EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, *v.* ANDREW BAILEY, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MISSOURI, *et al.*, *Defendants*.	Case No. 2:24-cv-04131-MDH

BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTERESTS OF *AMICI CURIAE*

Proposed *Amici* include two hospital associations with members in Missouri 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. *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 discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Missouri 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 **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

"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." Br. for Appellee Novartis Pharms. Corp. at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, 2022 WL 2072941 (D.C. Cir. June 8, 2022). 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). After banking that win, in this case Novartis abruptly switches course, now arguing that section 340B is not silent and preempts Missouri from filling that federal statutory hole. Seeking to avoid all accountability (be it from the federal government or the States) for its rapacious contract pharmacy restrictions, this whiplash-inducing, heads-I-win-tails-you-lose argument is contrary to law for the many reasons explained below. But it is also—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.

Four years ago, amid a devastating pandemic, Novartis and 36 other drug manufacturers broke 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. *See* 42 U.S.C. § 256b(a)(1)(4). Before 2020, Novartis and the other drug companies had provided drug pricing discounts to eligible hospitals for drugs dispensed *both* through in-house

pharmacies and community pharmacies with which the hospitals had contracts. *See PhRMA v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024) ("For 25 years, drug manufacturers . . . distributed 340B drugs to covered entities' contract pharmacies."). But in July 2020, one drug company suddenly refused to provide these discounts for drugs if dispensed to 340B patients at community pharmacies (or "contract pharmacies").[1] Recognizing an opportunity to boost its own bottom line, Novartis quickly followed suit,[2] as did 35 other major drug companies.[3]

The contract pharmacy arrangements that drug companies like Novartis honored for almost 30 years helped sustain hospitals 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. For rural Critical Access Hospitals, savings from partnerships with these pharmacies represented an average of 52% of overall 340B savings.[4] Of the 73 Missouri hospitals participating in the 340B drug program, 67 contract with at least one community pharmacy to dispense drugs to patients.[5]

The drug company restrictions have substantially cut the savings from the 340B program, which is devasting for hospitals in Missouri that provide 77% of all hospital care that is provided

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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* Compl. ¶ 37, ECF No. 1 (Aug. 2, 2024). Novartis initially imposed a 40-mile limitation on a 340B hospital's use of a contract pharmacy. *Id.* Novartis's current policy permits the use of a single contract pharmacy but only by hospitals lacking an in-house pharmacy. *Id.* ¶ 45.

[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] 340B Health, *Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* 8 (Mar. 2023), https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

[5] Health Res. & Servs. Admin, Off. of Pharmacy Affairs, *340B OPA Info. Sys.*, https://340bopais.hrsa.gov/coveredentitysearch (last visited Aug. 7, 2024).

to Medicaid patients.[6] For example, Golden Valley Memorial Healthcare (GVMH), which has facilities in Clinton, Warsaw, Windsor, and Osceola, uses 340B savings to provide critical healthcare services—including a diabetes management program, birthing center, and ambulance services—to rural communities.[7] GVMH relies entirely on its savings from the 340B program to subsidize its diabetes program, which entails not only diabetes care and medication but also patient education and counseling. Further, GVMH's patients have suffered the consequences of drug company greed. Last year, the restrictive contract pharmacy policies of drug companies like Novartis forced GVMH to reduce the number of available maternity beds.[8]

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[9] This is why 340B hospitals have relied on contract pharmacies since the beginning of the program.[10] 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-

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[6] Dobson DaVanzo Health Economics Consulting, *Missouri 340B Hospitals Serve More Patients With Low Incomes, Who Live With Disabilities, and/or Identify as Black* 2, 340B Health, https://www.340bhealth.org/files/MO-340B-Low-Income15023.pdf (last visited Aug. 28, 2024).

[7] Craig Thompson, *Opinion: 340B: Preserving Access to Hospital Care*, Missouri Times (Feb. 12, 2024), https://themissouritimes.com/opinion-340b-preserving-access-to-hospital-care/ (last visited Aug. 28, 2024).

[8] *Id.*

[9] 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.

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

specialty drugs.[11] 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.[12] 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.[13]

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 forego treatment and fall out of compliance with prescription drug regimens. This can lead to hospital readmission or avoidable emergency department visits,[14] 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.[15] This is not surprising: 340B hospitals provide a disproportionate amount of uncompensated care to the country's most

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[11] 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/2019/12/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 Aug. 7, 2024).

[12] 340B Health, *supra* note 9, at 7 (citing Fein, *supra* note 11).

[13] 340B Health, *supra* note 9, at 6.

[14] 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).

[15] AHA, *340B Drug Pricing Program: Fact vs. Fiction* 3 (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.

vulnerable patients.[16] Savings from the 340B program help to offset the cost of providing uncompensated health care. Contrary to Novartis's baseless assertion that access to 340B drugs does not benefit patients, *see* Novartis Mem. in Supp. of Prelim. Inj. Mot. (Novartis Mem.) at 12–13, ECF No. 9 (Aug. 8, 2024), the Supreme Court has recognized that "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).

Last month, the Missouri legislature acted to address the drug industry's unprecedented assault on its health care safety net. Codified at § 376.414.2 (2024), Mo. Rev. Stat., Senate Bill 751 (S.B. 751) provides that drug manufacturers:

> shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by a, covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services. A wholesale drug distributor, as defined in section 338.330, shall not be considered an agent or affiliate [of a drug manufacturer] for purposes of this subsection.

S.B. 751 also provides that "[n]othing in this section shall be construed or applied to be in conflict with . . . [a]pplicable federal law and related regulation[.]" *Id.* § 376.414.6.

Novartis now seeks to halt Missouri's lawful exercise of its police power to protect public health and safety. For the reasons set forth in Defendants' Combined Memorandum of Law in Support of Their Motion to Dismiss and Opposition to Novartis's Motion for a Preliminary Injunction (Defs.' Mem), ECF No. 32 (Aug. 23, 2024), Novartis's claims should be dismissed in their entirety. Further, the motion for preliminary injunction should be denied because Novartis cannot demonstrate that it is likely to succeed on the merits, which the Supreme Court has

[16] *See* L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018); AHA, *supra* note 15, at 3; Dobson, *supra* note 15, at 13–17.

highlighted as the most important factor, even if the equities and harms are equal between movants and the State (and the people it protects), although here they are not. *Ohio v. Env't Prot. Agency*, 144 S. Ct. 2040, 2053 (2024).

Here, Novartis has no chance of success because none of the grounds argued in its preliminary injunction motion are meritorious (and most have already been rejected by other courts). *First*, Novartis's preemption claim is squarely foreclosed by the Eighth Circuit decision in *PhRMA v. McClain*, which held that Congress did not create or occupy any field through its 340B legislation and that a virtually identical Arkansas statute does not conflict with the 340B statute. *See PhRMA v. McClain*, 95 F.4th at 1143–45. *Second*, S.B. 751 is likewise not preempted by the Federal Food, Drug, and Cosmetic Act. *Third*, the Missouri statute does not run afoul of the dormant Commerce Clause. The Supreme Court has recently rejected a sweeping reading of the Clause, which is similar to the reading advanced by Novartis, and which would essentially bar any state law that has extraterritorial effects. *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.*

Just last month, the Southern District of Mississippi denied preliminary injunction motions filed by Novartis, AbbVie Inc. (AbbVie), and the Pharmaceutical Research and Manufacturers of America (PhRMA), who brought similar claims in seeking to enjoin a materially identical Mississippi statute. *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); *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). In all three cases, the court found that the plaintiffs were unlikely to succeed on the merits of their claims because the Mississippi law is not preempted by 340B. *See AbbVie 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. Relying on the Eighth Circuit's decision in *McClain*, the court found that there was no conflict with the 340B statute, and that Congress did not create a federal field in which the state could not intrude in passing 340B legislation. *See AbbVie v. Fitch*, 2024 WL 3503965, at *9; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *Novartis v. Fitch*, 2024 WL 3276407, at *6. The district court likewise found in the Novartis case that the Mississippi statute is not preempted by federal drug laws. *Novartis v. Fitch*, 2024 WL 3276407, at *10.

Further, the Mississippi court rejected PhRMA's argument that the Mississippi statute "directly regulate[s] out-of-state" conduct in violation of the dormant Commerce Clause. *PhRMA v. Fitch*, 2024 WL 3277365, at *12–13. Applying the presumption against extraterritoriality, which also exists in Missouri, *see Tuttle v. Dobbs Tire & Auto Ctrs., Inc.*, 590 S.W.3d 307, 312 (Mo. 2019) (en banc), the district court found that the Mississippi law "does not exhibit a clear intent to regulate out-of-state conduct." *PhRMA v. Fitch*, 2024 WL 3277365, at *13.

At bottom, Novartis's 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. Novartis can no doubt afford[17] to fund a coordinated, nationwide attack on state efforts to exercise their historic police powers, but that doesn't make its legal claims any more valid.

[17] Novartis reported annual gross profits of over $34 billion in 2023 alone. *See* Novartis Annual Report 2023 188 (2024), https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf (last visited Aug. 28, 2024).

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. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Novartis fails to establish that it has met any of these factors. *See* Defs.' Mem. at 29–34. *Amici* focus on the first factor, on which they believe they can best assist the Court.

I. NOVARTIS'S 340B PREEMPTION CLAIM IS FORECLOSED BY *PHRMA V. MCCLAIN*.

Novartis's claim that the Missouri statute is preempted by the 340B program is foreclosed by the Eighth Circuit's decision in *PhRMA v. McClain*. So far, every court to consider whether the federal 340B statute preempts analogous state legislation (including the Eighth Circuit) has concluded that it does not. *PhRMA v. McClain*, 95 F.4th at 1144; *AbbVie v. Fitch*, 2024 WL 3503965, at *7; *PhRMA v. Fitch*, 2024 WL 3277365, at *8; *Novartis v. Fitch*, 2024 WL 3276407, at *6. The Eighth Circuit rejected the pharmaceutical manufacturing association's contentions that the 340B program preempts the field, that the analogous Arkansas statute directly conflicts with the federal 340B statute, and that the State statute made it impossible to comply with 340B. *First*, explaining that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts," the Eighth Circuit found that "Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." *PhRMA v. McClain*, 95 F.4th at 1144 (internal citation omitted). *Second*, the court found that the Arkansas 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." *Id.* at

1144–45. *Third*, the Eighth Circuit found no impossibility preemption in light of the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy requirements because "[j]ust because a medication is subject to multiple legal requirements does not make it impossible to comply with" the State law. *Id.* at 1145. *PhRMA v. McClain* disposes of Novartis's 340B preemption claims.

Novartis's contentions to the contrary merely serve to illustrate the weakness of its position. Novartis first argues essentially that *PhRMA v. McClain* was wrongly decided—an inexplicable claim because *McClain* is controlling law in the Eighth Circuit. In any event, Novartis's argument is based entirely on an inapposite case law. *See* Novartis Mem. at 23 (citing *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011)). *Astra* had nothing to do with preemption; rather, it addressed *only* whether covered entities could use a third-party beneficiary theory to enforce the 340B statute's federal requirements. *Id.* at 113. 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 v. Gen'l Elec. Co.*, 496 U.S. 72, 87 (1990). The *Astra* Court's ruling that "potentially thousands of covered entities" could not sue to correct "errors in manufacturers' price calculations" has no bearing on whether *States* can legislate to restore contract pharmacies as a means of dispensing for 340B drugs. *See Astra*, 563 U.S. at 114. The only *mention* of preemption in *Astra* is in a footnote concerning a different federal program, the Medicaid Drug Rebate Program.

Novartis is also wrong in its suggestion that the D.C. Circuit's decision in *Novartis v. Johnson* has any bearing on the Eighth Circuit's rejection of PhRMA's identical preemption argument. *See* Novartis Mem. at 24. After arguing in the D.C. Circuit that statutory silence does not prohibit manufacturers from limiting sales of 340B drugs dispensed through contract

pharmacies, *see* Novartis Br. at 4, Novartis inconsistently contends that statutory silence precludes state action. Novartis cannot have it both ways. The D.C. 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), *aff'd*, 95 F.4th 1136 (8th Cir. 2024).

II. S.B. 751 DOES NOT REGULATE DRUG PRICING AND WOULD NOT BE PREEMPTED EVEN IF IT DID.

Novartis next relies on a misreading of a Federal Circuit case to argue that S.B. 751 is preempted by federal drug laws governing regulatory exclusivity and patent protection periods. Novartis Mem. at 16–18 (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 S.B. 751 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 18 (quoting *BIO I*, 496 F.3d at 1374). The Federal Circuit's 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, S.B. 751 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, S.B. 751 "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). Missouri "is simply deterring pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements." *Id*. Far from regulating pricing, S.B. 751 merely "incorporates by reference" the independent federal scheme, which Missouri is free to do. *See Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 710 (1985).

Even if Novartis's characterization of S.B. 751 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[.]").

III. S.B. 751 DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE.

Lastly, Novartis claims that S.B. 751 runs afoul of the dormant Commerce Clause because it "regulate[s] conduct that takes place wholly outside of Missouri." Novartis Mem. at 24. But that claim is squarely foreclosed by *National Pork Producers*. 598 U.S. 356.

As a factual matter, the Missouri law applies *only* to drugs dispensed to patients of *Missouri* 340B providers. Like "many (maybe most) state laws," S.B. 751 may indirectly impact "extraterritorial behavior" for companies like Novartis that are headquartered outside of Missouri. *Nat'l Pork Producers*, 598 U.S. at 374. But S.B. 751 in no way targets "upstream pricing and sale of prescription drugs." Novartis Mem. at 26. No matter how "notoriously complicated" the "drug distribution chain" may be, *id.*, S.B. 751 is strikingly simple. It is focused entirely on drug dispensing to patients of 340B providers that are *inside* of Missouri's borders. Even if Novartis had a valid legal theory about extraterritorial effects, it would not apply to S.B. 751 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. Novartis's attempt to revive the "extraterritoriality doctrine" just one year after the Supreme Court rejected it, *id.* at 371, is foreclosed by *Pork Producers*.[18]

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 S.B. 751 discriminates against out-of-state drug manufacturers. But its argument grossly misapplies the leading Supreme Court cases analyzing the dormant Commerce Clause. Critically, Novartis never disputes that S.B. 751 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 S.B. 751 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

[18] *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. S.B. 751 does no such thing. It simply requires manufacturers to distribute 340B drugs to the pharmacies with which Missouri 340B hospitals have contracted. There is no tie to prices set by any other State. That alone refutes Novartis's reliance on *Frosh*.

demonstrates the weakness of its argument. Put simply, S.B. 751 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 S.B. 751 fails the balancing test in *Pike v. Bruce Church Inc.*, 397 U.S. 137 (1970). As the petitioners in *Pork Producers* contended, Novartis argues that the Court should evaluate whether "the burdens imposed on interstate commerce are 'clearly excessive in relation to the putative local benefits.'" Novartis Mem. at 30 (quoting *Pike*, 397 U.S. at 142); *see Nat'l Pork Producers*, 598 U.S. at 377. But the concurrences in *Pork Producers* call into question whether the Supreme Court would even apply a *Pike* balancing test. 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.

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 S.B. 751 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 state "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 Missouri'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.

Further, 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 Missouri'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, Missouri'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 Missouri covered entities. *Id.* at 400–02. Further, Novartis completely ignores the local benefits of S.B. 751, *see supra* at 2–8, to patients and covered entities. *See AHA v. Becerra*, 596 U.S. at 737–39.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court grant Defendants' motion to dismiss.

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Respectfully submitted,

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