United States Court of Appeals
For the Eighth Circuit

No. 25-1619

Novartis Pharmaceuticals Corporation

Plaintiff - Appellant

v.

Catherine L. Hanaway, in her official capacity as Attorney General of the State 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, 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; Darren Harris, in his official capacity as a member of the Missouri Board of Pharmacy

Defendants - Appellees

Missouri Hospital Association; Missouri Primary Care Association

Intervenors - Appellees

American Hospital Association; 340B Health; American Society of Health-System Pharmacists

Amici on Behalf of Appellee(s)

Appeal from United States District Court
for the Western District of Missouri - Jefferson City

Submitted: January 15, 2026
Filed: July 1, 2026

Before LAVENSKI R. SMITH, BENTON, and ERICKSON, Circuit Judges.

ERICKSON, Circuit Judge.

Section 340B of the Public Health Service Act ("Section 340B" or the "340B Program") requires pharmaceutical drug manufacturers participating in federal drug reimbursement markets to offer covered outpatient drugs ("340B drugs") to certain health care providers, called "covered entities," at a discounted price. Covered entities often partner with third-party pharmacies, called "contract pharmacies," to distribute these medications to their patients. As the number of contract pharmacies has grown and the volume of medication distributed through the 340B Program has increased, drug manufacturers have sought to restrict the number of contract pharmacies authorized to distribute 340B drugs on behalf of covered entities.

In response, several states have passed legislation preventing drug manufacturers from imposing these restrictions. At issue in this case is Missouri Senate Bill 751 ("S.B. 751"), which prohibits drug manufacturers from restricting the delivery of 340B drugs to contract pharmacies that have partnered with a Missouri covered entity to distribute medication on the covered entity's behalf. Novartis Pharmaceuticals Corporation ("Novartis"), one of the world's largest prescription drug manufacturers and a participant in the 340B Program, challenged the constitutionality of S.B. 751 alleging dormant Commerce Clause and preemption

claims. Novartis seeks both declaratory and injunctive relief. The district court[1] denied Novartis's motion for a preliminary injunction, concluding Novartis had not shown a likelihood of success on the merits of its claims, had not shown it would suffer irreparable harm without an injunction, and that the balance of equities and the public interest weighed against preliminary relief. Having jurisdiction to review the denial of a preliminary injunction under 28 U.S.C. § 1292(a)(1), we affirm.

I. BACKGROUND

In 1992, Congress amended the Public Health Service Act to create the 340B Drug Pricing Program. See Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (codified at 42 U.S.C. § 256b). Section 340B requires drug manufacturers to offer discounts on covered outpatient drugs to specified health care providers as a condition of the manufacturers' participation in Medicaid and Medicare Part B. 42 U.S.C. §§ 256b(a); 1396r-8(a)(1), (5). These "covered entities" include fifteen types of hospitals and health care centers, many of which provide safety-net services to low-income patients. Id. § 256b(a)(4).

Drug manufacturers' participation in the 340B Program is voluntary. To opt into the program, manufacturers enter a Pharmaceutical Pricing Agreement with the Department of Health and Human Services ("HHS") that sets out both parties' obligations under the program. Manufacturers participating in the 340B Program must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." Id. § 256b(a)(1); see also 42 C.F.R. § 10.10(a) (ceiling price formula). While the actual price of 340B drugs varies based on the pricing formula, covered entities may be able to obtain medication through the 340B Program for as little as $0.01. See 42 C.F.R. § 10.10(b) (setting the ceiling price at $0.01 when the formula results in a price less than $0.01). In exchange for offering 340B drugs to covered

[1]The Honorable M. Douglas Harpool, United States District Judge for the Western District of Missouri.

entities at these steep discounts, drug manufacturers receive access to lucrative Medicare and Medicaid markets. See 42 U.S.C. § 1396r-8(a)(1), (5).

Covered entities face several restrictions on medication purchased through the 340B Program. Because covered entities purchase 340B drugs at the discounted ceiling price, they are prohibited from requesting duplicate discounts or rebates for the same drugs through Medicaid or Medicare Part B. Id. § 256b(a)(5)(A). Covered entities are also prohibited from distributing 340B drugs to any person who is not a patient of the covered entity. Id. § 256b(a)(5)(B). Both HHS and drug manufacturers have the right to audit covered entities' compliance with Section 340B, and covered entities are subject to penalties for violating the program's prohibitions on duplicate discounts and drug diversion. Id. § 256b(a)(5)(C)-(D). When disputes related to covered entities' compliance with Section 340B arise, parties are required to use HHS' alternative dispute resolution procedures before initiating litigation. Id. § 256b(d)(3); see also 42 C.F.R. §§ 10.20-24. HHS may also take direct enforcement action against covered entities that violate Section 340B. 42 U.S.C. § 256b(d)(2)(b)(v).

Even though covered entities can obtain large quantities of 340B drugs at little cost, covered entities are not required to pass the discounts on to patients through free or subsidized medication. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996). Instead, Congress envisioned that covered entities would use 340B savings "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (102nd Cong., 2d Sess. 1992). Following Congress's lead, many covered entities use the excess revenues from the 340B Program to finance their operations and expand services. See U.S. Gov't Accountability Off., Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement at 17-18 (Sept. 23, 2011) (describing how covered entities use excess 340B revenue to expand services or maintain services that might otherwise be cut).

When Section 340B was enacted, less than five percent of covered entities had in-house pharmacies capable of distributing medication to patients. 61 Fed. Reg. at 43,550. To ensure these covered entities were still allowed to participate in the 340B Program, HHS allowed covered entities to partner with third-party contract pharmacies to distribute 340B drugs on the covered entity's behalf. See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994) (permitting covered entities to use "purchasing agents"). When a covered entity partners with a contract pharmacy to distribute 340B drugs, the contract pharmacy acts as an agent of the covered entity. See 61 Fed. Reg. at 43,554. The covered entity purchases the medication from the manufacturer and directs that the medication be delivered to the pharmacy. See id. at 43,553. Contract pharmacies do not purchase the medication and title to the medication remains with the covered entity. See id. at 43,552.

Recognizing that Section 340B is "silent as to permissible drug distribution systems," the Health Resources and Services Administration ("HRSA") issued guidance in 1996 allowing covered entities without an in-house pharmacy to partner with a single contract pharmacy.[2] Id. at 43,549, 43,555. The 1996 guidance was intended to allow covered entities with an in-house pharmacy to distribute 340B drugs through either their in-house pharmacy or a contract pharmacy, but not both. Id. at 53,555. But in 2010, HRSA changed course and issued updated guidance allowing covered entities without in-house pharmacies to partner with an unlimited number of contract pharmacies. See Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010). The 2010 guidance also allowed covered entities with in-house pharmacies to distribute 340B drugs through both their in-house pharmacy and an unlimited number of contract pharmacies. Id.

[2]The Health Resources and Services Administration is the unit within the Department of Health and Human Services responsible for administering the 340B Program.

After the issuance of the 2010 guidance, covered entities saw a significant arbitrage opportunity. Without the single-contract-pharmacy restriction, covered entities could partner with multiple contract pharmacies without regard to geographic proximity and maximize their distribution of 340B drugs. By increasing the volume of 340B drugs purchased at the ceiling price and sold to patients at full retail price, covered entities could maximize the profits available through the 340B Program. As a result, the number of contract pharmacies grew rapidly. See U.S. Gov't Accountability Off., 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement at 2 (Jan. 21, 2020) ("[T]he number of contract pharmacies increased from about 1,300 at the beginning of 2010 to around 23,000 in 2019.").

The expansion of contract pharmacies led to a corresponding rise in demand for drugs acquired through the 340B Program. Because manufacturers are required to offer 340B drugs to covered entities at the discounted ceiling price, the rise in demand for 340B drugs led to a proportional reduction in manufacturer profits. In 2022, for example, drug manufacturers sold $53.7 billion in 340B drugs to covered entities at the ceiling price, but those same drugs carried a market value of $106 billion. Adam J. Fein, EXCLUSIVE: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021, Drug Channels (Sept. 24, 2023), https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html. Covered entities and contract pharmacies, on the other hand, reap the financial gains by charging patients or their insurance the full retail price.

Even so, covered entities and contract pharmacies must take care that they do not divert drugs purchased at the ceiling price to anyone who is not a patient of a covered entity. See 42 U.S.C. § 256b(a)(5)(B). But because pharmacies dispense the same medications to patients of covered entities and patients of non-covered entities, pharmacies often lack the ability to determine whether a particular patient's medication was purchased at the ceiling price. To maintain compliance with drug diversion laws, pharmacies typically fill each prescription with medication from their general drug inventory and use a *post hoc* analysis to determine how many

drugs were dispensed to patients of covered entities. Pharmacies then replenish their inventory with the same quantity of drugs purchased by covered entities at the ceiling price.

Worried that this "replenishment model" was resulting in covered entities claiming more discounts than they were entitled, drug manufacturers began restricting covered entities' use of contract pharmacies. For its part, Novartis adopted a policy whereunder it would only deliver its medications to a covered entity's in-house pharmacy or a single outside contract pharmacy.[3] HHS responded by issuing an advisory opinion stating that "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." Dep't of Health & Hum. Servs., Off. Gen. Couns., Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program at 1 (Dec. 30, 2020). HHS explained that manufacturers' policies ignored the principal-agent relationship between covered entities and contract pharmacies and would "foreclose discounts to the neediest" covered entities in a manner "inconsistent with [the] purpose of the Program and common sense." Id. at 4.

Acting on the advisory opinion, HHS sent violation letters to manufacturers that had implemented policies restricting the use of contract pharmacies advising that such policies violated federal law. Drug manufacturers, including Novartis, subsequently sued to enjoin the advisory opinion. The Third Circuit sided with drug manufacturers, saying that because no language in Section 340B requires manufacturers to recognize an unlimited number of contract pharmacies, manufacturers' restrictions did not violate the federal statute. Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs., 58 F.4th 696, 704 (3d Cir. 2023). The D.C. Circuit also agreed with the drug manufacturers, holding that Section 340B's

[3]Novartis initially established a policy restricting delivery of its medications to contract pharmacies located within 40 miles of a covered entity but later abandoned that policy in favor of a single contract pharmacy restriction.

silence as to the delivery of medications "preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." Novartis Pharms. Corp. v. Johnson, 102 F.4th 452, 460 (D.C. Cir. 2024). Ultimately, HHS withdrew the advisory opinion. See Dep't of Health & Hum. Servs., Off. Gen. Couns., Withdrawing Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Issued Dec. 30, 2020) at 1 (June 18, 2021).[4]

After HHS withdrew its advisory opinion, many states sought to protect covered entities' ability to partner with multiple contract pharmacies. To date, 22 states have passed laws prohibiting manufacturers from limiting or restricting the delivery of 340B drugs to contract pharmacies partnering with a covered entity.[5] Missouri S.B. 751 is one such law. S.B. 751 provides:

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[4]Novartis asks the Court to take judicial notice of a June 9, 2025, HRSA decision regarding ADR ID 230925-17, in which HRSA concluded that Section 340B does not prevent drug manufacturers from imposing conditions on the delivery of 340B drugs to contract pharmacies. Novartis contends judicial notice of the administrative decision is appropriate because the decision is part of the public record, but a summary of the decision was not posted to HRSA's website within 120 days of issuance. See 89 Fed. Reg. 28,643, 28,654 (Apr. 19, 2024). Since Novartis filed its motion for judicial notice, HRSA published a summary of its June 9, 2025, decision. See Health Resources & Servs. Admin., 340B ADR Decision Summaries, https://www.hrsa.gov/opa/340b-administrative-dispute-resolution/340b-adr-decision-summaries (last updated May 6, 2026). Because the HRSA decision has been published as required by regulation, we deny Novartis's motion for judicial notice as moot.

[5]These 22 States are: Arkansas (Ark. Code Ann. § 23-92-604(c)); Colorado (Colo. Rev. Stat. § 6-29-105(1)(a)); Hawaii (Haw. Rev. Stat. § 481N-2(a)); Illinois (H.B. 2371 (104th Gen. Assemb. 2026)); Louisiana (La. Stat. Ann. § 40:2884(A)); Maine (Me. Stat. tit. 24-A, § 7753(1)); Maryland (Md. Code Ann., Health Occ. § 12-6C-09.1(c)(1)); Minnesota (Minn. Stat. § 62J.96(1)); Mississippi (Miss. Code Ann. § 41-149-7(1)); Missouri (Mo. Rev. Stat. 376.414.2); Nebraska (Neb. Rev. Stat. § 44-4620(1)); New Mexico (N.M. Stat. Ann. § 26-1-27(B)(1)); North Dakota (N.D. Cent. Code § 43-15.3-08(3)(b)(1)); Oklahoma (Okla. Stat. tit. 36, § 5403(A)); Oregon (Or. Rev. Stat. § 689.818(2)(a)); Rhode Island (5 R.I. Gen. Laws § 5-19.3-5(a)); South Dakota (S.D. Codified Laws § 58-29G-2); Tennessee (Tenn. Code Ann.

> A pharmaceutical manufacturer, third-party logistics provider, or an agent or affiliate of such pharmaceutical manufacturer or third-party logistics provider, 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. S.B. 751 (102nd Gen. Assemb. 2024) (codified at Mo. Rev. Stat. § 376.414.2). A violation of S.B. 751 constitutes an unlawful trade practice under the Missouri Merchandising Practices Act. See Mo. Rev. Stat. § 376.414.3.

Simply put, S.B. 751 requires that drug manufacturers participating in the 340B Program deliver 340B drugs to all of a Missouri covered entity's contract pharmacies, even if the manufacturer has policies limiting covered entities to a single contract pharmacy. This requirement conflicts with Novartis's current policy restricting the delivery of 340B drugs to a covered entity's in-house pharmacy or a single contract pharmacy designated by the covered entity.

In August 2024, Novartis sued the Missouri Attorney General and the individual members of the Missouri Board of Pharmacy, alleging that S.B. 751 is preempted by federal patent and drug exclusivity laws, preempted by the federal 340B statutory scheme, and violative of the dormant Commerce Clause of the U.S. Constitution. Novartis sought declaratory and both preliminary and permanent injunctive relief.

The Defendants moved to dismiss the Complaint under Federal Rule of Civil Procedure 12(b)(6), arguing that Novartis failed to state a claim on all counts. The district court granted the motion in part and dismissed Novartis's preemption claims.

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§ 47-18-136(c)); Utah (Utah Code Ann. § 31A-46-311(2)(a)); Vermont (Vt. Stat. Ann. tit. 18, § 4682(a)); Washington (2026 Wash. Sess. Laws Ch. 227, § 3(1)); and West Virginia (W. Va. Code § 60A-8-6a(b)(1)).

The court concluded that S.B. 751 does not conflict with federal drug and patent exclusivity laws or the federal 340B statutory scheme, and that Eighth Circuit precedent foreclosed Novartis's field preemption claim. The court denied the motion to dismiss Novartis's dormant Commerce Clause claim, finding that Novartis had plausibly alleged S.B. 751 discriminates against out-of-state entities and places an undue burden on interstate commerce.

The district court denied Novartis's motion for a preliminary injunction, concluding that Novartis is unlikely to prevail on the merits of its dormant Commerce Clause claim. The court also analyzed the field and conflict preemption claims it had dismissed and concluded that, even if the preemption claims had survived the motion to dismiss, Novartis had not shown a likelihood of success on the merits of those claims. The district court also found that Novartis had not made the required showing of irreparable harm, and that the balance of equities and the public interest weighed against preliminary relief.

II. DISCUSSION[6]

Novartis contends the district court erred by concluding that Novartis is unlikely to prevail on the merits of its dormant Commerce Clause and preemption claims, and that the other preliminary injunction factors do not support preliminary relief. "We review the district court's denial of a motion for a preliminary injunction

[6]Appellees assert Novartis is challenging 340B's replenishment model, not S.B. 751, and thus failed to allege a sufficient injury for Article III standing. See Lujan v. Defs. of Wildlife, 504 U.S. 555, 560-61 (1992) (identifying Article III standing requirements). To the contrary, Novartis challenges a statute prohibiting it from restricting delivery of 340B drugs to contract pharmacies, thereby preventing it from limiting the number of contract pharmacies in Missouri. Because Novartis alleges this restriction will cause financial loss, Novartis has standing. See FDA v. All. for Hippocratic Med., 602 U.S. 367, 382 (2024) ("Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish.").

under the deferential abuse of discretion standard, with the underlying factual findings examined for clear error and legal conclusions considered *de novo*." Lindell v. United States, 82 F.4th 614, 618 (8th Cir. 2023). When deciding whether to grant preliminary relief, courts consider the four factors set forth in Dataphase Systems, Inc. v. C L Systems, Inc., 640 F.2d 109 (8th Cir. 1981): "(1) the threat of irreparable harm to the movant; (2) the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that [the] movant will succeed on the merits; and (4) the public interest." Id. at 114. "While no single factor is determinative, the probability of success factor is the most significant." Home Instead, Inc. v. Florance, 721 F.3d 494, 497 (8th Cir. 2013) (citation modified).

A. Dormant Commerce Clause Claim

Novartis contends the district court erred when it concluded Novartis is unlikely to prevail on the merits of its dormant Commerce Clause challenge. The Commerce Clause grants to Congress the sole authority to regulate commerce "among the several states." U.S. Const. art. I, § 8, cl. 3. "The dormant Commerce Clause is the negative implication of the Commerce Clause: states may not enact laws that discriminate against . . . interstate commerce." S.D. Farm Bureau, Inc. v. Hazeltine, 340 F.3d 583, 592 (8th Cir. 2003). State laws that "directly control[] commerce occurring wholly outside the boundaries of a State" are likewise prohibited by the dormant Commerce Clause. Healy v. Beer Inst., Inc., 491 U.S. 324, 336 (1989). Even if a state law has only incidental effects on interstate commerce, the law still violates the dormant Commerce Clause if the burdens on commerce are "clearly excessive in relation to the putative local benefits." Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

1. Extraterritoriality

Novartis first argues that S.B. 751 violates the dormant Commerce Clause because it regulates wholly out-of-state transactions. "The Commerce Clause . . .

precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." Edgar v. MITE Corp., 457 U.S. 624, 642-43 (1982). "[A] statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." Healy, 491 U.S. at 336. Even so, states may enact laws that have the practical effect of regulating out-of-state transactions if those laws have only incidental effects on interstate commerce. See Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 373-76 (2023).

Novartis contends that S.B. 751 violates the dormant Commerce Clause by regulating out-of-state transactions between Novartis and its wholesalers who, in turn, sell 340B drugs to covered entities in Missouri. This interpretation misreads the statute. S.B. 751 does not purport to regulate transactions between drug manufacturers and their wholesalers; rather, it regulates only the delivery of 340B drugs to contract pharmacies that have partnered with a Missouri covered entity. Even assuming S.B. 751 has some incidental effect on out-of-state transactions, "[i]n our interconnected national marketplace, many (maybe most) state laws have the 'practical effect of controlling' extraterritorial behavior" without violating the Commerce Clause. Id. at 374.

Given S.B. 751's merely incidental effects on extraterritorial transactions, it is distinguishable from the laws invalidated in Styczinski v. Arnold, 46 F.4th 907 (8th Cir. 2022) and Association for Accessible Medicines v. Frosh, 887 F.3d 664 (4th Cir. 2018). In Styczinski, this Court held that a Minnesota statute violated the dormant Commerce Clause because it regulated transactions with Minnesota residents that occurred anywhere in the world, even when the transactions took place entirely outside of Minnesota or involved companies that had never conducted business in the state. 46 F.4th at 913. Similarly, in Frosh, the Fourth Circuit held that a Maryland law regulating the wholesale pricing of prescription medications controlled entirely extraterritorial conduct because the law specifically targeted upstream transactions between manufacturers and wholesalers even when those

drugs were not later sold or delivered to Maryland consumers. 887 F.3d at 671-72. Because S.B. 751 applies only to the delivery of 340B drugs to covered entities and contract pharmacies located in Missouri and does not target out-of-state transactions between drug manufacturers and wholesalers, the extraterritoriality concerns in Styczinski and Frosh are not present here.

Instead, S.B. 751 resembles the law upheld in Pork Producers. There, California enacted a statute "banning the in-state sale of certain pork products derived from breeding pigs confined in stalls so small they cannot lie down, stand up, or turn around" even if those pork products were raised and processed outside of California. 598 U.S. at 363. When out-of-state pork producers challenged the law under the dormant Commerce Clause, the Supreme Court concluded that even though the law had some effects on out-of-state conduct, it did not violate the dormant Commerce Clause because it did not have a specific impermissible extraterritorial effect. Id. at 374. Accordingly, the Court held that the statute was a permissible exercise of California's "legislative power . . . to act upon persons and property within the limits of its own territory." Id. at 375.

S.B. 751 operates in a similar manner. While S.B. 751 may incidentally bear on out-of-state transactions, it does not have a specific impermissible extraterritorial effect and directly regulates only the delivery of 340B drugs to covered entities and their contract pharmacies. Because S.B. 751 is consistent with Missouri's power to regulate conduct occurring within its borders, Novartis is not likely to prevail on the merits of its extraterritoriality challenge.

2. Discrimination Against Interstate Commerce

Next, Novartis argues that S.B. 751 violates the dormant Commerce Clause because it discriminates against interstate commerce. A state law impermissibly discriminates against interstate commerce when it provides "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." Jones v. Gale, 470 F.3d 1261, 1267 (8th Cir. 2006) (citing Or. Waste

Sys., Inc. v. Dep't of Env't Quality of State of Or., 511 U.S. 93, 99 (1994)). A law violates the dormant Commerce Clause "if it is discriminatory on its face, if it has a discriminatory purpose, or if it has a discriminatory effect." Id.

S.B. 751 does not facially discriminate against interstate commerce because it does not refer to in-state or out-of-state manufacturers or otherwise indicate a preference for in-state entities. Compare Mo. Rev. Stat. § 376.414.2 (applying equally to all pharmaceutical manufacturers, their agents, and affiliates) with Healy, 491 U.S. at 341 (invalidating statute that "applies solely to interstate brewers or shippers of beer" and not to "brewers and shippers engaging in solely domestic sales"). Instead, Novartis argues that because no drug manufacturers have a physical presence in Missouri, the entire burden of S.B. 751 falls on out-of-state commerce. We disagree. Because Missouri's entire prescription drug supply comes from out-of-state, "such claims of disparate treatment between interstate and local commerce [are] meritless." Exxon Corp. v. Governor of Md., 437 U.S. 117, 125 (1978) (holding that a Maryland law prohibiting fuel producers and refiners from operating retail service stations did not discriminate against interstate commerce when there were no producers or refiners of gasoline within the state). Without a demonstrated preference for in-state entities at the expense of out-of-state entities, Novartis fails to show a likelihood of success on its discrimination claim.

Novartis attempts to avoid this conclusion by arguing that S.B. 751 favors in-state hospitals and pharmacies at the expense of out-of-state drug manufacturers. According to Novartis, this discrimination is sufficient to establish a constitutional violation. This argument misapplies the comparison required under the dormant Commerce Clause. A "fundamental element" of the dormant Commerce Clause is that "any notion of discrimination assumes a comparison of substantially similar entities." Dep't of Revenue of Ky. v. Davis, 553 U.S. 328, 342 (2008). Drug manufacturers, hospitals, and pharmacies, while all part of an interconnected healthcare system, are not substantially similar such that they can be said to operate in economic competition with one another. See Pharm. Rsch. & Mfrs. of Am. v. Cnty. of Alameda, 768 F.3d 1037, 1042 n.1 (9th Cir. 2014) (saying an ordinance

requiring drug manufacturers, but not local pharmacies, to operate and finance a drug collection and disposal program did not violate the dormant Commerce Clause because "no 'actual or prospective competition' exists between the pharmacies and [drug] manufacturers"); see also Ford Motor Co. v. Tex. Dep't of Transp., 264 F.3d 493, 502 (5th Cir. 2001) (concluding that vehicle manufacturers and dealers are not in competition with one another for purposes of discrimination against commerce).

Novartis again cites Association for Accessible Medicines v. Frosh to suggest that a state law regulating pharmacies could unconstitutionally discriminate against drug manufacturers. According to Novartis, Frosh stands for the proposition that "[t]here is no requirement that the advantaged in-state industry be the 'same' as the disadvantaged out-of-state industry, or that the two groups be substantially similar." This argument extends Frosh too far.

In Frosh, the court struck down a Maryland statute that directly regulated drug pricing, saying the statute "sets prescription drug prices in a way that interfere[s] with the natural function of the interstate market by superseding market forces that dictate the price of a good." 887 F.3d at 673 (internal quotations omitted). The Frosh court expressly noted that "the dormant commerce clause does not protect[] the particular structure or methods of operation in a retail market" and emphasized that Maryland's law was unconstitutional because it "requires manufacturers and wholesale distributors to do more than alter their distribution channels." Id. (internal quotations omitted).

Unlike the Maryland statute in Frosh, S.B. 751 regulates the distribution of 340B drugs without affecting their price. Once covered entities purchase 340B drugs at the ceiling price set by federal law, S.B. 751 prevents drug manufacturers from prohibiting covered entities from directing the delivery of those drugs to its contract pharmacies. Novartis fails to show how such a policy discriminates against out-of-state economic interests or affects the price of 340B drugs. Because Novartis has not shown a discriminatory purpose or effect of S.B. 751, Novartis has not shown

a likelihood of success on its claim that S.B. 751 discriminates against interstate commerce.

3. Pike Balancing

Finally, Novartis argues that even if S.B. 751 is nondiscriminatory and has only incidental effects on interstate commerce, it still violates the dormant Commerce Clause because it fails the Pike balancing test. When a state law "regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Pike, 397 U.S. at 142. Appellees contend that Novartis's argument fails as a matter of law because Pork Producers abrogated Pike when the courts lack judicially comparable standards for balancing economic and noneconomic benefits and harms.

Contrary to Appellees' argument, Pike balancing remains a valid approach when considering dormant Commerce Clause challenges. In Pork Producers, "six Justices . . . affirmatively retain[ed] the longstanding Pike balancing test for analyzing dormant Commerce Clause challenges to state economic regulations." 598 U.S. at 403 (Kavanaugh, J., concurring). But the Court split on whether courts can balance economic burdens against noneconomic benefits. Compare id. at 380-81 (plurality) (concluding courts are not "institutionally suited" to draw comparisons between the economic burdens and social benefits of state legislation), with id. at 392-93 (Sotomayor and Kagan, JJ., concurring in part) (saying the means-ends analysis required by Pike does not raise incommensurability problems), and id. at 396-97 (Roberts, C.J., with Alito, Kavanaugh, and Jackson, JJ., concurring in part) (recognizing the "need to weigh seemingly incommensurable values" and concluding that it is possible for courts to balance economic and non-economic interests under Pike). Parsing of the various concurring opinions in Pork Producers shows that a majority of Justices approved Pike balancing even when that analysis requires balancing economic and noneconomic benefits and costs. See 598 U.S. at

392 (Sotomayor and Kagan, JJ., concurring in part); id. at 396-97 (Roberts, C.J., with Alito, Kavanaugh, and Jackson, JJ., concurring in part).

Novartis contends S.B. 751 imposes burdens on commerce by subjecting drug manufacturers to an ever-expanding patchwork of varying state regulatory regimes governing the delivery of 340B drugs to contract pharmacies. Because 22 states have adopted legislation identical or similar to S.B. 751, Novartis argues that it "must now contend with a patchwork of state laws carving out their own regimes for the federal 340B system," and that these various state laws make it more costly for Novartis to participate in the 340B Program.

The Supreme Court rejected a similar argument in Exxon Mobil Corp. v. Governor of Maryland. When Maryland enacted legislation prohibiting petroleum refiners from operating service stations within the state, Exxon challenged the law under the dormant Commerce Clause arguing that because the petroleum market is nationwide, the cumulative effect of the legislation had "serious implications for [Exxon's] national marketing operations." 437 U.S. at 128. The Supreme Court declined to adopt Exxon's approach, because "[t]he evil that [Exxon] perceive[s] . . . is not that the several States will enact differing regulations, but rather that they will all conclude" unfavorable regulations are appropriate. Id.

The same is true here. Various state regulations on contract pharmacies and their role in the 340B Program will undoubtedly affect the volume of 340B drugs Novartis delivers in interstate commerce. But the evil Novartis perceives is only that it "must now contend with a patchwork of state laws" that "will cost it millions of dollars per year" to comply with. These burdens are insufficient to prevail on Pike balancing.

Moreover, Novartis contends that no local benefits justify S.B. 751 because the legislation is nothing more than a "direct cash transfer from out-of-state drug manufacturers to in-state hospitals and clinics, and for-profit pharmacies." To support this argument, Novartis cites to a study showing that "the average profit

margin of [contract] pharmacies on commonly dispensed 340B drugs is . . . 72%, compared to 22% for non-340B drugs." Peter J. Pitts & Robert Popovian, 340B and the Warped Rhetoric of Healthcare Compassion, Food & Drug Law Inst. (Fall 2022).

But the fact that covered entities profit from 340B discounts is consistent with the purpose of the 340B Program. HRSA recognized that "[c]overed entities could . . . use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies." 61 Fed. Reg. at 43,549. "While some may pass all or a significant part of the discount to their patients, others may set the price slightly higher than the actual acquisition cost plus a reasonable dispensing fee, using the savings to reach more eligible patients and provide more comprehensive services." Id. at 43,551. Even if Novartis is correct that some covered entities do, in fact, pocket the entire profit from the sale of 340B drugs, many other covered entities use 340B drug revenues to provide better services to their patients. See Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, supra, at 17.

Novartis has not shown, at this stage in litigation, that the burdens of S.B. 751 are excessive in relation to the statute's potential benefits. Novartis is unlikely to prevail on its Pike balancing challenge.

* * *

Because Novartis has not shown that S.B. 751 violates the dormant Commerce Clause by applying extraterritorially, by discriminating against interstate commerce, or by imposing excessive burdens on interstate commerce, we agree with the district court that Novartis is not likely to prevail on the merits of its dormant Commerce Clause claim. The district court did not abuse its discretion in denying Novartis's motion for a preliminary injunction.

B. Novartis's Preemption Claims

Novartis also contends S.B. 751 is preempted by federal law. The Supremacy Clause provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Under this principle, Congress has the power to preempt state law." Arizona v. United States, 567 U.S. 387, 399 (2012). State law must yield to federal law in at least two circumstances. "First, the States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." Id. "Second, state laws are preempted when they conflict with federal law." Id. Novartis challenges S.B. 751 under both types of preemption.

1. Jurisdiction

Before reviewing whether Novartis is likely to succeed on the merits of its preemption claims, we must first consider our jurisdiction to review those claims. H&T Fair Hills, Ltd. v. Alliance Pipeline L.P., 154 F.4th 899, 901 (8th Cir. 2025) ("[O]ur first task in any case . . . is to ensure we have jurisdiction over an appeal."). Appellees contend we lack jurisdiction over Novartis's preemption claims because those claims became moot when the district court partially granted the motion to dismiss. Novartis contends we have jurisdiction because, notwithstanding the district court's dismissal of Novartis's preemption claims, the district court analyzed them in its order denying preliminary relief.

While Novartis does not appeal the partial dismissal, we may consider the preemption claims to the extent the district court analyzed those claims in its order denying preliminary relief because the preemption claims are "inextricably intertwined" with the court's ruling on the preliminary injunction. See Lee v. Driscoll, 871 F.3d 581, 586 (8th Cir. 2017) ("A pendent appellate claim can be regarded as inextricably intertwined with a properly reviewable claim on collateral appeal only if the pendent claim is coterminous with, or subsumed in, the claim

before the court on interlocutory appeal . . . ."). If we disagree with the district court and conclude that Novartis is entitled to a preliminary injunction on its preemption claims, that conclusion implies that Novartis has plausibly stated a claim for relief and the preemption claims were erroneously dismissed. See Polk v. Montgomery Cnty. Pub. Schs., 166 F.4th 400, 410-11 (4th Cir. 2026) (exercising pendent jurisdiction over dismissal of claims when the court denied a preliminary injunction on those same claims and a decision in the plaintiff's favor "would necessitate reinstatement" of the dismissed claims).

We have jurisdiction to consider whether Novartis has shown a likelihood of success on the merits of its preemption claims.

2. Field Preemption

Novartis first contends that S.B. 751 is field preempted. "Field preemption occurs when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" Murphy v. Nat'l Collegiate Athletic Ass'n, 584 U.S. 453, 478 (2018) (quoting R.J. Reynolds Tobacco Co. v. Durham Cnty., 479 U.S. 130, 140 (1986)); see also AbbVie, Inc. v. Murrill, 166 F.4th 528, 541 (5th Cir. 2026) (describing enforcement preemption as an implied preemption where federal law vests exclusive enforcement power in the federal government). "In such situations, Congress has forbidden the State to take action in the field that the federal statute pre-empts." Oneok, Inc. v. Learjet, Inc., 575 U.S. 373, 377 (2015) (italics omitted). Novartis argues that Section 340B preempts the field of 340B regulation because federal law established a standardized market for 340B drugs and vested sole enforcement power in the federal government.

This Court held in Pharmaceutical Research & Manufacturers of America v. McClain, 95 F.4th 1136 (8th Cir. 2024), that Section 340B does not preempt the field of 340B regulation and that the 340B Program's enforcement mechanisms do not preempt the field of 340B enforcement. Id. at 1143-44. In McClain, this Court considered whether Arkansas Act 1103, which, like S.B. 751, "prohibits

manufacturers from limiting covered entities' ability to contract with outside pharmacies" was field preempted. Id. at 1139. The McClain Court noted that "the federal government 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 (quotations omitted) (citing Lefaivre v. KV Pharm. Co., 636 F.3d 935, 940-41 (8th Cir. 2011)). Relying on this tradition of parallel state and federal regulation, the Court concluded that the "Congressional silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." Id. at 1144.

The McClain Court also held that Section 340B's enforcement mechanism did not preempt the field of 340B enforcement. Id. The Court reasoned that Section 340B provides HHS with jurisdiction to enforce Section 340B's rules on drug pricing and diversion, while Arkansas' law established separate state-level enforcement mechanisms and penalties to ensure manufacturers complied with the separate state law delivery requirements. Because Congress vested HHS with only limited enforcement authority and left open the possibility that states would enact parallel health and welfare laws, the McClain Court concluded that federal law did not preempt the field of 340B enforcement. Id.

Recognizing that its field preemption argument is foreclosed, Novartis contends McClain was wrongly decided and should be overturned. We decline Novartis's request to reconsider McClain. "It is a cardinal rule in our circuit that one panel is bound by the decision of a prior panel." Mader v. United States, 654 F.3d 794, 800 (8th Cir. 2011) (en banc). Because Novartis's field preemption claims are foreclosed by McClain, we find no abuse of discretion in the district court's denial of Novartis's motion for a preliminary injunction.

3. Conflict Preemption

Novartis also contends that S.B. 751 is conflict preempted. Even if Congress has not occupied a field of regulation, a state law is preempted "to the extent it

actually conflicts with federal law, that is, when compliance with both state and federal law is impossible," or "when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." California v. ARC Am. Corp., 490 U.S. 93, 100-01 (1989) (citation modified).

Novartis argues that S.B. 751 is preempted because it stands as an obstacle to the purpose and objectives of the 340B Program. According to Novartis, Section 340B preserves the ability of drug manufacturers to impose at least some delivery restrictions, including limiting the delivery of 340B drugs to a single contract pharmacy, and S.B. 751 conflicts with the federal scheme by requiring drug manufacturers to recognize an unlimited number of contract pharmacies. Novartis argues McClain does not apply because it did not consider the obstacle preemption theory advanced here. Contrary to Novartis's assertions, McClain reached the obstacle preemption theory Novartis raises. Just like Novartis in this case, the plaintiffs in McClain alleged that Arkansas Act 1103 was preempted because the requirement that manufacturers deliver 340B drugs to an unlimited number of contract pharmacies conflicts with Section 340B's prohibition on the diversion of 340B drugs. See Complaint, Pharm. Rsch. & Mfrs. of Am. v. McClain, No. 4:21-cv-00864, ECF No. 1 ¶¶ 68-72 (E.D. Ark. Sept. 29, 2021).

This Court rejected that argument and said that Act 1103 did "not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite[.]" McClain, 95 F.4th at 1144. Because Section 340B is silent on the delivery of 340B drugs, federal law neither prohibits nor requires the use of contract pharmacies, nor does federal law fix the number of contract pharmacies a covered entity may use to distribute 340B drugs on its behalf. See id. at 1143-45. The price at which 340B drugs are offered to covered entities is set by federal statutory formula. See 42 C.F.R. § 10.10(a). State laws like Arkansas Act 1103 and Missouri S.B. 751 do not alter that pricing formula or otherwise set the price of 340B drugs; rather, these laws provide that, once 340B drugs are offered to covered entities at the ceiling price, drug manufacturers cannot prevent covered entities from directing the delivery of those drugs to its contract pharmacies. Because state laws like Arkansas

Act 1103 and Missouri S.B. 751 regulate an area beyond the purview of federal law and do not pose an obstacle for drug manufacturers to comply with both federal and state law, such state laws are not conflict preempted. See McClain, 95 F.4th at 1145.

The Fifth Circuit's recent decisions in AbbVie, Inc. v. Fitch, 152 F.4th 635 (5th Cir. 2025), and AbbVie, Inc. v. Murrill, 166 F.4th 528 (5th Cir. 2026), reinforce this conclusion. In Fitch, the Fifth Circuit held that AbbVie and other drug manufacturers were not likely to succeed on the merits of their claim that Mississippi H.B. 728, which is materially similar to Missouri S.B. 751, is obstacle preempted. According to the Fifth Circuit, laws requiring manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies do not pose an obstacle to manufacturers' compliance with federal law because these state laws only require manufacturers to deliver discounted drugs to contract pharmacies insofar as they have partnered with covered entities, and do not impose drug pricing obligations that conflict with federal law. Fitch, 152 F.4th at 647.

Similarly, in Murrill, the court affirmed summary judgment upholding the constitutionality of a materially similar Louisiana statute requiring drug manufacturers to recognize an unlimited number of contract pharmacies. Citing McClain, the court concluded that these state laws regulate delivery, not prices. Murrill, 166 F.4th at 541. Recognizing the silence in Section 340B regarding drug delivery, the court concluded that "Congress decided not to undertake regulation of the delivery of 340B drugs or the role of pharmacies in that process—thereby leaving, absent congressional amendment, those matters to state law." Id. at 542. Because state laws like S.B. 751 "operate[] comfortably within that space" and do "not disturb the federally regulated relationship between manufacturers and covered entities," the federal and state laws "work in tandem to advance Congress's central aim" in creating the 340B Program. Id.

Because S.B. 751 regulates the delivery of 340B drugs in a manner consistent with federal law and does not stand as an obstacle to the drug pricing objectives of Section 340B, Novartis has not shown that it is likely to succeed on the merits of its

conflict preemption claim. The district court did not abuse its discretion in denying Novartis's motion for a preliminary injunction.

C. The Remaining Dataphase Factors.

Finally, Novartis contends that the district court erred when it found that the irreparable harm, balance of equities, and public interest factors weighed against preliminary relief. Novartis's claims of irreparable harm are premised on its belief that S.B. 751 is unconstitutional. Because we conclude that Novartis is not likely to succeed on the merits of its claims, we agree with the district court that Novartis has failed to show it would be irreparably harmed in the absence of a preliminary injunction. See Powell v. Noble, 798 F.3d 690, 702 (8th Cir. 2015) ("[A]s we have concluded Powell is unlikely to succeed in showing his [constitutional] rights have been violated, we agree with the district court that Powell has not shown a threat of irreparable harm that warrants preliminary injunctive relief."). Because Novartis has not shown a likelihood of success on the merits or irreparable harm, we do not need to address the balance of equities or public interest factors. Id.

III. CONCLUSION

The district court's denial of Novartis's motion for a preliminary injunction is affirmed.
