UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ABBVIE INC., *et al.*, *Plaintiffs*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, *et al*. *Defendants*.	Case No. 1:24-cv-01816-MJM

AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MARYLAND HOSPITAL ASSOCIATION, MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS' UNOPPOSED MOTION TO FILE OVERSIZE *AMICUS* BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Pursuant to Local Rule 105.12.b, the American Hospital Association, 340B Health, the Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and 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' motion to dismiss and opposition to Plaintiffs' Motion for Preliminary Injunction (Exhibit A), as follows:

1. Proposed *Amici* include four hospital associations 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 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 Maryland's legislative efforts to protect the 340B program.

2. Further, the attached *amicus* brief is desirable and asserts matters relevant to the disposition of the case. The attached *amicus* brief provides the Court, for example, information regarding how Proposed *Amici's* members use the 340B discounts they receive for drugs dispensed through contract pharmacies and how Plaintiff's restrictive contract pharmacy policies negatively impact Proposed *Amici's* members' patients.

3. Proposed *Amici*'s brief, which is timely filed within seven days after the filing of Defendants' opposition, *see* D. Md. L. R. 105.12.e, provides the Court with a unique perspective and specific information the parties cannot otherwise provide about 340B hospitals in Maryland and nationwide that can assist the Court's evaluation of the case, and it expounds upon preemption, Takings Clause, and Excessive Fines Clause arguments that are directly responsive to the claims set forth in Plaintiffs' Memorandum in Support of their Motion for Preliminary Injunction. Additionally, the Court's ruling on Plaintiffs' Motion for Preliminary Injunction will directly affect Proposed *Amici's* members, further underlining the value of the *amicus* brief.

4. Proposed *Amici* also certify that neither party's counsel authored the attached *amicus* brief in whole or part, and neither party nor its counsel have contributed money to fund the preparation and/or submission of the brief.

5. Proposed *Amici* also seek leave to file an oversize *amicus* brief. Local Rule 105.12.c requires that *amicus* briefs are no longer than 15 pages. Proposed *Amici* seek leave to file a brief that is a little over 19 pages. Without leave, *Amici* would otherwise be unable to provide the Court with all the information that *Amici* believe will be helpful to this Court's deliberations.

6. Proposed *Amici* consulted with counsel for Plaintiffs and Defendants and represent that counsel for Defendants consent to this Motion and counsel for Plaintiffs do not oppose this Motion.

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

Dated: July 29, 2024

Respectfully submitted,

/s/ Alyssa Howard Card
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CERTIFICATE OF SERVICE

I certify that on July 29, 2024, I caused a true and correct copy of American Hospital Association, 340B Health, Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and American Society of Health-System Pharmacists' Unopposed Motion to File Oversize *Amicus* Brief in Support of Defendants' motion to dismiss and opposition to Plaintiffs' motion for preliminary injunction to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

/s/ Alyssa Howard Card
Alyssa Howard Card

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ABBVIE INC., *et al.*, *Plaintiffs*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, *et al*. *Defendants*.	Case No. 1:24-cv-01816-MJM

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MARYLAND HOSPITAL ASSOCIATION, MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTERESTS OF *AMICI CURIAE*

Amici are non-profit organizations whose members receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies. *Amici* and their members are committed to improving the health of the communities they serve. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Maryland'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. 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.

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 **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

Beginning four years ago, amid a devastating pandemic, multiple drug companies started to break with decades of precedent and devised a plan to undermine the 340B drug discount program. Under that program, drug companies that participate in Medicaid and Medicare Part B must provide discounts on drugs sold to patients of certain nonprofit 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).[1] Recognizing an opportunity to boost its own bottom line, Plaintiff AbbVie, Inc. (collectively with the other Plaintiffs, AbbVie) and 36 other major drug companies quickly followed suit.[2]

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[1] *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.

[2] 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/.

The contract pharmacy arrangements that drug companies honored for almost 30 years helped sustain 340B providers 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. Of the 24 Maryland hospitals and 16 health centers participating in the 340B drug program, all but three contract with at least one community pharmacy to dispense drugs to patients.[3] 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.[4]

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 programs designed to help vulnerable and

[3] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, https://340bopais.hrsa.gov/coveredentitysearch (last visited July 25, 2024).

[4] 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 (last visited July 25, 2024); Health Res. & Servs. Admin, *Maryland Health Center Program Uniform Data System Data*, https://data.hrsa.gov/tools/data-reporting/program-data/state/MD (last visited July 25, 2024).

underserved patients, regardless of their ability to pay, which could force patients to delay or forego care.

Much like JHH, the University of Maryland Medical Center (UMMC) and Maryland General Hospital (Midtown), member organizations of the University of Maryland Medical System, use their 340B savings to expand patient and community services in numerous important ways. To take just one example, the Midtown Community Health Education Center provides free health screenings, lifestyle change programs, and support groups. 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) is another Maryland hospital that relies on 340B savings to serve vulnerable persons. 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.[5] 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. They become a consistent point of contact should someone wish to enter care. It is an innovative response to the reality that those who survive an opioid overdose have a high mortality rate unless they are actively engaged in treatment. MedStar Health also uses 340B dollars to provide prescription assistance to help patients in need afford their medicines, and the 340B savings support "Food as Medicine" Initiatives, which address food insecurity issues and improve health. 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] In addition, the restrictive drug manufacturer policies do not recognize that payors and pharmacy benefit managers

[5] *See, e.g.*, *Community Health: MedStar Good Samaritan Hospital*, MedStar Health, https://www.medstarhealth.org/locations/medstar-good-samaritan-hospital/community-health; *Community Health: MedStar Harbor Hospital*, MedStar Health, https://www.medstarhealth.org/locations/medstar-harbor-hospital/community-health; *Community Health: MedStar St. Mary's Hospital*, MedStar Health, https://www.medstarhealth.org/locations/medstar-st-marys-hospital/community-health; *Community Health: MedStar Southern Maryland Hospital Center*, MedStar Health, https://www.medstarhealth.org/locations/medstar-southern-maryland-hospital-center/community-health; *Community Health: MedStar Union Memorial Hospital*, MedStar Health, https://www.medstarhealth.org/locations/medstar-union-memorial-hospital/community-health (all URLs last visited July 25, 2024).

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

(PBMs) influence where patients must fill their prescriptions. For example, many payors require that certain specialty drugs be filled only at a PBM-owned "specialty pharmacy." Such "specialty" drugs are typically used to treat chronic, serious, or life-threatening conditions, and are often priced much higher than non-specialty drugs.[8] Only one in five 340B hospitals have in-house "specialty" pharmacies. Thus, 340B hospitals typically *must* contract with at least one specialty pharmacy to receive the 340B discount for their patients' high-priced specialty drugs.[9] 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.[10]

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 often negative) margins.[11] This is not surprising: 340B covered entities provide a disproportionate amount of uncompensated care to the country's most vulnerable patients.[12] Savings from the 340B program help to offset the cost of providing uncompensated health care. As the Supreme Court recognized, "340B hospitals perform

[8] 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 July 25, 2024).

[9] 340B Health, *supra* note 6, at 7 (citing Adam J. Fein, *supra* note 8).

[10] 340B Health, *supra* note 6, at 6.

[11] 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.

[12] *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.

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 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." Maryland House Bill 1056 (H.B. 1056).[13] This law prohibits 340B manufacturers from directly or indirectly denying, restricting, prohibiting, discriminating against, or otherwise limiting the delivery of 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 distribution restrictions imposed by the Food and Drug Administration.[14]

AbbVie now seeks to halt Maryland's lawful exercise of its police power to protect public health and safety. The preliminary injunction motion should be denied because AbbVie cannot demonstrate that it is likely to succeed on the merits, the most important factor of the Court's analysis. *See Casa de Md., Inc. v. Wolf*, 486 F. Supp. 3d 928, 949 (D. Md. 2020). And here, AbbVie has no chance of success. *First*, H.B. 1056 is not preempted. Congress did not create or occupy any field through its 340B legislation, nor does H.B. 1056 conflict with the 340B statute. *See PhRMA v. McClain*, 95 F.4th at 1143–45. *Second*, H.B. 1056 does not constitute a taking under the Fifth Amendment because it does not implicate a protected property interest. *Third*, H.B. 1056 does not impose unconstitutionally excessive fines under the Eighth Amendment.

Indeed, this month, the Southern District of Mississippi has denied preliminary injunction motions filed by AbbVie, Novartis Pharmaceuticals Corporation, and the Pharmaceutical Research

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

[14] Under 21 U.S.C. § 355-1 the U.S. Food and Drug Administration may require a drug to have in place a Risk Evaluation and Mitigation Strategy pursuant to which the distribution of a drug may be limited.

and Manufacturers of America (PhRMA) seeking to enjoin a similar Mississippi statute. *AbbVie Inc. v. Fitch*, No. 1:24-cv-00184-HSO-BWR, ECF No. 28 (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 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); *Novartis Pharm. Corp. v. Fitch*, ___ F. Supp. 3d ___, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024). In all three cases, the court found that the plaintiffs were unlikely to succeed on the merits of their claims because the Mississippi law is not preempted by 340B. *See AbbVie Inc. v. Fitch*, slip op. at 16–36; *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 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 intrude in passing 340B legislation. *See AbbVie Inc. v. Fitch*, slip op. at 19; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *Novartis v. Fitch*, 2024 WL 3276407, at *6. Further, the Mississippi federal court rejected AbbVie's argument in that case that the State statute effects 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 Inc. v. Fitch*, slip op. at 39 (internal citations and quotation marks omitted) (quoting *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991)).

At bottom, AbbVie takes the position in these cases that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. It is especially untrue because "[p]harmacy has

traditionally been regulated at the state level, and we must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *PhRMA v. McClain*, 95 F.4th at 1144; *AbbVie v. Fitch*, slip op. at 20; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *Novartis v. Fitch*, 2024 WL 3276407, at *6; *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir. 1988) (citing *Hillsborough Cnty. v. Automated Med. Labs.*, 471 U.S. 707, 715 (1985)) ("The presumption [against preemption] is *even stronger* with state or local regulation of matters related to health and safety.") (emphasis added).

Put simply, invalidating Maryland's valid exercise of State authority would turn upside down the very "federalism concerns" that underlie preemption questions and upend "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). This Court should reject AbbVie's motion and grant the Attorney General's motion to dismiss.

ARGUMENT

To meet the requirements for a preliminary injunction, AbbVie 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 preliminary 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) (explaining that "*each* of these four factors must be satisfied to obtain preliminary injunctive relief"). AbbVie fails to establish that it has met any of these factors. *Amici* focus on the first factor, AbbVie's likelihood of success on the merits, on which they believe they can best assist the Court.

I. H.B. 1056 IS NOT PREEMPTED BY THE 340B STATUTE.

In determining whether a state statute is preempted by federal law, courts "are guided first and foremost by the maxim that 'the purpose of Congress is the ultimate touchstone in every pre-

emption case.'" *Epps v. JP Morgan Chase Bank, N.A.*, 675 F.3d 315, 322 (4th Cir. 2012) (quoting *Wyeth v. Levine*, 555 U.S. 555, 565 (2009)). In every preemption case, "and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,'" *Medtronic*, 518 U.S. at 485 (internal citation omitted), courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *S. Blasting Servs., Inc. v. Wilkes Cnty., N.C.*, 288 F.3d 584, 590 (4th Cir. 2002) (quoting *Medtronic*, 518 U.S. at 485). AbbVie has the burden to show that Congress intended to preempt H.B. 1056. *PhRMA v. Walsh*, 538 U.S. 644, 661–62 (2003).

AbbVie does not claim that H.B. 1056 is expressly preempted. Nor does it deny that States have police power over public health policy, including the regulation of healthcare.[15] Thus, H.B. 1056 is presumptively *not* preempted, and AbbVie must demonstrate Congress's "clear and manifest purpose" to supersede Maryland's historic authority to regulate in the public health arena, *Medtronic*, 518 U.S. at 485 (internal citation and quotation marks omitted), which it has failed to do.

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

Courts do not infer field preemption of a State statute in an area traditionally within the scope of States' police powers. *See, e.g.*, *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Instead, field preemption is found only in rare instances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 479 (2018) (internal citation omitted). Indeed, "[t]he

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

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. 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.*; *see also English*, 496 U.S. at 87. 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.

AbbVie erroneously argues that the "comprehensive regulatory scheme" of the 340B program supports its contention that Congress intended to occupy the field through the program. *See* Pls.' Mem of Law in Supp. of their Mot. for Prelim. Inj., at 13, ECF No. 14-1 ("AbbVie Mem."). But the fact that Congress limited which providers can participate in the 340B program, dictated the maximum price at which drug companies can sell 340B drugs, prohibited duplicate discounts and diversion of 340B drugs, and developed federal enforcement mechanisms to enforce those requirements and prohibitions does not show that Congress intended to create (or occupy) a field. If it did, every time Congress created a federal program, it would create an exclusively federal field into which States cannot intrude. But that is not the law. *See English*, 496 U.S. at 89 ("Absent some specific suggestion in the text or legislative history of § 210 [of the Energy Restoration Act of 1974], which we are unable to find, we cannot conclude that Congress intended to pre-empt all state actions that permit the recovery of exemplary damages.") (emphasis added); *Hillsborough*, 471 U.S. at 717 ("To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence."); *Hurley v. Lederle Labs.*

Div. of Am. Cyanamid Co., 863 F.2d 1173, 1177 (5th Cir. 1988) ("[Appellant] also argues that the Public Health Service Act and its attendant regulations represent a pervasive federal scheme, and as such, preempt state law products liability for vaccine manufacturers. As Justice Marshall explains in *Hillsborough*, this argument is over inclusive.").

To support its argument, AbbVie relies on *Arizona v. United States*, 567 U.S. 387 (2012), an inapposite preemption case that, as the Supreme Court explained, turned on the unique context of immigration. *See* AbbVie Mem. at 13–14. In *Arizona*, the Court found that federal law preempted an Arizona statute imposing criminal penalties for violations of federal immigration registration requirements. 567 U.S. at 393–94. The Court did *not* find preemption merely because of the comprehensive nature of the federal law. Rather, as the Court emphasized, "[t]he federal power to determine immigration policy is well settled," in part because "[i]t is fundamental that foreign countries concerned about the status, safety, and security of their nationals in the United States must be able to confer and communicate on this subject with one national sovereign, not the 50 separate States." *Id.* at 395; *see id*. at 394–95 (citations omitted) ("The Government of the United States has broad, undoubted power over the subject of immigration and the status of aliens. This authority rests, in part, on the National Government's constitutional power to 'establish an uniform Rule of Naturalization,' and its inherent power as sovereign to control and conduct relations with foreign nations."). In stark contrast to immigration regulation, the 340B program and H.B. 1056 address matters of public health and safety—matters that are squarely within the historic police powers of the States.

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

AbbVie next claims that H.B. 1056 is preempted because it conflicts with the federal 340B statute. But AbbVie is not able to identify any actual conflict between H.B. 1056 and the 340B statute, particularly because H.B. 1056 only requires drug companies to continue a practice (*i.e.*,

recognizing multiple contract pharmacies) that had been in place since 2010. No one, including AbbVie, disputes that 340B hospitals are entitled to discounts under the 340B statute if the 340B drugs are dispensed at a hospital pharmacy. The Maryland law simply allows 340B covered entities to prescribe 340B drugs to eligible patients which can be dispensed by pharmacies with which they have contractual relationships. H.B. 1056 does not change the prices that drug companies may charge.

Relying on a decision made in connection with a claim that there is a *federal* statutory requirement to honor contract pharmacies, AbbVie asserts that the omission of a contract pharmacy requirement reflects a deliberate choice by Congress to confer the pricing benefit on a narrow class of covered entities while minimizing the reciprocal burden on manufacturers. AbbVie Mem. at 15 (citing *Sanofi Aventis U.S. LLC v. U.S. Dept. of Health & Hum. Servs.*, 58 F.4th at 696, 703 (3d Cir. 2023)).

AbbVie distorts that decision. Contrary to its argument, the *Sanofi Aventis* court found that the 340B statute's "text is silent about delivery," and accordingly, *HHS* lacked authority under the statute to require drug companies to honor contract pharmacy arrangements. *Sanofi Aventis*, 58 F.4th at 703. The court said nothing about what *States* may do in the face of the federal law's "silence." *See id.* at 707. AbbVie cannot spin this statutory silence into preemptive substance. *See PhRMA v. McClain*, 645 F. Supp. 3d. 890, 899 (E.D. Ark. 2022), *affirmed*, 95 F.4th 1136 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *PhRMA v. Fitch*, 2024 WL 3277365, at *9; *Novartis v. Fitch*, 2024 WL 3276407, at *7.

AbbVie also again relies on inapposite precedent to support its argument. AbbVie Mem. at 16 (citing *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 120 (2011)). Contrary to AbbVie's contention, *Astra* addressed *only* whether covered entities could use a third-party beneficiary

theory to enforce the 340B statute's federal requirements, not whether the 340B program preempts state law. Nothing about *Astra* displaced the Supreme Court's well-established principle that "the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply pre-emption of state remedies." *English*, 496 U.S. at 87. The *Astra* Court's hesitance to allow "potentially thousands of covered entities" to sue to correct "errors in manufacturers' price calculations" has no bearing on whether *States* can legislate to restore contract pharmacies as a means of dispensing for 340B drugs. *See Astra*, 563 U.S. at 114. 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.

AbbVie claims another false conflict—that H.B. 1056 "creat[es] its own enforcement scheme entirely separate and apart from federal law." AbbVie Mem. at 16. But the state penalties "are aimed at activity that falls outside the purview of 340B." *PhRMA v. McClain*, 95 F.4th at 1145, so "adjudications under [H.B. 1056] will not interfere with federal enforcement of Section 340B's compliance mechanisms." *PhRMA v. Fitch*, 2024 WL 3277365, at *11. That Maryland may impose different penalties on drug companies that violate its state statute does not create a conflict with the federal 340B penalties for diversion, duplicate discounts, or overcharging. *See, e.g.*, *Medtronic*, 518 U.S. at 495.

At bottom, AbbVie's conflict preemption arguments miss the forest for the trees. The 340B program was designed to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also, e.g.*, *AHA v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (quoting same), *rev'd on other grounds sub nom. AHA v. Becerra*, 596 U.S. 724 (2022). 340B providers and their patients benefit greatly from the use of contract pharmacies, which allow 340B

providers to provide more comprehensive services and allow patients to access more affordable drugs, including by allowing them to pick up their medicines more conveniently at their local pharmacies. H.B. 1056, in turn, enables 340B providers to reach more patients and to provide more comprehensive services. 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 ("[Arkansas' similar 340B law] does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: Act 1103 assists in fulfilling the purpose of 340B."); *AbbVie v. Fitch*, slip op. at 23–24; *PhRMA v. Fitch*, 2024 WL 3277365, at *9; *Novartis v. Fitch*, 2024 WL 3276407, at *4.

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

AbbVie's claim under the Fifth Amendment's Takings Clause likewise fails because H.B. 1056 does not constitute a taking. Rather, the statute regulates AbbVie's sales of drugs to patients of Maryland 340B covered entities. To our knowledge, a court has never found a property interest subject to Fifth Amendment protection where a healthcare provider or pharmaceutical company voluntarily participates in a government program. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *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); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983); *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*, slip op. at 37–47.

Indeed, all three courts to consider this issue in the 340B context—including identical arguments raised by AbbVie—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*, slip op. at 37–47. 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 the hospital chooses to participate in the federal 340B program, in addition to offering 340B prices to inhouse hospital pharmacies AbbVie must offer 340B prices to community pharmacies with which the hospitals have a contract.

AbbVie tries to avoid this well-established principle by arguing that "AbbVie's participation in *federal* Medicare and Medicaid programs . . . cannot justify the separate *state* requirements H.B. 1056 seeks to impose." AbbVie Mem. at 22–23. But that position emphasizes a distinction without a difference for Fifth Amendment purposes. *Minnesota Association of Health Care Facilities* is instructive. 742 F.2d at 446. As in this case, the Eighth Circuit considered the constitutionality of a State statute that established requirements for healthcare entities participating in a federal program. *Id.* The court found that a Minnesota statute requiring nursing homes participating in Medicaid to accept limits on rates charged to certain residents did not constitute a

taking under the Fifth Amendment because "[d]espite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless *voluntary*," which "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." *Id.* (emphasis added).

III. H.B. 1056 DOES NOT IMPOSE UNCONSTITUTIONALLY EXCESSIVE FINES.

AbbVie scrapes the bottom of the rhetorical barrel in claiming that H.B. 1056 violates the Excessive Fines Clause of the Eighth Amendment and the Maryland Constitution's analogous provision. *See* Md. Const. Art. 25.[16] As an initial matter, AbbVie's Eighth Amendment challenge is not yet ripe for the reasons set forth in Defendants' opposition to AbbVie's preliminary injunction motion. *See* Defs.' Mem. of Law in Opp'n to Pls.' Mot. for Prelim. Inj. at 21, ECF No. 15. Even if this claim were ripe for consideration, AbbVie would face 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 cannot demonstrate that H.B. 1056 could ***never*** be constitutionally applied. H.B. 1056 authorizes—but does not require—the Attorney General to impose civil and criminal penalties in limited circumstances. The Attorney General has

[16] Because Maryland courts undertake the same analysis with respect to Article 25 of the Maryland Constitution as federal courts perform with respect to the Eighth Amendment, we focus on Eighth Amendment precedent. *See Aravanis v. Somerset Cnty.*, 664 A.2d 888, 893–94 (Md. 1995) (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 265 (1989)).

discretion as to whether to impose the fines, demonstrating that AbbVie's facial challenge has absolutely no merit.

Even if AbbVie could make an as-applied challenge—and it cannot—that too clearly 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 H.B. 1056 fail 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 $15,000 fine for a single violation, including $5,000 for the violation of H.B. 1056 and $10,000 for the violation of the Maryland Consumer Protection Act, *see* Md. Code Ann., Com. Law § 13-410 (LexisNexis Supp. 2023). This maximum penalty is far lower than civil penalties of $13,946 to $27,894 per violation of the False Claims Act (FCA). *See* 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5, Table 1. Further, in the FCA context, courts have upheld penalties of more than $5,000 per violation, even when the total assessed dwarfs the actual damage claimed by the government. *See, e.g.*, *Tuomey*, 792 F.3d at 387–90 (upholding civil penalties of almost $11,000 per violation plus treble damages award); *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1315–16 (11th Cir. 2021) (affirming award of $5,500 per violation plus treble damages).

Moreover, a drug manufacturer's refusal to comply with H.B. 1056 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 2–9. Given the serious consequences of violations of H.B. 1056, the fines are plainly not excessive, especially in the context of AbbVie's facial challenge.[17]

[17] Even if H.B. 1056's fines were "excessive" under the Eighth Amendment, that provision is automatically severable from the rest of the statute, such that the rest of H.B. 1056 would remain valid. *See* Md. Code Ann., Gen. Provis. § 1-210 (LexisNexis Supp. 2023).

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court deny AbbVie's motion for a preliminary injunction and grant Defendants' motion to dismiss.

Dated: July 29, 2024

Respectfully submitted,

s/ Alyssa Howard Card

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ABBVIE INC., *et al.*, *Plaintiffs*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, *et al*. *Defendants*.	Case No. 1:24-cv-01816-MJM

[PROPOSED] ORDER

UPON CONSIDERATION of the American Hospital Association, 340B Health, Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and American Society of Health-System Pharmacists' Unopposed Motion for Leave to File Oversize *Amicus* Brief in Support of Defendants' Motion to Dismiss and Opposition to Plaintiffs' Motion for a Preliminary Injunction (the "Motion"), and being advised that Plaintiffs do not oppose and Defendants consent to the relief requested,

it is this _____ day of July, 2024, by the United States District Court for the District of Maryland hereby **ORDERED** that the Motion is GRANTED.

_____

Matthew J. Maddox, United States District Judge