

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

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,

Plaintiff,

v.

PATRICK MORRISEY, et al.,

Defendants.

Case No. 2:24-cv-00271

ABBVIE INC., et al.,

Plaintiffs,

v.

PATRICK MORRISEY, et al.,

Defendants.

Case No. 2:24-cv-00298

**AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, WEST VIRGINIA
HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM
PHARMACISTS' UNOPPOSED MOTION TO FILE OVERSIZE *AMICUS* BRIEF IN
SUPPORT OF DEFENDANTS' OPPOSITION TO PHRMA AND ABBVIE'S
PRELIMINARY INJUNCTION MOTIONS**

The American Hospital Association, 340B Health, the West Virginia Hospital Association, and the American Society of Health-System Pharmacists (collectively, the “Proposed *Amici*”) move this Court for leave to file the attached *amicus curiae* brief in support of Defendants Attorney General Patrick Morrissey, Allen L. McVey, and John Bernabei’s omnibus opposition to Motions for Preliminary Injunction filed by Plaintiffs Pharmaceutical Research and Manufacturers of America (PhRMA) and AbbVie Inc. (AbbVie) (along with Allergan, Inc., Durata Therapeutics,

Inc., AbbVie Products LLC, Aptalis Pharma US Inc., Pharmacylics LLC, and Allergan Sales, LLC) (Exhibit A), as follows:

1. Proposed *Amici* include three hospital associations with members in West Virginia that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings many of which benefit from the 340B program. Proposed *Amici* and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The 340B program is essential to achieving this goal. Proposed *Amici* therefore have a strong interest in the success of West Virginia's legislative efforts to protect the 340B program.

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

3. Proposed *Amici's* brief, which is timely filed, provides the Court with a unique perspective and specific information the parties cannot otherwise provide about 340B hospitals in West Virginia and nationwide that can assist the Court's evaluation of the case, and it also addresses preemption, Takings Clause, and Excessive Fines Clause arguments made by Plaintiffs in support of their motions for preliminary injunction. Additionally, the Court's ruling on Plaintiffs' motions for preliminary injunction will directly affect Proposed *Amici's* members, further supporting the filing of the *amicus* brief.

4. *Amici* also seek leave to file a brief 12 pages in length, which would exceed the page limit by two pages, assuming that the page limit under this Court’s Local Rules and the Federal Rules of Appellate Procedure is 10 pages. *See* S.D. W. Va. L.R. 7.1.a.2; *see* Fed. R. App. P. 29(a)(5) (providing that an *amicus* brief “may be no more than one-half the maximum length authorized by these rules for a party’s principal brief”). Unless *Amici* are permitted to file an oversize brief *Amici* would be unable to provide the Court with all the information that *Amici* believe will be helpful to this Court’s deliberations.

5. Proposed *Amici* consulted with counsel for Plaintiffs and Defendants and represent that Plaintiffs’ and Defendants’ counsel do not oppose this Motion.

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

Dated: August 16, 2024.

Respectfully submitted,

/s/ Robert M. Sellards

Robert M. Sellards
SPILMAN THOMAS & BATTLE, PLLC
401 10th Street, Suite 500
Huntington, WV 25701
Tel: (304) 697-8565
Fax: (304) 697-4714
rsellards@spilmanlaw.com

William B. Schultz*
Margaret M. Dotzel*
Alyssa Howard Card*
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
acard@zuckerman.com

**pro hac vice motion forthcoming*

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I certify that on August 16, 2024, I caused a true and correct copy of American Hospital Association, 340B Health, West Virginia Hospital Association, and American Society of Health-System Pharmacists' Unopposed Motion to File Oversize *Amicus* Brief in Support of Defendants' opposition to PhRMA and AbbVie's motions for preliminary injunction to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

/s/ Robert M. Sellards
Robert M. Sellards

EXHIBIT A

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

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,

Plaintiff,

v.

PATRICK MORRISEY, et al.,

Defendants.

Case No. 2:24-cv-00271

ABBVIE INC., et al.,

Plaintiffs,

v.

PATRICK MORRISEY, et al.,

Defendants.

Case No. 2:24-cv-00298

**BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH,
WEST VIRGINIA HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF
HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' OPPOSITION
TO PHARMA AND ABBVIE'S PRELIMINARY INJUNCTION MOTIONS**

Robert M. Sellards
John H. Zickefoose
Spilman Thomas & Battle, PLLC
401 10th Street, Suite 500
Huntington, WV 25701
Tel: (304) 697-8565
Fax: (304) 697-4714
rsellards@spilmanlaw.com
jzickefoose@spilmanlaw.com

*Counsel of Record
Counsel for Amici Curiae*

William B. Schultz*
Margaret M. Dotzel*
Alyssa Howard Card*
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
ahoward@zuckerman.com
*pro hac vice motion forthcoming
Counsel for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

INTERESTS OF *AMICI CURIAE* 1

BACKGROUND AND SUMMARY OF ARGUMENT 2

ARGUMENT 7

 A. S.B. 325 is Not Preempted..... 8

 B. The West Virginia Statute Does Not Constitute an Unconstitutional Taking. 9

 C. S.B. 325 Does Not Violate the Eighth Amendment’s Excessive Fines Clause 10

CONCLUSION..... 12

TABLE OF AUTHORITIES

CASES

AbbVie Inc. v. Fitch,
 No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024)..... 7, 8, 9, 10

AHA v. Becerra,
 596 U.S. 724 (2022)..... 6

Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.,
 763 F.3d 1274 (11th Cir. 2014) 9

Burditt v. U.S. Dep’t of Health & Hum. Servs.,
 934 F.2d 1362 (5th Cir. 1991) 9

Eli Lilly & Co. v. U.S. Dep’t of Health & Hum. Servs.,
 No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021)..... 9

Garelick v. Sullivan,
 987 F.2d 913 (2d Cir. 1993) 9

Henderson v. Bluefield Hosp. Co. LLC,
 902 F.3d 432 (4th Cir. 2018) 7

Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare,
 742 F.2d 442 (8th Cir. 1984) 9

Novartis Pharms. Corp. v. Fitch,
 ___ F. Supp. 3d ___, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407
 (S.D. Miss. July 1, 2024) 7, 8, 9

Ohio v. Env’t Prot. Agency,
 603 U.S. ___, No. 23A349 (June 27, 2024)..... 7

PhRMA v. Fitch,
 No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365 (S.D. Miss. July 1, 2024)..... 8, 9

PhRMA v. McClain,
 95 F.4th 1136 (8th Cir. 2024) 2, 8

Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.,
 570 F. Supp. 3d 129 (D.N.J. 2021)..... 9

St. Francis Hosp. Ctr. v. Heckler,
 714 F.2d 872 (7th Cir. 1983) 9

State Farm Mut. Auto. Ins. Co. v. Campbell,
 538 U.S. 408 (2003)..... 11, 12

Timbs v. Indiana,
586 U.S. 146 (2019)..... 11

United States ex rel. Drakeford v. Tuomey,
792 F.3d 364 (4th Cir. 2015) 11

United States v. Jalaram, Inc.,
599 F.3d 347 (4th Cir. 2010) 11

United States v. Salerno,
481 U.S. 739 (1987)..... 10

United States v. Stevens,
559 U.S. 460 (2010)..... 10

United States v. United Mine Workers of Am.,
330 U.S. 258 (1947)..... 11

Whitney v. Heckler,
780 F.2d 963 (11th Cir. 1986) 9

Winter v. Nat. Res. Def. Council, Inc.,
555 U.S. 7 (2008)..... 7

STATUTES

42 U.S.C. § 256b..... 2

W. Va. Code § 60A-8-6a 6, 7, 8, 10, 11, 12

W. Va. Code Ann. § 60A-6-605 12

W. Va. Code Ann. §§ 60A-8-6a 11

W. Va. Const. art. III, § 5..... 10

OTHER AUTHORITIES

340B Health,
*Drugmakers Pulling \$8 Billion Out of Safety-Net Hospitals: More Expected as
Growing Number Impose or Tighten 340B Restrictions* 5, 6

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*..... 3

340B Informed,
*Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021
(updated Jan. 13, 2023)*..... 3

Adam J. Fein,
Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?, Drug Channels Institute (Dec. 12, 2019) 5

Adam J. Fein,
The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute (Mar. 2022) 5

AHA,
340B Drug Pricing Program: Fact vs. Fiction (Apr. 2021)..... 6

AHA,
The Value of the 340B Program: WVU Medicine St. Joseph’s Hospital Case Study (July 2023) 4

Allen Dobson *et al.*,
The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients (July 10, 2020) 6

Craig Blair,
‘Big Pharma’ is Using West Virginia to Scare GOP Supporters of 340B Pharmacies, The Parkersburg News and Sentinel (June 15, 2024)..... 4

Dobson DaVanzo Health Economics Consulting,
West Virginia 340B Hospitals Serve More Patients with Low Incomes and Provide the Majority of Hospital Care to Medicaid Patient..... 3

Health Res. & Servs. Admin, Off. of Pharmacy Affairs,
 340B OPAIS 3

L&M Policy Research, LLC,
Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients (Mar. 12, 2018) 6

Maya Goldman,
Hospital Groups Worry As More Drugmakers Limit 340B Discounts, Modern Healthcare (Mar. 25, 2022) 2

U.S. Dep’t of Health & Hum. Servs. Off. of Inspector Gen.,
Specialty Drug Coverage and Reimbursement in Medicaid..... 5

REGULATIONS

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (Nov. 1, 1995) 5

INTERESTS OF AMICI CURIAE¹

Amici include three hospital associations with members in West Virginia that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists 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. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of West Virginia's legislative efforts to protect the 340B program.

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

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,500 public and private nonprofit hospitals and health systems participating in the 340B program.

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

¹ *Amici Curiae* state that that they are not-for-profit organizations. None of *Amici* has a parent company, and no publicly traded company holds ten percent or more interest in any of *Amici*.

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

Four 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). 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 PhRMA v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024) (“For 25 years, drug manufacturers . . . distributed 340B drugs to covered entities’ contract pharmacies.”). But in July 2020, one drug company 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, Plaintiffs AbbVie Inc. (collectively with other Plaintiffs in *AbbVie Inc. v. Morrissey*,³ AbbVie) and 36 other major drug

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 Other Plaintiffs include Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US Inc., Pharmacylics LLC, and Allergan Sales, LLC.

companies, including fellow members of the Pharmaceutical Research and Manufacturers of America (PhRMA), followed suit.⁴

The contract pharmacy arrangements that drug companies like AbbVie and the members of PhRMA honored for almost 30 years helped sustain hospitals and their patients. Prior to the implementation of contract pharmacy restrictions, discounts on drugs dispensed at community and specialty contract pharmacies made up about one-quarter of overall 340B savings for hospitals participating in 340B. For rural Critical Access Hospitals, savings from partnerships with these pharmacies represented an average of 52% of overall 340B savings.⁵ Of the 37 West Virginia hospitals participating in the 340B drug discount program, 36 contract with at least one community pharmacy.⁶

The drug company restrictions have substantially cut the savings from the 340B program, which is devastating for the very hospitals in West Virginia that provide 86% of all hospital care that is provided to Medicaid patients.⁷ 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

⁴ Collectively, 19 of these companies made more than \$660 billion in profits in 2021. *See* 340B Informed, *Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021* (updated Jan. 13, 2023), <https://340binformed.org/2023/01/updated-drugmakers-cutting-340b-discounts-reported-record-revenues-in-2021/> (last visited Aug. 14, 2024).

⁵ 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf (last visited Aug. 14, 2024).

⁶ Health Res. & Servs. Admin, Off. of Pharmacy Affairs, 340B OPAIS, <https://340bopais.hrsa.gov/coveredentitysearch> (last visited Aug. 14, 2024).

⁷ Dobson DaVanzo Health Economics Consulting, *West Virginia 340B Hospitals Serve More Patients with Low Incomes and Provide the Majority of Hospital Care to Medicaid Patients*, <https://www.340bhealth.org/files/WV-340B-Low-Income15040.pdf> (last visited Aug. 14, 2024).

ranging from diabetes to black lung.”⁸ Several hospitals, including West Virginia University (WVU) Summersville Regional Medical Center, WVU St. Joseph’s Hospital, and Boone Memorial Hospital use their 340B savings to provide prescriptions at no cost for those unable to pay.⁹

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

Plaintiffs’ restrictive policies also threaten hospitals in the Marshall Health Network, like Cabell Huntington Hospital (CHH). As a disproportionate share hospital, CHH predominantly serves low-income patients and provided \$149 million in uncompensated care last year—*more than double* its 340B savings. CHH uses 340B savings for critical programs supporting patients

⁸ See Craig Blair, ‘*Big Pharma*’ is Using West Virginia to Scare GOP Supporters of 340B Pharmacies, The Parkersburg News and Sentinel (June 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> (last visited Aug. 14, 2024).

⁹ AHA, *The Value of the 340B Program: WVU Medicine St. Joseph’s Hospital Case Study* (July 2023), <https://www.aha.org/system/files/media/file/2023/07/340B-Case-Study-WVU-St-Josephs-Hospital-West-Virginia.pdf>; Boone Memorial Health, *Brighter Futures*, <https://www.bmh.org/our-services/brighter-futures> (last visited Aug. 14, 2024).

¹⁰ *The Value of the 340B Program* *supra* note 9.

who cannot afford their prescriptions; medication adherence; mothers with substance use disorders; and babies of mothers with substance use disorders.¹¹

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.¹² This is why they have relied on contract pharmacies since the beginning of the program.¹³ Even fewer—only one in five—have in-house “specialty” pharmacies, which many payers require for the dispensing of “specialty” drugs. These drugs are typically used to treat chronic, serious, or life-threatening conditions, and are generally priced much higher than non-specialty drugs.¹⁴ Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy to receive the 340B discount for their patients’ high-priced specialty drugs.¹⁵ In fact, for seven of the 21 drug companies with restrictive contract pharmacy policies as of June 1, 2023, specialty drugs make up more than three-quarters of the savings associated with restricted drugs.¹⁶ Denied these and other 340B savings associated with contract pharmacies, 340B

¹¹ This brief focuses on a few hospitals, but other examples of programs funded by 340B savings are legion. *See, e.g.,* Roane General Hospital, *Prescription For Your Health* (2024), <https://roanegeneralhospital.com/services/p4yh/>.

¹² 340B Health, *Drugmakers Pulling \$8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions 2*, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf (last visited Aug. 14, 2024).

¹³ Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (Nov. 1, 1995).

¹⁴ Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels Institute (Dec. 12, 2019), <https://www.drugchannels.net/2020/05/insurers-pbms-specialty-pharmacies.html>; U.S. Dep’t of Health & Hum. Servs. Off. of Inspector Gen., *Specialty Drug Coverage and Reimbursement in Medicaid*, <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp> (last visited Aug. 14, 2024).

¹⁵ 340B Health, *supra* note 5, at 7 (citing Adam J. Fein, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2022), <https://drugchannelsinstitute.com/files/2022-PharmacyPBM-DCI-Overview.pdf>).

¹⁶ *Id.* at 6.

hospitals have been forced to cut critical programs and services, and patients have been denied discounts on their drugs.¹⁷

In stark contrast to the pharmaceutical industry, 340B hospitals typically operate with razor-thin (and often negative) margins to provide a disproportionate amount of uncompensated care, community health services, and other services to underserved patients.¹⁸ Indeed, “340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support.” *AHA v. Becerra*, 596 U.S. 724, 738 (2022).

Faced with the drug industry’s unprecedented assault on West Virginia’s health care safety net, the West Virginia legislature responded. By an overwhelming 127/1 vote, it passed a new law, which added a new section to the statute entitled: “Distribution of Safety-Net Drugs to Contract Pharmacies; Penalties and Preemption.” *See* W. Va. Code § 60A-8-6a (S.B. 325).¹⁹ This law prohibits manufacturers, wholesale drug distributors, and third-party logistics providers from directly or indirectly denying, restricting, or prohibiting the acquisition of 340B drugs by 340B covered entities for delivery to pharmacies that are authorized by covered entities to receive 340B drugs on their behalf, unless prohibited by the United States Department of Health and Human Services (HHS). *Id.* The act further prohibits manufacturers, wholesale drug distributors, and third-

¹⁷ *Id.* at 1.

¹⁸ AHA, *340B Drug Pricing Program: Fact vs. Fiction 2* (Apr. 2021), <https://www.aha.org/system/files/2018-02/340BFactvsFiction.pdf>; Allen Dobson *et al.*, *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 12–13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf; L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf (last visited Aug. 14, 2024).

¹⁹ The text of the statute can be found at https://www.wvlegislature.gov/Bill_Text_HTML/2024_SESSIONS/RS/bills/sb325%20sub2%20enr.pdf.

party logistics providers from requiring 340B entities to submit claims or utilization data, unless required by HHS. *Id.* Any violation of this provision is considered an unfair, abusive, or deceptive trade practice, subject to enforcement and penalties under the West Virginia Consumer Protection Act. *Id.*

Plaintiffs AbbVie and PhRMA now join Novartis in seeking a preliminary injunction that would halt West Virginia's lawful exercise of its police power to protect public health and safety. The motions for preliminary injunction should be denied because Plaintiffs cannot demonstrate that they are likely to succeed on the merits, which the Supreme Court has highlighted as the most important factor, even if the equities and harms are equal between movants and the State (and the people it protects). *Ohio v. Env't Prot. Agency*, 603 U.S. ___, No. 23A349, slip op. at 11 (June 27, 2024). Here, Plaintiffs have no chance of success because all of the grounds argued in their preliminary injunction motions are unmeritorious (and most have already been rejected by other courts).

ARGUMENT

To meet the requirements for a preliminary injunction, Plaintiffs must establish (1) that it is likely to succeed on the merits; (2) that it is likely to suffer irreparable harm in the absence of relief; (3) that the balance of equities tips in its favor; and (4) that an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Henderson v. Bluefield Hosp. Co. LLC*, 902 F.3d 432, 439 (4th Cir. 2018). *Amici* focus on the first factor, which is determinative because Plaintiffs do not come close to meeting it.²⁰ Plaintiffs advance three

²⁰ The Mississippi district court determined that there was no need to reach the other preliminary injunction factors but noted that it had considered them and determined that they would not alter the Court's conclusion. *Novartis Pharms. Corp. v. Fitch*, ___ F. Supp. 3d ___, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407, at *10 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024); *AbbVie Inc. v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965, at

legally insufficient arguments to support their preliminary injunction motions: that S.B. 325 (1) is preempted by the federal 340B statute; (2) violates the Takings Clause of the Fifth Amendment; and (3) runs afoul of the Eighth Amendment’s prohibition on excessive fines. All of these claims fail as a matter of law.

A. S.B. 325 is Not Preempted.

For the reasons set forth in *Amici*’s brief filed in this Court in *Novartis Pharms. Corp. v. Morrissey*, No. 1:24-cv-00272-TEJ, *see* Brief of Amici Curiae AHA et al. in Support of Defendants’ Opposition to Plaintiff’s Motion for Preliminary Injunction (Amicus Br.) at 8–16, ECF No. 31,²¹ S.B. 325 is not preempted. This year, the Eighth Circuit and the District Court for the Southern District of Mississippi both rejected similar arguments by drug manufacturers seeking to enjoin State statutes that are identical West Virginia’s statute in all material respects. *PhRMA v. McClain*, 95 F.4th at 1141–46; *AbbVie v. Fitch*, 2024 WL 3503965; *PhRMA v. Fitch*, 2024 WL 3277365; *Novartis Pharm. Corp. v. Fitch*, 2024 WL 3276407. Both courts rejected the drug companies’ claims that the relevant State laws are preempted by section 340B. *See PhRMA v. McClain*, 95 F.4th at 1141–46; *AbbVie v. Fitch*, 2024 WL 3503965, at *7–16; *PhRMA v. Fitch*, 2024 WL 3277365, at *7–13; *Novartis v. Fitch*, 2024 WL 3276407, at *5–10. Applying the presumption against preemption because the Mississippi statute “plainly falls under the umbrella of a health and safety regulation,” the Mississippi district court found that there was no conflict with the 340B statute, and that Congress did not create a federal field in which the state could not

*20–21 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024); *PhRMA v. Fitch*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365, at 20 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024).

²¹ In accordance with the Court’s instruction at the status conference of July 15, 2024, *Amici* incorporate their *amicus* brief supporting Defendants’ opposition to Novartis’s preliminary injunction motion.

intrude in passing 340B legislation. *See AbbVie v. Fitch*, 2024 WL 3503965, at *9; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *Novartis v. Fitch*, 2024 WL 3276407, at *6.

B. The West Virginia Statute Does Not Constitute an Unconstitutional Taking.

For the reasons set forth in Defendants' Omnibus Memorandum in Support of Motion to Dismiss PhRMA's Claims and Opposing PhRMA and AbbVie's Preliminary Injunction Motions (Defs.' Mem.) at 21–24, ECF No. 43, AbbVie is also unlikely to succeed on the merits of its Takings Clause claim. 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. To the contrary, every court to consider the issue has found that there is no taking. *See, e.g., 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 v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991); *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. Likewise, all three courts to consider this issue in the 340B context have rejected the Fifth Amendment challenges of pharmaceutical companies. *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.

The Southern District of Mississippi’s analysis in *AbbVie v. Fitch* is instructive. There, the court rejected AbbVie’s nearly identical allegations, finding that the substantively identical Mississippi statute did not amount to an unconstitutional taking. *See AbbVie v. Fitch*, 2024 WL 3503965, at *16–20. The court concluded that because the Mississippi statute “does not compel Plaintiffs to directly sell 340B drugs to pharmacies, it does not cause takings for private use.” *Id.* at *19. Further, the court declined to find that the State law effected a *per se* taking because “Plaintiffs are still only required to sell at 340B discounts to covered entities, and [covered entities] can still only have drugs dispensed to their patients.” *Id.*

C. S.B. 325 Does Not Violate the Eighth Amendment’s Excessive Fines Clause.

Likewise, AbbVie is unlikely to succeed on the merits of its claim that it is entitled to a preliminary injunction because S.B. 325 imposes unconstitutionally excessive fines. AbbVie scrapes the bottom of the rhetorical barrel in claiming that S.B. 325 violates the Excessive Fines Clause of the Eighth Amendment and the West Virginia Constitution’s analogous provision. *See* W. Va. Const. art. III, § 5. As Defendants point out, *see* Defs.’ Mem. at 25, AbbVie faces a high burden because it challenges the law on its face instead of as applied to it. *See United States v. Salerno*, 481 U.S. 739, 745 (1987). While an as-applied challenge requires only that a court evaluate the constitutionality of a law’s application to the particular parties and facts of the case before it, *see United States v. Stevens*, 559 U.S. 460, 473 n.3 (2010), a facial challenge requires that there be “no set of circumstances” in which the law could be constitutionally applied. *Salerno*, 481 U.S. at 745. AbbVie fails to meet this rigorous standard because it does not and cannot demonstrate that S.B. 325 could *never* be constitutionally applied.

Even if AbbVie could make an as-applied challenge—and it cannot—that too would fall flat. To establish that a punitive fine violates the Eighth Amendment because it is

unconstitutionally excessive as applied, a party must show that it was “grossly disproportionate to the gravity of [a defendant’s] offense.” *Timbs v. Indiana*, 586 U.S. 146, 149 (2019); *see also United States v. Jalaram, Inc.*, 599 F.3d 347, 354–55 (4th Cir. 2010). In considering challenges to punitive damages awards, including civil penalties, under the Eighth Amendment Excessive Fines Clause, courts consider (1) the degree of reprehensibility of a party’s misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the monetary penalty; and (3) the difference between the civil penalties and the penalties authorized or imposed in comparable cases. *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 388 (4th Cir. 2015) (citing *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003)). The culpability of the defendant’s conduct is the most important factor, and on that point, the Supreme Court has instructed courts to consider whether, among other things,

the tortious conduct evinced an indifference to or a reckless disregard of the health or safety of others; the target of the conduct had financial vulnerability; the conduct involved repeated actions or was an isolated incident; and the harm was the result of intentional malice, trickery, or deceit, or mere accident.

State Farm, 538 U.S. at 419. Further, courts consider a defendant’s ability to pay when assessing the excessiveness of a fine. *See, e.g., United States v. United Mine Workers of Am.*, 330 U.S. 258, 304–05 (1947) (finding that a \$3.5 million fine against a union was excessive, but a \$700,000 fine was not).

Applying these principles, the penalties imposed by S.B. 325 fail the Excessive Fines test on multiple grounds. The penalties are not “grossly disproportionate” to any violation, and AbbVie plainly has the ability to pay any fines levied against it. AbbVie cannot seriously contend that a multi-billion-dollar drug manufacturer would struggle to pay a \$50,000 fine for a single violation. *See W. Va. Code Ann. § 60A-8-6a(c)(1)(A)*.

Moreover, a drug manufacturer’s refusal to comply with S.B. 325 plainly satisfies the reprehensibility factor; it is an intentional decision to protect the company’s bottom line at the expense of low-income patients with “financial vulnerability” who rely on 340B discounts to access life-saving medications and other services that 340B covered entities are able to provide because of 340B savings. *See State Farm*, 538 U.S. at 419. Further, a manufacturer violating the statute would cause significant public harm—threatening critical community health services provided by 340B covered entities. *See supra* at 2–7. Given the serious consequences of violations of S.B. 325, the fines are plainly not excessive, especially in the context of AbbVie’s facial challenge.²²

CONCLUSION

For the foregoing reasons, and those outlined in *Amici*’s brief in *Novartis Pharm. Corp. v. Morrissey*, *Amici* respectfully request that the Court deny the pending motions for preliminary injunction brought by all Plaintiffs.

Respectfully submitted,

/s/ Robert M. Sellards

Robert M. Sellards
John H. Zickefoose
SPILMAN THOMAS & BATTLE, PLLC
401 10th Street, Suite 500
Huntington, WV 25701
Tel: (304) 697-8565
Fax: (304) 697-4714
rsellards@spilmanlaw.com
jzickefoose@spilmanlaw.com

²² Even if S.B. 325’s fines were “excessive” under the Eighth Amendment, that provision is automatically severable from the rest of the statute, such that the rest of S.B. 325 would remain valid. *See* W. Va. Code Ann. § 60A-6-605.

William B. Schultz*
Margaret M. Dotzel*
Alyssa Howard Card*
ZUCKERMAN SPAEDER LLP
1800 M Street NW, Suite 1000
Washington, DC 20036
Tel: (202) 778-1800
Fax: (202) 822-8106
wschultz@zuckerman.com
mdotzel@zuckerman.com
ahoward@zuckerman.com

**pro hac vice motion forthcoming*

Counsel for Amici Curiae