories of express, implied, or conflict preemption"). Indeed, field preemption may even be "understood as a species of" conflict preemption because state law that falls within a preempted field "conflicts" with Congress's implied claim to exclusive authority. *English*, 496 U.S. at 79 n.5. And "specific conflicts between state and federal law" can "underscore the reason for field preemption." *Arizona*, 567 U.S. at 402–03 (holding that Arizona law intruded on the preempted field of alien registration and identifying a further "inconsistency" in state and federal sanctions, creating a conflict).

"In order to determine whether Congress has implicitly ousted the States from regulating in a particular field, we must first identify the field in which this is said to have occurred." *Garcia*, 589 U.S. at 208. If the state and federal laws "operate in different

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obstacle to the "accomplishment and execution of the full purposes and objectives of Congress." *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

fields," the state law is not preempted. *GenBioPro*, 144 F.4th at 273; *see also Garcia*, 589 U.S. at 208–10 (holding that while Congress occupied the field of alien registration, it did not occupy the state law's field of employment verification, though the two fields were related).

We start with the state law. If there is a preempted field, it is based on "*what* the State did, not *why* it did it." *Va. Uranium, Inc. v. Warren*, 587 U.S. 761, 774 (2019) (plurality opinion) (emphasis in original); *English*, 496 U.S. at 84 (defining the field in part by state law's "actual effect"). S.B. 325 prohibits manufacturers from imposing conditions on the acquisition of a drug, offered for purchase at the 340B price, to a "covered entity" as defined by federal law. W. Va. Code §§ 60A-8-6a(a)(1), (b) (defining substantive provisions by reference to 42 U.S.C. § 256b). That means that S.B. 325 targets *only* manufacturers that participate in the 340B program. It imposes restrictions *only* on drug manufacturers when they *comply* with their end of the 340B bargain. So, because the effects are limited to 340B manufacturers, the field must be the 340B program requirements.

To be sure, this Court has frowned upon the "tautological" definition of a field to reflect the federal statute's content. *GenBioPro*, 144 F.4th at 273. Indeed, were such a formulation generally appropriate, we would often find state laws preempted, contrary to our federalist scheme. Though we reach the same result in this case *as if* we had defined the field by the federal statute's subject matter, *how* we reach the result is distinct, and comports with *GenBioPro*'s approach: We look at the text of the state law. *See* 144 F.4th at 270, 273; *see also English*, 496 U.S. at 84.

S.B. 325 directly changes the terms of drug manufacturers' federally created 340B relationships with covered entities. *Cf. GenBioPro*, 144 F.4th at 273 (finding state law not preempted when it regulated statewide availability of a medical procedure, leading only to an incidental, downstream effect on access to a type of federally regulated drug). And it does not merely compel its own constituents to participate in an otherwise-voluntary federal program. *Cf. Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 608 (2011). It instead affects only those who have already agreed to participate in 340B. In doing so, S.B. 325 alters the 340B program's fundamental bargain.

Congress has ousted States from this field. Section 340B did not merely set a floor to which States may add additional obligations. Instead, Congress struck a careful bargain. Recall that Congress incentivized drug manufacturers to offer their products at discounted prices in exchange for access to the massive Medicaid market. These manufacturers determined that the upside of Medicaid market access outweighed the downside of selling drugs for a lower price than they otherwise would, and they accepted *that bargain*. Courts have already made clear that Congress *did not* require manufacturers to distribute drugs to an unlimited number of contract pharmacies as part of the 340B program. *Sanofi*, 58 F.4th at 703–04. Yet, unsatisfied with that bargain, West Virginia now seeks to add its own downsides, without offering any additional upside to compensate. S.B. 325 singles out 340B manufacturers and explicitly adds requirements to compel the very result HHS could not mandate. *Id.* In effect, S.B. 325 says to manufacturers: "Even though you upheld your

end of the congressional bargain, we want more." That cannot be.[7] *See Lawrence County*, 469 U.S. at 269–70.

If West Virginia hadn't specifically targeted 340B manufacturers for unfavorable treatment, the analysis would look different. *Cf. Dawson v. Steager*, 586 U.S. 171, 179 (2019). For example, had West Virginia sought to regulate statewide pharmacy inventory practices; required the use of refrigerated trucks when delivering certain covered drugs; or expanded the category of persons authorized to prescribe covered drugs, all of which would incidentally touch the 340B program, both the field and the preemption result would certainly be different.[8] *See Hillsborough Cnty v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 716 (1985) (finding no preemption when a county imposed additional health-and-

[7] Nor could a state *prohibit* 340B offers from including delivery to contract pharmacies. A state is no more free to diminish the downside of Congress's bargain than to expand it.

[8] West Virginia might have sought its *own* bargain with manufacturers. Congress expressly invited such state-manufacturer bargains in the drug-rebate program. Congress gave states flexibility to subject covered outpatient drugs to prior authorization, exclude or restrict coverage of an outpatient drug, and set the quantities per prescription or number of refills. § 1396r-8(d)(1), (6). States could use these statutory grants of discretion as levers to extract discounts from drug manufacturers. *See Walsh*, 538 U.S. at 662–68 (plurality opinion) (holding that the Medicaid statute did not preempt Maine's use of prior authorization and position as market participant as bargaining leverage to extract discounts for its *uninsured* citizens); Kimberley Fox et al., *State Pharmacy Discount Programs: A Viable Mechanism for Addressing Prescription Drug Affordability?*, 60 N.Y.U. Ann. Surv. Am. L. 187, 192 (2004).

The only leverage states have against drug manufacturers within the rebate scheme is their leverage as market participants: Within this regime, a state acts as a transacting counterparty, not as *the State*. Unlike other spending-power programs, there is no invitation for the State to jointly regulate. *Cf. Lawrence County*, 469 U.S. at 269–70. As the complement to the rebate program, 340B is naturally read to preserve this treatment of the States. Indeed, the text of 340B includes no invitation for States to play *any* market participant or legislator role. *See* §§ 256b(a)(5), 1396r-8(a)(5)(C)(ii).

safety requirements on *all* blood plasma collection centers). But that's not this case. West Virginia chose to directly alter the terms of a federal bargain. But Congress has ousted the States from this field.[9]

To be clear, the problem is not that manufacturers lacked "clear notice" of the State's delivery obligations when they opted into the 340B program. That notice element is only relevant to the legitimacy of *Congress's* spending-power legislation. *See Cummings*, 596 U.S. at 219–20. But the element of unfair surprise is still relevant because it distorts the attractiveness of the spending-power bargain. Complying with myriad state 340B delivery regimes will introduce additional burdens "not contemplated by Congress in enacting" the drug rebate program or § 340B. *See Buckman*, 531 U.S. at 350. Though perhaps companies like AbbVie or Novartis will remain in the program, smaller drug manufacturers may be deterred from entry. And even if West Virginia and other States manage not to upset the bargain here, they set the stage for entities to face unique obligations whenever States are unhappy with the terms of the bargain struck by Congress.

[9] The dissent claims we have overstepped by relying on cases and analysis not briefed by the parties. But because federal preemption of this state law is properly before us, we are "not limited to the particular legal theories advanced by the parties, but rather retain[] the independent power to identify and apply the proper construction of governing law." *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 99 (1991); *see Moreno v. Bosholm*, 151 F.4th 543, 558 (4th Cir. 2025). Focusing only on whether and how the state law regulates delivery, as the dissent would have us do, ignores the logically antecedent issue: Any delivery requirement is *downstream* of the fact that *only* those manufacturers that have opted into the 340B program face such a requirement. *Cf. U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 447 (1993). That is, state law does not merely regulate entities already regulated by federal law—it regulates relationships that would not exist *but for* 340B. It's hard to think how this could *not* be a federal domain, when the state law could apply to no one if the federal spending bargain vanished.

This threatens the efficacy of Congress's spending-power scheme today *and* its ability to effectively use its spending power to encourage private participation in future bargains. State regimes targeting participants in spending-power legislation frustrate Congress's very exercise of its spending power.

Beyond hampering the spending-power bargain itself, S.B. 325 also likely interferes operationally with multiple aspects of the 340B program. *See Arizona*, 567 U.S. at 402–03 (noting that "specific conflicts between state and federal law" can "underscore the reason for field preemption"). First, S.B. 325 intrudes on HHS's enforcement authority. Congress made HHS the 340B program's sole enforcer. *See Astra*, 563 U.S. at 120. From the program's inception, HHS has weighed in on the appropriateness of contract pharmacies. *See* 59 Fed. Reg. at 25,111–12; 61 Fed. Reg. at 43,551, 43,555. The fact that the statute did not give HHS authority to compel offers to include *unlimited* contract pharmacies does not mean it left an enforcement gap for States to fill. HHS maintains the power to enforce *bona fide* offers to covered entities. *See Novartis*, 102 F.4th at 462–63 (noting that manufacturer policies eliminating any contract pharmacy delivery could make acceptance of the offer impossible); 59 Fed. Reg. at 25,113–14 (prohibiting certain conditions on the offer of statutory discounts). That the state law does not impose penalties for violating § 340B itself doesn't save it. *See Arizona*, 567 U.S. at 403–07 (finding state law preempted though it regulated activity not expressly covered by federal law); *id.* at 407–10 (finding state law preempted where it broadened bases for arrest and allowed state officers to make independent judgments about when federal requirements were met). Here's the problem: Before deciding whether to impose penalties, the attorney general and

state courts must decide whether there has been "any offer" made under § 340B. W. Va. Code § 60A-8-6a(a)(1)(B). But answering that question is central to HHS enforcement, and states providing their own answers necessarily intrudes upon the uniform system of enforcement.

HHS even oversees overcharge claims "that a manufacturer has limited the covered entity's *ability to purchase* covered outpatient drugs at or below the 340B ceiling price."[10] 42 C.F.R. § 10.21(a)(1) (emphasis added). And overcharge claims could include unduly restrictive contract pharmacy policies. *See* 89 Fed. Reg. at 28,643, 28,644. Because HHS already mediates disputes relating to pharmacy delivery policies, States have no room to create new enforcement schemes in the same arena.

Finally, S.B. 325 likely interferes with manufacturers' ability to conduct audits, which are necessary to launch the HHS-administered dispute resolution process. § 256b(d)(3). Recognizing that manufacturers were incentivized to guard against diversion and duplicate discounts, Congress required covered entities to permit manufacturer-led audits. § 256b(a)(5)(C). But to begin an audit of a covered entity, a manufacturer "must set forth a clear description of why it has reasonable cause to believe that a violation" of § 340B has occurred. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). Similarly, if a manufacturer believes a contract

[10] Unlike in *Astra*, today's overcharge claims are less likely to involve a pure pricing dispute, since HHS began providing 340B ceiling prices to authorized covered entities through a database known as the 340B Office of Pharmacy Affairs Information System ("340B OPAIS"). 89 Fed. Reg. at 28,644 (noting only "three covered entity overcharge complaints since making 340B ceiling prices available to covered entities through 340B OPAIS").

pharmacy is diverting drugs and reports the violation to HHS, it must also submit "supporting documentation." 61 Fed. Reg. at 43,549. In practice, for manufacturers to get this documentation or reasonable cause, they likely need to "require" submission of claims or utilization data as a condition of delivery to contract pharmacies.[11] *See also* 61 Fed. Reg. at 43,552 (contemplating that contract pharmacies "will agree to be subject to audits"). But S.B. 325 prevents exactly that. *See* W. Va. Code § 60A-8-6a(b)(2) (prohibiting a manufacturer from "requir[ing] a 340B entity to submit any claims or utilization data as a condition" of delivery to contract pharmacies). So S.B. 325 frustrates the operation of the audit mechanism and thus the enforcement of § 340B.

To summarize: Because S.B. 325 attaches obligations solely to entities that accept a spending-power bargain, it must be scrutinized without the usual deference given to traditional state regulations. The substantive provisions interfere at a high level with Congress's exercise of its spending power and at an operational level with HHS's enforcement authority and specific enforcement activities. No possible construction of

[11] Manufacturers cannot require this information as a condition of sale to the covered entity itself. Even after reasonable cause has been demonstrated, the audit process completed, and the informal dispute process initiated, the manufacturer *still* must extend the discount to the covered entity. 61 Fed. Reg. at 65,408. Only after HHS removes the covered entity from the list are manufacturers absolved from any obligation to sell discounted drugs to that covered entity. *Id.*

The dissent notes that no manufacturer could "identify a time when it requested an audit but was denied due to a lack of claims data." Dissent at 65. But this captures our point: They did not have to work with a lack of claims data in the past.

S.B. 325 avoids this result. As such, it is likely preempted and unenforceable.[12] *Crosby*, 530 U.S. at 388.

III. THE REMAINING *WINTER* FACTORS SUPPORT A PRELIMINARY INJUNCTION

Demonstrating a likelihood of success on the merits is just one requirement for a preliminary injunction. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).[13] But the district court also concluded that the pharmaceutical manufacturers met the remaining requirements: They are likely to suffer irreparable harm if preliminary relief is not granted; the balance of equities favors granting an injunction; and an injunction is in

[12] As states across the country have passed laws like S.B. 325, courts have split on whether § 340B preempts these laws. *Compare, e.g.*, *AbbVie, Inc. v. Drummond*, No. CIV-25-726, 2025 WL 3048929 (W.D. Okla. Oct. 31, 2025) (state law preempted), *with AbbVie, Inc. v. Fitch*, 152 F.4th 635 (5th Cir. 2025) (state law not preempted), *and Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) (state law not preempted); *see also* Dissent at 41–42 nn.2–3 (listing district court opinions holding state law not preempted). That split lies in whether laws like S.B. 325 regulate "price" (in which case they are preempted) or "delivery" (not preempted). For example, in *Fitch*, the Fifth Circuit characterized the field as "the distribution of drugs to patients and the role of pharmacies in such distribution." 152 F.4th at 647; *see also McClain*, 95 F.4th at 1143 (characterizing the field as "pharmacy distribution"). That characterization fails to appreciate that the state laws do not address drug distribution generally but explicitly single out *340B* and set distribution rules for participating manufacturers alone. And it also neglects to consider how spending-power legislation can oust the state even without laying comprehensive terms, when the state *directly* regulates on the basis of voluntary participation in the federal program.

[13] Beyond the preemption claim, the manufacturers also assert the West Virginia statute violates the Takings Clause. *See Drummond*, 2025 WL 3048929, at *8–9 (finding similar state law to be a taking). But the manufacturers need only be likely to prevail on one claim to be likely to succeed on the merits. So we need not address the takings theory to affirm the preliminary injunction.

the public interest. *Id.* Reviewing these requirements for an abuse of discretion, we find none. *Air Evac EMS, Inc. v. McVey*, 37 F.4th 89, 103 (4th Cir. 2022).

The district court found that—absent an injunction—the manufacturers[14] would suffer unrecoverable financial loss rising to the level of irreparable harm. *See Mountain Valley Pipeline, LLC v. 6.56 Acres of Land, Owned by Sandra Townes Powell*, 915 F.3d 197, 218 (4th Cir. 2019). Failure to comply with S.B. 325 leaves manufacturers exposed to a $50,000 penalty *per violation*, among other sanctions, and the district court found that enforcement is "imminent" given the "growing number of complaints pending before the Board of Pharmacy following the enactment of S.B. 325." *Morrisey*, 760 F. Supp. 3d at 463. These penalties would likely be unrecoverable. Compliance, on the other hand, is similarly costly, from the millions incurred in compliance, to the millions in lost revenue, to the manufacturers' lessened ability to invest in research and development. *Id*. at 462. Nor is there an obvious path for the manufacturers to recoup these discounts from covered entities or their pharmacies. *Id.* This "Hobson's choice" on top of the unrecoverable financial losses is enough to satisfy this inquiry. *Id.* at 461; *see* Samuel L. Bray, *The Purpose of the Preliminary Injunction*, 78 VAND. L. REV. 809, 832 n.152 (2025).

[14] Plaintiffs include several manufacturers that participate in the 340B program along with a trade association, the Pharmaceutical Research and Manufacturers of America ("PhRMA").

The district court found that the third and fourth *Winter* factors—the balance of equities and public interest—also support granting an injunction.[15] We agree. As West Virginia recognizes, to some degree, the equities and public interest rise and fall with the case's merits. Appellant's Br. at 91. After all, a State is not seriously harmed by a preliminary injunction that prevents the State from enforcing laws that are likely unconstitutional. *Leaders of a Beautiful Struggle v. Balt. Police Dep't*, 2 F.4th 330, 346 (4th Cir. 2021). And patients—who do not directly enjoy the benefits of the 340B program—should not find their access to the underlying drugs impeded. *Morrisey*, 760 F. Supp. 3d at 464. On appeal, West Virginia also claims that enjoining S.B. 325 "could result" in the "reduction or elimination of services" to the State's most vulnerable patients. Appellant's Br. at 91. That covered entities have long relied on the financial resources generated from a broad network of contract pharmacies supports this possibility. This is a

[15] Our Court has suggested that when the government is the opposing party, the third and fourth factors of the *Winter* test—the balance of the equities and the public interest—merge. *See Pierce v. N.C. State Bd. of Elections*, 97 F.4th 194, 225 (4th Cir. 2024). This concept—what we can call "merger"—typically draws its support from the Supreme Court's decision in *Nken v. Holder*, 556 U.S. 418, 435 (2009). There are a couple theoretical distinctions between *Nken* and this case that caution applying the merger concept here. For starters, *Nken* applied the test for a stay, not an injunction. While the tests are very similar, the third factors slightly differ. In the *Nken* context, the third factor only asks whether other parties are harmed, while the *Winter* test requires the court to balance the equities. It makes sense to merge the factors when applying *Nken*—where the government defendant's harm and the public interest will almost always be aligned. But one might think merger makes less sense when applying *Winter*—where the public interest might more often diverge from the balance of the equities. Another reason to proceed cautiously in applying the merger doctrine here is that the "government" defendant is a state government, not the federal government. Perhaps the federal government's interest is normally a fair proxy for the interest of the national "public," whereas a State's interest may more often diverge from the interests of the public living outside that State. But these distinctions do not matter here because the "merged" factors both favor Plaintiffs.

serious consideration in whether an injunction is appropriate. Particularly where the very viability of covered entities is threatened, and we have only a probabilistic judgment of the manufacturers' ultimate success on the merits, an injunction may not "safeguard[] the efficacy of the court's remedial options." *See* Bray, *supra*, at 845 (emphasis removed). But West Virginia does not assert that covered entities are likely to fail or even begin to assess the likely impact on underserved patients, so its bare assertion here does not meaningfully alter the analysis. *See* Appellee's Br. at 90–91.[16]

* * *

Congress struck a careful bargain when it enacted the 340B program. If manufacturers want the benefit of that bargain, they must sell drugs to certain healthcare providers at a bargain price. West Virginia has attempted to alter this bargain by singling out federal program participants for extra burdens. So S.B. 325 likely intrudes on the field of Congress's bargain and clashes with Congress's operational mechanisms. It therefore must yield. And because the equities favor a preliminary injunction, West Virginia cannot enforce S.B. 325.

AFFIRMED

[16] As the district court noted, enjoining West Virginia's S.B. 325 does not remove the drug manufacturers' federal obligations. So particularly onerous policies may make acceptance of the statutory "offer" impossible. *See Novartis*, 102 F.4th at 462; *Sanofi*, 58 F.4th at 703–04. The preliminary injunction does not prevent manufacturers and covered entities from negotiating in good faith to ensure that covered entities may use the 340B program. And the injunction does not restrict West Virginia's wide latitude within its traditional police powers to better support covered entities' missions to provide care to the most vulnerable.

DEANDREA GIST BENJAMIN, Circuit Judge, dissenting:

"In our adversarial system of adjudication, we follow the principle of party presentation." *Clark v. Sweeney*, 146 S. Ct. 410, 412 (2025) (citing *United States v. Sineneng-Smith*, 590 U.S. 371, 375 (2020)). "The parties ' "frame the issues for decision," ' while the court serves as " 'neutral arbiter of matters the parties present." ' " *Id*. (quoting *Greenlaw v. United States*, 554 U.S. 237, 243 (2008)). "To put it plainly, courts 'call balls and strikes'; they don't get a turn at bat." *Id*. (citing *Lomax v. Ortiz-Marquez*, 590 U.S. 595, 599 (2020)).

The majority today took a turn at bat. The parties here submitted more than 300 total pages of briefing (including a 60-page reply brief). Four amicus curiae weighed in as well. Yet not one word was devoted to Congress' spending power or why it should change our preemption analysis. Because there is no binding or persuasive authority requiring a different preemption analysis for laws passed under the Spending Clause, I would have reversed the district court because it abused its discretion by enjoining S.B. 325.

I. Facts & Background

A. 340B Program

In 1992, Congress established Section 340B of the Public Health Service Act (the "340B program"). 42 U.S.C. § 256b. The 340B program requires drug manufacturers, as a condition of coverage of their products under Medicaid and Medicare Part B, to agree to offer certain drugs to "covered entities" "at or below the applicable ceiling price." *Id.* § 256b(a)(1). "Covered entities," as enumerated by the statute, include fifteen types of

federal- or state-funded hospitals, community health centers, and clinics that serve low-income patients. *See id.* § 256b(a)(4); *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (covered entities are "providers of safety-net services to the poor"). Both the type of drug that is sold and the ceiling price for any drug sold is also set out by the statute. *See* §§ 256b(a)(1), (3), 1396r-8(a)(1), (5). Congress intended for the 340B program to support covered entities in stretching "scarce [f]ederal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

Manufacturers "opt into the 340B Program by signing" Pharmaceutical Pricing Agreements ("PPAs") with the United States Department of Health and Human Services ("HHS"). *Astra*, 563 U.S. at 113. But PPAs " 'are not transactional, bargained-for contracts'—rather, they are 'uniform agreements' that merely 'recite' the statutory obligations of manufacturers and the HHS Secretary." *AbbVie, Inc. v. Murrill*, 166 F.4th 528, 535 (5th Cir. 2026) (citing *Astra*, 563 U.S. at 113). So, "[b]y signing a PPA, a manufacturer agrees to provide 340B discounts to covered entities as a condition of receiving Medicaid and Medicare Part B reimbursements." *Murrill*, 166 F.4th at 535.

The 340B program is administered by HHS and superintended by the Health Resources and Services Administration ("HRSA"), an HHS agency. *Astra*, 563 U.S. at 113. The HRSA implements and enforces the prices that pharmaceutical manufacturers charge to covered entities. *Id.*; *see generally* 42 U.S.C. § 256b(a). The 340B program includes extensive compliance mechanisms, penalties for noncompliance or abuse by manufacturers and covered entities, and a dispute resolution process through HHS. *See* 42

U.S.C. §§ 256b(a)(1), (5). For example, the 340B program bars "duplicate discounts or rebates," meaning covered entities cannot seek both the 340B discount and a Medicaid rebate on the same drug. *Id.* § 256b(a)(5)(A). It also bars "diversion," providing that a covered entity "shall not resell or otherwise transfer" a discounted drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

The 340B program requires transparency from covered entities, as they "*shall permit* the Secretary and the manufacturer of a covered outpatient drug . . . to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertains to the entity's compliance." *Id.* § 256b(a)(5)(C) (emphasis added). To conduct an audit, HHS or a drug manufacturer must have "reasonable cause." 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Obtaining "reasonable cause" does not require pre-approval—"[s]ignificant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity may be a basis for establishing reasonable cause." *Id.* When payment, pricing, diversion, or discount disputes arise between manufacturers and covered entities, 340B mandates parties first go through HHS' administrative dispute resolution ("ADR") process to resolve the issue. *Id.* § 256b(d)(3). If HHS finds that a covered entity is in violation of § 256b(a)(5)(A) or (B), the covered entity "shall be liable" to the manufacturer for the amount improperly received. *Id.* § 256b(a)(5)(D). A covered entity could even be removed from the program. *See* § 256b(d)(2)(B)(v)(II).

B. Developments in 340B Program Guidance and Subsequent Litigation

The 340B program posed a logistical difficulty for covered entities that lacked an in-house dispensing pharmacy: they were unable to distribute discounted 340B drugs. So these covered entities began to contract with outside pharmacies to dispense the 340B drugs to patients. Covered entities that use contract pharmacies still order and pay for the 340B drugs, but the 340B drugs are shipped directly to the contract pharmacies.

HHS has issued guidance that deals directly with the distribution of 340B drugs to covered entities and the use of contract pharmacies. In 1994, HHS initially interpreted the 340B program to allow covered entities "to use a purchasing agent without forfeiting its right to the section 340B drug discounts." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). In 1996, HHS acknowledged that the 340B program "is silent as to permissible drug distribution systems," but interpreted the 340B program to have a "limitation of one pharmacy contractor per entity." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996). In 2010, HHS changed its stance and adopted a different interpretation of the 340B program in a guidance letter to covered entities. *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). In HHS' 2010 guidance letter, it stated that covered entities could use "multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition."

Id. HHS expected this change to significantly benefit patients and "permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.*

After HHS' guidance letter, the use of contract pharmacies greatly increased. Drug manufacturers responded by adopting policies to limit the use of contract pharmacies. In response, HHS issued an advisory opinion which stated that the text of the 340B program unambiguously required drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. Dep't Health & Hum. Servs., Off. Gen. Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* 1 (Dec. 30, 2020).

The advisory opinion gave rise to lawsuits around the country. Most notably: *Sanofi Aventis U.S. LLC v. United States Department of Health and Human Services*, 58 F.4th 696 (3d Cir. 2023) and *Novartis Pharmaceuticals Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024). In *Sanofi*, the Third Circuit found "unpersuasive the agency's interpretation of the statute"—that the 340B program explicitly "requires drug makers to deliver drugs to an unlimited number of contract pharmacies." 58 F.4th at 703. The *Sanofi* court importantly noted that "[n]owhere does Section 340B mention contract pharmacies," and the statute's "*text is silent about delivery.*" *Id.* (emphasis added). The Third Circuit warned that statutory silence may "tempt speech," "[b]ut courts must resist the urge to fill in words that Congress left out." *Id.* at 699. And thus, it held that no legal duties sprung from that silence and that the government overstepped the statute's bounds by enforcing the "supposed requirement" of delivering to an "unlimited number of contract pharmacies." *Id.* at 707. In *Novartis*, the D.C. Circuit "agree[d] entirely" with the Third Circuit that the 340B program is "silent about delivery conditions." 102 F.4th at 460–61. The *Novartis*

court could not "plausibly interpret [340B's] statutory silence to subject manufacturers to whatever delivery conditions any covered entity might find most convenient." *Id.* at 461.

C. S.B. 325 & Drug Manufacturers' Challenge

To preserve patient access to 340B drugs, West Virginia enacted S.B. 325. W. Va. Code § 60A-8-6a. S.B. 325 prohibits manufacturers from "deny[ing], restrict[ing], or prohibit[ing] the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such a drug." *Id.* § 60A-8-6a(b)(1). It also prohibits manufacturers from requiring covered entities "to submit any claims or utilization data as a condition" of their 340B drug offer to that entity. *Id.* § 60A-8-6a(b)(2). Also at issue is S.B. 325's enforcement provisions, which include a civil penalty of $50,000 for violations of the substantive provisions. *See id.* § 60A-8-6a(c). S.B. 325 includes multiple "savings clauses," to allow manufacturers to comply with and prioritize any demands from the HHS. *See id.* § 60A-8-6a(b)(1) (providing that the statute applies "unless the receipt of the 340B drug is prohibited by [HHS]"); *see also* § 60A-8-6a(b)(2) (providing that the statute applies "unless the claims or utilization data sharing is required by [HHS]"). S.B. 325 also instructs that "[n]othing in this section is to be construed or applied to be in conflict with any . . . [a]pplicable federal law and related regulations." *Id.* § 60A-8-6a(d).

In response, plaintiff manufacturers sued in federal court to enjoin S.B. 325's enforcement. The district court granted a preliminary injunction after holding that the 340B program likely preempts S.B. 325. *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 446 (S.D. W. Va. 2024).

D. Decisions in Other State Delivery Statute Challenges

West Virginia was not the first state to enact such a delivery statute, nor is this the plaintiff manufacturers' first challenge to a delivery statute. Drug manufacturers have consistently responded to new delivery statutes with preemption-based suits, arguing that § 340B overrides or preempts the state law. But federal courts are not "split" on whether § 340B preempts state delivery statutes. Maj. Op. at 31 n.12. Drug manufacturers have been largely unsuccessful. The Fifth Circuit, in two separate opinions, and the Eighth Circuit have opined on this issue and held that the respective state delivery laws were not preempted. *AbbVie, Inc. v. Murrill*, 166 F.4th 528, 538–42 (5th Cir. 2026) & *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 648 (5th Cir. 2025); *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024). While the district court in this appeal and a district court in Oklahoma[1] enjoined comparable state delivery laws, those decisions stand as outliers within the broader judicial landscape. So far, they seem to have been the only ones to reach that conclusion. At least seven district courts have refused to enter preliminary injunctions on comparable state delivery statutes.[2] And at least four other district courts dismissed a manufacturer's preemption claims on a motion to dismiss or motion for summary

[1] *AbbVie, Inc. v. Drummond*, 2025 WL 3048929 (W.D. Okla. Oct. 31, 2025).

[2] *Novartis Pharm. Corp. v. Frey*, 2025 WL 2813787 (D. Me. Sept. 23, 2025); *AbbVie, Inc. v. Weiser*, 2025 WL 3041825 (D. Colo. Oct. 31, 2025); *AbbVie Inc. v. Neronha*, 1:25-cv-00388-JJM-AEM (D.R.I. Sept. 30, 2025); *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657 (S.D. Miss. 2024); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. 2024); *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271 (M.D. Tenn. June 30, 2025); *AbbVie, Inc. v. Brown*, 1:24-cv-01557-MJM (D. Md. Sept. 10, 2024).

judgment.[3] By affirming the district court's grant of a preliminary injunction, the majority departs dramatically from the unanimous view of the circuit courts and the consensus view of the district courts that § 340B preempts state delivery statutes.

E. The Majority's Novel Analytical Framework

The majority not only diverges from the near-unanimous view among federal courts but also introduces unnecessary confusion into the preemption analysis. It starts by introducing the intergovernmental-immunity doctrine, asserting that there is no "rigid demarcation between" it and the preemption doctrine. Maj. Op. at 17 (quoting *North Dakota v. United States*, 495 U.S. 423, 452–53 (1990) (Brennan, J., concurring in the judgment in part and dissenting in part)). The majority then explains the law on preemption and asserts that the preemption categories are also "not rigidly distinct." *Id.* at 23. The majority effectively collapses these doctrines into one amorphous framework to get to its conclusion that S.B. 325 "interfere[s] at a high level with Congress's exercise of its spending power." *Id.* at 30. There is one fundamental problem: the preemption analysis (amorphous or not) is not more stringent for laws passed under Congress' spending power.

[3] *Pharm. Rsch. and Mfrs. of Am. v. McClain*, 645 F. Supp. 3d 890, 902 (E.D. Ark. 2022) (granting summary judgment for Arkansas official on manufacturers' claim that Arkansas law was preempted), *aff'd*, 95 F.4th 1136 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768, (2024); *Astrazenca Pharms. LP v. Bailey*, 2025 WL 644285, at *3 (W.D. Mo. Feb. 27, 2025) (granting motion to dismiss manufacturer's claims that Missouri law was preempted); *Pharm. Rsch. and Mfrs. of Am. v. Murrill*, 2024 WL 4361597, at *8–9 (W.D. La. Sept. 30, 2024) (granting summary judgment for state on manufacturers' claims that Louisiana law was preempted); *Astrazenca Pharms. LP v. Bailey*, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025) (granting defendant's motion to dismiss preemption claim).

As discussed below through the traditional preemption analysis, I would reverse the district court's grant of preliminary injunction.

II. Preliminary Injunction Standard: The *Winter* Factors

A preliminary injunction[4] is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief" and may never be awarded "as of right." *Mt. Valley Pipeline, LLC, v. W. Pocahontas Props., Ltd. P'ship*, 918 F.3d 353, 366 (4th Cir. 2019) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22, 24 (2008)). Plaintiffs bear the burden of establishing such circumstances by showing that (1) they are "likely to succeed on the merits," (2) they are "likely to suffer irreparable harm in the absence of preliminary relief," (3) "the balance of equities tips in [their] favor," and (4) "an injunction is in the public interest." *Winter*, 555 U.S. at 20.

III. *Winter* Factors Analysis

A. First *Winter* Factor – Likelihood of Success on the Merits

The chief issue is whether the plaintiff manufacturers are "likely to succeed" on their preemption arguments. *See Winter*, 555 U.S. at 22.

The law on preemption begins with the Supremacy Clause, which provides that "the Laws of the United States which shall be made in Pursuance" of the Constitution are "the supreme Law of the Land[,] . . . any Thing on the Constitution or Laws of any State to the

[4]The district court's grant of a preliminary injunction is reviewed for abuse of discretion. *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002).

Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. So, a state law that conflicts with federal law is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

The "purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citing *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). The Supreme Court has long held that the starting consideration of a Supremacy Clause analysis is the assumption that Congress has made " 'its intention "clear and manifest" if it intends to pre-empt the historic powers of the States.' " *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 230 (1947)); *see also Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) ("[T]he background principles of our federal system also belie the notion that Congress would use such an obscure grant of authority to regulate areas traditionally supervised by the States' police power."). And because "states have long possessed primary responsibility in our federal system for protecting the health and safety of their citizens," "[t]his presumption is strongest when Congress legislates a field traditionally occupied by the states." *N. Va. Hemp & Agric., LLC v. Virginia*, 125 F.4th 472, 492 (4th Cir. 2025) (citing *Medtronic*, 518 U.S. at 485).

Congress can overcome the high presumptive bar and preempt state law in a few ways. "It may do so through express language in a statute." *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376 (2015). Without express language, as here[5], any preemption can arise

[5] *See Sanofi*, 58 F.4th at 703 (Section 340B's text is "silent about delivery"); *see also Novartis*, 102 F.4th at 460 (Section 340B is "silent about delivery conditions").

only by implication, through either "field" or "conflict" preemption. *See id.* at 377. Field preemption occurs when a state seeks to regulate conduct "in a field that Congress has determined must be regulated by its exclusive governance." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citing *Gade v. National Solid Wastes Mgmt. Assn.*, 505 U.S. 88, 115 (1992)). And a state law is conflict preempted if "compliance with both state and federal law is impossible, or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Oneok*, 575 U.S. at 377 (cleaned up).

1. Presumption Against Preemption

The presumption against preemption applies here. State legislators have long "exercised their police powers to protect the health and safety of their citizens" and "traditionally have had great latitude" to do so. *Medtronic*, 518 U.S. at 475 (quoting *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)). That is why there is a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 715 (1985).

I agree with the reasoning of our two sister circuits[6] and district courts across the country that delivery statutes like S.B. 325 implicate traditional areas of state regulation

[6] *McClain*, 95 F.4th at 1143–44 (" '[T]he practice of pharmacy is an area traditionally left to state regulation' . . . [and] the federal government has ' "traditionally regarded state law as a complementary form of drug regulation" and has "long maintained that state law offers an additional, and important, layer of consumer protection that complements [federal] regulation." ' " (first quoting *Pharm. Care Mgmt. Assoc. v. Wehbi*, (Continued)

and police power. S.B. 325, by prohibiting drug manufacturers from refusing delivery of 340B drugs (for which the manufacturers have already agreed to provide a discount), maximizes necessary drug access for patients of covered entities. In doing so, it fosters the public health of West Virginians. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) (applying the "presumption against federal pre-emption of a state statute designed to foster public health"). This court has also recently explained that "the states have a 'long history' of regulating drugs, and they have continued to play a significant role since the emergence of federal oversight." *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 275 (4th Cir. 2025) (citing Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 852–61 (2017)).

It is true that the presumption against preemption "is not triggered when the State regulates in an area where there has been a history of significant federal presence." *GenBioPro*, 144 F.4th at 272 (quoting *United States v. Locke*, 529 U.S. 89, 108 (2000)). "But this principle has been confined to situations where the state law *targets a federal domain*." *Id.* (emphasis added). Our court in *GenBioPro* provides examples, such as state laws "regulating oil tankers," "criminalizing the circumvention of federal immigration

18 F.4th 956, 972 (8th Cir. 2021) then *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 940–41 (8th Cir. 2011))); *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 646 (5th Cir. 2025) (citing *Castro v. Collecto, Inc.*, 634 F.3d 779, 784–85 (5th Cir. 2011)) ("[S]tates have traditionally governed matters regarding contracts and consumer protections."); *AbbVie, Inc. v. Murrill*, 166 F.4th 528, 539 (5th Cir. 2026) ("Public health and consumer protection fall squarely within a State's historic police powers.").

law," and "restricting the authority of national banks." *Id.* (collecting cases). The majority fails to identify such a subject or issue within a federal domain here.

The majority instead states that "S.B. 325 is anything but a traditional health-and-safety regulation" because it injects the state into an inherently federal relationship between a federal agency and the entity it regulates. Maj. Op. at 19. But that is not a specific issue that is regulated within a traditionally federal domain, nor is that fact dispositive. The Supreme Court in *Hillsborough County v. Automated Medical Laboratories, Inc.* encountered similar Supremacy Clause issues surrounding a federal law that regulated plasma collection and a county's local ordinances that added regulations and requirements on blood donation centers "beyond those contained in the federal regulations." 471 U.S. at 709–10, 716. While the county in *Hillsborough* also "injected" itself between a federal agency and what it was regulating (the collection of blood plasma), the Supreme Court held that there was no showing "strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Id.* at 716. Here, like *Hillsborough*, there has been no showing strong enough to overcome the presumption that S.B. 325—a state regulation of health and safety matters—can constitutionally coexist with the 340B program.

The majority attempts to liken our case to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but *Buckman* arose in a significantly different context. *See* Maj. Op at 17. In *Buckman*, a host of plaintiffs brought "2,300 civil actions" over alleged injuries from orthopedic bone screws implanted in their spines. *Id*. at 343, 346. The plaintiffs sued under several state-law causes of action, claiming that the petitioner

"made fraudulent representations to the Food and Drug Administration." *Id.* at 343. The Supreme Court held that the "fraud-on-the-FDA" state-law claims were preempted, reasoning that those state laws "polic[ed] fraud against federal agencies." *See id.* at 347, 348–51. But policing fraud against a federal agency (i.e., duplicate discounts or diversion) is a function that S.B. 325 neither assumes nor authorizes. Further, while the fraud-on-the-FDA claims in *Buckman* were being brought by *individual plaintiffs* for essentially "any violation of the FDCA," any violation of § 340B would not result in state-law suits through S.B. 325, let alone "2,300 civil actions" that land before the Judicial Panel on Multidistrict Litigation. *Id.* at 353, 347. *Buckman's* reasoning not to apply the presumption against preemption cannot transfer to the facts here.

Accordingly, West Virginia's historic police powers are not to be superseded by § 340B without Congress' clear and manifest purpose. The presumption against preemption applies.

2. Field Preemption

With the presumption established, I turn to whether Congress intended to impliedly preempt S.B. 325 under field preemption. For the reasons below, it did not.

Field preemption occurs when a state seeks to regulate conduct "in a field that Congress has determined . . . must be regulated by its exclusive governance." *Arizona*, 567 U.S. at 399 (citing *Gade*, 505 U.S. at 115). This "intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same

subject.' " *Id.* (citing *Rice*, 331 U.S. at 230). The Supreme Court has noted that Congress rarely " 'legislate[s] so comprehensively' in a particular field that there is no room for 'supplementary state legislation.' " *Kansas v. Garcia*, 589 U.S. 191, 208 (2020) (quoting *R.J. Reynolds Tobacco Co. v. Durham Cnty.*, 479 U.S. 130, 140 (1986)). The plaintiff manufacturers failed to show that Congress—through § 340B's statutory framework or because it was legislated within a dominant federal subject matter—intended to leave West Virginia no room to supplement.

a.

First, the 340B program's framework cannot be said to be "so pervasive" that "Congress left no room for the States to supplement." *Rice*, 331 U.S. at 230.

Here, § 340B is the "supreme" federal law. Its "[s]tatutory text and structure provide the most reliable guideposts" for whether there was congressional intent to displace state law. *PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 474 (4th Cir. 2014) (citing *Medtronic, Inc.*, 518 U.S. at 486); *Medtronic, Inc.*, 518 U.S. at 486 ("Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the statutory framework surrounding it."); *see also CSX Transp., Inc.*, 507 U.S. at 664 ("Evidence of pre-emptive purpose is sought in the text and structure of the statute at issue."). So I begin with a review of § 340B's text.[7]

[7] I question the majority's choice to begin its preemption analysis with the text of S.B. 325. *See* Maj. Op. at 24. The "purpose of Congress is the ultimate touchstone" in each preemption case. *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963). It follows then that Congress' purpose is found within the language of the federal statute or its "statutory framework," rather than the state law's language. *See Medtronic, Inc.*, 518 U.S. (Continued)

Apart from the enforcement and ADR provisions, the statute has two basic parts: "(1) a cap on drug makers' prices and (2) restrictions on covered entities." *See Sanofi*, 58 F.4th at 699; 42 U.S.C. §§ 256b(a)(1), (a)(5)(A)–(C). First, drug manufacturers that wish to participate in the Medicare or Medicaid program must enter into written agreements with HHS to provide a discounted ceiling price, or "cap," "for covered outpatient drugs purchased by a covered entity." *Id.* § 256b(a)(1). The ceiling price is determined by a statutory formula. *Id.* §§ 256b(a)(2), 1396r-8(c). The second part of 340B mandates that the discounted prices are only made available to covered entities, as defined by the statute. *See id.* § 256b(a)(4). Covered entities are prohibited from engaging in duplicate discounts and diversion. *Id.* §§ 256b(a)(5)(A)(i), (a)(5)(B). Section 340B also includes compliance mechanisms and penalties for noncompliance or abuse by both manufacturers and covered entities. *See, e.g.*, *Astra*, 563 U.S. at 115–16.

Notably, Congress "regulate[d] neither the distribution of drugs to patients [(i.e., delivery)] nor the role of pharmacies in this distribution." *Fitch*, 152 F.4th at 646 (parenthetical "noting 'many gaps in the legislation' and that Section 340B 'is silent as to permissible drug distribution systems' " (quoting Notice Regarding Section 602, 61 Fed. Reg. at 43549–50)); *see also Sanofi*, 58 F.4th at 700 (noting that "Section 340B's substantive requirements and restrictions are few"). The Supreme Court has held that in situations like this, where a "matter [is] left unaddressed" in an otherwise "comprehensive

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at 484, 486 ("[W]e are presented with the task of interpreting a statutory provision that expressly pre-empts state law." (internal citations omitted)); *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (same).

and detailed" federal regulatory scheme, that matter is "presumably left subject to the disposition provided by state law." *O'Melveny & Meyers v. FDIC*, 512 U.S. 79, 85 (1994).

What's more, Congress has elected to not regulate delivery. Early in the 340B program, HRSA observed that most covered entities relied on contract pharmacies, while only about four percent (500 out of 11,500) of such entities used in-house pharmacies. *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). Contract pharmacies are decades-long participants that are and have been integral to the dispensation of 340B drugs. That also means for decades, Congress was likely aware but "chose not to" regulate distribution. *Sanofi*, 58 F.4th at 704. Because Section 340B authorizes distribution of drugs by manufacturers and third-party wholesalers, Congress certainly "knew how to impose delivery-related requirements" and regulate distribution. *Id.* And while courts across the country have opined on Congress' intent behind § 340B, it has yet to react or legislate. This congressional silence on pharmacies in the context of § 340B makes the case for federal preemption particularly weak. *C.f. Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–167 (1989) ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to 'stand by both concepts and to tolerate whatever tension there [is] between them.' " (alteration in original)). While Section 340B's silence on delivery may "tempt speech," it cannot indicate a congressional intent to preempt the field, leaving West Virginia no room to legislate. *Sanofi*, 58 F.4th at 699.

Even if 340B's regulations were sufficiently pervasive, "the Supreme Court has consistently resisted inferring field preemption solely from 'pervasive regulation.' " *GenBioPro*, 144 F.4th at 274 (citing *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973)). Courts should consider that "modern issues 'often by their very nature require intricate and complex responses from the Congress' even when it does not intend 'its enactment as the exclusive means of meeting the problem.' " *Id.* (quoting *Dublino*, 413 U.S. at 415). There is no dispute that Congress brought forth a detailed regulatory framework. But at the same time, "Section 340B's substantive requirements and restrictions are few." *Sanofi*, 58 F.4th at 700. The majority and the plaintiff manufacturers cannot circumvent § 340B's silence on the delivery of 340B drugs to patients and contract pharmacies. It is a mistake to conflate Congress' "intricate and complex response" to this modern issue as a regulatory framework so pervasive that it left West Virginia no room to supplement.

Thus, § 340B's regulatory framework was not so pervasive as to leave West Virginia no room to supplement.

b.

Second, S.B. 325 does not regulate in an area with a dominant federal interest. As stated above, the West Virginia statute implicates public health, which is a traditional area of state regulation. At times the Supreme Court has held that federal law preempts state law even in the face of a "traditional state power," but that is reserved for when a "principal and essential feature" of the federal law is replicated in the state law. *See, e.g.*, *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 325 (2016) ("The fact that reporting is a principal and

essential feature of ERISA demonstrates that Congress intended to pre-empt state reporting laws like Vermont's.").

That is not the situation here. S.B. 325 regulates delivery—an area where the 340B program is silent. And thus, S.B. 325 could not replicate a "principal and essential feature" of the 340B program, especially a nonexistent feature like 340B drug delivery. And like "pervasive regulation," the Supreme Court has also consistently resisted inferring field preemption from the presence of a "dominant federal interest." *GenBioPro*, 144 F.4th at 274 (citing *Dublino*, 413 U.S. at 415). "[T]he presence of a 'dominant federal interest' offers little insight since 'every subject that merits congressional legislation is, by definition, a subject of national concern.' " *Id.* (citing *Hillsborough*, 471 U.S. at 719). "Yet it cannot follow 'that every federal statute ousts all related state law.' " *Id.* At bottom, there is no implicit congressional intent to preempt S.B. 325, nor any state law that regulates the delivery of 340B drugs to patients and the role of contract pharmacies in such distribution.

The majority sidesteps Congress' lack of intent and the § 340B's silence on delivery by reasoning that, since Congress enacted § 340B under its spending power, the characteristics of that spending-power bargain must be considered. Maj. Op. at 22. And after considering the nature of the 340B bargain, the majority concludes that S.B. 325's substantive provisions interfere with Congress' exercise of its spending power. *See id.* at 30.

But here is the issue: the preemption analysis does not change for laws passed under Congress' spending power. The Supreme Court has never adopted a rule that either

requires a finding of preemption or heightens[8] the preemption analysis if "a state law is directly addressed to those participating in a federal program where the federal statute does not rely on the state to implement the program." *AbbVie, Inc. v. Weiser*, 2025 WL 3041825, at *7 (D. Colo. Oct. 31, 2025) (quoting *Novartis Pharm. Corp. v. Frey*, 2025 WL 2813787, at *10 (D. Me. Sept. 23, 2025)). On the contrary, the Supreme Court applies ordinary preemption principles to spending legislation even where, as here, a non-state entity is the recipient of federal funds. *See e.g.*, *Coventry Health Care of Missouri, Inc. v. Nevils*, 581 U.S. 87, 90–91, 95–96 (2017) (preempting state law where federal statute enacted under Congress' spending power contained an express state law preemption provision).

The Supreme Court has also never held that "[s]tate regimes targeting participants in spending-power legislation frustrate Congress's very exercise of its spending power." Maj. Op. at 28. While the majority correctly notes that there are " 'scheme[s] of cooperative federalism' [that] invit[e] States to supplement federal conditions with state

[8] We specifically asked the plaintiff manufacturers' counsel whether a case states, "because it's a spending clause, a bargain handshake between a private entity and the federal government, that therefore we do a different preemption analysis?" Oral Argument at 00:22:01–00:22:12, *AbbVie, Inc. v. Anthony Brown*, No. 24-1939 (4th Cir. argued Sep. 9, 2025), https://www.ca4.uscourts.gov/OAarchive/mp3/24-1939-20250909.mp3, [perma.cc/95GW-7L3L]. Counsel responded with *Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212 (2022). *Id.* at 00:59:25. But *Cummings* does not stand for that proposition, and I have not found a case that does. In *Cummings*, the Supreme Court had to decide whether plaintiffs who allege a violation of an antidiscrimination Spending Clause statute could recover emotional distress damages. 596 U.S. at 216. The Court answered that question in the negative, as a prospective Spending Clause funding recipient would not have been on notice that it could be subject to emotional distress damages at the time it decided whether to accept federal funding. *See id.* at 220–21. Because *Cummings* is not about preemption, nor does it even mention the word preemption, it is not relevant here.

laws that address local variations and fill gaps," it loses me by then saying that "[s]tate interventions in spending-power bargains with non-State entities—such as local governments, schools, or private organizations—provoke interference concerns under the Supremacy Clause." *Id.* at 20, 21. (citing *Lawrence Cnty. v. Lead-Deadwood Sch. Dist. No. 40-1*, 469 U.S. 256 (1985)). The majority relies heavily on *Lawrence* in creating a heightened preemption analysis where "courts must consider the type of interference" and "characteristics of" a spending-power bargain. Maj. Op. at 22.

But *Lawrence* is just another case where the Supreme Court applied ordinary preemption principles to a federal statute enacted under Congress' spending power. *Lawrence* involved the Payment in Lieu of Taxes Act ("the Act"), which compensates local governments for the loss of tax revenues resulting from the tax-immune status of federal lands and for the cost of providing services associated with those lands. *Lawrence Cnty.*, 469 U.S. at 258. The Act expressly stated that local governments "may use the payment for *any governmental purpose*." *Id.* at 258–59 (emphasis added) (citing 31 U.S.C. § 6902(a)). South Dakota then enacted a statute that required local governments to distribute those federal payments in lieu of taxes in the same way they distribute general tax revenues. *Id.* at 259 (citing S.D. Codified Laws § 5–11–6 (1980)). Because Lawrence County (the local government) allocated about 60% of its general tax revenues to its school districts, the South Dakota statute thus required Lawrence County to give school districts 60% of the payments it received from the Act. *See id.*

The Supreme Court held that the South Dakota statute was invalid under the Supremacy Clause. *Id.* at 270. But it did so because the Act, by using the word "any,"

"endow[ed] local governments with the discretion to spend in-lieu payments for any governmental purpose." *Id.* at 260–61. South Dakota's statute "drained [the Act] of almost all meaning," as it demanded that "the funds must be allocated" "in accordance with the state statute." *Id.* at 259, 261. While the Supreme Court noted that Congress does have the power to spend and "impose conditions on the receipt of federal funds," in no way did that shape its preemption analysis, let alone give special consideration to the bargain at hand. *Id.* at 269–70. The Supreme Court based its holding on Congress' "sufficiently clear" "intention to funnel [the Act's] moneys directly to local governments, so that they might spend them for governmental purposes without substantial interference."[9] *Id.* at 270.

Under *Lawrence*, S.B. 325 must survive. Section 340B does not have language analogous to the federal statute in *Lawrence*, which endowed local governments with discretion—that they "may use the payment for any governmental purpose." *Id.* at 258. *Lawrence* may have been more helpful to the majority if § 340B endowed drug manufacturers with the same discretion—for example, that they "may limit the number of contract pharmacies." But it does not. Section 340B is silent on 340B drug delivery by contract pharmacies. In *Lawrence*, Congress was "sufficiently clear" that the local government could spend its received payments "for governmental purposes without substantial interference." 469 U.S. at 270. So unless Congress provides at least

[9] In fact, the Supreme Court in *Lawrence* only mentioned the Spending Clause once—just to announce the "far from novel proposition" that "Congress may impose conditions on the receipt of federal funds." *Id.* at 269–70.

Lawerence-level clarity, the majority is wrong to conclude that a state regulation related to a spending-power agreement with a non-state entity is preempted.

This type of congressional clarity is also not found in the 340B program's bargain. As noted throughout my dissent, the bargain lacks any language on the delivery and distribution of 340B drugs by contract pharmacies. Courts have made it abundantly clear that Congress' silence on delivery within the text of § 340B does not require manufacturers to distribute drugs to an unlimited number of contract pharmacies. But drug manufacturers cannot have it both ways. That silence cannot dually mean that Congress intended to grant drug manufacturers a blanket immunity to be free from all state-law requirements regarding drug distribution or delivery. *See Frey*, 2025 WL 2813787, at *11 (citing *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 985 (7th Cir. 2012) ("The question is not whether [the federal law] expressly allows a recipient state to impose its own subgrant conditions[.] . . . Instead, the pertinent question is whether [the federal law] prohibits state-imposed eligibility conditions, either expressly or by necessary implication. [C]ongressional and regulatory silence usually defeats a claim of preemption, not the other way around." (emphasis omitted))). That silence should be afforded even less weight when Congress likely knew of the gap in § 340B regarding the delivery of 340B drugs by contract pharmacies. *See* Section III.A.2.a., at 51 (citing *Sanofi*, 58 F.4th at 704); *see also McClain*, 95 F.4th at 1143.

And as stated above, the mere fact that the bargain may be an exercise of Congress' spending power is not dispositive. Certainly, it is a power "historically reserved to the federal government," but that is not a "special feature" relevant to the preemption analysis.

GenBioPro, 144 F.4th at 274. What's relevant is whether a "statute addresses *an area* historically reserved to the federal government." *Id.* (emphasis added). For example, federal dominance has been evident for decades in areas such as the regulation of interstate navigation, oil tankers, aircrafts, and nuclear safety. *Id.* (collecting cases); *see also Hines v. Davidowitz*, 312 U.S. 52, 61 (1941) (the field of "foreign affairs" is "intimately blended and intertwined with responsibilities of the national government"). This emphasis on the underlying subject matter that Congress seeks to legislate also appears in *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644 (2003). At issue in *Walsh* was the "Maine Rx Program," which authorized citizens of Maine to purchase prescription drugs at the lower prices negotiated on behalf of and available to those who purchased drugs through the Medicaid Program. *Id.* at 649. The *Walsh* district court enjoined Maine's statute, as "[n]o matter how modest an obstacle the new prior authorization amounts to it is an obstacle—drugs on the list must be approved by the state Medicaid Medical Director before they can be dispensed or prescribed." *Pharm. Rsch. & Mfrs. of Am. v. Comm'r., Maine DHS*, 2000 WL 34290605, at *6 (D. Me. Oct. 26, 2000). The Supreme Court reversed the district court because there is a requirement of more than a "modest impediment" or harm to a federal statutory "goal." *See Walsh*, 538 U.S. at 663–65, 667.

Here, the majority hinges the preemption of S.B. 325 on Congress' enumerated power, rather than the subject or goal of the federal statute at hand. The majority, in effect, bestows a gift on the plaintiff manufacturers by allowing them to circumvent their burden "to identify a compelling federal interest warranting preemption by pointing to the mere existence" of a federal spending power scheme. *Weiser*, 2025 WL 3041825, at *7. Simply

put, Congress' use of an enumerated power is not enough to displace a state statute. To do so seems akin to a "freewheeling judicial inquiry" into an alternative balance that Congress may have hidden between the lines—something courts are not permitted to do. *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011).

While I do not question Congress' power to spend, I am not convinced that it heightens or changes the preemption analysis. Because of that, I conclude that S.B. 325 is not field preempted.

3. Conflict Preemption

S.B. 325 likewise survives conflict preemption. A state law is conflict preempted if "compliance with both state and federal law is impossible, or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Oneok*, 575 U.S. at 377 (cleaned up). "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). A conflict is imminent when "two separate remedies are brought to bear on the same activity." *Id.* at 380 (internal citations omitted). But "courts should not seek out conflicts where none clearly exist." *N. Va. Hemp & Agric., LLC*, 125 F.4th at 493 (citing *Coll. Loan Corp. v. SLM Corp.*, 396 F.3d 588, 598 (4th Cir. 2005)). And again, courts must proceed with the assumption that the "historic police powers of the States" are not superseded "unless that was the clear and manifest purpose of Congress." *Arizona*, 567 U.S. at 400 (quoting *Rice*, 331 U.S. at 230).

Here, it "is not difficult to discern," *Frey*, 2025 WL 2813787, at *9, Congress' "significant objectives in passing [§ 340B]." *Just Puppies, Inc. v. Brown*, 123 F.4th 652, 662 (4th Cir. 2024). The Supreme Court observed that Congress "intended for the 340B program's drug reimbursements to subsidize other services provided by 340B hospitals" because they "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, 730, 738 (2022). Other courts have observed similarly. *See Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 316 (D.S.C. 2023) ("[T]he purpose of the 340B program was to provide a means to make 340B entities profitable."); *see also Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *7 (D.D.C. Nov. 5, 2021) ("The purpose of Section 340B is clear—it provides discounts on drugs to certain kinds of healthcare facilities."). "The legislative history indicates that Congress was not willing 'to continue to allow the DVA, [f]ederally-funded clinics, and their patients to remain unprotected against manufacturer price increases.' " *Becerra*, 701 F. Supp. 3d at 316 (citing H.R. Rep. No. 102-384 (pt. 2), at 11). This is consistent with Congress' intent to protect covered entities from such price increases as they would "reduce[] the level of services and the number of individuals that these hospitals and clinics" could serve. H.R. Rep. No. 102-384 (pt. 2), at 11. Simply, Congress' goal was "to enable these entities to stretch scare Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." *Id.* at 12.

Considering this context, S.B. 325 "does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: [S.B. 325] assists in

fulfilling the purpose of 340B." *McClain*, 95 F.4th at 1144–45. Insofar as contract pharmacies have partnered with covered entities to distribute 340B drugs to patients, S.B. 325 acts only to restrict drug manufacturers from infringing on the delivery of 340B drugs bought by covered entities using the 340B program. Nowhere does S.B. 325 set discount pricing, which would then conflict with federal law, as that authority lies exclusively with HHS under § 340B. Drug manufacturers face no obstacle complying with both S.B. 325 and the 340B program.

The majority holds that S.B. 325 specifically creates conflict with two other aspects of the 340B program: HHS' enforcement authority and a drug manufacturer's ability to conduct audits. Maj. Op. at 28–30. I disagree.

a.

First, S.B. 325 does not encroach on HHS's enforcement authority. It is well-known that Congress made HHS the sole enforcer of the 340B program. *See Astra*, 563 U.S. at 120. But as almost every other court has held, S.B. 325 does not impose any penalties for violations of the 340B program. *See, e.g.*, *Fitch*, 152 F.4th at 647–48. HHS has exclusive authority over "disputes between covered entities and manufacturers regarding pricing, overcharges[10], refunds, and diversion of 340B drugs to those who do not qualify for

[10] The majority asserts that HHS oversees overcharge claims, which could include unduly restrictive contract pharmacy policies. Maj. Op. at 29. The *Frey* and *Weiser* courts make good points on this. HRSA did not explicitly define "overcharge," and instead chose "to explain only that '[w]hen an overcharge claim is presented before a 340B ADR Panel, the Panel will follow the 340B statute' and 'relevant case law,' among other sources." *Weiser*, 2025 WL 3041825, at *10 (citing 89 Fed. Reg. 28,643, 28, 649 (Apr. 19, 2024)). In considering the seminal Third and D.C. Circuit cases that "have held that manufacturers (Continued)

discounted drugs." *McClain*, 95 F.4th at 1144. That authority is wholly separate from S.B. 325 imposing a penalty when drug manufacturers interfere with the distribution of 340B drugs pursuant to a covered entities' partnership with a contract pharmacy. *See Murrill*, 166 F.4th at 541 ("[T]here is no overlap in the enforcement Venn Diagram—and thus no conflict."); *see also Fitch*, 152 F.4th at 648. Here, "[t]wo things can be true at once"—that HHS is the enforcer of the 340B program and West Virginia's attorney general is the enforcer of S.B. 325. *Murrill*, 166 F.4th at 541.

The majority instead asserts that West Virginia was not allowed to fill this legislative gap. The majority deduces the "conflict" with § 340B's enforcement provisions to whether the attorney general and state courts must decide if there has been "any offer" made under § 340B and contends that "states providing their own answers necessarily intrudes upon the uniform system of enforcement." Maj. Op. at 29. To support its conclusion, the majority relies heavily on *Arizona v. United States*, 567 U.S. 387 (2012). *See id.* at 28.

But *Arizona* does not apply or control here. In *Arizona*, the United States sued the state of Arizona, seeking to enjoin Arizona's statute that sought to "discourage and deter the unlawful entry and presence of [noncitizens] and economic activity by persons unlawfully present in the United States." *Id.* at 393 (internal citations omitted). The

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do not violate Section 340B when they restrict a covered entity's ability to distribute drugs to patients through contract pharmacies," I agree that it is "difficult to see how that conduct 'could be challenged as a limitation on the ability to purchase drugs at or below the ceiling price under federal law' before the ADR Panel." *Id.* (citing *Frey*, 2025 WL 2813785, at *11).

Supreme Court enjoined the Arizona statute, recognizing the federal government's "broad, undoubted power over the subject of immigration and the status of [noncitizens]." *Id.* at 394. "It is fundamental that foreign countries concerned about the status, safety, and security of their nationals in the United States must be able to confer and communicate on this subject with one national sovereign, not the 50 separate States." *Id.* at 395. Against this backdrop, the Supreme Court highlighted Congress' "deliberate choice not to impose criminal penalties on [noncitizens] who seek, or engage in, unauthorized employment." *Id.* at 405. That choice was evidenced by the federal legislative background, as a "commission established by Congress to study immigration policy recommended and concluded that those penalties would be unnecessary and unworkable." *Id.* (internal citations omitted). Notably, after those recommendations were made, proposals to criminalize unauthorized work were debated and rejected. *See id.* Thus, the Supreme Court justly concluded that the Arizona statute's enforcement provisions interfered with Congress' "deliberate choice" by criminalizing noncitizens who sought or engaged in "unauthorized employment." *Id.*

Here, no comparable decisions or "deliberate choices" were made with respect to the 340B program. The absence of such choice is particularly notable, given the federal government's undoubted constitutional power over immigration and noncitizen status in *Arizona*. *See id.* at 395 (the government's authority rests in part on the power to "establish an uniform Rule of Naturalization"); *see also United States v. South Carolina*, 720 F.3d 518, 531 (4th Cir. 2013) (recognizing immigration as a long recognized and "overwhelmingly dominant" area of federal interest). Furthermore, in *Arizona*, the United States *itself* sued to enjoin a state enforcement provision to ensure that foreign countries

would be "able to confer . . . with one national sovereign, not the 50 separate States." 567 U.S. at 395. Here, S.B. 325 regulates public health—a matter unlike immigration policy—that is traditionally in the domain of the States. While the Arizona enforcement provision added a "penalty for conduct proscribed by federal law," S.B. 325 does not invade HHS' system of enforcement on 340B pricing and eligibility because it only regulates drug delivery and distribution—neither of which is addressed in § 340B.

S.B. 325 and the 340B program do not concern the same subject matter and "operate in distinct spheres." *Murrill*, 166 F.4th at 541. Accordingly, neither HHS' enforcement authority nor its enforcement system is encroached upon.

b.

Second, S.B. 325 does not interfere with a manufacturer's ability to conduct audits. Yes, it is true that S.B. 325 does not allow drug manufacturers to *condition* the delivery of a 340B drug with the submission of claims or utilization data. *See* W. Va. Code § 60A-8-6a(b)(2) ("A manufacturer . . . shall not, either directly or indirectly, require a 340B entity to submit any claims or utilization data *as a condition* for . . . delivery" (emphasis added)). But S.B. 325 does not inhibit a drug manufacturer's ability to obtain that data through any means authorized by federal law. In fact, "[a] covered entity *shall permit* the Secretary and the manufacturer . . . to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance." 42 U.S.C. § 256b(a)(5)(C) (emphasis added).

To begin an audit of a covered entity, a manufacturer must have "reasonable cause." Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406,

65,410 (Dec. 12, 1996). But the majority overstates how demanding that standard is. *See* Maj. Op. at 29–30. Reasonable cause in this context "means that a reasonable person could believe that a covered entity may have violated a requirement of section 340B(a)(5)(A) or (B)." 61 Fed. Reg. at 65,409. Reasonable cause does not require any "pre-approval" and can be met by "[s]ignificant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity may be a basis for establishing reasonable cause." 61 Fed. Reg. at 65,406. The plaintiff manufacturers failed to show that reasonable cause would be difficult to establish in practice. It did not identify a time when it requested an audit but was denied due to a lack of claims data. Further, whether a manufacturer should submit "supporting documentation" if it believes a contract pharmacy is diverting drugs is beside the point. *See* Maj. Op. at 30. A manufacturer can submit "documentation of *good faith efforts*, including for example, documentation demonstrating that the initiating party has made attempts to contact the opposing party regarding the specific issues cited in the ADR claim." 42 C.F.R. § 10.21(b)(4) (emphasis added).

At bottom, manufacturers do not need claims or utilization data to meet the reasonable cause standard. There is no need to condition data or documentation on 340B drug delivery. Accordingly, § 60A-8-6a(b)(2) of S.B. 325 does not frustrate § 340B's audit mechanism.

* * *

For the above reasons, I conclude that the plaintiff manufacturers have not established a likelihood of success that S.B. 325 is field or conflict preempted.

B. Remaining *Winter* Factors

Even if I were to find that the plaintiff manufacturers demonstrated a likelihood of success on its preemption claim[11], they would also need to show that they are likely to suffer irreparable harm if preliminary relief is not granted; the balance of equities favors granting an injunction; and an injunction is in the public interest. *Winter*, 555 U.S. at 20.

While my analysis would have ended after the first *Winter* factor[12], I disagree with the majority's resolution of the remaining *Winter* factors. I would instead decide that the district court abused its discretion in ruling for the plaintiff manufacturers on those factors.

First, the district court abused its discretion in finding that the "irreparable harm" factor weighed in favor of the plaintiff manufacturers. The 340B program constitutes only a fraction (about 5%) of the overall prescription drug market, and a relatively small

[11] The plaintiff manufacturers brought other claims and arguments, including that S.B. 325 "effectuates an unconstitutional taking." Appellee's Br. (ECF No. 51) at 101. My dissent focuses mostly on their preemption arguments because it is the heart of the majority's opinion. But I share the district court's observation that many of the other arguments appear "dubious." *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 460 (S.D. W. Va. 2024). In a footnote, the majority points to the one district court that has found a similar state delivery law to be a taking. *See* Maj. Op. at 31 n.13 (citing *Drummond*, 2025 WL 3048929, at *8–9). Yet it is the only one in a sea of cases that have found otherwise. *Murrill*, 166 F.4th at 542–44; *Fitch*, 152 F.4th at 642–44; *Fitch*, 2024 WL 3503965, at *19–20; *Frey*, 2025 WL 2813787, at *14; *Skrmetti*, 2025 WL 1805271, at *19–20; *Bailey*, 2025 WL 644285, at *5–6; *Murrill*, 2024 WL 4361597, at *15; *Brown*, 1:24-cv-01557-MJM. Accordingly, I will not substantively address the plaintiff manufacturers' other arguments.

[12] *See Frazier v. Prince George's Cnty.*, 86 F.4th 537, 544 (4th Cir. 2023) ("[D]enying a preliminary injunction only takes the rejection of a single factor.").

percentage of the branded drug market (about 14%).[13] It follows that the plaintiff manufacturers do not argue that they will suffer insolvency. *See Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 694 (4th Cir. 1994) (noting that an injunction could be appropriate in situations of insolvency and where assets were in danger of dissolution and depletion). Further, the mere possibility of irreparable harm is insufficient to permit the issuance of a preliminary injunction. *See Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017) (quoting *Winter*, 555 U.S. at 22)). The plaintiff manufacturers have not argued that they are currently subject to an enforcement action in West Virginia, or that they have received notice of an investigation into its business practices.

Second, the district court abused its discretion in finding that the "balance of equities" and "public interest" factors weighed in favor of the plaintiff manufacturers. The plaintiff manufacturers' restrictive drug delivery policies risk the viability of essential medical programs and care. "Rural hospitals have been under significant financial pressure and have seen a growing number of closures." 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*, at 1, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf, [https://perma.cc/DSU6-32TM]. For 340B hospitals that offer patients discounted drugs

[13] *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 208 (D.N.J. 2021), *aff'd in part, rev'd on other grounds*, *Sanofi*, 58 F.4th 696 at 700 ("Not only does Novo reap billions of dollars in annual revenue from 340B drug sales, but such sales represent about 5% of the prescription drug market and 14% of the branded drug market, leaving the vast majority of Novo's sales untouched.").

at contract pharmacies, "two-thirds reported restrictions caused patients to experience delayed access and/or logistical difficulties in obtaining needed medications." *Id.* at 2. Further, "[h]ospitals have reported contract pharmacy restrictions have led to patients going without prescribed drugs, rationing medications, or delaying care, sometimes with severe health consequences." *Id.* And pertinent to this case, of the 37 West Virginia hospitals participating in the 340B program, 36 (about 97%) contract with at least one community pharmacy. *See* Brief of Amicus Curiae, Brief of Am. Hosp. Ass'n. & 340B Health, at 4–5.

What's more, 340B providers generally operate on razor-thin (even negative) margins. *See* Am. Hosp. Ass'n, *Fact Sheet - 340B Drug Pricing Program: Fact v. Fiction*, at 3 (Oct. 2025).[14] This makes sense, as covered entities are often providing uncompensated care to the county's most vulnerable patients. No wonder why Congress, in passing the 340B program, specifically sought "to stretch scarce [f]ederal resources as far as possible." H.R. Rep. No. 102-384 (pt. 2), at 12 (1992). The Supreme Court has recognized this congressional interest, stating that "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Becerra*, 596 U.S. at 738.

Several hospitals in West Virginia, 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.

[14] https://www.aha.org/system/files/media/file/2025/10/fact-sheet-340b-drug-pricing-program-fact-vs-fiction-R.pdf, [perma.cc/9Y6B-VSXU].

See Brief of Amicus Curiae, Brief of Am. Hosp. Ass'n. & 340B Health, at 5. Hospitals within the WVU system use 340B savings to fund numerous other activities, such as bedside prescription counseling, a mobile mammography unit, diabetes support groups, and a mobile lung cancer screening unit. *Id.* Cabell Huntington Hospital ("CHH"), in the Marshall Health Network, uses its 340B savings for critical programs that support patients that cannot afford their prescriptions; mothers with substance use disorders; and babies of mothers with substance use disorders. *Id.* at 6. CHH predominantly serves low-income patients and provided $149 million in uncompensated care last year—more than double its 340B savings. *Id.* Allowing drug manufacturers to unilaterally restrict the delivery of 340B drugs threatens the viability of rural hospitals that already operate on razor thin margins. These restrictive delivery policies by drug manufacturers have already caused $39 million in annual losses to the WVU hospital system. *Id.* at 5–6. Accordingly, the consequences are profound and immediate: they jeopardize the viability of these hospitals, their essential services, and receipt of drugs that many low-income patients in West Virginia rely on.

The majority has widened a gap that Congress intended to close, leaving low-income patients to shoulder the burden. The district court abused its discretion because it failed to "pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter*, 555 U.S. at 24. The balance of equities rests entirely in the state's favor, as enjoining S.B. 325 will harm the interests and public health of West Virginians.

IV. Conclusion

The court does not act as the "older brother or sister" of Congress. Our role is not to anticipate when it may feel frustrated in its exercise of its spending power. Our role is closer to a referee that calls "balls and strikes," or here, to determine when a State "crosses the line" and oversteps its bounds in legislating. West Virginia did not overstep its bounds by enacting S.B. 325. For decades, Congress has almost certainly been aware of its silence on "delivery." Yet, through those decades, Congress has remained silent. If Congress truly felt frustrated, it could have acted on its own. For that reason and the others above, I respectfully dissent.