No. 25-1619

United States Court of Appeals for the Eighth Circuit

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff-Appellant*

v.

ANDREW BAILEY, in his official capacity as Attorney General of Missouri; JAMES L. GRAY, in his official capacity as President of the Missouri Board of Pharmacy; CHRISTIAN S. TADRUS, in his official capacity as Vice President of the Missouri Board of Pharmacy; DOUGLAS R. LANG, I in his official capacity as a Member of the Missouri Board of Pharmacy; COLBY GROVE, in his official capacity as a Member of the Missouri Board Of Pharmacy; ANITA K. PARRAN, in her official capacity as a Member of the Missouri Board of Pharmacy; TAMMY THOMPSON, in her official capacity as a Member of the Missouri Board of Pharmacy; and DARREN HARRIS, I in his official capacity as a Member of the Missouri Board of Pharmacy, *Defendants-Appellees*,

&

MISSOURI HOSPITAL ASSOC. AND MISSOURI PRIMARY CARE ASSOC., *et al.*, *Intervenors-Appellees*

On Appeal from the U.S. Dist. Court for the Western District of Missouri - No. 2:24-cv-04131-MDH

BRIEF OF DEFENDANTS-APPELLEES

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SUMMARY OF THE CASE

Novartis wants a preliminary injunction because it believes S.B.751 contains contract-pharmacy policies that violate the dormant Commerce Clause and are preempted. But Novartis cannot get its story straight. A few years ago, Novartis won a case by arguing that contract-pharmacy policies are about *delivery*, not price. Now it claims S.B.751's contract-pharmacy policy is unlawful because it is about price, *not delivery*. Novartis was right the first time around. This Court should affirm the denial of Novartis's preliminary injunction motion for several reasons.

First, this Court lacks jurisdiction to address preemption because the district court dismissed the preemption claims before ruling on the preliminary injunction motion (Juris. Stmt., Part I). Second, Novartis lacks standing because it bases its claims on the replenishment model, not S.B. 751 (Part II). Third, Novartis cannot demonstrate any of the requirements for a preliminary injunction (Parts III, IV)—merits or equitable factors. This Court addressed the merits of preemption *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024), which governs here and causes Novartis to lose. Nor does Novartis demonstrate or even allege facts that amount to a Dormant Commerce Clause violation.

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JURISDICTIONAL STATEMENT

In this interlocutory appeal, Novartis claims the district court erred by denying a preliminary injunction based on two claims—(1) Dormant Commerce Clause and (2) Preemption. This Court has jurisdiction over the first claim, but not the second.

The district court had jurisdiction under 28 U.S.C. §1331 because Novartis's complaint alleges that a Missouri statute (S.B.751 (2024)) violates the U.S. Constitution. App. 1; R. Doc. 1. Novartis moved for a preliminary injunction based on its Dormant Commerce and Preemption claims. App. 44; R. Doc. 9, at 15–31. The State opposed the preliminary injunction and moved to dismiss the complaint, including the Dormant Commerce and Preemption claims. App. 1; R. Doc. 1; App. 95; R. Doc. 31; App. 98; R. Doc. 32. The district court granted the motion to dismiss on all but the Dormant Commerce claim (Count III). App. 1; R. Doc. 1; App. 301; R. Doc. 77. About a week later, the district court denied the preliminary injunction motion, holding that neither Dormant Commerce nor Preemption claims merited a preliminary injunction (despite preemption claims already being dismissed). App. 316; R. Doc. 78.

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This Court has limited jurisdiction over interlocutory appeals. *Webster v. Westlake*, 41 F.4th 1004, 1009 (8th Cir. 2022). The only basis Novartis invokes for interlocutory jurisdiction is 28 U.S.C. §1292(a)(1), which permits "appeals from…interlocutory orders of the district courts…refusing…injunctions…." App.Br.6–7. This Court has jurisdiction for the appeal of the denial of the preliminary injunction based on the dormant Commerce Clause, but not based on preemption.

Though the district court purported to deny Novartis a preliminary injunction based on its preemption claims, this issue was moot when the district court decided it and remains moot now. "A case becomes moot, and is therefore no longer a case or controversy, when the issues presented are no longer live…." *See Prowse v. Payne*, 984 F.3d 700, 702 (8th Cir. 2021) ((internal quotation marks omitted)). The issue was no longer live when the district court ruled on the preliminary injunction motion. Thus, this Court lacks jurisdiction over the preemption argument but has jurisdiction over the dormant Commerce Clause argument. 28 U.S.C. §1292(a)(1). Even if there were a statutory jurisdictional basis for appealing the Preemption claims, this Court would lack Article III jurisdiction over the Preemption claims. *Prowse*,

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984 F.3d at 702 (if issues not live, no "case or controversy"). This Court should dismiss the appeal to the extent it raises preemption arguments.

Novartis does not claim this Court has final-judgment jurisdiction over the preemption claims. Rightly so. Though appellate courts typically have jurisdiction over appeals of final judgments, *see* 28 U.S.C. §1291, the order granting in part the motion to dismiss in this case is not a final judgment. A "final judgment is "one which ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." *Riley v. Kennedy*, 553 U.S. 406, 419 (2008). The order dismissing the preemption claims but not the Dormant Commerce claim did not end the litigation because the Dormant Commerce claim remains active. *SD Voice v. Noem*, 987 F.3d 1186, 1191 (8th Cir. 2021) ("[O]rder…resolv[ing] fewer than all claims is paradigmatically not final."). "[G]enerally, when a party appeals from a non-final order, [this Court] must dismiss for lack of jurisdiction." *Id.*

This Court has jurisdiction to determine whether the district court erred by denying the motion for preliminary injunction on the basis of the Dormant Commerce claim, but lacks jurisdiction to address the same based on preemption.

STATEMENT OF ISSUES

I. Whether this Court lacks jurisdiction to determine whether the district court erred by denying the preliminary injunction based on preemption.

- *Prowse v. Payne*, 984 F.3d 700 (8th Cir. 2021)
- *Riley v. Kennedy*, 553 U.S. 406 (2008)
- *SD Voice v. Noem*, 987 F.3d 1186 (8th Cir. 2021)

II. Whether Novartis lacks Article III standing because its harms are not fairly traceable to S.B.751 but to the replenishment model.

- *Spokeo, Inc. v. Robins*, 578 U.S. 330 (2016)
- *In re SuperValu, Inc.*, 870 F.3d 763 (8th Cir. 2017)

III. Whether the district court correctly denied the motion to preliminarily enjoin S.B.751 based on Novartis's Dormant Commerce Clause Claim.

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- *Winter v. Natural Resource Defense Council, Inc.*, 555 U.S. 7 (2008)
- *National Pork Producers v. Ross*, 598 U.S. 356 (2023)
- *Animal Legal Defense Fund v. Reynolds*, 8 F.4th 781 (8th Cir. 2021)
- *General Motors v. Tracy*, 519 U.S. 278 (1997)

IV. Whether the district court correctly denied the motion to preliminarily enjoin S.B.751 based on Novartis's Preemption Claims.

- *Pharmaceutical Research and Mfrs. of Am. v. McClain* 95 F.4th 1136, 1145 (8th Cir. 2024)
- *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023)
- *Novartis v. Johnson*, 102 F.4th 452 (D.C.Cir. 2024)

STATEMENT OF THE CASE

I. The 340B program helps provide low-cost drugs to hospitals and clinics that serve poor and rural patients.

Missouri's Senate Bill 751 ("S.B.751") (Mo.Rev.Stat. §376.414), protects freedom of contract for hospitals and medical clinics that serve disadvantaged patient populations. It complements the federal 340B program (42 U.S.C. §256b)—which sets prices for drugs purchased by those "covered entities"—by ensuring that patients can access 340B drugs through a convenient pharmacy. S.B.751 also ensures that Missouri's safety-net medical providers benefit from the federal 340B program. Many states have laws just like S.B.751, and courts across the country—including this Court—have upheld them against a variety of challenges.

Novartis's description of the 340B program makes it sound like a government-mandated cash grab for wealthy hospitals at the expense of drug manufacturers. Novartis accuses safety-net hospitals of colluding with "major for-profit chains such as Walmart and CVS" to leverage 340B's "price controls" through a "deliberately opaque" algorithm to create a "massive windfall." App.Br.1–2, 13. That is not how the Supreme Court and this Court have described 340B. The truth is that

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Novartis dislikes 340B because it cuts into Novartis's already massive profits.

The federal 340B program offers drug manufactures like Novartis a bargain: Novartis can access Medicare and Medicaid Part B drug markets—a benefit worth billions of dollars—if it agrees to "offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 115 (2011). Participation in the 340B program is voluntary, but Congress created the program to "incentivize[ ]" drug manufacturers to provide "pricing discounts on certain drugs prescribed to individuals and families whose incomes fall below the federal poverty level." *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1139 (8th Cir.).

Congress designed 340B to "enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384, *12. Per the Supreme Court: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). 340B helps them continue to provide those important

services. "Participation in the 340B Program" "benefits both drug manufacturers and covered entities—it allows manufacturers to participate in Medicaid and Medicare Part B programs, and it allows covered entities to obtain drugs at lower cost." *Oregon Health & Sci. Univ. v. Engels*, 2025 WL 1707630, at *1 (D.D.C. June 17, 2025).

"340B…'has three basic parts: (1)…cap on drug makers' prices, (2) restrictions on covered entities, and (3) compliance mechanisms' for…covered entities and manufacturers." *McClain*, 95 F.4th at 1141 (quoting *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023)).

Manufacturers "opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement" ("PPA")." *McClain*, 95 F.4th at 1141. Those who do must "sell drugs to covered entities at a discounted 'ceiling price.'" *Id.* The ceiling price is set by a federal "statutory formula." *Id.* "[D]iscounted prices are only made available to covered entities." *Id.* "Covered entities are defined by statute to include fifteen different types of public and not-for-profit hospitals, community centers, and clinics that are 'dominantly, local facilities that provide medical care for the poor.'" *Id.*; 42 U.S.C. §256b(a)(4). 340B "does not dictate how

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covered entities…use this revenue or require discounts…be passed…to patients." GAO Report No. 18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 2 (2018).[1] Even so, GAO estimates more than half of covered entities using contract pharmacies pass along 340B discounts to "low-income, uninsured patients." *Id.* at 30. 340B "gives [covered entities] extra revenue from serving insured patients: they turn a profit when insurance companies reimburse them at full price for drugs…they bought at the 340B discount." *Sanofi*, 58 F.4th at 699. 340B also "enables [covered entities] to give uninsured patients drugs at little or no cost." *Id.*

340B "includes compliance mechanisms, penalties for noncompliance or abuse by manufacturers and covered entities, and a dispute resolution process through HHS." *McClain*, 95 F.4th at 1141. "Covered entities may only prescribe 340B discounted drugs to patients who qualify and may not request or receive duplicative 340B discounts and Medicaid rebates for the same drug." *Id.* at 1141–42 (citing 42 U.S.C. §256b(a)(5)(B)). "[C]overed entities may not engage in diversion of

[1] https://www.gao.gov/assets/gao-18-480.pdf

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covered outpatient drugs through 'resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity.'" *Id.* at 1142 (quoting 42 U.S.C. §256b(a)(5)(B)).

II. Covered entities have always used contract pharmacies to distribute 340B drugs.

340B "'is silent about delivery' and distribution of pharmaceuticals to patients." *Id.*; *see also Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). "Since the beginning, covered entities have contracted with outside pharmacies, referred to as 'contract pharmacies,' for the distribution and dispensation of 340B drugs." *McClain*, 95 F.4th at 1139. Contract pharmacies help covered entities when "building or maintaining a pharmacy is cost-prohibitive." Contract pharmacies also allow "outsourcing…pharmacy services" to "allowed…drug dispensation closer to where low-income patients reside." *Id.* That makes sense. Normally the patient—not the drug manufacturer—gets to choose a convenient pharmacy.

Contract pharmacies are "essential, and legally required, as part of the drug distribution chain," but their role in 340B has changed over time. *Id.* at 1142. "In 1996, HHS issued guidance saying that covered entities could use one contract pharmacy each." *Sanofi*, 58 F.4th at 700

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(citing 61 Fed.Reg. 43,549). In 2010, HRSA "issued new guidance, saying…covered entities could use an unlimited number of contract pharmacies." *Id.* (citing 75 Fed.Reg. 10,272). In response, "[d]rug makers rebelled," "adopting policies to limit…use of contract pharmacies." *Id.*

III. Novartis implements a contract-pharmacy delivery policy and successfully challenges HRSA's contract-pharmacy guidance.

In response to manufacturers' restrictive policies, HHS issued an advisory opinion and sent enforcement letters to manufacturers, stating that the 340B statute required manufacturers to deliver 340B drugs to unlimited contract pharmacies. HHS Off. Gen. Couns., Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020).[2] Manufacturers challenged this guidance, arguing that the 340B statute did not grant HHS power to require delivery to all contract pharmacies. The Third and D.C. Circuits agreed with the manufacturers because "section 340B is 'silent about delivery.'" *Novartis*, 102 F.4th at 461 (quoting *Sanofi*, 58 F.4th at 703).

[2]https://www.mhanet.com/mhaimages/Legal/DHHS%20Counsel%20Advisory%20Opinion%20on%20340B%20Contract%20Pharmacies%2012-30-20.pdf

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Two points about *Novartis* and *Sanofi* bear emphasizing. First, both held that contract-pharmacy policies were about drug *delivery and distribution*, not price. *Novartis*, 102 F.4th at 460, 464 (quoting 42 U.S.C. §256b(a)(1)); *Sanofi*, 58 F.4th at 704 (340B "imposes only a price term for drug sales to covered entities, leaving all other terms blank"). Second, *Sanofi* and *Novartis* are decisions about agency power. *Novartis*, 102 F.4th at 461 ("[B]ecause section 340B is 'silent about delivery,' HRSA erred in concluding that the statute 'requires drug makers to deliver drugs to an unlimited number of contract pharmacies.'"). Neither decision addressed whether states could regulate 340B-drug distribution or delivery.

IV. States enact legislation to protect covered entities and patients.

After manufacturers like Novartis began implementing restrictive contract-pharmacy policies, those policies "caused covered entities dependent on contract pharmacies to become unable to serve patients in need." *McClain*, 95 F.4th at 1139. Missouri and more than a dozen other States passed laws accordingly. While the specifics of the laws vary, they generally prohibit manufacturers from refusing to sell 340B drugs to

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covered entities on the grounds that the drug will be distributed through a contract pharmacy.[3]

Drug manufacturers challenged these laws under a variety of theories—preemption, Takings Clause, Contracts Clause, Dormant Commerce Clause. Nearly every challenge has been rejected.[4] With one outlier—a materially different statute—courts have rejected preemption claims. *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271, at *13,*19 (collecting cases). *No court* has ruled in favor of the manufacturers on Dormant

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[3] *See* Ark.Code §23-92-604; Colo.Rev.Stat. §10-16-1505; Haw.Rev.Stat. §2; La.Stat. §40:2884; Md.Code, Health Occ. §12-6C-09.1; Mo.Rev.Stat. §376.414; Minn.Stat. §62J.96; Miss.Code §41-149-5; Neb.Rev.Stat. LB 168 §3; N.M.Stat. §26-1-27; N.D.Cent.Code §43-15.3-08; Or.Rev.Stat. §743A.062; S.D. Codified Laws §58-29G-2; Tenn.Code §47-18-136; Utah Code §31A-46-311; Vt.Stat.tit. 18, §4682; W.Va.Code §60A-8-6a.

[4] *See AbbVie Inc. v. Bailey,* 2025 WL 1918948 (E.D. Mo. July 11, 2025); *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271 (M.D. Tenn. June 30, 2025); *AbbVie, Inc. v. Ellison*, 777 F. Supp. 3d 971 (D. Minn. 2025); *Astrazenca Pharms. LP v. Bailey*, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025); *PhRMA v. Bailey*, 2025 WL 644281 (W.D. Mo. Feb. 27, 2025); *PhRMA v. Murrill*, 2024 WL 4361597 (W.D. La. Sept. 30, 2024); *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657 (S.D. Miss. 2024); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737, 748 (S.D. Miss. 2024); Order, *Novartis Pharm. Corp. v. Brown*, No. 1:24-cv-01557 (D. Md. Sept. 5, 2024), Doc. 57 (consolidating four challenges); *AbbVie Inc. v. Fitch*, 2024 WL 3503965 (S.D. Miss. July 22, 2024); *PhRMA v. Fitch*, 2024 WL 3277365 (S.D. Miss. July 1, 2024); *PhRMA v. McClain*, 645 F. Supp. 3d 890 (E.D. Ark. 2022).

Commerce Clause claims. *PhRMA v. Fitch*, 2024 WL 3277365, at *12 (S.D.Miss. July 1, 2024).

This Court is the only circuit to have considered a contract-pharmacy delivery law like S.B.751—Arkansas "Act 1103," which prohibits "manufacturers from limiting covered entities' ability to contract with outside pharmacies." *McClain*, 95 F.4th at 1139. PhRMA sued on behalf of its members—including Novartis[5]—alleging Act 1103 was preempted and violated the Commerce Clause. *Id.* at 1140 & n.3. Considering only preemption, the district court held Act 1103 was not field or obstacle preempted. *McClain*, 645 F. Supp. 3d at 897–901. This Court agreed. On field preemption, this Court held that "the text of 340B is silent about delivery of drugs to patients" and is thus "not so pervasive that Congress left no room for the States to supplement it." *McClain*, 95 F.4th at 1143 (citation modified). On obstacle preemption, *McClain* held that "Act 1103 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.

[5] *About Us: Members*, PhRMA, https://phrma.org/about#members (listing Novartis as member).

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Two other holdings support *McClain*'s outcome. First, *McClain* held that Act 1103 regulates delivery, not price. 95 F.4th at 1144–45. Second, *McClain* held that 340B does not permit covered entities to transfer ownership of 340B drugs. *Id.* at 1142. (citing 61 Fed. Reg. at 43,550–52). "[C]overed entities maintain legal title to the 340B drugs," and contract-pharmacy arrangements do "not…extend [340B] pricing to entities which do not meet program eligibility." *Id.* "Instead, the pharmacy becomes an agent of the covered entity with the authorization to 'dispense 340B drugs to patients of the covered entity pursuant to a prescription.'" *Id.* (quoting 61 Fed. Reg. at 43,550). "Covered entities purchase and maintain title to…340B-discounted drugs, while contract pharmacies dispense these drugs to covered entities' patients." *Id.* at 1144.

PhRMA's petitions for rehearing, rehearing en banc, and writ of certiorari in *McClain* were denied. *See* 2024 WL 1919676 (8th Cir. May 2, 2024); 145 S. Ct. 768 (2024).

V. Missouri passes S.B.751 and Novartis sues.

In July 2024—after *McClain* issued—Missouri adopted S.B.751, which states (among other things) that drug manufacturers:

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> 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.

Mo. Rev. Stat. §376.414.2. S.B. 751 defines "340B drug" and "covered entity" with reference to the federal 340B program. *Id*. §376.414.1(1), (2). S.B.751 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(1).

Novartis sued and moved for a preliminary injunction, arguing S.B.751 was preempted by 340B and violated the Dormant Commerce Clause. App. 1; R. Doc. 1; App. 40; R. Doc. 3; App. 44; R. Doc. 9. Despite seeking to enjoin a democratically enacted state law, Novartis provided almost zero evidence in support of its preliminary injunction motion. Novartis attached only a short, six-page declaration from an employee to its motion for preliminary injunction. App. 89; R. Doc. 9-1. Its brief cites a handful of reports and articles that discuss 340B in general terms. App. 52, R. Doc. 9, at 9. The evidence for the Dormant Commerce Clause claim is especially weak: two paragraphs of the complaint, a single paragraph of the declaration, and an openly biased article discussing contract

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pharmacies generally, but not discussing state laws like S.B.751. *See* App. 78, 82, 83n.7; R. Doc. 9, at 35, 39, 40n.7; App. 152; R. Doc. 35, at 13.

Missouri and Intervenors opposed the preliminary injunction and moved to dismiss. *See* App. 98; R. Doc. 32. The district court dismissed Novartis's preemption claims but declined to dismiss the Dormant Commerce Clause claim. *See* App. 301; R. Doc. 77. About a week later, the district court issued an order denying Novartis's motion for preliminary injunction. Add. 1; App. 316; R. Doc. 78. Though the court had already dismissed Novartis's preemption claims, it explained that Novartis had failed to establish a likelihood of success on both preemption and Dormant Commerce Clause claims. Add. 1; App. 316; R. Doc. 78. Novartis appealed the denial of the preliminary injunction on preemption and Dormant Commerce Clause claims. App.Br.7–8.

SUMMARY OF THE ARGUMENT

Novartis loses on two threshold issues, meaning this Court need not address the merits. First: this Court should not consider whether the district court correctly denied a preliminary injunction based on the preemption claims because those claims were moot when the district court issued its order denying the preliminary injunction. The claims remain moot on appeal. Second: Novartis lacks Article III standing because it has not demonstrated that S.B.751 causes its alleged injury. Instead, the replenishment model is the cause of Novartis's alleged injury.

Novartis also loses on the merits. The district court correctly denied the preliminary injunction because Novartis failed to demonstrate the factors required—either the merits or the equities. Novartis cannot demonstrate a likelihood on the merits. Novartis admits that its Dormant Commerce Clause argument depends on S.B.751 regulating price. App.Br.28. But Novartis is judicially estopped from making that argument, and S.B.751 does no such thing. The 340B statute governs price; S.B.751 governs delivery. Further, Novartis presented barely any evidence to support its Dormant Commerce Clause claim. This lack of

evidence alone is sufficient reason to deny a preliminary injunction—especially a preliminary injunction of a democratically enacted state statute. *See Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds*, 530 F.3d 724, 733 (8th Cir. 2008) ("[W]here a preliminary injunction is sought to enjoin…implementation of a duly enacted state statute,…district courts [must] make a threshold finding that a party is likely to prevail on the merits."). Nor does S.B.751 violate the Dormant Commerce Clause on the basis of unlawful extraterritoriality or discriminatory intent. Further, the *Pike* balancing no longer exists in the Eighth Circuit, so this is not a basis for finding S.B.751 violates the Dormant Commerce Clause. But even if *Pike* were still applicable in the Eighth Circuit, S.B.751 would pass the balancing test.

Novartis's claim that the district court should granted a preliminary injunction based on preemption also fails. Novartis's preemption claims are all foreclosed by this Court's *McClain* case. Novartis openly admits that it loses its field and "enforcement" preemption arguments under *McClain*. And its attempts to split hairs and present a third, "new" preemption claim fail. Across the U.S., courts

have nearly universally rejected preemption claims against similar laws. Because it is not likely that Novartis will succeed on the merits, this Court should affirm the denial of preliminary injunction on this basis alone.

This Court should affirm the denial of the preliminary injunction also because the balance of the equities favors the State. Specifically, Novartis has not demonstrated irreparable harm, though the State has. Novartis previously delivered 340B drugs to all contract pharmacies, and after that, it willingly delivered 340B drugs to all contract pharmacies within 40 miles of a covered entity. Thus, harm to Novartis of complying with S.B.751 is minimal. Meanwhile, the State would be unable to enforce a lawfully enacted statute. Finally, a preliminary injunction would be against the public interest because Novartis has acted opportunistically to undermine a federal program developed to help institutions that serve disadvantaged populations. This Court should affirm the district court's denial of the preliminary injunction.

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STANDARD OF REVIEW

This Court applies a "layered" standard of review to preliminary injunctions. *Tumey v. Mycroft AI, Inc.*, 27 F.4th 657, 665 (8th Cir. 2022). It reviews "the district court's conclusions of law de novo, its findings of fact for clear error, and its application of the law to the facts for abuse of discretion." *Cigna Corp. v. Bricker*, 103 F.4th 1336, 1343 (8th Cir. 2024). "Because a district court exercises the traditional authority of a chancellor, its discretion to grant or deny a preliminary injunction is broad." *Id.*

ARGUMENT

I. This Court lacks jurisdiction to consider whether the district court correctly denied the motion for preliminary injunction under Novartis's Preemption Claims.

As discussed in the Jurisdictional Statement, this Court lacks jurisdiction to consider whether the district court erred by denying the preliminary injunction based on preemption. This Court should dismiss the appeal of the preemption issues.

II. Novartis lacks Article III standing because its alleged harms are not fairly traceable to S.B.751.

Novartis lacks Article III standing because its alleged harms are caused by the replenishment model, not S.B.751. Another court recently

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dismissed a similar case challenging S.B.751 based on standing. As here, the plaintiff in that case raised preemption and Dormant Commerce Clause challenges to S.B.751. *See AbbVie Inc. v. Bailey*, 2025 WL 1918948, at *4 (E.D.Mo. July 11, 2025).

For standing, a plaintiff must allege it "(1) suffered an injury in fact, (2)…fairly traceable to the challenged conduct of the defendant…(3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "To establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Id.* at 339. An "injury is fairly traceable if the plaintiff shows 'a causal connection between the injury and the conduct complained of ' that is 'not the result of the independent action of some third party not before the court.'" *In re SuperValu, Inc.*, 870 F.3d 763, 768 (8th Cir. 2017) (alterations and omission adopted). "[T]he plaintiff must 'clearly…allege facts demonstrating' each element." *Spokeo*, 578 U.S. at 338.

The *AbbVie* court found that AbbVie lacked Article III standing because its alleged injuries were caused by "(1) section 340B, and

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(2) illegal transfers of 340B drugs through the replenishment model," not by S.B.751. *See* 2025 WL 1918948, at *8. So too here for Novartis. Novartis's allegations of harm from S.B.751 are either (1) legal conclusions, (2) injuries caused by the 340B program, or (3) potential abuses of the 340B program caused by the replenishment model.

Novartis's legal conclusions include arguments that S.B.751 "overrides federal law by purporting to require manufacturers to provide the federal 340B discount on an unlimited number of transactions involving for-profit pharmacies (known as 'contract pharmacies')." App. 1. R. Doc. 1, ¶1. That is a legal conclusion, not a well-pleaded fact, and an incorrect one at that. Per *McClain*, the "340B Program" "addresses discount pricing," not state law. 95 F.4th at 1144.

On causation, Novartis alleges that delivery to contract pharmacies leads to use of the replenishment model, which in turn leads to "abuse" of 340B through increased diversion and duplicative discounts. App. 11–14, R. Doc. 1, ¶¶36,43,45. But use of the replenishment model is not required by S.B.751 at all—it is the "result of the independent action of some third party not before the court," namely contract pharmacies and covered entities. *In re SuperValu*, 870 F.3d at 768 (alterations adopted).

Absent third parties use the replenishment model, and they did so long before S.B.751 existed. App. 12–13, R. Doc. 1, ¶¶42–43. In fact, S.B.751 expressly does not apply when receipt of a 340B drug by a contract pharmacy is prohibited by HHS. Mo.Rev.Stat. §376.414.2. Among the things prohibited by HHS is "resale of drugs." 42 U.S.C. §256b(a)(5)(B). Additionally, §376.414.6, .6(1) of the Missouri Revised Statutes instructs that it nothing in S.B.751 "shall be construed or applied to be in conflict with…[a]pplicable federal law." If Novartis wants a remedy for diversion or other alleged abuses of the 340B program, it must use the federally mandated administrative dispute resolution process, *see* 42 U.S.C. §256b(d)(3)(A), (d)(3)(B)(i), rather than suing Missouri.

The majority of other allegations in Novartis's complaint are legal conclusions about the 340B program, state contract-pharmacy delivery laws like S.B.751, and the various cases interpreting those laws. *See, e.g.*, App. 1–12; R. Doc. 1, at ¶¶1–2,7–14,24–26,31–32,36–39. The few factual allegations in the complaint demonstrate not how S.B.751 causes Novartis's alleged injury, but how the 340B program itself does so by allowing the replenishment model. *See, e.g.*, *id.* ¶¶3–6, 27–35, 40. As in *AbbVie*, "S.B. 751 has no hand in" Novartis's injury. *See* 2025 WL

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1918948, at *8. This Court should remand with instructions to dismiss for lack of standing.

III. The district court correctly denied the motion to preliminarily enjoin S.B.751 based on Novartis's Dormant Commerce Clause Claim.

In order to be granted a preliminary injunction, Novartis (the movant) "must establish [1] that [it] is likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [its] favor, and [4] that an injunction is in the public interest." *Winter v. Natural Resource Defense Council, Inc.*, 555 U.S. 7, 20 (2008). The most important factor is the likelihood of success on the merits. *Craig v. Simon*, 9780 F.3d 614, 617 (8th Cir. 2020). This Court should affirm the district court's denial of Novartis's motion for preliminary injunction on the basis of preemption for four independent reasons: (1) it is unlikely to succeed on the merits; (2) it is unlikely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in favor of the State; and (4) an injunction would not be in the public interest.

A. Novartis is unlikely to succeed on the merits.

"[A] party seeking a preliminary injunction of the implementation of a state statute must demonstrate…that [it] is likely to prevail on the

merits." *Rounds*, 530 F.3d at 731–32. Novartis raises three independent arguments for why its Dormant Commerce Clause claim should succeed: (1) that S.B.751 regulates wholly out-of-state transactions; (2) that S.B.751 discriminates against out-of-state economic interests; and (3) that S.B.751 fails *Pike* balancing. None of these theories are likely to succeed on the merits.

The U.S. Supreme Court's most recent dormant Commerce Clause case, *National Pork Producers v. Ross*, was a fractured, plurality opinion. 598 U.S. 356 (2023). When there is a fractured plurality opinion, this Court applies the reasoning of the justices who agreed with the holding on the narrowest grounds (*i.e.*, where a concurring opinion is a logical subset of the rationale of other court members who agree in the outcome). *Animal Legal Defense Fund v. Reynolds*, 8 F.4th 781, 785 (8th Cir. 2021) (citing *Marks v. United States*, 430 U.S. 188 (1977)). When one opinion is not a logical subset of another, courts are not bound by the Supreme Court's reasoning—only its result. *Id.* at 785. In *Pork Producers*, at least five votes held that "[p]reventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of extreme delicacy, something courts should do only

where the infraction is clear." 598 U.S. at 390 (internal quotation marks omitted). Here, the alleged infraction is anything but clear. This Court should affirm the district court's decision to deny the preliminary injunction.

1. S.B.751 regulates delivery, not price, Novartis should be estopped from claiming otherwise, and therefore this Court should affirm denial of the preliminary injunction on the dormant Commerce Clause claim.

Before jumping into the dormant Commerce Clause argument, this section addresses Novartis's incorrect argument that S.B.751 somehow regulates price. It does not. In *McClain*, this Court held that laws like S.B.751 do "not set or enforce discount pricing." 95 F.4th at 1145. Yet Novartis's lead argument—I.A.1—is that "S.B. 751 Regulates Drug Prices." App.Br.28. Novartis hangs its entire case on that argument, acknowledging that "the Dormant Commerce Clause violations" "follow" "[o]nce the price regulation aspect of S.B.751 is understood." *Id*. Novartis also is estopped from arguing that S.B.751 regulates price because it took the opposite position in litigation before the D.C. Circuit (and won).

a. McClain rejected the argument that laws like S.B.751 regulate price.

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Novartis's argument that "S.B.751 is a drug pricing statute" is foreclosed by binding precedent. *McClain*'s holding that Arkansas's 340B-drug-delivery law ("Act 1103") "does not set or enforce discount pricing" applies to S.B.751 because the two laws are functionally the same. 95 F.4th at 1145. Act 1103 "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by" (1) "denying the pharmacy access to a covered entity's 340B drugs" or (2) "denying 340B drug pricing to covered entities who use contract pharmacies for distribution." *McClain*, 95 F.4th at 1143; *see also* Ark.Code §23-92-604(c). Likewise, S.B.751 provides that

> [a] pharmaceutical manufacturer … 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.

Mo.Rev.Stat. §376.414.2. Both laws prevent drug manufacturers from interfering with covered entities that want to use contract pharmacies to distribute their 340B drugs. And like Act 1103, S.B.751 "does not require manufacturers to provide 340B pricing discounts to contract pharmacies" and "does not set or enforce discount pricing." *McClain*, 95 F.4th at 1145.

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The pricing versus delivery issue was central in *McClain*. An entire section of PhRMA's brief was titled "The Conflict Between Act 1103 And 340B Cannot Be Resolved By Recasting Act 1103 As A Distribution Requirement." PhRMA Appellant Brief, *PhRMA v. McClain*, No. 22-3675, 2023 WL 2337833, at *49 ((8th Cir. Feb. 22, 2023)). PhRMA raised the same arguments about pricing v. delivery in *McClain*, and this Court rejected them. *Compare id.* at *49–*51, *and* PhRMA Reply Brief, No. 22-3675, 2023 WL 3661005, at *8 (8th Cir. May 16, 2023), *with* App.Br.28–33. Novartis provides no reason to overrule *McClain* here. At minimum, *McClain*'s holding precludes entry of a preliminary injunction this Court's rejection of its primary argument in an indistinguishable context makes it unlikely that Novartis will "prevail on the merits." *See Rounds*, 530 F.3d at 733.

Against *McClain*, Novartis relies on an out-of-circuit, district-court decision: *PhRMA v. Morrisey,* 760 F. Supp. 3d 439 (S.D.W. Va. 2024). App.Br.32. Reliance on *Morrisey* fails for three reasons. First, *McClain* is binding precedent; *Morrisey* is not. But even worse for Novartis, *Morrisey* expressly rejected this Court's analysis in *McClain*, something panels and district courts within the Eighth Circuit cannot do. 760 F.

Supp. 3d at 458–59; *Hood v. United States*, 342 F.3d 861, 864 (8th Cir. 2003) (district court and Eighth Circuit bound by Eighth Circuit precedent). *Morrisey* also is an outlier among federal district courts—the "sole…opinion ruling in favor of drug manufacturers challenging state laws seeking to limit the manufacturers' ability to impose delivery conditions on 340B drugs." *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271, at *18 (M.D. Tenn. June 30, 2025) (rejecting "*Morrissey*'s characterization of" Tennessee law "as controlling price rather than delivery"); *see also AstraZeneca v. Fitch*, 766 F. Supp. 3d 657, 667–68 (S.D. Miss. 2024) (*Morrisey* not "persuasive" or "mainstream").

Second, Novartis's own arguments against *McClain* apply against *Morrisey*. If Novartis is correct (it is not) that *McClain* is irrelevant because it "addressed federal preemption claims and does not speak to the merits of the unrelated Dormant Commerce Clause claim," App.Br.33, then Novartis also cannot use *Morrisey* as precedent because it does not address the Dormant Commerce Clause.

Third, the law challenged in *Morrisey* is materially different from S.B.751. *Morrisey* focused on the West Virginia law's "No-Audits Provision," which restricted drug manufacturer access to data from

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covered entities that could be used to determine if covered entities were violating the 340B laws. 760 F. Supp. 3d at 452–53; W. Va. Code Ann. §60A-8-6a. S.B.751 lacks a "No-Audits Provision," rendering *Morrisey's* analysis inapposite.

b. Novartis is estopped from arguing that S.B.751 regulates price.

Novartis's argument that S.B.751 regulates price also conflicts with its own position in the D.C. Circuit. "Where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position." *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (citation modified). By arguing that "S.B. 751 regulates drug prices," App.Br.28 (citation modified), Novartis is trying to "gain an advantage" by asserting an argument "incompatible" with its arguments to the D.C. Circuit in *Novartis v. Johnson*, 102 F.4th 452 (D.C.Cir. 2024). *New Hampshire*, 532 U.S. at 749 (quoting 18 C. Wright, A. Miller, & E. Cooper, Federal Practice and Procedure §4477, p.782 (1981)). This Court should reject Novartis's attempt to gain an "unfair advantage." *Id.* at 751.

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In Novartis's challenge to HRSA's contract-pharmacy policy, Novartis argued that 340B does not prohibit "manufacturers from imposing *delivery limitations* on drugs purchased at the 340B *price*" by limiting the number of contract pharmacies they deliver to. Appellee Brief, *Novartis v. Johnson*, 2022 WL 2072941, at *25 (D.C. Cir. June 8, 2022) (emphasis added) ("The Statute Does Not Prohibit Manufacturers From Imposing *Delivery Conditions* On Sales To Covered Entities Using Contract Pharmacies." (emphasis added)) (hereinafter *D.C. Cir. Brief*). In other words, determining the number of contract pharmacies that a manufacturer delivers to determines delivery, not price. Novartis has now done a 180° and argues that whatever determines the number of contract pharmacies a manufacturer delivers to "is a pricing regulation, pure and simple." App.Br.31. If Novartis's own determination of how many contract pharmacies it will deliver to does not determine price (as it cannot in order to comply with the 340B program, which *does* govern price, *see* 42 U.S.C. §256b(a)(1)), then a state's determination of how many contract pharmacies a manufacturer must deliver to also does not determine price.

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This Court's three-factor test strongly favors estopping Novartis from taking a contrary position here. First, Novartis's "later position is 'clearly inconsistent' with its previous position." *Van Horn v. Martin*, 812 F.3d 1180, 1182 (8th Cir. 2016) (citing *Stallings v. Hussmann Corp.*, 447 F.3d 1041, 1047 (8th Cir. 2006)). As explained, Novartis's position that Missouri's contract-pharmacy policy regulates price is irreconcilable with its prior position that its own contract-pharmacy policy regulates only delivery. Second, Novartis "succeeded in persuading the first court to accept its position." *Id.* The D.C. Circuit agreed with Novartis's argument that 340B's "silence" gives Novartis the option to "impose at least some delivery conditions." *Novartis*, 102 F.4th at 460. And third, Novartis will "derive an unfair advantage" from these inconsistent arguments. *Van Horn*, 812 F.3d at 1182. It would be a "perversion of the judicial process"—to allow Novartis "deliberately chang[e] positions according to the exigencies of the moment." *New Hampshire*, 532 U.S. at 750 (citations omitted). Novartis cannot tell the D.C. Circuit that its own contract-pharmacy policies are "delivery limitations" while insisting that Missouri's contract-pharmacy policies in S.B.751 are all about price. But even if this Court declines to apply judicial estoppel, the D.C. Circuit's

reasoning still defeats Novartis's argument about contract-pharmacy policies being about price. While the 340B statute set the "price" term of a drug sale, Novartis's contract-pharmacy policy set "non-price terms" for "the place or manner of delivery." *Id.* at 460. S.B.751 likewise regulates the "non-price" term for delivery of 340B drugs to covered entities in Missouri. If Novartis's contract-pharmacy policy was about pricing, it would be in open violation of 340B, which requires Novartis to sell its drugs to "at or below the applicable ceiling price." 42 U.S.C. §256b(a)(1). Of course, the truth is that both S.B.751 and Novartis's policy are about "delivery conditions," not price. *Novartis*, 102 F.4th at 460.

c. Abuses of the replenishment model are not attributable to S.B.751.

Novartis also falls back on its favorite boogeyman—the replenishment model. But as explained above, S.B.751 does not mandate or even prefer the replenishment model. Covered entities that use the replenishment model to account for 340B drug sales do so as "the result of [their] independent action," which is not "fairly traceable" to S.B.751 or the State of Missouri. *In re SuperValu*, 870 F.3d at 768. Nor does S.B.751 permit violations of 340B's anti-duplication or anti-diversion provisions. On the contrary, S.B.751 does not apply if "receipt is

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prohibited by the [HHS]." Mo.Rev.Stat. §376.414.2. For this reason, the Eastern District of Missouri dismissed AbbVie's Dormant Commerce Clause and preemption claims "for lack of standing." *AbbVie*, 2025 WL 1918948, at *10.

And though Novartis argues that Missouri pharmacies use the replenishment model, Novartis cites no evidence to support that claim. App. Br. at 29. Novartis's only declaration says nothing about use of the replenishment model in Missouri. *See* App.89; R. Doc. 9-1. And the Complaint includes only general allegations about the how the replenishment model works it and its potential abuses. *See* App. 1; R. Doc. 1, ¶¶3–6, 32–35. There is no evidence in the record about how covered entities and pharmacies *in Missouri* operate to support Novartis's arguments. Novartis "bears the burden of demonstrating" that the "extraordinary remedy" of a "preliminary injunction is warranted." *Morehouse Enters. v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 78 F.4th 1011, 1016 (8th Cir. 2023). That evidence presented below falls far short of the "clear showing" required to enjoin a "presumptively reasonable" state law. *Rounds*, 530 F.3d at 733, 736 (citation omitted).

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2. S.B.751 does not violate the dormant Commerce Clause based on unlawful extraterritoriality.

Novartis claims that S.B.751 violates the dormant Commerce Clause because it is unlawfully extraterritorial on one ground. It claims that the statute targets transactions between drug manufacturers and wholesalers that typically take place outside of the State by stating:

> A pharmaceutical manufacturer…shall not [] restrict…indirectly, the…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.

App.Br.34. There are several problems with this theory.

First, S.B.751 does not apply extraterritorially. A statute presumptively has no extraterritorial application. *Kiobel v. Royal Dutch Petroleum Co.*, 569 U.S. 108, 115 (2013). This canon of construction applies equally "to the laws of our states." Scalia & Garner, *Reading Law* at 268 (2012 ed.). And it applies to Missouri statutes like S.B. 751 "absent express text to the contrary." *See Tuttle v. Dobbs Tire & Auto Ctrs., Inc.*, 590 S.W.3d 307, 311 (Mo. 2019). Here, S.B. 751 does not expressly state that it applies outside "the boundaries of this state," meaning that it

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"ha[s] no extraterritorial effect." *Id.* Thus, Novartis cannot claim that S.B.751 regulates out-of-state conduct.

Second, Novartis failed to allege facts sufficient to demonstrate that S.B.751 regulates a wholly extraterritorial transaction. In its Brief, Novartis identifies one transaction it claims S.B.751 regulates, writing: "S.B. 751 requires drug manufacturers *anywhere in the country* to honor the wholesaler's refund request for units subject to [S.B.751], even when the drug manufacturer did not conduct a single transaction in Missouri or with a Missouri-based entity." App.Br.34. As a preliminary matter, this allegation does not exist in Novartis's complaint, its motion for preliminary injunction, or its reply in support of that motion. App. 1; R. Doc. 1; App. 44; R. Doc. 9; App. 140; R. Doc. 35. Thus, this Court should not consider it. *Central Valley Ag Coop. v. Leonard*, 986 F.3d 1082, 1090 (8th Cir. 2021) (appellate courts do not consider arguments made for the first time on appeal). Even if this Court did consider this argument, it is difficult to understand how S.B.751's prohibition on indirectly restricting delivery to contract pharmacies requires drug manufacturers to honor wholesalers' refund requests. Neither this nor any other part of S.B.751

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facially appears to govern whether Novartis must honor a wholesaler's refund request—or any other out-of-state transaction for that matter.

Novartis appears to equate this alleged extraterritorial regulation with "mandat[ing] a discounted price be given by manufacturers." App.Br.35. But S.B.751 is about delivery, not price.

Third, Novartis is wrong to suggest that the dormant Commerce Clause bars regulation of actions outside of a state when those actions are "intended to produce…effects within it." *See Pork Producers*, 598 U.S. at 375–76 (citing favorably *Strassheim v. Daily*, 221 U.S. 280, 285 (1911)). In *Strassheim*, the Supreme Court held that states may punish criminal acts committed by defendants outside of a state so long as those acts "intended to produce" and actually produced "detrimental effects within it." *See id.* The conduct Novartis wants to engage in falls within this category. Novartis wants to have a policy preventing its wholesalers from delivering 340B drugs to contract pharmacies. This action is "intended to produce" and actually produces "effects within" Missouri. *See id.* Thus, regulation of this conduct is not wholly extraterritorial. *Pork Producers*, 598 U.S. at 375–76.

This holding from *Pork Producers* makes many cases Novartis cites inapposite or incorrect. For instance, *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 671–72 (4th Cir. 2018), is inapposite because the court invalidated the law in that case on the basis that it "controls the price of transactions that occur wholly outside the state," and here that is not the case. *Frosh* also clashes with *Pork Producers*'s holding that states may punish conduct outside of its borders that is intended to and actually does produce results inside of the state. *Association for Accessible Medicines v. Ellison* is unhelpful to Novartis for similar reasons. 704 F.Supp.3d 947, 953 (D.Minn. 2023). *Ellison recognizes* that—post-*Pork Producers*—there is no per se bar on regulating out-of-state transactions but only "out-of-state transactions by those with *no* connection to the State." *Id.* ("The only issue, then, is whether those transactions have a sufficient connection to Minnesota to give the Minnesota Legislature authority to regulate them."). And unlike this case, in *Ellison*, the transactions allegedly affected by in-state regulations did not relate to the state. Similarly, this Court's pronouncement in *Styczinski v. Arnold*, 46 F.4th 907 (2022), of what is unlawful under the Dormant Commerce Clause clashes with *Pork*

Producers because *Styczinski* holds that "The Commerce Clause precludes the application of a state statute to commerce that takes place wholly outside the State's borders, whether or not the commerce has effects within the State." 46 F.4th at 913. But *Pork Producers* holds that states can regulate activities outside of their borders that are intended to and do produce effects within the state. 598 U.S. at 375–76. *Pharmaceutical Research and Manufacturers of America v. District of Columbia*, 406 F.Supp.2d 56, 67 (D.D.C. 2005), conflicts with *Pork Producers* on similar lines. *Pharmaceutical Research*, 406 F.Supp.2d at 67 ("[A] state statute directly regulating commerce occurring beyond the boundaries of that state is *per se* invalid and generally struck down without further inquiry." (cleaned up)).

Fourth, in *Pork Producers*, the Supreme Court clarified that "impermissible extraterritorial effect" results in violation of the Dormant Commerce Clause in three categories only—none of which exist here. Laws that violate the Dormant Commerce Clause for "extraterritorial effect" are limited to (1) tariffs, (2) laws requiring sales at a particular price, and (3) price-control or price-affirmation statutes that tie the price of in-state products to out-of-state prices. *See id.* at 372. The other cases

cited for impermissible extraterritorial effect in *Pork Producers* were, the Supreme Court said, only violations of the dormant Commerce Clause because they were discrimination cases. *Id*. at 374. Thus, because S.B. 751 is not a tariff, does not require sales at a particular price, and does not tie the price of in-state products to out-of-state prices, there is no Dormant Commerce Clause violation via "impermissible extraterritorial effect."

3. S.B.751 does not violate the dormant Commerce Clause by having an unlawfully discriminatory intent or effect.

Novartis claims that S.B.751 violates the dormant Commerce Clause because it has the discriminatory intent to, or effect of, targeting manufacturers and wholesalers, both of which are largely located out of state. Novartis claims that this unconstitutionally favors "an exclusively in-state hospital and clinic industry at the expense of an almost-exclusively out-of-state drug manufacturing industry." App.Br.42. But the facts in Novartis's complaint do not demonstrate a dormant Commerce Clause violation under the "discriminatory intent or effect" theory.

A majority in *Pork Producers* agreed that, at the heart of dormant Commerce Clause jurisprudence is the principle that States should not be allowed to pass laws that "advantage in-state firms or disadvantage out-of-state rivals." 598 U.S. at 370. That is not happening here because S.B.751 applies to drug manufacturers whether they are located in-state or out-of-state. For instance, Bayer is a pharmaceutical manufacturer[6] that has a large presence in Missouri,[7] and S.B.751 applies to Bayer as much as to any other pharmaceutical manufacturer. The same is true for other pharmaceutical manufacturers with a presence in Missouri, such as Pfizer, GlaxoSmithKline, and Mallinckrodt.[8] Thus, there is no obvious intent to favor in-state companies at the expense of their out-of-state rivals.

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[6] Bayer, *Pharmaceutical Brands*, https://www.bayer.com/en/us/divisions/pharmaceutical-brands; Bayer, *Pharmaceutical Division*, https://www.bayer.com/en/us/bayer-pharmaceuticals.

[7] Bayer, *Where We Operate*, https://www.bayer.com/en/us/our-locations.

[8] Greater St. Louis Inc., *Bioscience and Health Innovation*, https://greaterstlinc.com/industry-strengths/bioscience-and-health-innovation (describing how regional bioscience and health innovation companies like Bayer, Mallinckrodt, GlaxoSmithKline, and Pfizer are part of major St. Louis, Missouri, industry cluster of more than $1.5 billion in investment and 200,000 employees).

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Novartis argues that S.B.751 has a discriminatory intent or effect because it privileges in-state *hospitals and pharmacies* at the expense of out-of-state *manufacturers* like Novartis. There are multiple problems with this argument. First, both in-state and out-of-state manufacturers are subject to S.B.751, so S.B.751 does not pit in-state against out-of-state interests. Second, hospitals and pharmacies versus manufacturers is the wrong comparison. The question is whether S.B.751 discriminates against out-of-state drug *manufacturers* in favor of in-state drug *manufacturers*. *See Pork Producers*, 598 U.S. at 371–73 (listing dormant Commerce Clause violations in laws protecting in-state from out-of-state dairy farmers, in-state from out-of-state liquor distillers, in-state from out-of-state beer merchants). Novartis's own cases suggest that it cannot compare apples to oranges. *See Oregon Waste Sys., Inc. v. Dep't of Environ. Quality*, 511 U.S. 93, 99 (1994) (Dormant Commerce violation based on higher per-ton surcharge on out-of-state waste than on in-state waste); *General Motors v. Tracy*, 519 U.S. 278, 299 (1997) ("[A]ny notion of discrimination[] assumes a comparison of substantially similar entities."); *Dep't of Revenue of Kentucky v. Davis*, 553 U.S. 328, 342 (2008) (same); *Oneida*, 550 U.S. at 342 ("[A]ny notion of discrimination assumes

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a comparison of substantially similar entities."); *Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263, 265 (1984) (requiring "some competition" to find "discriminatory effect"). Nor is the "substantially similar" requirement limited to cases in which the parties are allegedly competing—that is simply one way of showing they are substantially similar. *See id.*; *Tracy* 519 U.S. at 299. *Frosh* is inapposite because it is based on extraterritoriality, not discrimination. 887 F.3d at 667–70.

Because S.B.751 treats in-state and out-of-state manufacturers the same, there is no Dormant Commerce Clause violation under the discrimination theory.

4. S.B.751 does not violate Dormant Commerce under *Pike*.

S.B.751 also does not violate the dormant Commerce Clause under Novartis's theory that it excessively burdens interstate commerce in relation to the putative local benefits. App.Br.43. The U.S. Supreme Court lacks a unified theory about what *Pike* balancing requires. Under Eighth Circuit precedent, the excessive-burden theory does not exist.

a. Under Eighth Circuit precedent, the excessive-burden theory does not exist.

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Of the five justices upholding the California law in *Pork Producers*, there was no agreement about whether an older U.S. Supreme Court case, *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), requires a court to "assess whether the burden imposed on interstate commerce by a state law . . . [is] clearly excessive in relation to the putative local benefits" (and, if so, prevent the law's enforcement). *Compare Pork Producers*, 598 U.S. at 377–383 (Gorsuch and Thomas, JJ. stating *Pike* does not require balancing) (cleaned up), *with id.* at 391–93 (Sotomayor and Kagan, JJ., stating *Pike* requires balancing), and *id.* at 393–94 (Barrett, J., stating *Pike* requires balancing, but *Pike* balancing should be overruled). Overall, of the five justices agreeing in the outcome, three voted that *Pike* did not allow judges to strike down state laws based on nothing more than the judges' own assessment of a law's costs and benefits. *Id.*

This Court applies the narrowest judicial opinion when judges who agree in the case outcome do so on various grounds. *Reynolds*, 8 F.4th at 785. The narrowest opinion is the concurring opinion that is a logical subset of the rationale of other court members who agree in the outcome. *Id.*

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In *Pork Producers*, Justice Barrett's concurrence is the narrowest opinion. The justices agreeing in the outcome fractured into three opinions. ***First***, Justices Gorsuch and Thomas upheld the California law because:

(1) the law did not discriminate in favor of in-state interests at the expense of out-of-state interests (this was a necessary factor but conceded), *Pork Producers*, 598 U.S. at 371;

(2) there was no per se rule forbidding enforcement of state laws that have the practical effect of controlling commerce outside the state, 598 U.S. at 371–76;

(3) there **is no** requirement that courts balance the burdens and benefits of a law in *Pike*, *id.* at 377–83; and

(4) even if courts were required to balance burdens and benefits, Plaintiffs failed to allege facts demonstrating a sufficient burden to succeed under their dormant Commerce Clause claim, *id.* at 383–87.

Second, Justices Sotomayor and Kagan upheld the law because:

(1)–(2), of the Justice Gorsuch and Justice Thomas reasoning, above, *id.* at 391 (Sotomayor and Kagan, JJ., concurring);

(3) there **is** a requirement that the courts balance the burdens and benefits of a law, *id.*; and

(4) Plaintiffs failed to demonstrate a sufficient burden, *id.* at 391–93.

Third, Justice Barrett upheld the law because:

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(1)–(2) of Justices Gorsuch, Thomas, Sotomayor, and Kagan's reasoning, *id.* at 393–94 (Barrett, J., concurring); and

(3) there **is no** requirement that courts balance the burdens and benefits of a law, *id.* 393–94.

Justice Barrett's test is the narrowest grounds for upholding the law because her test is a logical subset of both the other tests. *Reynolds*, 8 F.4th at 785. In her view, the only thing courts must address is discrimination against out-of-state interests in favor of in-state ones, *Pork Producers*, 598 U.S. at 393–94 (Barrett, J., concurring), which is something both the other portions of the majority agreed with considering. *Id.* at 371–72 (Gorsuch and Thomas, JJ.); *id.* at 391 (Sotomayor and Kagan, JJ., concurring) (concurring in opinion Part III.A). Justices Sotomayor and Kagan would have required one other requirement (if substantial burden, then balancing test), *see id.* at 393 (Sotomayor and Kagan, JJ., concurring) ("Alleging a substantial burden on interstate commerce is a threshold requirement that plaintiffs must satisfy before courts need even engage in *Pike*'s balancing and tailoring analyses."), that Justices Gorsuch, Thomas, and Barrett would not have required. Thus, under *Reynolds*, this Court need not perform a balancing

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test, meaning that Novartis's *Pike* balancing theory fails as a matter of law. This Court should dismiss on this reason alone.

b. Even if *Pike* balancing applies, Novartis cannot succeed on its Dormant Commerce Clause claim because it has not shown that S.B.751 imposes "substantial burden" on interstate commerce.

Even if this Court applied *Pike* balancing (it should not), Novartis cannot state a claim. Under *Pike*, "a plaintiff [must] plead facts plausibly showing that a challenged law imposes 'substantial burdens' on interstate commerce." 598 U.S. at 383 (Gorsuch and Thomas, JJ.); *see also id.* at 391 (Sotomayor and Kagan, JJ., concurring in part); *id.* at 394 (Barrett, J., concurring in part); *id.* at 395 (Roberts, Alito, Kavanaugh, and Jackson, JJ., concurring in part and dissenting in part). If a plaintiff pleads facts plausibly showing that a challenged law imposes substantial burdens on interstate commerce, the next step is for the court to "assess the law's competing benefits or weigh the two sides against each other." *Pork Producers*, 598 U.S. at 384.

The six justices in *Pork Producers* who believed *Pike* is good law (some of whom did not agree in the case's outcome), characterized "substantial burden" as whether the law would force compliance on

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persons who did not want to access the market in the state with the law. 598 U.S. at 400 (Roberts, C.J., and Alito, Kavanaugh, and Jackson, JJ., concurring in part and dissenting in part) (court must "consider whether, by effectively requiring compliance by [out-of-state persons] who do not even wish to ship their product into [the state with the challenged law], [the challenged law] has a 'nationwide reach' similar to the regulation at issue in *Edgar*," 457 U.S. 624). Here, Novartis did not plausibly allege facts or introduce evidence that it wanted to avoid Missouri markets. Thus, Novartis has not alleged a dormant Commerce Clause violation.

On appeal, Novartis argues that S.B. 751 substantially burdens interstate commerce in two ways: (1) that S.B.751 stratifies the market because drugs sold in Missouri give manufacturers reduced revenues whereas those same drugs can be sold elsewhere for much more money, and (2) a patchwork of laws regarding 340B makes it difficult for Novartis to comply with all of them. App.Br.43–45. Neither are substantial burdens.

The first allegation—stratification—is not a substantial burden. Novartis not make this argument below, meaning that it is waived. *Central Valley*, 986 F.3d at 1090. This also is neither true nor a

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substantial burden. It is not true because S.B.751 does not stratify drugs sold in Missouri from drugs sold outside it. Rather, the 340B statute stratifies 340B drugs from non-340B drugs wherever they are sold. There is no more substantial burden on drugs sold in Missouri from manufacturers outside of it (Novartis) than from manufacturers inside of it (Bayer, Pfizer, GlaxoSmithKline, Mallinckrodt).[9] Novartis cites no case suggesting reduced revenues rise to the level of "substantial burden."

The second allegation—patchwork of laws—does not "substantially burden" interstate commerce. S.B.751 does not force compliance with S.B. 751 on manufacturers who do not wish to access the market in Missouri. Patchwork-of-laws cases that violate the Dormant Commerce Clause are typically "state laws that impose burdens on the arteries of commerce, on trucks, trains, and the like." *Pork Producers*, 598 U.S. at 392 (Sotomayor and Kagan, JJ., concurring in part); *see also id.* at 397–98 (Roberts, C.J., and Alito, Kavanaugh, and Jackson, JJ., concurring in part). Not so here.

[9] *Id.*

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Novartis cites inapposite cases. S.B. 751 is not like the statute in *Frosh*, 887 F.3d at 674, or *Healy v. Beer Institute, Inc.*, 491 U.S. 324, 326 (1989), both of which controlled price. Nor does Novartis explain why it would be difficult for it to provide drugs at the 340B discount to contract pharmacies when the request comes to the manufacturers through wholesalers. App. 28–29; R. Doc. 1, ¶96. Because Novartis does not demonstrate a substantial burden on interstate commerce, S.B.751 is constitutional.

c. Even if Novartis demonstrated "substantial burden" on interstate commerce, it did not demonstrate the burden outweighs the benefits.

Even if Novartis demonstrated a "substantial burden" on interstate commerce (it has not), there is no Dormant Commerce Clause violation unless the "burden on interstate commerce [ ] outweighs any benefits received." *Styczinski*, 46 F.4th at 912. Here, the law's benefits far outweigh any alleged burden on interstate commerce. The benefit of the law is to permit "covered entities" freedom to contract with pharmacies to serve their patients without forfeiting 340B savings. Novartis's one-contract-pharmacy policy undermines the 340B program's benefits by limiting the number of patients who can access the covered entity's

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pharmacy (it may be far from patients) and thereby preventing covered entities from getting 340B prices.

Novartis claims S.B.751 lacks benefits because (1) it directs cash transfers from out-of-state manufacturers to in-state hospitals and clinics; and (2) 340B discounts are retained by covered entities rather than patients. But there is no preference for in-state versus out-of-state entities. All manufacturers are treated the same. And covered entities retaining discounts is well within the purpose of the 340B program. *See supra* Statement of the Case.

Novartis proffered no evidence that the burden on it outweighs benefits of the 340B program. Novartis has not demonstrated that sending 340B drugs to contract pharmacies is even minimally burdensome. Novartis does not handle delivery logistics—its wholesalers and distributors do. App.Br.21–22. Novartis proffers no evidence that its self-inflicted 40-mile policy or its prior, unlimited policy were burdensome. Nor does Novartis explain how much more burdensome S.B. 751's unlimited policy is than the 40-mile policy was, which Novartis apparently thought was reasonable.

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If various 340B delivery rules were a substantial burden on interstate commerce, Congress would regulate delivery. It did not. This explains why drug manufacturers "failed…to persuade Congress to use its express Commerce Clause authority to adopt a uniform rule." *See Pork Producers*, 598 U.S. at 390.

Novartis suggests courts "closely scrutinize" state interests when the statute bears disproportionately on out-of-state residents, citing cases. App.Br.47. But no tiers of scrutiny are required under *Kassel v. Consolidated Freightways Corp. of Delaware*, 450 U.S. 662, 675–76 (1981). *Cloverland-Green Spring Dairies, Inc. v. Pennslyvania Milk Marketing Board* references heightened scrutiny, but it is not an Eighth Circuit or Supreme Court case, and it applies heightened scrutiny only to discrimination cases, which this is not. 298 F.3d 201, 210–11 (3d Cir. 2002). *Minnesota v. Clover Leaf Creamery Co.* is not a Dormant Commerce case. 449 U.S. 456 (1981).

* * *

Because likelihood of success on the merits is required, this Court should affirm the preliminary injunction on this basis alone. *Winter*, 555 U.S. at 20.

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B. This Court should affirm denial of the preliminary injunction based on Dormant Commerce because Novartis has not shown irreparable harm.

Novartis has not demonstrated the second factor required for granting a preliminary injunction—that it will suffer irreparable harm without one. A preliminary injunction requires more than a mere possibility of irreparable harm. *Winter*, 555 U.S. at 22. Plaintiffs must show "that the harm is certain and great and of such imminence that there is a clear and present need for equitable relief." *Morehouse*, 78 F.4th at 1017.

Novartis claims the following irreparable harms: (1) penalties if it is found to have violated the law; and (2) inability to recover 340B discounts given to covered entities for more than one pharmacy if the law is later held unconstitutional. App.Br.57–58.

First, penalties identified by Novartis not irreparable harms. Those penalties are, according to Novartis: (1) civil suit under the Missouri Merchandising Practices Act (MMPA), which Novartis alleges includes potential punitive damages, attorney's fees, and other "equitable relief" under Mo.Rev.Stat. §407.025.1, and (2) criminal liability under Mo.Rev.Stat. §407.020.3–.4. App.Br.57–58. Neither harm was

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mentioned in district court. App. 57; R. Doc. 9, at 14 (arguing criminal penalties under different section, §407.095, and civil penalties under different section, §407.110). Because these arguments were not made below, they are waived. *Central Valley*, 986 F.3d at 1090.

Even if they were not waived, neither alleged injury is likely. *See Winter*, 555 U.S. at 20–21 (requiring *likelihood* of injury). Section 407.025.2 permits punitive damages only in the court's discretion, and there is no reason to believe the court would exercise its discretion against Novartis. Plus, Novartis should be able to assert its constitutionality defenses and, if those defenses are meritorious, Novartis will suffer no harm. Attorney's fees are available to prevailing parties only —so Novartis cannot argue that it will wrongly have to pay attorney's fees. Likewise with equitable relief. If S.B. 751 is unconstitutional, equitable relief will be unavailable.

Nor are monetary penalties generally "irreparable." The very definition of an irreparable harm is harm that cannot be adequately compensated by money damages. *Wildhawk Investments, LLC v. Brava I.P., LLC*, 27 F.4th 587, 597 (8th Cir. 2022). Punitive damages and attorney's fees are money damages. It is Novartis's burden to

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demonstrate why it thinks it cannot recover them back, which Novartis has not done. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (burden of persuasion on movant).

Novartis also is unlikely to be subject to suit under §407.025 because it permits only *persons*, not the State, to file suit: "Any person who purchases or leases merchandise primarily for personal, family, or household purposes and thereby suffers an ascertainable loss of money or property, as a result of the use or employment by another person of a method, act or practice declared unlawful by section 407.020, may bring a private civil action." Novartis does not explain why it is likely that an individual will sue Novartis or how Novartis disobeying S.B. 751 would cause any person to suffer an ascertainable loss of money or property due to that person's purchase of merchandise. Under Novartis's own argument, the drugs would cost the same to the individual purchasing them whether or not they are 340B drugs. App.Br.2 (arguing 340B discounts not passed to patients). Thus, Novartis is unlikely to be irreparably harmed.

Novartis is unlikely to be subject to criminal penalties because they apply only to acts taken "with the intent to defraud." §407.020.3.

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Novartis does not suggest it intends to defraud anyone. Thus, this penalty is unlikely and cannot be the basis for irreparable harm. Novartis cites *Morales v. Trans World Airlines*, but that case stands for the proposition that irreparable harm exists when "state officers…threaten and are about to commence proceedings," which is not the case here. 504 U.S. 374, 382 (1992) (cleaned up).

Second, Novartis will not be irreparably harmed by its alleged inability to recover 340B discounts to covered entities using more than one pharmacy if S.B. 751 is later deemed unconstitutional. Like any entity, Novartis could bake recovery terms into its contracts with covered entities. *See Novartis*, 102 F.4th at 461 (referencing "manufacturers, in their contracts with covered entities"). If Novartis cannot contract for recovery, it may have an unjust enrichment claim. Plus, Novartis can recover for wrongful discounts under the 340B statute. 42 U.S.C. §256b(d)(3)(A), (d)(3)(B)(i). Thus, Novartis is not irreparably harmed.

Even if Novartis could not recover wrongfully distributed 340B discounts, this alleged "harm" is not "irreparable" because the federal 340B program requires such discounts be given to covered entities. *Id.* §256b(a)(1).

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C. Balance of the equities favors denying injunction.

The balance of the equities favors affirming the denial of the injunction because (1) Novartis asks this Court to prevent the State from enforcing a duly enacted state law; (2) Novartis has not alleged irreparable harm, *see supra* Part III.B; (3) a preliminary injunction would be against the public interest, *see infra* Part III.D; and (4) Novartis has acted opportunistically and undermined a federal program developed to help institutions that serve disadvantaged populations.

Until recently, Novartis voluntarily provided 340B drugs to contract pharmacies within 40 miles of covered entities. App. 14; R. Doc. 1, at ¶45. Novartis does not allege this setup was difficult. Before that, Novartis provided 340B drugs to even more contract pharmacies. Only very recently did Novartis start limiting contract pharmacy deliveries. App. 17–18; R. Doc. 1, at ¶54. Because Novartis has until recently had a voluntary contract-pharmacy policy similar to S.B.751's, the balance of the equities favor denying the preliminary injunction.

D. A preliminary injunction is contrary to the public interest.

The public has an interest in permitting the State to enforce laws passed by the legislature. *Rounds*, 530 F.3d 724 ("governmental

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action...pursuant to…statutory or regulatory scheme" is "in…public interest" and higher standard applies for preliminarily enjoining such action). As noted in Parts III.A, *supra*, and IV.A, *infra*, S.B.751 is constitutional. Until recently, Novartis delivered 340B drugs to many more contract pharmacies, meaning that covered entities were receiving far more discounts. Covered entities serve disadvantaged populations. 42 U.S.C. §256b(a)(4). And the federal 340B program exists to help covered entities. *Id.* To better implement the 340B program, this Court should deny the preliminary injunction.

IV. The district court correctly denied the motion to preliminarily enjoin S.B.751 based on Novartis's Preemption Claims.

If this Court does not dismiss the preemption claims for lack of jurisdiction, this Court should affirm the district court's denial of Novartis's motion for preliminary injunction based on preemption for four independent reasons: (1) Novartis is unlikely to succeed on the merits; (2) Novartis is unlikely to suffer irreparable harm without preliminary relief; (3) the balance of equities favors the State; and (4) an injunction is not in the public interest.

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A. Novartis is unlikely to succeed on the merits.

Likelihood of success on the merits is required for preliminary injunctions. *Rounds*, 530 F.3d at 731–32. Novartis claims it succeeds on the merits of preemption under three theories: (1) "obstacle," (2) field, and (3) "enforcement" preemption. App.Br.48–55. Not so. Novartis admits the field and "enforcement" preemption claims lose under *McClain*. App.Br.52. *McClain* also governs its remaining "obstacle preemption" claim. Novartis also loses based on first principles.

1. Novartis's "obstacle preemption" theory was presented in *McClain*.

To evade *McClain*, Novartis claims this case presents a new theory of obstacle preemption. App.Br.51. This "new" theory is "[t]hat S.B. 751 is obstacle preempted because it requires manufacturers to recognize an *unlimited* number of contract pharmacies." App.Br.51–52. This is not new. In *McClain*, PhRMA argued "that the state-law obligation to deliver 340B-discounted drugs to an unlimited number of pharmacies with no constraints destroys the closed system Congress painstakingly created to limit manufacturer subsidies to intended beneficiaries." PhRMA *McClain* Br., 2023 WL 2337833, at *22–23. This is the same conflict alleged here: state laws requiring delivery of 340B drugs to contract

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pharmacies an obstacle to the 340B statute. *McClain* rejected that argument: "[D]elivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle." 95 F.4th at 1145.

Nor was *McClain*'s ruling somehow solely based on the narrow argument that the 340B statute forbids delivery to *any* contract pharmacies. App.Br.51. Rather, PhRMA clarified that many of its members allowed delivery to some contract pharmacies. *PhRMA McClain Brief*, 2023 WL 2337833, *14; Dec. of C.Drain, *PhRMA v. McClain*, No.4:21-cv-864, p.284, ¶50; (E.D.Ark. Aug. 6, 2022), Dkt. No. 24-1 (AstraZeneca contract-pharmacy policy allowing one contract pharmacy).

Finally, even if small differences exist between Novartis's argument and the *McClain* argument, the district court did not abuse its discretion by determining Novartis was *unlikely* to win on the merits.

2. Novartis's obstacle preemption theory fails because it distorts *Sanofi* and *Novartis*.

Even putting *McClain* aside, Novartis's preemption theory fails because it is based on a misreading of *Novartis* and *Sanofi*. App.Br.48–50. Novartis repeatedly argues those decisions hold that the 340B statute gives manufacturers a "right to limit delivery to one contract

pharmacy," and S.B.751 "frustrates" that right. *Id.* (citation modified). That argument stretches *Novartis* and *Sanofi* too far. Those cases held that 340B is *silent* about delivery conditions—not that it *affirmatively* gives manufacturers a *right* to impose conditions against state and local governments. *Sanofi*, 58 F.4th at 703; *Novartis*, 102 F.4th at 460. Both States and manufacturers can act in that silence.

Novartis also is wrong about the requirements for obstacle preemption. "The mere fact that state laws like" S.B.751 "overlap to some degree with federal" law "does not even begin to make a case for conflict preemption." *Kansas v. Garcia*, 589 U.S. 191, 211 (2020). S.B.751 "assists in fulfilling the purpose of 340B" by enabling "covered entities dependent on contract pharmacies to" continue to "serve patients in need." *McClain*, 95 F.4th at 1139, 1145. But even if S.B.751 did not accomplish this purpose, the "mere fact that" contract-pharmacy delivery laws "may impose a modest impediment" on some aspect of the 340B program "does not provide a sufficient basis for pre-emption of the entire" statute. *PhRMA v. Walsh*, 538 U.S. 644, 667 (2003).

"[T]here [also] is a 'presumption that state or local regulation of matters related to health and safety is not invalidated under the

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Supremacy Clause.'" *McClain*, 95 F.4th at 1140. That is especially true for "the practice of pharmacy" because Congress has "traditionally regarded state law as a complementary form of drug regulation and has long maintained that state law offers an additional, and important, layer of consumer protection that complements federal regulation." *Id*. at 1143 (citation modified). Novartis cannot show that Congress had "clear and manifest" intent to preempt S.B.751 when 340B is "silent about delivery" and "does not mention pharmacies or the delivery of drugs by pharmacies to patients." *Id*. at 1440, 1442.

None of Novartis's cases show otherwise. Unlike in *Geier v. American Honda Motor Co.*, here there is no evidence that Congress specifically intended manufacturers to have a mix of options and to choose to have some of each option. 529 U.S. 861, 881 (2000). And *Medtronic, Inc. v. Lohr* supports the State, not Novartis, because it held that despite language expressly preventing states from establishing requirements different from the federal law relating to safety or effectiveness for medical devices, common-law tort causes of action were not preempted. 518 U.S. 470, 486–87 (1996).

3. *McClain* was rightly decided.

Novartis admits its field and "enforcement" preemption arguments "are foreclosed under *McClain*" but raises them to preserve them. App.Br.52. Nothing warrants reconsidering *McClain*, which is not even 18 months old. Every development proves *McClain* is right. *McClain*, 2024 WL 1919676 (8th Cir. May 2, 2024) (denying en banc petition); *McClain*, 145 S. Ct. 768 (2024) (denying petition for certiorari). Nearly every other court has followed *McClain*'s lead, rejecting preemption arguments. *See AbbVie Inc. v. Skrmetti*, 2025 WL 1805271 (M.D.Tenn. June 30, 2025); *Astrazenca Pharms. LP v. Bailey*, 2025 WL 644285 (W.D.Mo. Feb. 27, 2025); *PhRMA v. Bailey*, 2025 WL 644281 (W.D.Mo. Feb. 27, 2025); *PhRMA v. Murrill*, 2024 WL 4361597 (W.D.La. Sept. 30, 2024); *AstraZeneca Pharms. LP v. Fitch*, 766 F.Supp.3d 657 (S.D.Miss. 2024); *Novartis Pharms. Corp. v. Fitch*, 738 F.Supp.3d 737, 748 (S.D.Miss. 2024); *AbbVie Inc. v. Fitch*, 2024 WL 3503965 (S.D.Miss. July 22, 2024); *PhRMA v. Fitch*, 2024 WL 3277365 (S.D.Miss. July 1, 2024).

Novartis's arguments for overturning *McClain* fail. As here, PhRMA's petitions for rehearing and certiorari in *McClain* claimed field preemption because Congress "exclusively occup[ied] the entire field of

340B transactions." App.Br.52; *see also* PhRMA Petition for Writ of Certiorari, *PhRMA v. McClain*, No. 24-118, 2024 WL 3654711, at *34 (U.S. July 31, 2024); Petition for Rehearing, *McClain*, No. 22-3675, *1 (8th Cir. Apr. 9, 2024). *McClain* correctly rejected field preemption because "the text of 340B 'is silent about delivery' of drugs to patients" and "Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field." 95 F.4th at 1143. *Sanofi* and *Novartis* confirm *McClain*'s reading. *Sanofi*, 58 F.4th at 707; *Novartis*, 102 F.4th at 460.

Novartis's "enforcement preemption" argument likewise fails. App.Br.53–55. Novartis argues that the "340B statute creates exclusive enforcement mechanisms, and *McClain*'s contrary holding runs afoul of *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011)." *Id.* at 53. PhRMA raised—and lost—this argument three times in *McClain*. PhRMA *McClain* Br. at 24, 2023 WL 2337833 ("Act 1103 is…strikingly similar to the common-law enforcement attempt the Supreme Court held…impermissible in *Astra*."); *McClain* Cert. Petition, 2024 WL 3654711, at *28–30; *McClain* Rehearing Petition, No.22-3675 at *8–15. Other courts agree *Astra* has "minimal bearing" on the issues in this case.

Novartis, 738 F.Supp.3d at 752; *PhRMA*, 2024 WL 4361597, *7 (W.D.La. Sept. 30, 2024) ("Plaintiffs misread…*Astra*.").

Nor is S.B.751 preempted by 42 U.S.C. §256b(d)(1)(A) or (d)(2)(B)(iv). Novartis argues these provisions preempt S.B.751 because the HHS Secretary is charged with compliance improvements for ordering, purchasing, and delivery. That is a mischaracterization. Section 256b(d)(1)(A) provides that the HHS Secretary shall provide for improvements in compliance by manufacturers to prevent *pricing violations*, and (d)(2)(B)(iv) is about identification systems by which a covered entity can be identified by manufacturers. Neither *Hines v. Davidowitz*, 312 U.S. 52 (1941), nor *American Insurance Association v. Garamendi*, 539 U.S. 396 (2003), require the opposite result. *Davidowitz* is about a distinctly national interest—aliens (read: foreigners)—whereas pharmacy is a health-and-safety interest often regulated by states. 312 U.S. 52. *Garamendi* describes how foreign-relations power tends to preempt state law. 539 U.S. 396, 419 n.11. Novartis claims that *Boyle v. United Technologies Corporation*, 487 U.S. 500 (1988), and *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) remove the presumption against preemption because the 340B program

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represents uniquely federal interests. Those cases state that uniquely federal interests favor preemption, but they do not turn pharmacy into a uniquely federal interest. *Boyle*, 487 U.S. at 504–05 (uniquely federal interests include obligations and rights of U.S. under its contracts and civil liability of federal officials); *Buckman*, 531 U.S. at 347–48 (fraud claim preempted by federal statute empowering FDA to punish fraud, but traditional health/safety matters retain presumption against preemption).

Courts do "not overturn…precedent lightly." *Michigan v. Bay Mills Indian Cmty.*, 572 U.S. 782, 798 (2014). "*Stare decisis* is the preferred course because it promotes the evenhanded, predictable, and consistent development of legal principles, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process." *Payne v. Tennessee*, 501 U.S. 808, 827 (1991). Novartis's arguments do not provide the "special justification" that "departure" from *stare decisis* "demands." *Arizona v. Rumsey*, 467 U.S. 203, 212 (1984).

Because likelihood of success on the merits is required, this Court should deny the preliminary injunction on this basis alone. *Winter*, 555 U.S. at 20.

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* * *

B. Novartis's preliminary injunction fails on the equities.

Novartis also fails to demonstrate the three equitable factors for a preliminary injunction on the basis of preemption for the reasons discussed in Parts III.B–D.

CONCLUSION

This Court should affirm the district court's denial of a preliminary injunction.

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I hereby certify that this document complies with the type-volume limits of Fed. R. App. P. 32(a)(7)(B)(i) in that it contains 12,825 words excluding the parts exempted by Fed. R. App. P. 32(f). I further certify that this document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) in that this document has been prepared in a proportionally spaced typeface using Microsoft Word (size 14 Century Schoolbook font). This brief has been scanned for viruses and is virus free.

/s/ *J. Patrick Sullivan*

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I hereby certify that a true and correct copy of the foregoing was electronically filed by using the CM/ECF system. Counsel for Appellee will receive a copy of the foregoing document through the CM/ECF system on August 15, 2025.

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