UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, *et al.*, *Defendants*.	Case No. 1:24-cv-01631-MJM

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

Pursuant to Local Rule 105.12.b, the American Hospital Association, 340B Health, the Maryland Hospital Association, and Mid-Atlantic Association of Community Health Centers (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 Plaintiff Pharmaceutical Research and Manufacturers of America's Motion for Preliminary Injunction (Exhibit A), as follows:

1. Proposed *Amici* are four hospital associations with members in Maryland that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies. 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 and dormant Commerce Clause arguments that are directly responsive to the claims set forth in Plaintiff's Memorandum in Support of its Motion for Preliminary Injunction. Additionally, the Court's ruling on Plaintiff's 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 19 pages, which is less than half of the 44-page motion to dismiss and opposition to Plaintiff's preliminary injunction motion filed by Defendants. *See* Order, ECF No. 18 (granting Defendants' Consent Motion for Leave to File Excess Page Limit for Opposition to Preliminary Injunction). *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 Plaintiff and Defendants and represent that counsel for Defendants consent to this Motion and counsel for Plaintiff does 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 9, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 9, 2024, I caused a true and correct copy of American Hospital Association, 340B Health, Maryland Hospital Association, and Mid-Atlantic Association of Community Health Centers' Unopposed Motion to File Oversize *Amicus* Brief in Support of Defendants' motion to dismiss and opposition to Plaintiff's 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 M. Howard
Alyssa M. Howard

EXHIBIT A

UNITED STATES DISTRICT COURT
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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, *et al.*, *Defendants*.	Case No. 1:24-cv-01631-MJM

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MARYLAND HOSPITAL ASSOCIATION, AND MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND OPPOSITION TO PLAINTIFF'S 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.

BACKGROUND AND SUMMARY OF ARGUMENT

Beginning four years ago, amid a devastating pandemic, multiple drug companies—many of which are members of Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA)—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 suddenly refused to provide these discounts for drugs if dispensed to 340B patients at community pharmacies (or contract pharmacies).[1] Recognizing an opportunity to boost their own bottom lines, 36 other major drug companies quickly followed suit.[2]

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

[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/.

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 the very 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 disproportionate 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 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

[3] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, https://340bopais.hrsa.gov/coveredentitysearch (last visited July 9, 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 9, 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 9, 2024).

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] In addition, 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

[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.

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 (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"

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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* 2 (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).

[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 & Human 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.

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 valuable services for low-income and rural communities but have to rely on limited federal funding for support." *AHA v. Becerra*, 142 S. Ct. 1896, 1905–06 (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." H.B. 1056.[13] This

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[9] 340B Health, *supra* note 8, at 7 (citing Adam J. Fein, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2022)).

[10] *Id.* at 6.

[11] AHA, *Setting the Record Straight on 340B: Fact vs. Fiction* 2 (Apr. 2023), 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; 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 12, at 2; Dobson et al., *supra* note 11, at 13–17.

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

law prohibits 340B manufacturers from directly or indirectly denying, restricting, prohibiting, discriminating against, or otherwise limiting the acquisition or delivery of 340B drugs by/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 under 21 U.S.C. § 355-1.[14]

PhRMA now seeks to halt Maryland's lawful exercise of its police power to protect public health and safety. The motion for preliminary injunction should be denied because PhRMA cannot demonstrate that it is likely to succeed on the merits, the most important factor of the Court's analysis. *See Casa de Maryland, Inc. v. Wolf*, 486 F. Supp. 3d 928, 949 (D. Md. 2020). And here, PhRMA 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 1136, 1143–45 (8th Cir. 2024). Likewise, the law is not preempted by the Federal Food, Drug, and Cosmetic Act. *Second*, PhRMA's argument that the Maryland statute violates the dormant Commerce Clause ignores the Supreme Court's analysis in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). That case eviscerates its dormant Commerce Clause claim.

Indeed, the Southern District of Mississippi, just last week, denied preliminary injunction motions filed by both PhRMA and Novartis Pharmaceuticals Corporation seeking to enjoin a similar Mississippi statute also passed with broad bipartisan support. *See PhRMA v. Fitch*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365 (S.D. Miss. July 1, 2024); *Novartis v. Fitch*, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407 (S.D. Miss. July 1, 2024). In *PhRMA v. Fitch*, the court found that PhRMA was unlikely to succeed on the merits of its claims because the state law

[14] *Id.* 21 U.S.C. § 355-1 is a provision that permits the U.S. Food and Drug Administration to require a drug to have in place a Risk Evaluation and Management Strategy pursuant to which, among other things, the distribution of a drug may be limited. 21 U.S.C. § 355-1.

there is not preempted by 340B and does not violate the dormant Commerce Clause. *See PhRMA v. Fitch*, 2024 WL 3277365, at *7–13. Applying the presumption against preemption because the Mississippi statute "plainly falls under the umbrella of a health and safety regulation," the court found that PhRMA did not persuasively show an actual conflict with the 340B statute, and that Congress did not create a federal field in which the state could not intrude in passing 340B. *See id.* at *8. Further, the court explained that the Mississippi law "does not exhibit a clear intent to regulate out-of-state conduct," and accordingly, it does not run afoul of the dormant Commerce Clause. *Id.* at *13.

At bottom, PhRMA 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; *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. Auto. Med. Labs.*, 471 U.S. 707, 710 (1985)) ("The presumption [against preemption] is *even stronger* with state or local regulation of matters related to health and safety.") (emphasis added). Similarly, PhRMA's sweeping reading of the dormant Commerce Clause, which would essentially bar any state law that has extraterritorial effects, was rejected just a year ago by the Supreme Court. *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 375 (2023). Like the petitioners in that case, PhRMA proposes an "'almost *per se*' rule against laws that have the 'practical effect' of 'controlling' extraterritorial commerce would cast a shadow

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

Put simply, invalidating Maryland's valid exercise of State authority would turn upside down the very "federalism concerns" that underlie preemption questions, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), upend "the historic primacy of state regulation of matters of health and safety," *id.*, and gut the basic constitutional principle that "[c]ompanies that choose to sell products in various States must normally comply with the laws of those various States." *Nat'l Pork Producers*, 598 U.S. at 364. This Court should reject PhRMA's motion.

ARGUMENT

To meet the requirements for a preliminary injunction, PhRMA 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. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Henderson for N.L.R.B. 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"). PhRMA fails to establish that it has met any of these factors. *Amici* focus on the first factor, PhRMA'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, 564 (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 (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). PhRMA has the burden to show that Congress intended to preempt H.B. 1056. *PhRMA v. Walsh*, 538 U.S. 644, 661–62 (2003).

PhRMA 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 PhRMA 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 (citation 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. NCAA*, 138 S. Ct. 1461, 1480 (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.*; *see also English*, 496 U.S. at 87. With the

[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).

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.

PhRMA erroneously argues that the "closed system" of the 340B program supports its contention that Congress intended to occupy the field through the program. *See* PhRMA Mem. at 16. PhRMA lists components of the federal scheme as proof of Congress's intent to create an exclusively federal field. Specifically, PhRMA notes that Congress (i) "carefully enumerated the fifteen categories of intended beneficiaries—the covered entities—with a high degree of specificity"; (ii) "carefully delineated the obligation of manufacturers, providing that they must 'offer' drugs to 'covered entities' with a specific 'price' term—the 340B 'ceiling price'"; (iii) "barred covered entities from 'reselling or otherwise transferring' 340B-discounted drugs 'to a person who is not a patient of the entity,'" *id.* (alterations adopted) (quoting 42 U.S.C. § 256b(a)(5)(B)); and (iv) "created a multi-faceted administrative enforcement scheme centralized within [the U.S. Department of Health and Human Services (HHS)]." *Id.* These features of the 340B program do not support the conclusion that Congress intended to create an exclusively federal field into which Maryland may not tread. 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.").

Further, PhRMA relies on inapposite precedent to support its argument. PhRMA Mem. at 16–18 (citing *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011)). Contrary to PhRMA'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 preemption 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 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.

PhRMA also tries to sidestep the well-established high bar for field preemption by arguing that "*Arizona*'s logic dictates the outcome here," *see* PhRMA Mem. at 22 (citing *Arizona v. United States*, 567 U.S. 387 (2012)), but that contention ignores how the unique context of immigration

shaped the Supreme Court's analysis in that case. 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 a 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.

PhRMA next claims that H.B. 1056 is preempted because it conflicts with the federal 340B statute. But PhRMA 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 PhRMA, 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.

PhRMA contends that H.B. 1056 conflicts with federal 340B law by "impermissibly changing and expanding manufacturers' obligations and their rights under the program." PhRMA Mem. at 23. Relying on decisions made in connection with claims that there is a *federal* statutory requirement to honor contract pharmacies, PhRMA 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. *Id.* at 24–25 (citing *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis v. U.S. Dept. of Health & Human Servs.*, 58 F.4th at 696, 703 (3d Cir. 2023)).

PhRMA distorts those decisions. Contrary to its argument, the *Sanofi* and *Novartis* courts 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, 707; *Novartis*, 102 F.4th at 460–61 (same). Neither court said anything about what *States* may do in the face of the federal law's "silence." *See Novartis*, 102 F.4th at 461 ("[W]e cannot plausibly interpret statutory silence to subject manufacturers to whatever delivery conditions any *covered entity* might find most convenient.") (emphasis added). PhRMA 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.

PhRMA claims another false conflict—that H.B. 1056 "conflicts with Congress's chosen scheme of exclusive federal oversight." PhRMA Mem. at 27. 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 mechanism." *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.[16] *See, e.g.*, *Medtronic*, 518 U.S. at 495.

At bottom, PhRMA'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*, 142 S. Ct. 1896 (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."); *PhRMA v. Fitch*, 2024 WL 3277365, at *9; *Novartis v. Fitch*, 2024 WL 3276407, at *4.

[16] PhRMA is also incorrect that "H.B. 1056 now bars . . . collection" of claims data collection for purposes of determining duplicate discounts. *See* PhRMA Mem. at 27. In any event, H.B. 1056 contains a provision that it should not be construed to conflict with applicable federal laws, including the 340B statute. *See* H.B. 1056 § 1.B.2.

C. H.B. 1056 Does Not Regulate Drug Pricing and Would Not Be Preempted Even if It Did.

PhRMA next relies on a misreading of a case from the Federal Circuit to argue that H.B. 1056 is preempted by federal drug laws governing regulatory exclusivity and patent protection periods. PhRMA Mem. at 32–34 (citing *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (*BIO I*)). But *BIO I* does not compel the conclusion that H.B. 1056 is preempted because States are not permitted to set the price of patented drugs or "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." PhRMA Mem. at 34 (quoting *BIO I*, 496 F.3d at 1374). The Federal Circuit explicitly stated that its holding did not apply to State regulation that "did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right." *Biotech. Indus. Org. v. Dist. of Columbia*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) (*BIO II*) (Gajarsa, J., concurring in the denial of the petition for rehearing en banc). Unlike the law at issue in that case, H.B. 1056 is *not* "targeted at the patent [or exclusivity] right," and it does not "appl[y] only to patented drugs" or drugs subject to market exclusivity. *BIO I*, 496 F.3d at 1374. That distinction alone defeats PhRMA's argument.

In addition, *BIO I* did not hold that States are barred from enacting laws that touch upon patented drugs. *BIO II*, 505 F.3d at 1346 n.1 (Gajarsa, J., concurring) ("It is well established that states can generally regulate patented products as part of their general exercise of police powers without preemption, even if this regulation incidentally affects the profits a patentee gains from its patent."). For example, States retain the power to tax patented products, regulate commercial contracts involving patents, and regulate deceptive practices involving patents. *See, e.g.*, *Webber v. Virginia*, 103 U.S. 344, 347–48 (1880) ("Congress never intended that the patent laws should displace the police powers of the States . . . by which the health, good order, peace, and general

welfare of the community are promoted."). Instead, *BIO I* narrowly held that the District of Columbia's penalties for excessive prices on patented drugs stood as an obstacle to Congress's determination of the "proper balance between innovators' profit and consumer access to medication." 496 F.3d at 1374; *see also BIO II*, 505 F.3d at 1348 (Gajarsa, J., concurring). Though not at issue in *BIO I*, the same analysis applies to market exclusivity. Here, Congress *already* concluded that 340B pricing appropriately balances "rewards and incentives" for drug companies. *BIO I*, 496 F.3d at 1374.

On its face and in its practical effect, H.B. 1056 "does not set or enforce discount pricing." *PhRMA v. McClain*, 95 F.4th at 1145. Quite the contrary, the law addresses the "acquisition" by and "delivery" of prescription drugs to contract pharmacies. All it requires is for drug companies to deliver 340B drugs at congressionally determined 340B prices to contract pharmacies if a 340B provider chooses to permit its patients to receive 340B drugs at contract pharmacies rather than at its own pharmacy (assuming it has one). Maryland "is simply deterring pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements." *Id*. Far from regulating pricing, H.B. 1056 merely "incorporates by reference" the independent federal scheme, which Maryland is free to do. *See Hillsborough*, 471 U.S. at 710.

Even if PhRMA's characterization of H.B. 1056 as a pricing statute were correct, it still would not be preempted. There is nothing in the 340B statute to indicate that Congress meant for it to be a regulatory ceiling. *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 147–48 (1963). In 340B, Congress expressed *no view whatsoever* on whether States can supplement federal pricing standards through requirements that may indirectly impact drug pricing. *See Hillsborough*, 471 U.S. at 717 ("[M]erely because the federal provisions were sufficiently

comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements.").

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

Lastly, PhRMA argues that H.B. 1056 violates the dormant Commerce Clause because it regulates conduct "wholly outside of" Maryland. *See* PhRMA Mem. at 31. But that contention is directly foreclosed by *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023).

As a factual matter, H.B. 1056 applies *only* to 340B drugs dispensed to patients of *Maryland* 340B covered entities pursuant to contract pharmacy arrangements. Even to the extent H.B. 1056, like "many (maybe most) state laws," may *indirectly* impact "extraterritorial behavior" for drug companies that are headquartered outside of Maryland, *see Nat'l Pork Producers*, 598 U.S. at 374, H.B. 1056 itself in no way targets "the sale and terms of the sale of drugs by manufacturers that occur wholly outside of the state." PhRMA Mem. at 31. To the contrary, H.B. 1056 is focused entirely on drug distribution in connection with Maryland covered entities and their contract pharmacy arrangements. Thus, even if PhRMA had a valid legal theory about extraterritorial effects, it would not apply to H.B. 1056 on the facts. *See Nat'l Pork Producers*, 598 U.S. at 375 (quoting *Hoyt v. Sprague*, 103 U. S. 613, 630 (1881)) ("[T]his Court has recognized the usual "legislative power of a State to act upon persons and property within the limits of its own territory.").

But, critically, PhRMA has no valid legal theory. *National Pork Producers* flatly rejected the kind of "almost *per se*" extraterritoriality rule that PhRMA seeks here, holding that the dormant Commerce Clause does *not* forbid "enforcement of state laws that have the "practical effect of controlling commerce outside the State." *Nat'l Pork Producers*, 598 U.S. at 371. Instead, *National Pork Producers* explained that the "very core" of its dormant Commerce Clause jurisprudence is the "antidiscrimination principle," *i.e.*, prohibiting States from engaging in "economic

protectionism" by privileging in-state competitors over out-of-state competitors. *Id*. at 369. Here, PhRMA does not claim that Maryland's state law is in some way discriminatory against out-of-state manufacturers. Nor could it. The law treats in-state and out-of-state manufacturers the same. PhRMA should not be permitted to revive this "extraterritoriality doctrine" just one year after the Supreme Court rejected it. *Id.* at 371. This is why, last week, the district court in Mississippi rejected PhRMA's extraterritoriality argument regarding a comparable law there. *PhRMA v. Fitch*, 2024 WL 3277365, at *12–13.

CONCLUSION

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

Dated: July 9, 2024

Respectfully submitted,

s/ Alyssa M. Howard

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, *et al.*, *Defendants*.	Case No. 1:24-cv-01631-MJM

[PROPOSED] ORDER

UPON CONSIDERATION of the American Hospital Association, 340B Health, Maryland Hospital Association, and Mid-Atlantic Association of Community Health Centers' Unopposed Motion for Leave to File Oversize *Amicus* Brief in Support of Defendants' Motion to Dismiss and Opposition to Plaintiff's Motion for a Preliminary Injunction (the "Motion"), and being advised that Plaintiff does 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