UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, and KRISTOPHER RUSINKO, in his official capacity as BOARD OF PHARMACY OF THE MARYLAND BOARD OF PHARMACY *Defendants*.	Case No. 1:24-cv-01557-MJM

AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MARYLAND HOSPITAL ASSOCIATION, AND MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS' CONSENT MOTION TO FILE OVERSIZE *AMICUS* BRIEF IN SUPPORT OF DEFENDANTS ANTHONY G. BROWN AND KRISTOPHER RUSINKO'S 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 Anthony G. Brown and Kristopher Rusinko's opposition to Plaintiff Novartis Pharmaceuticals Corporation'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 20 pages, which is half of the 40-page opposition filed by Defendants. *See* Order, ECF No.

24 (granting Defendants' Consent Motion for Leave to Exceed Page Limit for Opposition). *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 represents that counsel for both parties consent to this Motion.[1]

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: June 26, 2024

Respectfully submitted,

/s/ Alyssa M. Howard
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[1] Counsel for Plaintiff has only consented to Proposed *Amici*'s motion for leave to file an *amicus* brief and has not responded regarding Proposed *Amici*'s motion for leave to file excess pages.

CERTIFICATE OF SERVICE

I certify that on June 26, 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' Consent Motion to File Oversize *Amicus* Brief in Support of Defendants Anthony G. Brown and Kristopher Rusinko's 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
FOR THE DISTRICT OF MARYLAND

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, and KRISTOPHER RUSINKO, in his official capacity as BOARD OF PHARMACY OF THE MARYLAND BOARD OF PHARMACY *Defendants*.	Case No. 1:24-cv-01557-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 ANTHONY G. BROWN AND KRISTOPHER RUSINKO'S OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

REGULATIONS

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

"Section 340B, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to offer discounted drugs to covered entities for purchase. It is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies." Novartis Opening Br. at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5229, Doc. No. 1949831 (June 8, 2022) (Novartis D.C. Br.). Plaintiff Novartis Pharmaceuticals Corporation (Novartis) submitted these exact words to the United States Court of Appeals for the D.C. Circuit only two years ago when faced with the federal government's attempt to penalize the company's harsh restrictions on contract pharmacy arrangements. The D.C. Circuit adopted Novartis's position, holding that Section 340B is "silent about delivery conditions" and contract pharmacy arrangements. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). Banking that win, Novartis abruptly switches course, now arguing that Maryland also lacks the authority to fill that federal statutory hole. Seeking to avoid all accountability for its rapacious contract pharmacy restrictions, be it from the federal government or the States, this whiplash-inducing, heads-I-win-tails-you-lose argument is contrary to law for the many reasons explained below. But it is—regrettably—entirely consistent with Novartis's and the drug industry's pattern of behavior in connection with the 340B program and their desire to pad their profits at the expense of hospitals and the patients they serve.

Almost four years ago, amid a devastating pandemic, Novartis and 35 other 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 hospitals and community health centers (known as covered entities). 42 U.S.C. § 256b(a)(1)(4). Before 2020, Novartis and the other drug companies had provided drug pricing discounts to covered entities for drugs dispensed *both* through in-house pharmacies and community pharmacies with

which the providers had contracts (called contract pharmacies). *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 one of its drugs if dispensed to 340B patients at contract pharmacies, later expanding this new policy to cover essentially all its drugs.[1] Recognizing an opportunity to boost its own bottom line, Novartis quickly followed suit,[2] as did 34 other major drug companies.[3]

The contract pharmacy arrangements that drug companies like Novartis 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.[4] 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.[5]

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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] *See Novartis Pharms. Corp. v. Brown*, No. 1:24-cv-01557 (D. Md.), Compl. ¶ 31, 37, ECF No. 1. Novartis initially imposed a 40-mile limitation on a 340B hospital's use of a contract pharmacy. *Id.* ¶ 31. Novartis's current policy permits the use of a single contract pharmacy but only by hospitals lacking an in-house pharmacy. *Id.* ¶ 37.

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

[4] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, *https://340bopais.hrsa.gov/coveredentitysearch* (last visited June 15, 2024).

[5] *Maryland 340B Hospitals Serve More Patients with Low Incomes, Who Live with Disabilities And/Or Identify As Black or Hispanic*, Dobson DaVanzo, https://www.340bhealth.org/files/MD-340B-Low-Income15018.pdf (last visited June 24, 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 June 25, 2024.).

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 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 in the Baltimore area. 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). Novartis's 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.[6] 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 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. Novartis's contract pharmacy policy is a direct attack on programs like these.

[6] *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.

Although Novartis's restrictive policy does not apply to community health centers, other drug company policies do, meaning that community health centers 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.[7] This is why 340B covered entities have relied on contract pharmacies since the beginning of the program.[8] In addition, the restrictive drug manufacturer policies do not recognize that payers 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.[9] 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.[10] 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.[11]

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[7] *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* 2, 340B Health (July 2023), https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf; *340B: A Critical Program for Health Centers*, Nat'l Ass'n of Cmty. Health Ctrs. (June 13, 2022), https://www.nachc.org/wp-content/uploads/2022/06/NACHC-340B-Health-Center-Report_-June-2022-.pdf.

[8] 60 Fed. Reg. 55,586 (Nov. 1, 1995).

[9] 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.

[10] 340B Health, *supra* note 7, at 7 (citing Adam J. Fein, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2022).

[11] *Id.* at 6.

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.[12] This is not surprising: 340B covered entities provide a disproportionate amount of uncompensated care to the country's most vulnerable patients.[13] 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).[14]

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.[15] This 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.[16]

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[12] AHA, *Setting the Record Straight on 340B: Fact vs. Fiction* 2 (Apr. 2023)3 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; *340B: A Critical Program for Health Centers*, Nat'l Ass'n of Cmty. Health Ctrs. (June 13, 2022), https://www.nachc.org/wp-content/uploads/2022/06/NACHC-340B-Health-Center-Report_-June-2022-.pdf.

[13] *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 12, at 13–17.

[14] This finding by the Supreme Court illustrates just how ludicrous it is for Novartis to repeatedly assert that patients are not helped by the 340B program. *See* Novartis Mem. at 31, 35.

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

[16] *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.

Novartis 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 Novartis cannot demonstrate that it is likely to succeed on the merits, the most important factor of the Court's analysis, as Novartis recognizes. Novartis Mem. at 15 (citing *Casa de Maryland, Inc. v. Wolf*, 486 F. Supp. 3d 928, 949 (D. Md. 2020)). And here, Novartis has no chance of success. Congress did not create or occupy any field through its 340B legislation. *See PhRMA v. McClain*, 95 F.4th 1136, 1143–44 (8th Cir. 2024). Nor does H.B. 1056 conflict with the federal 340B statute. *See Id.* at 1144–45. Likewise, the law is not preempted by the Federal Food, Drug, and Cosmetic Act.

At bottom, Novartis takes the position that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. 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; *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, Novartis'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, Novartis's "'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 Novartis's motion.

ARGUMENT

To meet the requirements for a preliminary injunction, Novartis must establish (1) most importantly, 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"). Novartis fails to establish that it has met any of these factors. *Amici* focus on the first factor, on which they believe they can best assist the Court.

A. 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). Novartis has the burden to show that Congress intended to preempt H.B. 1056. *PhRMA v. Walsh*, 538 U.S. 644, 661–62 (2003).

Novartis 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.[17] Thus, H.B. 1056 is presumptively *not* preempted, and Novartis 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.

1. 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 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.

[17] *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).

Ignoring precedent, Novartis relies on what it describes as the "pervasive" and "comprehensive" character of the federal scheme to support its field preemption argument. Novartis Mem. at 16, 17. But Novartis fails to cite authority for its assertions about Congress's *intent* to create or occupy this purported 340B "field." In fact, recent authority holds the opposite—namely, that "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." *PhRMA v. McClain*, 95 F.4th at 1143.

In addition to wrongly asserting that Congress created a comprehensive and pervasive federal scheme, Novartis relies primarily on inapposite precedent. Novartis Mem. at 16–17 (citing *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011)). Contrary to Novartis'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.

Novartis mischaracterizes H.B. 1056 as "creat[ing] a separate, state-specific pathway to enforce 340B requirements." Novartis Mem. at 17. H.B. 1056 does not authorize the Attorney General to enforce the federal 340B statute. H.B. 1056 allows the Maryland Attorney General *only* to enforce H.B. 1056's state-law requirement that drug manufacturers not restrict the delivery of 340B discounted drugs to covered entities that dispense 340B drugs via contract pharmacies.

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

Novartis next claims that H.B. 1056 is preempted because it conflicts with the federal 340B statute. But Novartis 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 Novartis, 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 discounted drugs to eligible patients to be dispensed at pharmacies with which they have contractual relationships. H.B. 1056 does not change the prices that Novartis may charge.

Novartis contends that H.B. 1056 conflicts with federal 340B law by expanding the universe of sales eligible for the 340B discount. Novartis Mem. at 18. Relying on decisions made in connection with claims that there is a *federal* statutory requirement to honor contract pharmacies, Novartis 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.* (relying on *Sanofi Aventis v. U.S. Dept. of Health & Human Servs.*, 58 F.4th at 696, 703 (3d Cir. 2023); *Novartis* slip op.). It is rich that Novartis, after arguing in the D.C. Circuit that statutory silence does not prohibit manufacturers from adopting limitations on sales to covered entities that dispense 340B drugs through contract pharmacies, Novartis D.C. Br. 4, is now arguing that that same statutory silence precludes state action. Novartis Mem. at 18–19. Novartis cannot have it both ways.

In any event, Novartis distorts those decisions. Contrary to Novartis's argument, the *Sanofi* 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, 707. The Third Circuit said nothing about what *States* may do in

the face of the federal law's "silence." Novartis 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)).

Novartis also mischaracterizes the Congressional Record through its argument that Congress contemplated—and rejected—adding a provision to the 340B statute regarding contract pharmacy arrangements. Novartis Mem. at 18–19. But this is mistaken for a few reasons. First, HHS has embraced the role of contract pharmacies in the 340B program at least since 1996,[18] and it finalized guidance allowing multiple contract pharmacies shortly before Congress amended the 340B statute in 2010.[19] And contract pharmacies still play a role in the 340B program, even under Novartis and other drug companies' restrictive contract pharmacy policies. *See* Compl. ¶ 31–37.

Moreover, the legislative history cited by Novartis demonstrates that Congress did *not* reject the use of contract pharmacies. An earlier version of the bill addressed how and where 340B drugs must be dispensed, stating that 340B discounts would be required for drugs "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services with,*" a covered entity. S. Rep. No. 102-259, at 2 (1992) (emphasis added). If that language had been retained, 340B discounts would have been allowed *only* for drugs dispensed by "on-site" pharmacies. *Id.* The elimination of the phrases "dispensed by" and "on-site pharmacy services" changed the provision to *permit* contract pharmacy relationships.

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[18] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–50 (Aug. 23, 1996) ("The statute is silent as to permissible drug distribution systems. . . . It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities. . . . If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance.").

[19] *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 at 10,272 (Mar. 5, 2010); Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (Mar. 23, 2010) (codified at 42 U.S.C. § 256b(a)(1)).

Novartis claims another false conflict—that H.B. 1056 creates Maryland's "own enforcement pathway before state administrative agencies" for federal 340B requirements. Novartis Mem. at 19. But the state penalties "are aimed at activity that falls outside the purview of 340B." *PhRMA v. McClain*, 95 F.4th at 1145. 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, Novartis'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.").

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

Novartis next relies on a misreading of an out-of-Circuit case to argue that H.B. 1056 is preempted by federal drug laws governing regulatory exclusivity and patent protection periods.

Novartis Mem. at 22–23 (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." Novartis Mem. at 23–24 (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 Novartis'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 like Novartis 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 Novartis'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.").

C. HB 1056 Does Not Violate the Dormant Commerce Clause.

Novartis claims that H.B. 1056 runs afoul of the dormant Commerce Clause because it "regulate[s] conduct that takes place wholly outside of Maryland." Novartis Mem. at 24. But that contention is squarely foreclosed by *National Pork Producers*. 598 U.S. 356.

As a factual matter, the Maryland law applies *only* to drugs dispensed to patients of *Maryland* 340B providers. Like "many (maybe most) state laws," H.B. 1056 may indirectly impact "extraterritorial behavior" for companies like Novartis that are headquartered outside of Maryland. *Nat'l Pork Producers*, 598 U.S. at 374. But H.B. 1056 in no way targets "upstream pricing and sales of prescription drugs." Novartis Mem. at 26. No matter how "notoriously complicated" the "drug distribution chain" may be, *id.*, H.B. 1056 is strikingly simple. It is focused entirely on drug dispensing to patients of 340B providers that are *inside* of Maryland's borders. Even if Novartis 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 (1880)).

But Novartis has no valid legal theory. *Pork Producers* flatly rejected the "almost *per se*" extraterritoriality rule that Novartis seeks, 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, the "very core" of its dormant Commerce Clause jurisprudence is the "antidiscrimination principle," *i.e.*, whether a state engages in "economic protectionism" by privileging in-state competitors over out-of-state competitors. *Id.* at 369. This Court should not permit Novartis to revive the "extraterritoriality doctrine" just one year after the Supreme Court rejected it. *Id.* at 371.[20]

Perhaps recognizing the weakness of its dormant Commerce Clause "extraterritoriality" claim, Novartis makes a last-ditch effort to save it through a misleading argument that H.B. 1056 discriminates against out-of-state drug manufacturers. But its argument grossly misapplies the

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

leading Supreme Court cases analyzing the dormant Commerce Clause. Critically, Novartis never disputes that H.B. 1056 treats in-state and out-of-state drug manufacturers equally. *Both* are forbidden from interfering with contract pharmacy arrangements.

Faced with this insurmountable factual hurdle, Novartis attempts to distract the Court with an entirely different comparison: how H.B. 1056 treats in-state 340B providers and pharmacies on the one hand and drug manufacturers on the other. Novartis Mem. at 28. But that is irrelevant to the determination of whether the statute discriminates against out-of-state businesses. The *Pork Producers* Court's analysis of *Baldwin v. GAF Seelig, Inc*., 294 U.S. 511 (1935) is illustrative. In *Baldwin*, which Novartis cites, Novartis Mem. at 29, the Court considered the constitutionality of applying a New York statutory price control on milk to a dealer in interstate commerce. As *Pork Producers* explained, "the challenged laws [in *Baldwin*] deliberately robbed *out-of-state dairy farmers* of the opportunity to charge lower prices in New York thanks to whatever natural competitive advantage they might have enjoyed over *in-state dairy farmers*." *Nat'l Pork Producers*, 598 U.S. at 371–72 (emphasis added). Novartis's clumsy effort to elide this precedent demonstrates the weakness of its argument. Put simply, H.B. 1056 does not discriminate against out-of-state drug manufacturers and does not run afoul of any antidiscrimination principle set forth in the Supreme Court's dormant Commerce Clause jurisprudence.

Finally, Novartis is incorrect that H.B. 1056 fails the balancing test in *Pike v. Bruce*, 397 U.S. 137 (1970) for three reasons. *First*, three Justices (Justices Gorsuch, Thomas, and Barrett) would completely reject a *Pike* analysis, so they would necessarily reject Novartis's argument. *Nat'l Pork Producers*, 598 U.S. at 381–83.

Second, even assuming the Court would apply *Pike*, five Justices would require a "plaintiff to plead facts plausibly showing that a challenged law imposes 'substantial burdens' on interstate

commerce *before* a court may assess the law's competing benefits." *See id.* at 383 (emphasis in original); *id.* at 393 (Sotomayor, J., concurring) (joined by Justice Kagan)). Novartis cannot do so for the reasons stated above, especially because H.B. 1056 applies equally to in-state and out-of-state manufacturers and thus does not burden interstate commerce. Indeed, Justice Gorsuch's plurality opinion relied heavily on *Exxon Corp. v. Governor of Maryland*, 437 U. S. 117 (1978), in which the Court rejected a dormant Commerce Clause claim where the burden imposed by a Maryland law fell "solely on interstate companies." *Id.* at 383. And Justice Kavanaugh recognized in his partial concurrence/dissent, that part of Justice Gorsuch's opinion is controlling precedent for purposes of the petitioners' dormant Commerce Clause challenge under *Pike*. *Nat'l Pork Producers*, 598 U.S. at 403. Here, as in *Pork Producers*, if that Maryland "law did not impose a sufficient burden on interstate commerce to warrant further scrutiny, the same must be said for this one," which certainly applies both in-state and out-of-state. *See id.* at 384. And if all of that were not enough, it is hard to take seriously any contention that drug companies will find it "difficult to comply" with Maryland's law—a critical fact in the plurality's *Pike* analysis—given that they all honored contract pharmacy arrangements until 2020. *See id.* at 385. This alone disproves any *substantial* burden to interstate commerce that Novartis may have alleged.

Third, Novartis's dormant Commerce Clause challenge also would fail the *Pike* test discussed in the Chief Justice's opinion because it cannot establish that the out-of-state burden is "clearly excessive in relation to the putative local benefits." Novartis Mem. at 30 (citing *Pike*, 397 U.S. at 142). For starters, Novartis does not address the proper burdens under the *Pike* test. It does not allege, for example, any additional "compliance costs" that result from Maryland's law. *See Nat'l Pork Producers*, 598 U.S. at 399 (Roberts, C.J., concurring in part and dissenting in part). To be sure, Maryland's law may impose costs on Novartis itself, but it will not affect Novartis's

(or any other drug company's) activity in *other* States or otherwise require compliance by drug companies who do not even wish to sell their product to Maryland covered entities. *Id.* at 400–02. Further, Novartis completely ignores the local benefits of H.B. 1056, *see supra* at 2–7, to patients and covered entities. *See AHA v. Becerra*, 142 S. Ct. at 1905–06.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court deny Novartis's motion for a preliminary injunction.

Dated: June 26, 2024

Respectfully submitted,

s/ Alyssa M. Howard

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, *v.* ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, and KRISTOPHER RUSINKO, in his official capacity as BOARD OF PHARMACY OF THE MARYLAND BOARD OF PHARMACY *Defendants*.	Case No. 1:24-cv-01557-MJM

[PROPOSED] ORDER

UPON CONSIDERATION of the American Hospital Association, 340B Health, Maryland Hospital Association, and Mid-Atlantic Association of Community Health Centers' Consent Motion for Leave to File Oversize *Amicus* Brief in Support of Defendants Anthony G. Brown and Kristopher Rusinko's Opposition to Plaintiff's Motion for a Preliminary Injunction (the "Motion"), and being advised that Plaintiff and Defendants consent to the relief requested,

it is this _____ day of June, 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