UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* KEITH ELLISON, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MINNESOTA, *Defendant*.	Case No. 0:24-cv-02621-DSD-TNL

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, MINNESOTA HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT'S 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 Minnesota 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 **Minnesota Hospital Association** (MHA) is an organization representing non-profit hospitals and health systems across the state to advance the health of individuals and communities through leadership, advocacy, and collaboration. Over 100 MHA members participate in the 340B program.

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

[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.

AstraZeneca Pharmaceuticals LP (AstraZeneca) and 36 other major drug companies 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 104 Minnesota hospitals participating in the 340B drug program, 92 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 Minnesota that provide 88% of all hospital care that is provided to Medicaid patients.[4]

For example, 340B savings allow Fairview Health Services, a health system headquartered in Minneapolis, to provide critical care to patients throughout the metropolitan area at three Health Commons locations in economically and culturally diverse neighborhoods. The Health Commons locations are responsible for almost 11,000 patient visits annually and provide health education through an onsite community nurse,

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[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/.

[3] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, https://340bopais.hrsa.gov/coveredentitysearch.

[4] Dobson DaVanzo Health Economics Consulting, *Minnesota 340B Hospitals Serve More Patients With Low Incomes, Who Live With Disabilities, and/or Identify as Black* 1, https://www.340bhealth.org/files/MN-340B-Low-Income15021.pdf.

offer wellness classes, and distribute free meals, fresh produce, diapers, and more to those in need. The Cedar Riverside Health Commons location has also begun providing naloxone training and has been designated a Naloxone Access Point.

A rural health system headquartered in Duluth, Essentia Health (Essentia) has 14 hospitals throughout Minnesota, North Dakota, and Wisconsin, which care for a service area that is classified as 84% rural. All of these hospitals, including seven critical access hospitals in Minnesota, are 340B covered entities that leverage 340B savings to ensure the rural and underserved communities they serve have access to comprehensive, local health care services, such as 24/7 emergency care, intensive care, mental and behavioral health services, and primary and specialty care. As a rural safety-net hospital system that cares for some of the State's most vulnerable patients, Essentia relies heavily upon the 340B program to offset chronically low Medicaid and Medicare reimbursement rates that have been outpaced by the current costs of care. In 2023, underpayments from Medicaid and Medicare payments exceeded $368 million—far exceeding the $149 million Essentia saved through the 340B program.

Winona Health, an independent, rural hospital in Winona, Minnesota, has likewise been hit hard by increased drug costs resulting from manufacturers' restrictive contract pharmacy policies. At the end of June 2024, 340B revenues were down by $2.2 million (or 65.2%), and overall drug costs were up $1.05 million (or 12.8%). Winona Health uses 340B savings to subsidize programs that don't generate revenue, and the hospital has had to dip into investments to pay operating costs and cut back on capital investments as a result of these losses. For example, Winona Health recently almost had to close its dialysis

department. Although private donations have saved the dialysis program for the next three years, severe financial challenges remain, and they will be compounded if Minnesota's statute is invalidated.

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[5] This is why 340B hospitals have relied on contract pharmacies since the beginning of the program.[6] 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.[7] 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

[5] 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.

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

[7] 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.

patients' high-priced specialty drugs.[8] 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.[9]

If patients are unable to afford prescriptions or have other barriers to filling prescriptions, such as having to travel long distances to obtain a discount on a prescription drug, they are more likely to forgo treatment and fall out of compliance with prescription drug regimens. This can lead to hospital readmission or avoidable emergency department visits,[10] increasing the overall cost of care for the patient, the hospital, and the health care system.

Savings from contract pharmacy relationships are especially important for another reason: the fragile state of 340B hospital finances. In stark contrast to the pharmaceutical industry, 340B hospitals typically operate with razor-thin (and often negative) margins.[11] This is not surprising: 340B hospitals provide a disproportionate amount of uncompensated

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[8] 340B Health, *supra* note 4, at 7 (citing Fein, *supra* note 6).

[9] 340B Health, *supra* note 4, at 6.

[10] Holly C. Felix, et al., *Why Do Patients Keep Coming Back? Results of a Readmitted Patient Survey,* 54 SOC. WORK HEALTH CARE 1, 7 (2015).

[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.

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*, 596 U.S. 724, 738 (2022).

In late May 2024, the Minnesota legislature acted to address the drug industry's unprecedented assault on its health care safety net. Codified at Minnesota Statutes section 62J.96,[13] the relevant provision does not allow a manufacturer to "directly or indirectly restrict, prohibit, or otherwise interfere with the delivery of a covered outpatient drug to a pharmacy that is under contract with a 340B entity to receive and dispense covered outpatient drugs on behalf of the covered entity[.]" Minn. Stat. § 62J.96, subds 1, 3 (2024).[14]

AstraZeneca now seeks to halt Minnesota's lawful exercise of its police power to protect public health and safety. AstraZeneca's amended complaint should be dismissed because it fails to state a claim for relief. *First*, federal patent law does not preempt § 62J.96. *Second*, the Minnesota statute does not violate the Contracts Clause. And *third*,

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[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 9, at 2; Dobson et al., *supra* note 9, at 13–17.

[13] The text of the statute can be found at https://casetext.com/statute/minnesota-statutes/insurance/chapter-62j-health-care-cost-containment/prescription-drug-affordability-act/section-62j96-effective-812024-access-to-340b-drugs.

[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.

§ 62J.96 does not constitute a taking under the Fifth Amendment because it does not implicate a protected property interest.

AstraZeneca's claim that the Minnesota statute is preempted by federal patent law has already been rejected by the Western District of Louisiana in AstraZeneca's challenge to a materially identical State statute there. *See AstraZeneca v. Murrill*, No. 6:23-cv-01042-RRS-CBW, ECF No. 84 (W.D. La. Sept. 30, 2024). The Louisiana court found that the case law relied upon by AstraZeneca was easily distinguishable because the relevant statute "does not, on its face, target patent rights or, by its terms, apply only to patented drugs or the price of patented drugs." *Id.* at 18. Because the Louisiana law "addresses only contract pharmacies, a matter that is not addressed in Section 340B," the court found that AstraZeneca's preemption claim failed. *Id.*

Likewise, the Louisiana court found that that State's materially identical law did not violate the Contracts Clause. *Id.* at 24–27. Explaining that the Louisiana statute "does not change or expand which entities qualify as 340B 'covered entities,'" nor does the law "change what prices drug companies may charge covered entities," the court found that "AstraZeneca cannot point to any way in which the Act expands or contradicts its [pharmaceutical pricing agreement] because, like the statute, the [pharmaceutical pricing agreement] is silent as to delivery to or acquisition of Section 340B drugs to contract pharmacies." *Id.* at 25.

Further, the Southern District of Mississippi and Western District of Louisiana have both rejected arguments that analogous State statutes effect an unconstitutional taking under the Fifth Amendment, citing the fundamental principle that "[g]overnmental

regulation that affects a group's property interests does not constitute a taking of property where the regulated group is not required to participate in the regulated industry." *See AbbVie Inc. v. Fitch*, No. 1:24-cv-00184-HSO-BWR, 2024 WL 3503965, at *17 (S.D. Miss. July 22, 2024), *appeal docketed*, No. 24-60375 (5th Cir. July 24, 2024) (internal quotation marks omitted) (quoting *Burditt v. U.S. Dep't of Health & Hum. Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991)); *AbbVie v. Murrill*, No. 6:23-cv-01307-RRS-CBW, slip op. at 28–29, ECF No. 89 (W.D. La. Sept. 30, 2024).

At bottom, AstraZeneca's amended complaint is a grab bag of meritless claims, including ones that have been squarely rejected in this Circuit and others that have been correctly rejected elsewhere. AstraZeneca can no doubt afford[15] to fund a "coordinated, nationwide attack" on state efforts to exercise their historic police powers, *see* Br. in Support of Def.'s Mot. to Dismiss Am. Compl. at 7, ECF No. 33, but that doesn't make its legal claims any more valid.

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)). AstraZeneca's amended complaint does not state a claim to relief that is plausible on its face.

[15] AstraZeneca reported annual revenues of almost $46 billion in 2023 alone. *See* AstraZeneca, 2023 Annual Report 1 (2024), https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2023/pdf/AstraZeneca_AR_2023.pdf.

I. THE STATUTE DOES NOT REGULATE DRUG PRICING AND WOULD NOT BE PREEMPTED EVEN IF IT DID.

AstraZeneca relies on a misreading of a case from the Federal Circuit to argue that § 62J.96 is preempted by federal drug laws governing regulatory exclusivity and patent protection periods. Am. Compl. ¶¶ 7, 72–74, 92 (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 § 62J.96 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." Am. Compl. ¶¶ 73, 92 (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, § 62J.96 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 AstraZeneca'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, § 62J.96 "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). Minnesota "is simply deterring pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements." *Id*. Far from regulating pricing, § 62J.96 merely "incorporates by reference" the independent federal scheme, which Minnesota is free to do. *See Hillsborough Cnty. v. Auto. Med. Labs.*, 471 U.S. 707, 710 (1985).

Even if AstraZeneca's characterization of § 62J.96 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. SECTION 62J.96 DOES NOT VIOLATE THE CONTRACTS CLAUSE.

Further, AstraZeneca's contention that § 62J.96 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, cl. 1. 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. *Sveen 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 the Minnesota statute. 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 "HF 4757 seeks to unilaterally expand AstraZeneca's obligations under" its PPA. Am. Compl. ¶ 78. The Minnesota law does not change or expand the definition of covered entities that are entitled to 340B discounts. Nor does section 62J.96 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 the provision expands or contradicts its PPA because, by simply incorporating the 340B statute, the PPA is silent as to delivery. *See AstraZeneca v. Murrill*, slip op. at 25.

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 Minnesota statute here, where the terms of the PPA remain unchanged, the 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, Minnesota has not in any way increased or changed AstraZeneca's obligations under the PPA that it agreed to with the Secretary of HHS.

Moreover, even if § 62J.96 did substantially impair the contractual relationship between AstraZeneca and HHS (it does not), the Minnesota 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 Grp., Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 412–13 (1983) (internal citation omitted)). Almost 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 Minnesota. Section 62J.96 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 synchronized strike on Minnesota's health care safety net, the Minnesota legislature had a significant and legitimate justification for passing § 62J.96. Any impact the legislation has on drug companies is reasonable and necessary. It is reasonable because the law simply requires that hospitals be permitted to use contract pharmacies to distribute 340B drugs in the same manner that the drug companies had acquiesced in the use of these pharmacies between 2010 and 2020, and because the impact on the drug industry of requiring such discounts is minimal when compared to its profits,[16] while the impact of not permitting the discounts is devasting to covered entities that often operate on negative margins.[17]

III. SECTION 62J.96 DOES NOT VIOLATE THE TAKINGS CLAUSE.

AstraZeneca's claim under the Fifth Amendment's Takings Clause likewise fails because the challenged provision does not constitute a taking. Rather, the statute regulates AstraZeneca's sales of drugs for use by patients of Minnesota 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

[16] *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%)").

[17] *See, e.g.*, Dobson et al., *supra* note 10, 3–4.

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; *AbbVie v. Murrill*, slip op. at 27–31.

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; *AbbVie v. Murrill*, slip op. at 27–31. 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 Minnesota law prohibits AstraZeneca from selling drugs to Minnesota 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 substantively identical Mississippi statute did not amount to an unconstitutional taking. *See AbbVie v. Fitch*, 2024 WL 3503965, at *16–20. The court concluded that because the Mississippi statute "does not compel Plaintiffs to directly sell 340B drugs to pharmacies, it does not cause takings for private use." *Id.* at *19. Further, the court declined to find that the State law effected a *per se* taking because "Plaintiffs are still only required to sell at 340B discounts to covered entities, and [covered entities] can still only have drugs dispensed to their patients." *Id.*

As an alternative basis for its holding, the Mississippi district court also applied the test for regulatory takings articulated by *Penn Central Transportation 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 AstraZeneca'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 Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996)). 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). The same considerations apply here.

CONCLUSION

For the foregoing reasons and for the reasons set forth in *Amici*'s brief in the related case,[18] *Amici* respectfully request that the Court grant Defendant's motion to dismiss.

[18] *See AbbVie Inc. v. Ellison*, No. 0:24-cv-02605-DSD-TNL, AHA et al. Amicus Br., ECF No. 34.

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Respectfully submitted,

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