No. 24-1939 (L)

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

ABBVIE, INC., *ET AL.*,
Plaintiffs-Appellants,

v.

ANTHONY BROWN, *ET AL.*,
Defendants-Appellees.

On appeal from the United States District Court
for the District of Maryland
No. 1:24-cv-01816-MJM,
District Judge Matthew J. Maddox

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF AMERICAN HOSPITAL ASSOCIATION, MARYLAND HOSPITAL ASSOCIATION, MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS, 340B HEALTH, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

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Attorneys for Amici Curiae

Pursuant to Federal Rule of Appellate Procedure 29(a)(3), movants American Hospital Association, 340B Health, Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and American Society of Health-System Pharmacists respectfully move the Court for leave to file a brief as *amici curiae* in support of Defendants-Appellees. Defendants-Appellees as well as Plaintiffs-Appellants AbbVie Inc. *et al.* and Novartis Pharmaceuticals Corporation consent to the filing of this *amicus* brief. Plaintiff-Appellant Pharmaceutical Research and Manufacturers of America does not oppose the filing of this brief.

I. INTEREST OF MOVANTS

Movants include four non-profit organizations with members in Maryland that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists, many who are located in Maryland, who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings that benefit from the 340B program. Movants and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. Movants therefore have a strong interest in the success of Maryland's legislative efforts to protect the 340B program.

II. MOVANTS' BRIEF WILL BE USEFUL TO THE COURT'S CONSIDERATION OF THIS APPEAL.

Movants' brief complies with Federal Rule 29 and contains valuable insight to inform the Court's consideration of the merits of this appeal. As representatives of 340B covered entities and pharmacists serving patients, movants are uniquely positioned to explain the critical role of contract pharmacies, which have been used by covered entities since the beginning of the 340B program. Movants are also qualified to explain how the onerous contract pharmacy restrictions that drug companies began to impose in 2020 resulted in significant harms to patients and 340B providers, which operate on razor-thin margins to provide care to individuals with low incomes. Further, movants' brief explains why the challenged Maryland statute, which requires drug companies to honor the contract pharmacy relationships of Maryland covered entities, is an essential healthcare regulation within the State's historic police powers to promote public health.

III. CONCLUSION

Based on the foregoing, movants respectfully request that the Court grant this motion for leave to file a brief as *amici curiae* in support of Defendants-Appellees and accept for filing the *amicus curiae* brief submitted contemporaneously with this motion.

Date: February 28, 2025

Respectfully submitted,

/s/ William B. Schultz
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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 391 words, as counted by Microsoft Word, excluding the parts of the motion excluded by Federal Rule of Appellate Procedure 32(f). This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word in 14-point Times New Roman font.

/s/ William B. Schultz
Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I certify that on February 28, 2025, the foregoing Unopposed Motion for Leave to File Brief of American Hospital Association, 340B Health, Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and American Society of Health-System Pharmacists as *Amici Curiae* in Support of Defendants-Appellees was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

/s/ William B. Schultz
Counsel for Amici Curiae

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
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- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 24-1939 Caption: AbbVie Inc., et al. v. Brown, et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

American Hospital Association
(name of party/amicus)

who is amicus, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☐NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Alyssa Howard Card Date: 2/28/25

Counsel for: Amicus AHA

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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Pursuant to FRAP 26.1 and Local Rule 26.1,

Mid-Atlantic Association of Community Health Centers
(name of party/amicus)

who is amicus, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

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Signature: /s/ Alyssa Howard Card Date: 2/28/25

Counsel for: Amicus MACHC

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Pursuant to FRAP 26.1 and Local Rule 26.1,

American Society of Health-System Pharmacists
(name of party/amicus)

who is amicus, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

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Signature: /s/ Alyssa Howard Card Date: 2/28/25

Counsel for: Amicus ASHP

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Pursuant to FRAP 26.1 and Local Rule 26.1,

Maryland Hospital Association
(name of party/amicus)

who is amicus, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

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Signature: /s/ Alyssa Howard Card Date: 2/28/25

Counsel for: Amicus Maryland Hospital Associatior

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Pursuant to FRAP 26.1 and Local Rule 26.1,

340B Health
(name of party/amicus)

who is amicus, makes the following disclosure:
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Signature: /s/ Alyssa Howard Card Date: 2/28/25

Counsel for: Amicus 340B Health

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INTEREST OF *AMICI CURIAE*[1]

Amici include four non-profits with members in Maryland that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists, many who are located in Maryland, who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings many of which benefit from the 340B program. *Amici* and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care and the discounts provided by the 340B program are essential to achieving this goal. Amici therefore have a strong interest in the success of Maryland legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

[1] 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. The parties do not object to the filing of this brief.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Maryland Hospital Association** (MHA) represents approximately 60 hospital and health system members, and close to half participate in the 340B program. MHA serves Maryland's nonprofit hospitals and health systems through collective action to shape policies, practices, financing, and performance to advance health care and the health of all Marylanders.

The **Mid-Atlantic Association of Community Health Centers** (MACHC) represents Maryland's 16 federally qualified health centers—nonprofit primary care providers with a collective mission to treat all patients, regardless of ability to pay. All Maryland health centers participate in the 340B program. MACHC supports community health centers as they provide access to high-quality, affordable, and community-responsive primary and preventive care.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice;

advanced education and professional development; and served as a steadfast advocate for members and patients.

BACKGROUND AND SUMMARY OF ARGUMENT

Almost five years ago, amid a devastating pandemic, multiple drug companies broke with decades of precedent and began to undermine the 340B drug discount program. Under that program, drug companies that participate in Medicaid and Medicare Part B must provide discounts on drugs sold to patients of certain nonprofit or public hospitals and community health centers. *See* 42 U.S.C. § 256b(a)(1)–(4). These discounts, which are based on similar discounts which states receive when purchasing Medicaid drugs, are approximately 23.1% of the average manufacturing price, although the discount can be greater due to an inflation penalty exacted by the federal statute. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017). Through 340B, Congress sought to allow hospitals and other covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Without costing the government a dime, these discounts are designed to help hospitals serve more vulnerable patients with more comprehensive care.

Before 2020, drug companies had provided drug pricing discounts to eligible 340B providers for drugs dispensed *both* through in-house pharmacies and

community pharmacies with which the providers had contracts. *See Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024) (*PhRMA v. McClain*), *cert. denied*, ___ S. Ct. ___, No. 24-118, 2024 WL 5011712 (Dec. 9, 2024) ("For 25 years, drug manufacturers . . . distributed 340B drugs to covered entities' contract pharmacies."). But in July 2020, one drug company made an about-face and refused to provide these discounts for drugs if dispensed to 340B patients at community pharmacies (or contract pharmacies).[2] Recognizing an opportunity to boost their own bottom lines, 38 other major drug companies followed suit.[3]

The contract pharmacy arrangements that drug companies honored for almost 30 years have helped sustain 340B providers and their patients. There are two aspects of the 340B program that cannot reasonably be disputed. *First*, the 340B discounted price is established by federal law—not Maryland's statute. The 340B price of a drug is exactly the same if it is sold to a 340B hospital for delivery to its in-house pharmacy or for delivery to a contract pharmacy. *Second*, pharmaceutical companies

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[2] *See* Maya Goldman, *Hospital Groups Worry As More Drugmakers Limit 340B Discounts*, Modern Healthcare (Mar. 25, 2022), https://www.modernhealthcare.com/safety-net-hospitals/hospitals-worry-more-drugmakers-limit-340b-discounts.

[3] Collectively, 19 of these companies made more than $660 billion in profits in 2021. *See* 340B Informed, *Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021* (updated Jan. 13, 2023), https://340binformed.org/2023/01/updated-drugmakers-cutting-340b-discounts-reported-record-revenues-in-2021/.

must sell 340B drugs to 340B hospitals if the drugs are dispensed to patients by in-hospital pharmacies.

The issue here is whether Maryland can prohibit pharmaceutical companies from refusing to deliver drugs to pharmacies with which 340B hospitals and other 340B providers have contracts to dispense 340B drugs to 340B patients. The Maryland statute does not affect the federally-established 340B price, but instead *only* affects where the 340B drugs purchased by the 340B hospital are dispensed to patients. The purchaser of those drugs (typically a 340B hospital) remains the same; the price of those drugs (the 340B price) remains the same; the only difference is the delivery address (*i.e.*, a contract pharmacy or an in-house pharmacy). Put simply, the Maryland law's only requirement is that drug companies deliver 340B discounted drugs to pharmacies *outside* a 340B hospital for dispensing to 340B patients, under the same terms as they sell those drugs to 340B hospitals with *in-house* pharmacies. Prior to 2020, this same arrangement had been in place for almost 30 years.

Prior to the implementation of contract pharmacy restrictions, discounts on drugs dispensed at community and specialty contract pharmacies made up about one-quarter of overall 340B savings for hospitals participating in 340B. Of the 24 Maryland hospitals and 15 health centers participating in the 340B drug program, all but five contract with at least one community pharmacy to dispense drugs to

patients.[4] The drug company restrictions have substantially cut the savings from the 340B program, which is devasting for hospitals in Maryland that provide 81% of all hospital care that is provided to Medicaid patients, as well as the community health centers that serve primarily low income patients.[5]

For example, the Johns Hopkins Hospital (JHH) treats a large share of the area's low-income, uninsured, and Medicare/Medicaid beneficiaries. The 340B program is crucial to JHH's ability to provide community services and uncompensated care. For instance, JHH provides low-income patients with free and discounted outpatient drugs at its outpatient pharmacies and uses 340B savings to fund wrap-around services, including home visits and transportation to patients with limited access to adequate health care. In addition, by receiving access to discounted drugs, JHH is better able to absorb the rapidly rising cost of drugs. To the extent that drug companies continue to impose restrictions on 340B drugs dispensed to hospital patients through contract pharmacies, JHH's ability to maintain and expand these kinds of services and programs is hampered. For example, JHH may have to reduce

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[4] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, https://340bopais.hrsa.gov/coveredentitysearch (last visited Feb. 27, 2025).

[5] Dobson DaVanzo Health Economics Consulting, *Maryland 340B Hospitals Serve More Patients with Low Incomes, Who Live with Disabilities and/or Identify As Black or Hispanic*, https://www.340bhealth.org/files/MD-340B-Low-Income15018.pdf.

programs designed to help vulnerable and underserved patients, regardless of their ability to pay, which could force patients to delay or forgo care.

Much like JHH, the University of Maryland Medical Center (UMMC) and Maryland General Hospital use their 340B savings to expand patient and community services in numerous important ways. UMMC uses 340B savings to support violence prevention programs, including Stop the Bleed, trauma prevention with teens, and other related support groups. Savings that flow from 340B contract pharmacy arrangements are critical to the ongoing success of these expanded community services that are provided regardless of a patient's ability to pay for services.

Ascension Saint Agnes (Saint Agnes) also relies on 340B savings to serve vulnerable individuals. The savings from the 340B program help Saint Agnes serve residents that face socioeconomic challenges that create barriers to maintaining basic care. For example, 340B savings fund Saint Agnes's Oncology and Chronic Obstructive Pulmonary Disease Clinics, Peer Recovery Programs (where Peer Recovery Coaches share their stories of recovery from addiction and inspire patients to seek treatment), and Lyft Transportation Programs (which allow the hospital to fund transportation for low-income patients so they can receive timely and regular care). Manufacturers' contract pharmacy restrictions jeopardize these programs.

In addition, MedStar's many hospitals use their 340B savings to fund a variety of vital services to the community including diabetes management programs,

smoking cessation programs, and cancer screenings. MedStar Health has been able to establish harm reduction initiatives aimed at the opioid epidemic using funding from the 340B program. With this work, MedStar Health can support teams of peer recovery coaches in the community who are directly responsible for linking recent overdose survivors to treatment services, and naloxone trainings. Manufacturers' contract pharmacy policies are a direct attack on programs like these.

Some of the restrictive drug company policies also apply to community health centers, which mean that they have an equally strong interest in seeing the Maryland law upheld. Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals and only 60% of community health centers operate in-house pharmacies.[6] This is why 340B covered entities have relied on contract pharmacies since the beginning of the program.[7]

Savings from contract pharmacy relationships are especially important for another reason: the fragile state of 340B covered entity finances. In stark contrast to the pharmaceutical industry, 340B providers typically operate with razor-thin (and

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[6] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* (July 2023), https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf; Nat'l Ass'n of Cmty. Health Ctrs., *340B: A Critical Program for Health Centers* (June 13, 2022), https://www.nachc.org/wp-content/uploads/2022/06/NACHC-340B-Health-Center-Report_-June-2022-.pdf.

[7] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55, 586 (Nov. 1, 1995).

often negative) margins.[8] This is not surprising: 340B covered entities provide a disproportionate amount of uncompensated care to the country's most vulnerable patients.[9] 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." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022).

Faced with the drug industry's unprecedented assault on Maryland's health care safety net, the Maryland legislature, by an overwhelming 174/8 vote, passed a new law: "State Board of Pharmacy – Prohibition on Discrimination Against 340B Drug Distribution." Md. Code Ann., Health Occ. § 12-6C-09.1 (West 2024) (H.B. 1056).[10] This law prohibits 340B manufacturers from directly or indirectly denying, restricting, prohibiting, discriminating against, or otherwise limiting the delivery of

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[8] AHA, *340B Drug Pricing Program: Fact vs. Fiction* 2 (Apr. 2023), https://www.aha.org/system/files/2018-04/340BFactvsFiction.pdf; Allen Dobson *et al.*, *The Role of 340B Hospitals in Serving Medicaid and Low-Income Medicare Patients* 12–13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf; Nat'l Ass'n of Cmty. Health Ctrs., *340B: A Critical Program for Health Centers* (June 13, 2022), https://www.nachc.org/wp-content/uploads/2022/06/NACHC-340B-Health-Center-Report_-June-2022-.pdf.

[9] *See* L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf; AHA, *supra* note 11, at 2; Dobson et al., *supra* note 11, at 13–17.

[10] The text of the statute can be found at https://mgaleg.maryland.gov/2024RS/Chapters_noln/CH_962_hb1056t.pdf.

340B drugs purchased by 340B covered entities and delivered to pharmacies that are under contract with or otherwise authorized by a 340B covered entity to receive 340B drugs on their behalf, unless such limitation is required by distribution restrictions imposed by the Food and Drug Administration.[11]

Appellants now seek to halt Maryland's lawful exercise of its police power to protect public health and safety. This Court should rebuff that effort. The district court correctly found that Appellants did not demonstrate that they were entitled to a preliminary injunction because they are unlikely to succeed on the merits of *any* of their claims.

ARGUMENT

This Court should affirm the district court's well-reasoned ruling. *First*, Maryland's law is not preempted because Congress did not create or occupy any field through its 340B legislation, nor does it conflict with the 340B statute. At bottom, Appellants take the position that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. To the contrary, as the Eighth Circuit explained, "[p]harmacy has traditionally been regulated at the state level, and [courts] must assume that absent a strong showing that Congress intended

[11] Under 21 U.S.C. § 355-1 the Food and Drug Administration may require a drug to have in place a limited distribution system.

preemption, state statutes that impact health and welfare are not preempted." *PhRMA v. McClain*, 95 F.4th at 1144 (citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)); *see MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023 (5th Cir. 1994). For this reason, four out of five courts that have considered the issue, including the Eight Circuit, have rejected Appellants' preemption claims regarding materially similar state laws. *See PhRMA v. McClain*, 95 F.4th at 1143–45; *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737, 747, (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Fitch*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365, at *8 (S.D. Miss. July 1, 2024) (*PhRMA v. Fitch*), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); *AbbVie Inc. v. Fitch*, No. 1:24-cv-00184-HSO-BWR, 2024 WL 3503965, at *7 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 6:23-cv-00997, 2024 WL 4361597, at *9 (W.D. La. Sept. 30, 2024) (*PhRMA v. Murrill*), *appeal docketed*, No. 24-30673 (5th Cir. Oct. 21, 2024); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507, at *4–9 (S.D. Miss. Dec. 23, 2024); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 489881, at *2–5 (E.D. Mo. Feb. 13, 2025). As discussed below, moreover, the single decision overturning a state law protecting 340B contract pharmacies, *Pharm. Rsch. & Mfrs. of Am. v. Morrissey*, Nos. 2:24-cv-00271, 2:24-cv-00272, 2:24-cv-00298, 2024 WL 5147643

(S.D. W. Va. Dec. 17, 2024) (*PhRMA v. Morrissey*), *appeal docketed*, Nos. 25-1054, 25-1055, 25-1056 (Jan. 16, 2025), was based on a fundamental misunderstanding of the 340B statute and program. This Court should reject the flawed analysis of the Southern District of West Virginia and follow the consistent approach of other courts around the country.

Second, the district court correctly rejected AbbVie's claim that H.B. 1056 violates the Fifth Amendment. Mississippi and Louisiana district courts have both rejected arguments that analogous State statutes effect an unconstitutional taking under the Fifth Amendment, citing the fundamental principle that "[g]overnmental regulation that affects a group's property interests does not constitute a taking of property where the regulated group is not required to participate in the regulated industry." *See AbbVie v. Fitch*, 2024 WL 3503965, at *17 (quoting *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991)); *PhRMA v. Murrill*, 2024 WL 4361597, at *14.

Third, the Maryland statute is not an unconstitutional extraterritorial regulation. The sweeping reading of the dormant Commerce Clause advanced by Novartis and PhRMA was recently rejected by the Supreme Court. *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 375 (2023). Like the petitioners there, Appellants advocate an "'almost *per se*' rule against laws that have the 'practical effect' of 'controlling' extraterritorial commerce [which] would cast a shadow over

laws long understood to represent valid exercises of the States' constitutionally reserved powers." *Id.*[12]

I. APPELLANTS ARE NOT LIKELY TO SUCCEED ON THE MERITS OF THEIR PREEMPTION CLAIMS.

"'The purpose of Congress is the ultimate touchstone' of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which the States have traditionally occupied,'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432 (2002)). Appellants have the burden to show that Congress intended to preempt H.B. 1056. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 661–62 (2003). Unlike state laws that intrude into uniquely federal areas such as immigration and foreign relations that Appellants have cited during this litigation, H.B. 1056 is presumptively *not* preempted.[13] Appellants therefore must demonstrate

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[12] For the reasons set forth in Appellees' Brief at 77–81, the district court also correctly ruled that a preliminary injunction of H.B. 1056 would not serve the public interest and that Appellants would not suffer irreparable harm from enforcement of H.B. 1056.

[13] *See, e.g.*, *Arizona v. United States*, 567 U.S. 387 (2012); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000).

Congress's "clear and manifest purpose" to supersede Maryland's historic authority to regulate in the public health arena, *Lohr*, 518 U.S. at 485 (citation omitted), which they cannot do.

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

Field preemption occurs only in rare instances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has rejected "the contention that pre-emption is to be inferred merely from the comprehensive character" of federal provisions. *Id.* With the 340B program, "a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent." *Dublino*, 413 U.S. at 415.

Ignoring this well-established precedent, Appellants rely on what they describe as the "comprehensive federal scheme" of the 340B statute to support their argument that the federal government intended to occupy a field with the 340B program. Appellants' Br. at 26. But Appellants fail to cite any authority supporting

their assertions about Congress's *intent* to create (or occupy) this purported 340B "field."

Worse yet, Appellants rely primarily on *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), an inapposite precedent. *Astra* addressed *only* whether covered entities could use a third-party beneficiary theory to enforce the 340B statute's federal requirements and does not ever mention the question of whether the 340B program preempts state law. *See Astra*, 563 U.S. at 113. The only mention of preemption in *Astra* is in a footnote concerning a different federal program, the Medicaid Drug Rebate Program. *Id.* at 120 n.5.

Nothing about *Astra* displaced the Supreme Court's well-established principle that "the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply pre-emption of state remedies." *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990). Moreover, Appellants' reliance on *Astra* is further undermined by the federal government's decades-old recognition of State authority over contract pharmacy arrangements.[14] Thus, the *Astra* Court's hesitance to allow "potentially thousands of covered entities" to sue to correct "errors in manufacturers' price

[14] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) (noting that, "[a]s a matter of State law, . . . covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs," and that, "[b]y issuing guidelines in this area, [the federal agency] is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law").

calculations" has no bearing on whether *States* can legislate as Maryland did here to restore contract pharmacies as an outlet for 340B drugs. *Astra,* 563 U.S. at 114. Even if Congress had created a "340B field," Appellants would have to demonstrate that H.B. 1056 intrudes into that field, which they cannot do.

B. H.B. 1056 Does Not Conflict with the 340B Statute.

Appellants also are not able to identify any actual conflict between H.B. 1056 and the federal 340B statute, particularly because H.B. 1056 only requires drug companies to continue a practice (recognition of multiple contract pharmacy arrangements) that had been in place since 2010. No one, including Appellants, disputes that 340B hospitals are entitled to discounts under the 340B statute if the 340B drugs are dispensed at a hospital pharmacy. H.B. 1056 simply allows 340B hospitals to prescribe discounted drugs to eligible patients to be dispensed at pharmacies with which they have contractual relationships. H.B. 1056 does not change the prices that Appellants may charge for these drugs.

Nor does H.B. 1056 change the character of the contract pharmacies, which function as the covered entities' pharmacies, not covered entities themselves. Consequently, Appellants cannot meet the "high threshold [that] must be met if a state law is to be preempted for conflicting with the purposes of a federal Act." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citation omitted).

Ultimately, Appellants' conflict preemption arguments miss the forest for the trees. The 340B program was designed to help covered entities "reach[] more eligible patients and provid[e] more comprehensive services." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (internal quotation omitted), *rev'd on other grounds sub nom. Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022). H.B. 1056, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer improved and expanded health care to their patients. Therefore, not only does H.B. 1056 not interfere with Congress's 340B scheme; it "furthers" it. *CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 82 (1987); *PhRMA v. McClain*, 95 F.4th at 1144–45.

C. The Single Court To Find Preemption Did So on the Basis of Flawed Legal Analysis and a Misunderstanding of the 340B Statute and Program.

The West Virginia district court's preliminary injunction ruling that that State's contract pharmacy law is likely preempted both ignores the presumption against preemption, *Lohr*, 518 U.S. 470 (1996), and is based on a flawed interpretation of the federal 340B statute and how the program operates. That outlier decision should carry no weight with this Court, just as it carried no weight in the Southern District of Mississippi, which explicitly rejected the West Virginia decision's reasoning only days later. *AstraZeneca v. Fitch*, 2024 WL 5345507, at *9

(refusing to "disregard mainstream decisions and the Eighth Circuit's ruling in *McClain* without clear precedential support").

The West Virginia court erred in several critical respects. *First*, it incorrectly found obstacle preemption, arguing that the State statute "hampers the ability of drug manufacturers to formulate the 'reasonable cause' necessary to conduct an audit," which the manufacturer must do to "access the administrative dispute resolution process." *PhRMA v. Morrissey*, 2024 WL 5147643, at *6 (S.D. W. Va. Dec. 17, 2024). This conclusion flows from a basic misunderstanding of the federal 340B audit process. Under the federal statute, audits may be initiated by HRSA or manufacturers. When manufacturers wish to conduct an audit of a covered entity, they must demonstrate "reasonable cause," defined broadly to mean that a reasonable person could believe that a covered entity *may* have violated a requirement of section 340B(a)(5) (A) or (B) of the PHS Act. *See* 61 Fed. Reg, 65,406, 65,409 (Dec. 12, 1996).

HRSA's guidance and practice confirm that the "reasonable cause" showing that a drug manufacturer must make to obtain authority to audit a covered entity is a modest one. According to long-standing HRSA guidance, manufacturers can satisfy this standard in various ways, including by pointing to "[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." 61 Fed. Reg at

65,406. Critically, we are not aware of an instance when HRSA has *ever* required the claims or utilization data that the pharmaceutical companies now demand to initiate an audit. Nor has HRSA ever expected that a manufacturer would have access to claims data until *after* it conducted an audit. Tellingly, Appellants *cannot point to a single instance* of HRSA rejecting a manufacturer's audit plan due to the absence of claims data, and we are aware of none.

The West Virginia district court's reasoning turns the audit process upside down. There is no role in the audit process for a drug company to require hospitals to *prospectively* turn over massive amounts of data as a precondition to receiving 340B discounts. Instead, the purpose of an audit, as established by the 340B statute, is to *retrospectively* measure a covered entity's compliance *after* 340B transactions have occurred. In fact, longstanding HRSA guidance makes clear that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at, 25,113; *see* Health Res. & Servs. Admin., Release No. 2011 – 1.1, Clarification of Non-Discrimination Policy (2012) (same); *Loper Bright v. Raimondo*, 144 S. Ct. 2244, 2258 (2024) (an agency interpretation "issued roughly contemporaneously with enactment of the statute" and held "consistent over time" is entitled to a court's "most respectful consideration"). The same agency that established and oversees the

"reasonable cause" standard takes the position that manufacturers *cannot* condition discounts on 340B compliance—exactly what Appellants admit they wish to do in this litigation. It is therefore difficult to understand how the West Virginia district court concluded that its State law—which barred such preconditions—is an obstacle to the HRSA's compliance and audit processes.[15]

The West Virginia court also erred by ruling that the enforcement provision in the state statute is likely preempted. In its view, the West Virginia law would require State actors to determine questions of federal law if a drug manufacturer refuses delivery of a drug to a contract pharmacy when it believes that drug is being diverted within the meaning of the federal 340B statute. *PhRMA v. Morrissey*, 2024 WL 5147643, at *7. But under the federal statute, 340B's anti-diversion provisions are enforced either by HRSA directly or in the *post hoc* Alternative Dispute Resolution process. 42 U.S.C. §§ 256b(d)(2)(B)(vi) & (3). The statute does not permit manufacturers to take the law into their own hands. This is true for delivery of 340B drugs in contract pharmacies *or* in-house hospital pharmacies—any claims of diversion are addressed *after-the-fact* by HRSA or in the ADR process. As such, state laws that require drug companies to deliver drugs to contract pharmacies (on

[15] The West Virginia statute, unlike H.B. 1056, has a separate provision prohibiting manufacturers from preconditioning delivery on the submission of claims data. Regardless of whether the claims data prohibition is explicit or implied, it would not be preempted.

the same terms as they deliver to in-house hospital pharmacies) will never raise questions of diversion since those will be addressed, per the 340B statute, in the federal processes *after* the drugs have been delivered.[16]

Finally, the West Virginia court wrongly concluded that its state statute regulated 340B drug price and not delivery. The court stated that under the replenishment model, "[b]ecause the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy, the question is not about the delivery of the drug." *PhRMA v. Morrissey*, 2024 WL 5147643, at *8. But this puts form over substance. If a contract pharmacy received each 340B drug at the 340B price and then dispensed the drug, one-by-one, directly to the patient at the contract pharmacy, the West Virginia court would logically have to conclude that the law does not regulate price because the price was set by the 340B statute. The only difference with the replenishment model is that the drug is dispensed at a

[16] As a factual matter, moreover, the hypothetical posed in the West Virginia case whereby a drug company would decline delivery would never come to pass. At the time 340B drugs are delivered (whether to an in-house pharmacy or to a contract pharmacy), drug companies do not have contemporaneous information about the patients who receive the drugs. Thus, manufacturers have no practical ability to deny the 340B discount based on some in-the-moment belief that diversion is occurring. This is true under the replenishment model discussed by the West Virginia district court because the 340B discount is provided when the pharmacy's stock is replenished with 340B discounted drugs to replace the drugs already distributed to 340B patients. There is no patient information involved in this transaction other than the covered entity's representation that the discount is being provided for drugs distributed to 340B patients.

contract pharmacy and is then replenished. In both cases, the price is set by federal statute and in neither case is the State law establishing the price. All the State law is doing is ensuring that drug companies continue to deliver drugs to contract pharmacies, where those drugs can be dispensed to 340B patients on equal terms as if they were delivered to and dispensed at hospital pharmacies. Viewed from a different lens, there is no question that 340B drugs may be sold at hospital pharmacies using the replenishment model. Appellants have never disputed this. All the State law allows for is the hospital to warehouse the drug at a contract pharmacy using the replenishment model as an inventory management system. Thus, by refusing to deliver to those contract pharmacies, the drug companies are imposing *delivery* restrictions—namely, they are saying, "We will deliver to your hospital but not your functional warehouse that makes it easier to get those drugs into the hands of needy patients."

Ultimately, the only impact of state laws like West Virginia's and Maryland's is to ensure that manufacturers deliver 340B drugs purchased by the 340B covered entity at the federally-mandated price, regardless of whether the covered entity is using an in-house pharmacy or an outside pharmacy. This is undoubtedly a question of delivery rather than price. The West Virginia court failed to understand this important fact. It is yet another reason why this Court should disregard that erroneous decision and instead follow the overwhelming number of courts that have

upheld similar State statutes as regulations of drug delivery.

II. H.B. 1056 DOES NOT VIOLATE THE TAKINGS CLAUSE.

AbbVie's claim under the Fifth Amendment's Takings Clause likewise fails because the challenged provision does not constitute a taking. To our knowledge, no court has ever found that there is a property interest subject to Fifth Amendment protection where a healthcare provider or pharmaceutical company is *voluntarily participating* in the government program that it claims is taking its property. In fact, at least ten courts that have considered the issue have found that there is no taking. *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014), *cert. denied*, 575 U.S. 1008 (2015); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied*, 469 U.S. 1215 (1985); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993), *cert. denied*, 510 U.S. 821 (1993); *Burditt*, 934 F.2d at 1376; *Whitney v. Heckler*, 780 F.2d 963, 968–73 (11th Cir. 1986), *cert. denied*, 479 U.S. 813 (1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984); *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 207–10 (D.N.J. 2021), *rev'd on other grounds*, 58 F.4th 696 (3d Cir. 2023); *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20; *PhRMA v. Murrill*, 2024 WL 4361597, at *13–15.

This includes four courts that have considered this issue in the 340B context. *Eli Lilly*, 2021 WL 5039566, at *21; *Sanofi-Aventis*, 570 F. Supp. 3d at 207–10; *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20; *PhRMA v. Murrill*, 2024 WL 4361597, at *13–15. In *Eli Lilly*, the court found that the plaintiff's voluntary participation in the 340B Drug Program "forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation." 2021 WL 5039566, at *21 (quoting *S.E. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016)). Although withdrawing from the 340B program—and therefore, necessarily, Medicaid and Medicare Part B (because 340B participation is required to participate in these markets)—would "result in a significant financial impact for" Eli Lilly, this consequence was insufficient to find legal compulsion for the purposes of the court's takings analysis. *Id.* Of course, nothing in the Maryland law prohibits AbbVie from selling drugs to Maryland hospitals. It simply says that if AbbVie chooses to participate in the federal 340B program, in addition to offering 340B prices to covered entities with in-house pharmacies, AbbVie must offer 340B prices to covered entities where the covered entities' patients purchase drugs at community pharmacies with which the entities have contracts, as it did for more than 20 years.

III. H.B. 1056 DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

Novartis and PhRMA also are unlikely to succeed on the merits of their claim that H.B. 1056 runs afoul of the dormant Commerce Clause. Their arguments are squarely foreclosed by *National Pork Producers*. *See, e.g.*, *PhRMA v. Fitch*, 2024 WL 3277365, at *13; *Novartis v. Bailey*, 2025 WL 595189, at *3–5. As the *National Pork Producers* Court held, "[p]reventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of extreme delicacy, something courts should do only where the infraction is clear." 598 U.S. at 390 (quotation marks omitted). Novartis and PhRMA do not come close to meeting that exacting standard.

As a factual matter, the Maryland law applies *only* to drugs dispensed to patients of *Maryland* 340B providers. Like "many (maybe most) state laws," H.B. 1056 may indirectly impact "extraterritorial behavior" for drug companies that are headquartered outside of Maryland. *Nat'l Pork Producers*, 598 U.S. at 374. But H.B. 1056 does not target the regulation of extraterritorial activities. To the contrary, it is focused entirely on drug dispensing to patients of 340B providers that are *inside* of Maryland's borders. Even if Novartis and PhRMA had a valid legal theory about extraterritorial effects, it would not apply to H.B. 1056 on the facts. *See id*. at 375 (quoting *Hoyt v. Sprague*, 103 U. S. 613, 630 (1880)).

But Novartis and PhRMA have no valid legal theory. *National Pork Producers* flatly rejected the "almost *per se*" extraterritoriality rule that they seek, holding that the dormant Commerce Clause does *not* forbid "enforcement of state laws that have the "practical effect of controlling commerce outside the State[.]" 598 U.S. at 371. Instead, the "very core" of its dormant Commerce Clause jurisprudence is the "antidiscrimination principle," *i.e.*, whether a state engages in "economic protectionism" by privileging in-state competitors over out-of-state competitors. *Id.* at 369. PhRMA's attempt to revive the "extraterritoriality doctrine" so soon after the Supreme Court rejected it, *id.* at 371, is foreclosed by *National Pork Producers*.[17]

For the same reasons, the Southern District of Mississippi and the Western District of Missouri rejected extraterritoriality challenges to those States' materially identical laws. Applying the presumption against extraterritoriality, which also exists in Maryland, *see Chairman of Bd. of Trs. of Emps.' Ret. Sys. v. Waldron*, 285 Md. 175, 183–84 (1979), both district courts found that the manufacturer plaintiffs were unlikely to succeed on the merits of their dormant Commerce Clause claims. *PhRMA v. Fitch*, 2024 WL 3277365, at *13 (explaining that the Mississippi law

[17] *National Pork Producers* also fatally undermines PhRMA's reliance on *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 674 (4th Cir. 2018). As the Supreme Court explained, *Frosh* stands for the principle that one State may not tie "the price of . . . in-state products to out-of-state prices." *Nat'l Pork Producers*, 598 U.S. at 374. H.B. 1056 does no such thing. It simply requires manufacturers to distribute 340B drugs to the pharmacies with which Maryland 340B hospitals have contracted.

"does not exhibit a clear intent to regulate out-of-state conduct"); *see also Novartis v. Bailey*, 2025 WL 595189, at *3–5.[18] The same is true of H.B. 1056.

CONCLUSION

For the foregoing reasons and for the reasons set forth in Appellees' Brief, this Court should affirm the judgment of the district court.

[18] While the Missouri district court concluded that Novartis was unlikely to succeed on the merits of its dormant Commerce Clause claim, the same court also previously denied motions to dismiss filed by the State defendants and an intervenor. *See Novartis v. Bailey*, 2025 WL 489881, at *5–9. *Amici* cannot explain the discrepancy in that court's approaches. But the law is clear: "the dormant Commerce Clause doesn't prohibit differential treatment of companies that perform *different services*, because any notion of discrimination assumes a comparison of substantially similar entities." *Paul's Industrial Garage, Inc. v. Goodhue Cnty.*, 35 F.4th 1097, 1099–1100 (8th Cir. 2022). Rather, a plaintiff must demonstrate "actual or prospective competition between the supposedly favored and disfavored entities in a single market" to bring a dormant Commerce Clause claim. *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 300 (1997). That does not exist here because, as the same district court recognized only a few days later, covered entities or in-state pharmacies, on the one hand, and out-of-state drug companies, on the other hand, are *not* substantially similar entities and do *not* compete in the same market.

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CERTIFICATE OF COMPLIANCE

1. 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 6,495 words, excluding the parts of the brief exempted by Rule 32(f).

2. 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
William B. Schultz

CERTIFICATE OF SERVICE

I certify that on February 28, 2025, the foregoing Brief of American Hospital Association, 340B Health, Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and American Society of Health-System Pharmacists as *Amici Curiae* in Support of Defendants-Appellees was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

/s/ William B. Schultz
Counsel for Amici Curiae