UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Northern Division)

ASTRAZENECA PHARMACEUTICALS LP, *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-01868-MJM

AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MARYLAND HOSPITAL ASSOCIATION, MID-ATLANTIC ASSOCIATION OF COMMUNITY HEALTH CENTERS, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS' CONSENT MOTION TO FILE *AMICUS* BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Pursuant to Local Rule 105.12.b, the American Hospital Association, 340B Health, the Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and American Society of Health-System Pharmacists (collectively, the Proposed *Amici*) move this Court for leave to file the attached *amicus curiae* brief in support of Defendants' motion to dismiss (Exhibit A), as follows:

1. Proposed *Amici* include four hospital associations with members in Maryland that receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies, and one organization that represents pharmacists who serve patients in hospitals, health systems, ambulatory clinics, and other healthcare settings many of which benefit from the 340B program. Proposed *Amici* and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care.

The 340B program is essential to achieving this goal. Proposed *Amici* therefore have a strong interest in the success of Maryland's legislative efforts to protect the 340B program.

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

3. Proposed *Amici*'s brief, which is timely filed within seven days after the filing of Defendants' motion to dismiss, *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 Takings Clause and Contracts Clause arguments that are directly responsive to the claims set forth in Plaintiff's Complaint. Additionally, the Court's ruling on Defendants' motion to dismiss 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* consulted with counsel for Plaintiff and Defendants and represent that counsel for both consent to 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: August 2, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 2, 2024, I caused a true and correct copy of American Hospital Association, 340B Health, Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and American Society of Health-System Pharmacists' Consent Motion to File *Amicus* Brief in Support of Defendants' motion to dismiss to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

/s/ Alyssa Howard Card
Alyssa Howard Card

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
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ASTRAZENECA PHARMACEUTICALS LP, *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-01868-MJM

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

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INTERESTS OF *AMICI CURIAE*

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

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

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

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

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

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

BACKGROUND AND SUMMARY OF ARGUMENT

Four years ago, amid a devastating pandemic, multiple drug companies broke with decades of precedent and began to undermine the 340B drug discount program. Under that program, drug companies that participate in Medicaid and Medicare Part B must provide discounts on drugs sold to patients of certain nonprofit or public hospitals and community health centers. *See* 42 U.S.C. § 256b(a)(1)–(4). Before 2020, drug companies had provided drug pricing discounts to eligible 340B providers for drugs dispensed *both* through in-house pharmacies and community pharmacies with which the providers had contracts. *See PhRMA v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024) ("For 25 years, drug manufacturers . . . distributed 340B drugs to covered entities' contract pharmacies."). But in July 2020, one drug company made an about-face and refused to provide these discounts for drugs if dispensed to 340B patients at community pharmacies (or contract pharmacies).[1] Recognizing an opportunity to boost its own bottom line, Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca) and 36 other major drug companies followed suit.[2]

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

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

The contract pharmacy arrangements that drug companies honored for almost 30 years helped sustain 340B providers and their patients. Prior to the implementation of contract pharmacy restrictions, discounts on drugs dispensed at community and specialty contract pharmacies made up about one-quarter of overall 340B savings for hospitals participating in 340B. Of the 24 Maryland hospitals and 16 health centers participating in the 340B drug program, all but three contract with at least one community pharmacy to dispense drugs to patients.[3] The drug company restrictions have substantially cut the savings from the 340B program, which is devasting for hospitals in Maryland that provide 81% of all hospital care that is provided to Medicaid patients, as well as the community health centers that serve primarily low income patients.[4]

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

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

[4] Dobson DaVanzo Health Economics Consulting, *Maryland 340B Hospitals Serve More Patients with Low Incomes, Who Live with Disabilities and/or Identify As Black or Hispanic*, https://www.340bhealth.org/files/MD-340B-Low-Income15018.pdf (last visited July 31, 2024); Health Res. & Servs. Admin, *Maryland Health Center Program Uniform Data System Data*, https://data.hrsa.gov/tools/data-reporting/program-data/state/MD (last visited July 25, 2024).

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

Much like JHH, the University of Maryland Medical Center (UMMC) and Maryland General Hospital (Midtown), member organizations of the University of Maryland Medical System, use their 340B savings to expand patient and community services in numerous important ways. To take just one example, the Midtown Community Health Education Center provides free health screenings, lifestyle change programs, and support groups. UMMC uses 340B savings to support violence prevention programs, including Stop the Bleed, trauma prevention with teens, and other related support groups. Savings that flow from 340B contract pharmacy arrangements are critical to the ongoing success of these expanded community services that are provided regardless of a patient's ability to pay for services.

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

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

and cancer screenings.[5] MedStar Health has been able to establish harm reduction initiatives aimed at the opioid epidemic using funding from the 340B program. With this work, MedStar Health can support teams of peer recovery coaches in the community who are directly responsible for linking recent overdose survivors to treatment services, and naloxone trainings. They become a consistent point of contact should someone wish to enter care. It is an innovative response to the reality that those who survive an opioid overdose have a high mortality rate unless they are actively engaged in treatment. MedStar Health also uses 340B dollars to provide prescription assistance to help patients in need afford their medicines, and the 340B savings support "Food as Medicine" Initiatives, which address food insecurity issues and improve health. Manufacturers' contract pharmacy policies are a direct attack on programs like these.

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

[5] *See, e.g.*, *Community Health: MedStar Good Samaritan Hospital*, MedStar Health, https://www.medstarhealth.org/locations/medstar-good-samaritan-hospital/community-health; *Community Health: MedStar Harbor Hospital*, MedStar Health, https://www.medstarhealth.org/locations/medstar-harbor-hospital/community-health; *Community Health: MedStar St. Mary's Hospital*, MedStar Health, https://www.medstarhealth.org/locations/medstar-st-marys-hospital/community-health; *Community Health: MedStar Southern Maryland Hospital Center*, MedStar Health, https://www.medstarhealth.org/locations/medstar-southern-maryland-hospital-center/community-health; *Community Health: MedStar Union Memorial Hospital*, MedStar Health, https://www.medstarhealth.org/locations/medstar-union-memorial-hospital/community-health (all URLs last visited July 31, 2024).

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

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

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" 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

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[8] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels Institute (Dec. 12, 2019), https://www.drugchannels.net/2020/05/insurers-pbms-specialty-pharmacies.html; U.S. Dep't of Health & Hum. Servs. Off. Of Inspector Gen., *Specialty Drug Coverage and Reimbursement in Medicaid*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp (last visited July 31, 2024).

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

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

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

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

valuable services for low-income and rural communities but have to rely on limited federal funding for support." *AHA v. Becerra*, 596 U.S. 724, 738 (2022).

Faced with the drug industry's unprecedented assault on Maryland's health care safety net, the Maryland legislature, by an overwhelming 174/8 vote, passed a new law: "State Board of Pharmacy – Prohibition on Discrimination Against 340B Drug Distribution." Maryland House Bill 1056 (H.B. 1056).[13] This law prohibits 340B manufacturers from directly or indirectly denying, restricting, prohibiting, discriminating against, or otherwise limiting the delivery of 340B drugs purchased by 340B covered entities and delivered to pharmacies that are under contract with or otherwise authorized by a 340B covered entity to receive 340B drugs on their behalf, unless such limitation is required by distribution restrictions imposed by the Food and Drug Administration.[14]

AstraZeneca now seeks to halt Maryland's lawful exercise of its police power to protect public health and safety. AstraZeneca's complaint should be dismissed because it fails to state a claim for relief. For the reasons set forth in *Amici*'s briefs filed in this Court in *Novartis Pharm. Corp. v. Brown*, No. 1:24-cv-01557-MJM, *see* AHA et al. Amicus Br. at 9–16, ECF No. 35, *PhRMA v. Brown*, No. 1:24-cv-01631-MJM, *see* AHA et al. Amicus Br. at 9–18, ECF No. 20-1, and *AbbVie Inc. v. Fitch*, No. 1:24-cv-01816-MJM, *see* AHA et al. Amicus Br. at 9–15, ECF No. 16-1, H.B. 1056 is not preempted. To avoid duplication of briefing that is currently before the Court in related cases, *Amici* focus on AstraZeneca's remaining two arguments here and respectfully refer the Court to the arguments *Amici* have made in their briefs in the related cases. *First*, H.B. 1056 does not run afoul of the Contracts Clause. *Second*, H.B. 1056 does not constitute a taking under the Fifth Amendment because it does not implicate a protected property interest.

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

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

This year, the Eighth Circuit and Southern District of Mississippi have rejected similar arguments by drug manufacturers and interest groups seeking to enjoin State statutes that are identical in material respects. *PhRMA v. McClain*, 95 F.4th at 1141–46; *AbbVie Inc. v. Fitch*, No. 1:24-cv-00184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024); *PhRMA v. Fitch*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60340 (5th Cir. July 5, 2024); *Novartis Pharm. Corp. v. Fitch*, ___ F. Supp. 3d ___, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407 (S.D. Miss. July 1, 2024), *appeal docketed*, No. 24-60342 (5th Cir. July 9, 2024). In all four cases, the courts rejected the drug companies' claims that the relevant claims because the relevant State laws, which are materially identical to Maryland's law, are not preempted by 340B. *See PhRMA v. McClain*, 95 F.4th at 1141–46; *AbbVie v. Fitch*, 2024 WL 3503965, at *7–16; *PhRMA v. Fitch*, 2024 WL 3277365, at *7–13; *Novartis v. Fitch*, 2024 WL 3276407, at *5–10. Applying the presumption against preemption because the Mississippi statute "plainly falls under the umbrella of a health and safety regulation," the Mississippi district court found that there was no conflict with the 340B statute, and that Congress did not create a federal field in which the state could not intrude in passing 340B legislation. *See AbbVie v. Fitch*, 2024 WL 3503965, at *9; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *Novartis v. Fitch*, 2024 WL 3276407, at *6. Further, the Mississippi federal court rejected AbbVie's argument that the State statute effects an unconstitutional taking under the Fifth Amendment, citing the fundamental principle that "[g]overnmental regulation that affects a group's property interests does not constitute a taking of property where the regulated group is not required to participate in the regulated industry." *See AbbVie v. Fitch*, 2024 WL 3503965, at *17 (internal citations and quotation marks omitted) (quoting *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991)).

ARGUMENT

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When considering a motion to dismiss, courts must construe factual allegations in the light most favorable to the Plaintiff, *see Lambeth v. Bd. of Comm'rs of Davidson Cnty.*, 407 F.3d 266, 268 (4th Cir. 2005), but they are "not required to accept as true 'a legal conclusion couched as a factual allegation,'" *England v. Marriott Int'l, Inc.*, 764 F. Supp. 2d 761, 769 (D. Md. 2011) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). AstraZeneca's complaint does not state a claim to relief that is plausible on its face.

I. H.B. 1056 DOES NOT VIOLATE THE CONTRACTS CLAUSE.

AstraZeneca's contention that H.B. 1056 runs afoul of the Contracts Clause of the Constitution is little more than a thin repackaging of its deficient preemption claim, and it fails to state a claim for relief. The Contract Clause prohibits States from passing any law that "impair[s] the Obligations of Contracts[.]" U.S. Const. Art. I, § 10. The Supreme Court's two-step analysis for Contracts Clause challenges requires first that a court determine whether the State law at issue substantially impairs a contractual relationship, and if so, whether it did so for a legitimate purpose. *Sven v. Melin*, 584 U.S. 811, 819 (2018).

AstraZeneca's Contracts Clause challenge fails at the first step. The contract on which AstraZeneca relies, the pharmaceutical pricing agreement (PPA), is unaffected by H.B. 1056. Under the 340B program, a drug manufacturer that participates in Medicaid and Medicare Part B is required to enter a PPA with the Secretary of HHS pursuant to which it must offer 340B covered entities outpatient drugs at or below a statutorily-determined discount price, referred to as the ceiling price. 42 U.S.C. § 256b(a)(1). The terms of the PPA basically parrot the federal 340B

statute. The Supreme Court has explained that "the PPAs simply incorporate statutory obligations and record the manufacturers' agreement to abide by them. The form agreements, composed by HHS, contain no negotiable terms . . . . [T]he 340B Program agreements serve as the means by which drug manufacturers opt into the statutory scheme." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011).

AstraZeneca is incorrect that "H.B. 1056 seeks to unilaterally expand AstraZeneca's obligations under" its PPA. Compl. ¶ 84. The Maryland law does not change or expand the definition of covered entities that are entitled to 340B discounts. Nor does H.B. 1056 change what prices drug companies may charge covered entities. Rather, it only affects the *delivery* of 340B drugs, which is not addressed in the PPA. AstraZeneca cannot identify any way in which H.B. 1056 expands or contradicts its PPA because, by simply incorporating the 340B statute, the PPA is silent as to delivery.

The cases on which AstraZeneca relies are inapposite. In *Allied Structural Steel Co. v. Spannaus*, the Supreme Court struck down a Minnesota law that required a company to provide additional pension benefits after it had agreed to provide such benefits under specific contractual provision. 438 U.S. 234, 245–46 (1978). Unlike the Maryland statute here, where the terms of the PPA remain unchanged, the Minnesota law in that case effectively changed the terms of the contract. Likewise, in *United Healthcare Ins. Co. v. Davis*, the Fifth Circuit held that the Contracts Clause prohibited Louisiana from enacting legislation increasing obligations on companies that had agreed to insure state employees under specific conditions. 602 F.3d 618, 630 (5th Cir. 2010). Again, Maryland has not in any way increased or changed AstraZeneca's obligations under its PPA.

Moreover, even if H.B. 1056 did substantially impair the contractual relationship between AstraZeneca and HHS (it does not), the Maryland legislature would have had a legitimate purpose for doing so. The Supreme Court has "repeatedly held that unless the State is itself a contracting party, courts should 'properly defer to legislative judgment as to the necessity and reasonableness of a particular measure.'" *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 505 (1987) (quoting *Energy Reserves Group, Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 413 (1983) (internal citations omitted)). Over four years ago, AstraZeneca suddenly refused to provide 340B discounts to covered entities that relied on contract pharmacies to dispense their drugs to 340B patients, even though up until then, it had been doing just that. Now, AstraZeneca permits a 340B covered entity to rely on a single contract pharmacy if it has no in-house pharmacy. The contract pharmacy arrangements previously honored by manufacturers around the country for almost 30 years had helped sustain 340B providers and their patients. For the reasons explained above, *supra* at 2 –9, savings from 340B discounts allow covered entities to provide life-saving health care and programs in Maryland. H.B. 1056 merely requires that drug companies continue to do what they were doing prior to 2020—that is, provide the 340B discount to drugs purchased by patients of statutorily-defined covered entities, even when the covered entities rely on contract pharmacies to dispense those drugs.

Faced with the drug industry's unprecedented assault on Maryland's health care safety net, the Maryland legislature had a significant and legitimate justification for passing H.B. 1056. Any impact the legislation has on drug companies is reasonable and necessary. It is reasonable because the impact on the drug industry of requiring such discounts is minimal when compared to its

profits,[15] while the impact of not permitting the discounts is devasting to covered entities that often operate on negative margins.[16]

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

AstraZeneca's claim under the Fifth Amendment's Takings Clause likewise fails because H.B. 1056 does not constitute a taking.[17] Rather, the statute regulates AstraZeneca's sales of drugs for use by patients of Maryland 340B covered entities. To our knowledge, no court has ever found that there is a property interest subject to Fifth Amendment protection where a healthcare provider or pharmaceutical company is voluntarily participating in the government program that it claims is taking its property. In fact, every court to consider the issue has found that there is no taking. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014), *cert. denied*, 575 U.S. 1008 (2015); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied*, 469 U.S. 1215 (1985); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993), *cert. denied*, 510 U.S. 821 (1993); *Burditt*, 934 F.2d at 1376; *Whitney v. Heckler*, 780 F.2d 963, 968–73 (11th Cir. 1986), *cert. denied*, 479 U.S. 813 (1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984); *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 207–10 (D.N.J. 2021), *rev'd on other grounds*, 58 F.4th 696 (3d Cir. 2023); *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20.

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[15] *See* Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, 323(9) JAMA 834–43 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308 (finding that between 2010 and 2018, "the median net income (earnings) expressed as a fraction of revenue was significantly greater for pharmaceutical companies compared with nonpharmaceutical companies (13.8% vs 7.7%)").

[16] *See, e.g.*, Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients,* 3-4.

[17] For the reasons set forth in the Attorney General's Motion to Dismiss, AstraZeneca's takings claim based on Maryland law is barred by sovereign immunity. *See* Defs.' Mot. Dismiss at 19–20, ECF No. 17-1.

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

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

As an alternative basis for its holding, the court also applied the test for regulatory takings articulated by *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104 (1978), which "requires 'balancing factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action.'" *AbbVie v. Fitch*, 2024 WL 3503965, at *17 (quoting *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021)). With respect to AbbVie's "reasonable investment-backed expectations," the court found that the Mississippi law "should have been foreseeable to Plaintiffs, as Section 340B has had a well-known 'gap' about how delivery must occur since Congress enacted it." *Id.* at *19 (quoting August 1996 Guidance at 43,549–50). The district court concluded that enhanced regulation in the pharmaceutical industry—which "long has been the focus of great public concern and significant government regulation"—was foreseeable. *Id.* at *20 (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1008–09 (1984)). Further, the statute is "rationally related to a legitimate Government interest," given that "[t]he Mississippi Legislature has evidently determined that dispensation of 340B drugs at contract pharmacies advances public health, which falls squarely within its police powers." *Id.* (internal citation omitted). Lastly, "'the economic impact of the regulation' is not drastic, and will not deprive Plaintiffs of all economically beneficial use of their products." *Id.* (internal citations omitted).

CONCLUSION

For the foregoing reasons and for the reasons set forth in *Amici*'s briefs in the related cases[18] regarding Plaintiffs' meritless preemption claims, *Amici* respectfully request that the Court grant Defendants' motion to dismiss.

Dated: August 2, 2024

Respectfully submitted,

/s/ Alyssa Howard Card

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**pro hac vice* motion forthcoming
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[18] *See Novartis Pharm. Corp. v. Brown*, No. 1:24-cv-01557-MJM, AHA et al. Amicus Br. at 9–16, ECF No. 35; *PhRMA v. Brown*, No. 1:24-cv-01631-MJM, AHA et al. Amicus Br. at 9–18, ECF No. 20-1; *AbbVie Inc. v. Fitch*, No. 1:24-cv-01816-MJM, AHA et al. Amicus Br. at 9–15, ECF No. 16-1.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Northern Division)

ASTRAZENECA PHARMACEUTICALS LP, *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-01868-MJM

[PROPOSED] ORDER

UPON CONSIDERATION of the American Hospital Association, 340B Health, Maryland Hospital Association, Mid-Atlantic Association of Community Health Centers, and American Society of Health-System Pharmacists' Consent Motion for Leave to File *Amicus* Brief in Support of Defendants' Motion to Dismiss (the "Motion"), and being advised that Plaintiff and Defendants consent to the relief requested,

it is this _____ day of August, 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