No. 25-1054 (L)

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff-Appellee,

v.

JOHN B. MCCUSKEY, *ET AL.*,
Defendants-Appellants.

On appeal from the United States District Court
for the Southern District of West Virginia
No. 2:24-cv-00271,
District Judge Thomas E. Johnston

BRIEF OF AMERICAN HOSPITAL ASSOCIATION, WEST VIRGINIA HOSPITAL ASSOCIATION, 340B HEALTH, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS AND *EN BANC* REVIEW

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INTEREST OF *AMICI CURIAE*[1]

Amici have a strong interest in the success of West Virginia's efforts to protect the 340B program.

The **American Hospital Association** represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to ensuring that healthcare is available to and affordable for all Americans.

340B Health is a national, not-for-profit organization that represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program—a vital part of the nation's healthcare safety net.

The **West Virginia Hospital Association** is a statewide not-for-profit organization representing hospitals and health systems across the continuum of care.

The **American Society of Health-System Pharmacists** is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings.

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[1] No party's counsel authored this brief in whole or in part. No one other than *Amici* or their counsel contributed any money to fund its preparation or submission. Defendants-Appellants consent and Plaintiff-Appellee Novartis Pharmaceuticals Corp. takes no position with respect to the filing of this amicus brief. Counsel for Plaintiffs-Appellees AbbVie Inc. *et al.* and PhRMA did not respond to *Amici*'s request for consent.

INTRODUCTION

This case satisfies all of the Rule 40(b) factors. The full court of appeals should grant West Virginia's petition for rehearing *en banc*.

Over the past five years, 40 drug companies, including Plaintiffs-Appellees, broke with decades of practice by refusing to ship drugs purchased by 340B hospitals to contract pharmacies. When drug companies first announced this plan, the federal government determined it was unlawful and sought to require them to deliver 340B drugs to contract pharmacies on the same terms as to in-house hospital pharmacies.

The drug companies fought that effort tooth and nail, arguing that the federal government could not interfere with their contract pharmacy restrictions. They insisted that their policies were permissible because: (1) they were delivery restrictions, and (2) the 340B statute had nothing to say about delivery to contract pharmacies. They won. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi-Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703, 707 (3d Cir. 2023) (Section 340B's "text is silent about delivery" and "[l]egal duties do not spring from silence.").

After fighting to establish that gap and when states started passing laws to protect contract pharmacy relationships, the drug companies made an abrupt about-face, arguing that the federal 340B statute's silence carries preemptive force. Their 180-degree reversal raises the central question in this case: can States regulate within

the federal 340B statute's gap regarding the delivery of 340B drugs? The answer is yes—which until the panel's decision had been the "unanimous view of the circuit courts and the overwhelming consensus view of the district courts." *AbbVie Inc. v. Brown*, 2026 U.S. App. LEXIS 10581, at *4 (4th Cir. Apr. 14, 2026) (Benjamin, J., dissenting) (unpublished). In holding otherwise, the panel cast aside traditional preemption analysis, invented a new test for federal supremacy that has no basis in precedent, and upset bedrock principles of federalism.

The panel's flawed decision suffered greatly from lack of party presentation. "[T]he panel decided on its own—without any party raising the issue and without requesting supplemental briefing— . . . to create [its] new test" *National Association of Immigration Judges v. Owen*, 160 F.4th 100, 107-08 (4th Cir. 2025) (Quattlebaum, J., joined by, Agee, Richardson, and Rushing, JJ., dissenting from the denial of rehearing en banc). In fact, the panel majority itself recognized that its decision rested on "cases and analysis not briefed by the parties," Maj. Op. 27, n. 9, but treated that concern as a mere question of waiver or forfeiture.

But "the crucible of adversarial testing is crucial to sound judicial decisionmaking." *Sessions v. Dimaya*, 584 U.S. 148, 190 (2018) (Gorsuch, J., concurring in part and concurring in the judgment); *see Maslenjak v. United States*, 582 U.S. 335, 354 (2017) (Gorsuch, J., joined by Thomas, J., concurring in part and concurring in the judgment) (party presentation "yield[s] insights" and "reveal[s]

pitfalls"). Had West Virginia (and Maryland) been given the opportunity to test the panel's new theory of federal supremacy, it would have exposed the decision's many shortcomings. The full Court should grant the States that courtesy—especially given the overwhelming weight of conflicting authority and the exceptional importance of the issues presented.

ARGUMENT

I. The Panel Decision Conflicts With Fifth and Eighth Circuit Decisions.

Most directly, the panel's decision to invalidate West Virginia's statute conflicts with two Circuit Courts upholding materially identical State laws. On several important subsidiary legal issues, moreover, the panel's analysis squarely conflicts with other Courts of Appeals:

- Application of the presumption against preemption and what area the state was regulating in (*i.e.*, public health), *compare* Maj. Op. 18–19 *with AbbVie Inc. v. Fitch*, 152 F.4th 635, 646–47 (5th Cir. 2025);[2] *PhRMA v. McClain*, 95 F.4th 1136, 1140 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024);

- Definition of the field, *compare* Maj. Op. 24 *with Fitch*, 152 F.4th at 646–47; *McClain*, 95 F.4th at 1140;[3]

[2] *See also AbbVie Inc. v. Murrill*, 166 F.4th 528 (5th Cir. 2026), *Novartis Pharms. Corp. v. Fitch*, 2026 WL 963504, at *2 (5th Cir. Apr. 9, 2026) (unpublished), and *PhRMA v. Fitch*, 2026 WL 963501 (5th Cir. Apr. 9, 2026) (unpublished).

[3] Days after the panel's decision, the Fifth Circuit refused to define the field as the panel did here. *Novartis v. Fitch*, 2026 WL 963504, at *2 (rejecting definition of the field as "the Section 340B program").

- Significance of the 340B statute's silence regarding drug delivery, *compare* Maj. Op. 14 *with Fitch*, 152 F.4th at 646; *McClain*, 95 F.4th at 1143; *see Conti v. Citizens Bank, N.A.*, 157 F.4th 10, 21 (1st Cir. 2025); *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1143 (9th Cir. 2015); *Frank Bros., Inc. v. Wis. Dep't of Transp.*, 409 F.3d 880, 891 (7th Cir. 2005);

- Whether the state law alters a drug company's obligations under the 340B statute or "bargain," *compare* Maj. Op. 20–21 *with Murrill*, 166 F.4th at 545;

- Whether to apply the traditional preemption test or the panel's new "intergovernmental-immunity/preemption/Spending-Clause" test, *compare* Maj. Op. 17–31 *with Fitch*, 152 F.4th at 645–48; *McClain*, 95 F.4th at 1142–46; *see also Planned Parenthood of Houston & S.E. Tex. v. Sanchez*, 403 F.3d 324, 329–30 (5th Cir. 2005) ("traditional preemption doctrine" applies to claims that "a state law purportedly conflicts with federal statutes enacted under the Spending Clause."); *Texas v. DHS*, 123 F.4th 186, 209 (5th Cir. 2024) (rejecting attempt to "smuggle in preemption" into the intergovernmental immunity analysis); and

- Whether the state law conflicts with federal government's enforcement authority, *compare* Maj. Op. 28–30 *with McClain*, 95 F.4th at 1144; *Fitch*, 152 F.4th at 647–48.[4]

II. The Panel Decision Conflicts With GenBioPro.

GenBioPro, Inc. v. Raynes, 144 F.4th 258 (4th Cir. 2025) rejected the argument that "the preempted field [should be defined] by restating the precise subject addressed by the [federal statute at issue]," because that "strikes us as

[4] The panel's finding that drug companies would not be able to initiate audits under the federal 340B statute without the ability to require covered entities to provide claims data conflicts with district court authority. *E.g.*, *AbbVie Inc. v. Skrmetti*, 2026 WL 542712, at *11–12 (M.D. Tenn. Feb. 26, 2026); *AstraZeneca Pharms. LP v. Weiser*, 2025 WL 3653161, at *10 (D. Colo. Dec. 17, 2025).

tautological." 144 F.4th at 273. But the panel did just that here, narrowing the field to "the 340B program requirements." Maj. Op. 24. The majority reasoned that its tautological field definition does not conflict with *GenBioPro* because "[w]e look[ed] at the text of the state law," which by its terms applies to participants in the federal 340B program. *Id.* at 24. But nothing in *GenBioPro* suggests that an explicit reference to a federal program is a reason to permit tautological field definitions. In fact, although *GenBioPro* held that "the Supreme Court long ago rejected the notion that federal statutes automatically preempt state laws on the same topic," *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 273 (4th Cir. 2025), the panel never explained why it matters that a state law expressly references the federal law "on the same topic."

The panel decision further conflicts with *GenBioPro* because it "infer[s] field preemption solely from 'pervasive regulation' or the presence of a 'dominant federal interest.'" 144 F.4th at 274 (quoting *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973) (pervasiveness); *Hillsborough Cnty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 719 (1985) (federal interest)). As *GenBioPro* pointed out, however, "every subject that merits congressional legislation is, by definition, a subject of national concern," and so a "'dominant federal interest' offers little insight" into whether a State law is preempted. 144 F.4th at 274 (quoting *Hillsborough Cnty.*, 471 U.S. at 719).

Finally, in concluding that the West Virginia statute is preempted under its cramped field definition, the panel ignored *GenBioPro*'s recognition of the States' "long history' of regulating drugs" and the well-established "complementary exercise of federal and state power" with respect to drug regulation. *GenBioPro*, 144 F.4th at 275 (citation omitted).

III. The Panel Decision Conflicts With Supreme Court Precedent.

There also is a conflict—or at least a sharp tension—between the panel's invented "intergovernmental-immunity/preemption/Spending-Clause" test and the Supreme Court's consistent application of traditional preemption principles in cases involving Spending Clause legislation. *See, e.g.*, *PhRMA v. Walsh*, 538 U.S. 644, 670 (2003); *Coventry Health Care of Mo., Inc. v. Nevils*, 581 U.S. 87, 95-99 (2017); *Dalton v. Little Rock Family Planning Servs.*, 516 U.S. 474, 478 (1996) (per curiam); *Bennett v. Arkansas*, 485 U.S. 395, 396 (1988) (per curiam); *Lawrence Cnty. v. Lead-Deadwood Sch. Dist. No. 40-1*, 469 U.S. 256, 257-258 (1985); *Philpott v. Essex County Welfare Bd.*, 409 U.S. 413, 417 (1973); *Townsend v. Swank*, 404 U.S. 282, 285 (1971); *cf. Dublino*, 413 U.S. at 421 ("Where coordinate state and federal efforts exist within a complementary administrative framework, and in the

pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one.").[5]

IV. This Case Presents a Question of Exceptional Importance.

This case is exceptionally important. *First*, it impacts the laws of two of the five states in this Circuit. *See Manning v. Caldwell for City of Roanoke*, 930 F.3d 264 (4th Cir. 2019) ("[T]he crux of Plaintiffs' appeal concerns an issue of 'exceptional importance' to the Commonwealth of Virginia . . . ."); *Richmond Med. Ctr. For Women v. Hicks*, 422 F.3d 160 (4th Cir. 2005) (Niemeyer, J., dissenting) (supporting review where case raised "questions of exceptional importance to the people of Virginia"). Two state legislatures enacted the statutes by wide margins (West Virginia with a unanimous State Senate vote and only one *nay* vote in the State House of Representatives; Maryland with a unanimous State House and only eight *nay* votes in the State Senate). This demonstrates the importance of the issue to the people of those States—and the perils of invalidating state laws without presentation from party-States.

Second, striking down a state law is always a grave act that deserves the most careful consideration. *E.g.*, *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582 (2016) (Alito, J., joined by Roberts and Thomas, JJ., dissenting) ("Under the

[5] The panel relied on a single case for its new Spending Clause-inflected preemption test. The dissenting opinion refutes that reliance, *see* Op. 54–59, and underscores the conflict between the majority's decision and Supreme Court precedent.

Supremacy Clause, federal courts may strike down state laws that violate the Constitution or conflict with federal statutes, Art. VI, cl. 2, but in exercising this power, federal courts must take great care. The power to invalidate a state law implicates sensitive federal-state relations."); *Cnty. of Maricopa v. Lopez–Valenzuela*, 575 U.S. 1044, 1044 (2015) (Thomas, J., joined by Scalia, J., dissenting from denial of certiorari) ("This Court once emphasized the need for judicial restraint when asked to review the constitutionality of state laws.").

Third, the validity of *this* state law is exceptionally important to West Virginia patients and caregivers. As the Supreme Court recognized, "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *AHA v. Becerra*, 596 U.S. 724, 738 (2022); *see* Damond Boatright, *340B Is Not a Problem To Be Solved, But a Promise To Be Kept and Secured*, Becker's Hospital Review (Apr. 6, 2026), https://www.beckershospitalreview.com/hospital-management-administration/340b-is-not-a-problem-to-be-solved-but-a-promise-to-be-kept-and-secured/ ("Weakening 340B . . . would simply shift financial burden onto rural hospitals, Catholic ministries and the patients least able to absorb it, ultimately threatening the availability of care in the very communities that depend on it most."). 340B providers typically operate with razor-thin (and often negative) margins,

which is unsurprising since 340B covered entities provide a disproportionate amount of uncompensated care to the country's most vulnerable patients.

In West Virginia, the 340B program is an irreplaceable lifeline for cash-strapped safety-net providers. Of the 37 West Virginia hospitals participating in the 340B drug discount program, 36 contract with at least one community pharmacy. Before the implementation of contract pharmacy restrictions, discounts on drugs dispensed at these pharmacies constituted one-quarter of overall 340B savings for hospitals participating in 340B. Contract pharmacy restrictions have substantially slashed savings from the 340B program, which is devasting for the very hospitals in West Virginia that provide 86% of all hospital care to Medicaid patients. As one West Virginia legislator explained, the 340B program "provides a lifeline to rural hospitals and clinics in our state by allowing them to . . . pass that discount on to patients in the form of free or low-cost prescriptions and care for conditions ranging from diabetes to black lung."[6]

Consider the following examples:

- West Virginia University (WVU) Medicine, Summersville Regional Medical Center, WVU St. Joseph's Hospital, and Boone Memorial Hospital use their 340B savings to provide prescriptions at no cost for patients who are unable to pay.

[6] Craig Blair, *Op-ed: 'Big Pharma' is Using West Virginia to Scare GOP Supporters of 340B Pharmacies*, Parkersburg News & Sentinel (Jun. 15, 2024), https://www.newsandsentinel.com/opinion/local-columns/2024/06/op-ed-big-pharma-is-using-west-virginia-to-scare-gop-supporters-of-340b-pharmacies/.

- WVU hospitals use 340B savings to fund a mobile mammography unit, diabetes support groups, and a mobile lung cancer screening unit. The contract pharmacy policies have caused a whopping $39 million in annual losses to WVU—threatening not only these patient-friendly services, but the viability of its rural hospitals.[7]

- Cabell Huntington Hospital (CHH) uses 340B savings for critical programs that support patients who cannot afford their prescriptions, mothers with substance use disorders and their babies, and medication adherence.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies. Even fewer—only one in five—have in-house "specialty" pharmacies, which dispense "specialty" drugs that are typically used to treat chronic, serious, or life-threatening conditions. 340B hospitals typically must contract with at least one "specialty" pharmacy to receive a 340B discount for high-priced specialty drugs.

In short, the "consequences" of the panel decision "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." Dissent Op. 69. If that is not exceptionally important, *Amici* do not know what is.

CONCLUSION

For these reasons and for those set forth in Defendants-Appellants' petition, this Court should grant *en banc* review.

[7] AHA, *The Value of the 340B Program: WVU Medicine St. Joseph's Hospital Case Study* (Jul. 31, 2023), https://www.aha.org/system/files/media/file/2023/07/340B-Case-Study-WVU-St-Josephs-Hospital-West-Virginia.pdf.

Dated: April 17, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 17, 2026, the foregoing Brief of American Hospital Association and 340B Health as *Amici Curiae* in Support of Defendants-Appellants and En Banc Review was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

/s/ William B. Schultz
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CERTIFICATE OF COMPLIANCE

i. This brief complies with the type volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and Local Rule 32(b) because it contains 2,592 words, excluding the parts of the brief exempted by Rule 32(f).

ii. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Rule 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in fourteen-point Times New Roman font.

/s/ William B. Schultz
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