

IN THE
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 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; and DARREN HARRIS, in his official capacity as a member
of the Missouri Board of Pharmacy,

Defendants-Appellees,

—*and*—

MISSOURI HOSPITAL ASSOCIATION and MISSOURI PRIMARY CARE ASSOCIATION,

Intervenors-Appellees.

On Appeal from the United States District Court for the Western District of Missouri

2:24-cv-04131-MDH

The Honorable M. Douglas Harpool

**PLAINTIFF-APPELLANT NOVARTIS PHARMACEUTICALS CORPORATION'S
OPENING BRIEF**

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SUMMARY OF THE CASE

After Missouri enacted S.B. 751, Novartis Pharmaceuticals Corporation filed suit and sought a preliminary injunction to enjoin the law, arguing that it violates both the Dormant Commerce Clause and the Supremacy Clause. The District Court denied Novartis’s motion for a preliminary injunction, and this appeal followed.

S.B. 751 dramatically expands the scope of a federal program (known as the 340B Drug Pricing Program) that requires drug manufacturers, like Novartis, who wish to participate in Medicare and Medicaid to sell their drugs at steeply discounted prices to a specified list of hospitals and clinics known as “covered entities.” In doing so, S.B. 751 sets the price that out-of-state drug manufacturers may charge out-of-state wholesalers for drugs that are later dispensed in Missouri.

In seeking a preliminary injunction, Novartis articulated three independent ways that S.B. 751 violated the Dormant Commerce Clause and three independent ways that S.B. 751 is preempted under the federal 340B statute. The District Court ruled that Novartis was unlikely to prevail on the merits of these claims and denied Novartis’s motion for a preliminary injunction. Because Novartis believes that the statute violates these provisions, it respectfully appeals to this Court.

Novartis respectfully requests 15 minutes of argument time given the numerous constitutional and statutory issues presented.

CORPORATE DISCLOSURE STATEMENT

Novartis Pharmaceuticals Corporation is a wholly-owned indirect subsidiary of Novartis AG, a multinational pharmaceutical corporation incorporated and headquartered in Switzerland. Novartis AG publicly trades on the New York Stock Exchange. No person or entity has a 10% or greater ownership interest in Novartis AG's outstanding stock.

TABLE OF CONTENTS

	<u>Page</u>
SUMMARY OF THE CASE.....	i
CORPORATE DISCLOSURE STATEMENT	ii
TABLE OF AUTHORITIES	iv
INTRODUCTION	1
JURISDICTIONAL STATEMENT	6
STATEMENT OF ISSUES	7
STATEMENT OF THE CASE.....	8
A. Legal And Factual Background.....	8
1. <i>Federal 340B Program And The Emergence Of Contract Pharmacies</i>	8
2. <i>Manufacturers Sue To Enforce The 340B Statute</i>	16
3. <i>Recent State Laws Concerning “Delivery” Of 340B Drugs And This Court’s Decision In McClain</i>	18
4. <i>Missouri Enacts S.B. 751</i>	20
B. Procedural History	22
STANDARD OF REVIEW	24
SUMMARY OF THE ARGUMENT	25
ARGUMENT	28
I. THE DISTRICT COURT ERRED IN RULING THAT NOVARTIS IS UNLIKELY TO SUCCEED ON THE MERITS	28
A. Novartis Is Likely To Prevail On Its Dormant Commerce Clause Claim.....	28
1. <i>S.B. 751 Regulates Drug Prices</i>	28

TABLE OF CONTENTS—Continued

	<u>Page</u>
2. <i>S.B. 751 Likely Violates The Dormant Commerce Clause In Three Independent Ways</i>	33
i. S.B. 751 unlawfully regulates wholly out-of-state transactions.....	33
ii. S.B. 751 discriminates against out-of-state economic interests.....	40
iii. S.B. 751 fails the Pike balancing test.....	43
B. Novartis Is Likely To Prevail On Its Claim That S.B. 751 Conflicts With The Federal 340B Statute, And <i>McClain</i> Does Not Hold Otherwise.....	48
C. Novartis Preserves An Argument That <i>McClain</i> Was Wrongly Decided.....	52
1. <i>McClain’s Field Preemption Holding Conflicts With Supreme Court Case Law</i>	52
2. <i>McClain’s Enforcement Preemption Holding Conflicts With Supreme Court Case Law</i>	53
II. THE DISTRICT COURT ERRED IN RULING THAT NOVARTIS FAILED TO SATISFY THE REMAINING PRELIMINARY INJUNCTION FACTORS	56
A. Novartis Has Established Irreparable Harm.....	56
B. The Balance Of The Equities And Public Interest Favor Granting An Injunction.....	58
CONCLUSION	59
CERTIFICATE OF COMPLIANCE	
CERTIFICATE OF SERVICE	
ADDENDUM	

TABLE OF AUTHORITIES

CASES:

<i>Abbott v. Perez</i> , 585 U.S. 579 (2018).....	8, 58
<i>Altana Pharma AG v. Teva Pharms. USA, Inc.</i> , 566 F.3d 999 (Fed. Cir. 2009)	57
<i>American Ins. Ass’n v. Garamendi</i> , 539 U.S. 396 (2003).....	53
<i>Arizona v. United States</i> , 567 U.S. 387 (2010).....	53
<i>Association for Accessible Meds. v. Ellison</i> , 704 F. Supp. 3d. 947 (D. Minn. 2023).....	35, 37, 39
<i>Association for Accessible Medicines v. Frosh</i> , 887 F.3d 664 (4th Cir. 2018)	36, 38, 41, 44
<i>Astra USA, Inc. v. Santa Clara Cnty.</i> , 563 U.S. 110 (2011).....	8, 53, 54, 55
<i>Bacchus Imports, Ltd. v. Dias</i> , 468 U.S. 263 (1984).....	41
<i>Bank One, Utah v. Guttau</i> , 190 F.3d 844 (8th Cir. 1999)	59
<i>Boyle v. United Techs. Corp.</i> , 487 U.S. 500 (1988).....	53
<i>Buckman Co. v. Plaintiffs’ Legal Comm.</i> , 531 U.S. 341 (2001).....	8, 53
<i>C&A Carbone, Inc. v. Town of Clarkstown</i> , 511 U.S. 383 (1994).....	5, 7, 27, 45
<i>Chicago, B. & Q. R. Co. v. Chicago Great W. R. Co.</i> , 190 F.2d 361 (8th Cir. 1951)	58

TABLE OF AUTHORITIES—Continued

	<u>Page(s)</u>
<i>City of Philadelphia v. New Jersey</i> , 437 U.S. 617 (1978).....	38
<i>Clover-Green Spring Dairies Inc. v. Pennsylvania Milk Marketing Bd.</i> , 298 F.3d 201 (3d Cir. 2002)	47
<i>Crosby v. National Foreign Trade Council</i> , 530 U.S. 363 (2000).....	50
<i>CTS Corp. v. Dynamics Corp. of America</i> , 481 U.S. 69 (1987).....	44
<i>Dakotans for Health v. Noem</i> , 52 F.4th 381 (8th Cir. 2022)	59
<i>Dataphase Sys., Inc. v. CL Sys., Inc.</i> , 640 F.2d 109 (8th Cir. 1981)	28, 58
<i>Department of Revenue of Ky. v. Davis</i> , 553 U.S. 328 (2008).....	41, 42
<i>Downs v. Holder</i> , 758 F.3d 994 (8th Cir. 2014)	32
<i>Edgar v. MITE Corp.</i> , 457 U.S. 624 (1982).....	34
<i>English v. General Elec. Co.</i> , 496 U.S. 72 (1990).....	52
<i>Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta</i> , 458 U.S. 141 (1982).....	49, 51
<i>Fulton Corp. v. Faulkner</i> , 516 U.S. 325 (1996).....	45
<i>Geier v. American Honda Motor Co.</i> , 529 U.S. 861 (2000).....	8, 50

TABLE OF AUTHORITIES—Continued

	<u>Page(s)</u>
<i>General Motors Corp. v. Tracy</i> , 519 U.S. 278 (1997).....	42, 43
<i>General Motors Corp. v. Harry Brown’s, LLC</i> , 563 F.3d 312 (8th Cir. 2009)	56
<i>GLBT Youth in Iowa Task Force v. Reynolds</i> , 114 F.4th 660 (8th Cir. 2024)	25
<i>Guy v. Baltimore</i> , 100 U.S. 434 (1880).....	41
<i>Healthcare Distrib. All. v. Zucker</i> , 353 F. Supp. 3d 235 (S.D.N.Y. 2018)	37
<i>Healy v. Beer Inst., Inc.</i> , 491 U.S. 324 (1989).....	26, 33, 38, 43, 44
<i>Heartland Acad. Cmty. Church v. Waddle</i> , 335 F.3d 684 (8th Cir. 2003)	25
<i>Hines v. Davidowitz</i> , 312 U.S. 52 (1941).....	53
<i>Iowa Utilities Bd. v. F.C.C.</i> , 109 F.3d 418 (8th Cir. 1996)	8, 56
<i>Interlink Prods. Int’l, Inc. v. Crowfoot</i> , 678 F. Supp. 3d 1216 (E.D. Cal. 2023)	39
<i>Kassel v. Consolidated Freightways Corp. of Del.</i> , 450 U.S. 662 (1981).....	47
<i>Lankford v. Sherman</i> , 451 F.3d 496 (8th Cir. 2006)	25
<i>Legato Vapors, LLC v. Cook</i> , 847 F.3d 825 (7th Cir. 2017)	34

TABLE OF AUTHORITIES—Continued

	<u>Page(s)</u>
<i>Medicine Shoppe Intern., Inc. v. S.B.S. Pill Dr., Inc.</i> , 336 F.3d 801 (8th Cir. 2003)	58
<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (1996).....	50
<i>Minnesota v. Clover Leaf Creamery Co.</i> , 449 U.S. 456 (1981).....	47
<i>Morales v. Trans World Airlines, Inc.</i> , 504 U.S. 374 (1992).....	57
<i>National Pork Producers Council v. Ross</i> , 598 U.S. 356 (2023).....	37, 38, 43
<i>National Pork Producers Council v. Ross</i> , 6 F.4th 1021 (9th Cir. 2019)	39
<i>Novartis Pharms. Corp. v. Espinosa</i> , No. 21-cv-1479-DLF, 2021 WL 5161783 (D.D.C. Nov. 5, 2021).....	17
<i>Novartis Pharms. Corp. v. Johnson</i> , 102 F.4th 452 (D.C. Cir. 2024).....	<i>passim</i>
<i>Oklahoma Tax Comm’n v. Jefferson Lines, Inc.</i> , 514 U.S. 175 (1995).....	33
<i>Oregon Waste Sys., Inc. v. Department of Env’t Quality of State of Or.</i> , 511 U.S. 93 (1994).....	5, 40
<i>PhRMA v. District of Columbia</i> , 406 F. Supp. 2d 56 (D.D.C. 2005).....	37
<i>PhRMA v. McClain</i> , 95 F.4th 1136 (8th Cir. 2024)	<i>passim</i>
<i>PhRMA v. Morrisey</i> , 760 F. Supp.3d 439, (S.D. W. Va. Dec. 17, 2024)	32, 54

TABLE OF AUTHORITIES—Continued

	<u>Page(s)</u>
<i>PhRMA v. Walsh</i> , 538 U.S. 644 (2003).....	38
<i>Pike v. Bruce Church, Inc.</i> , 397 U.S. 137 (1970).....	5, 43, 45
<i>Rodriguez v. United States</i> , 480 U.S. 522 (1987).....	50
<i>Sam Francis Found. v. Christies, Inc.</i> , 784 F.3d 1320 (9th Cir. 2015)	39
<i>Sanofi Aventis U.S. LLC v. United States Dep’t of Health & Human Servs.</i> , 58 F.4th 696 (3d Cir. 2023)	<i>passim</i>
<i>Styczinski v. Arnold</i> , 46 F.4th 907 (8th Cir. 2022)	<i>passim</i>
<i>Tennessee Wine & Spirits Retailers Ass’n v. Thomas</i> , 588 U.S. 504 (2019).....	40
<i>United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.</i> , 550 U.S. 330 (2007).....	7, 26, 41
<i>United States v. Green</i> , 691 F.3d 960 (8th Cir. 2012)	32
<i>Wisconsin Dep’t of Indus., Lab. & Hum. Rels. v. Gould Inc.</i> , 475 U.S. 282 (1986).....	54
STATUTES:	
28 U.S.C. § 1331	6
28 U.S.C. § 1292(a)(1)	7
42 U.S.C. § 1396r-8(a)(1)	9
42 U.S.C. § 1396r-8(a)(1)	9

TABLE OF AUTHORITIES—Continued

	<u>Page(s)</u>
42 U.S.C. § 256b	
(a)	8
(a)(1)	9, 29, 46, 49
(a)(2)	11
(a)(4)	9
(a)(4)(L)(i).....	9
(a)(5)(A).....	10
(a)(5)(B)	10
(b)(1)	9
(d)(1)(A).....	52
(d)(1)(B)(vi)	10
(d)(2)(B)(iv)	53
(d)(2)(B)(v)(I)	10
(d)(2)(B)(v)(II).....	10
(d)(3)(A).....	11, 56
H.B. 1056 (Md. 2024).....	19
H.B. 728 (Miss. 2024).....	19
H.F. 4991 (Minn. 2024)	19
Kan. Stat. § 65-483	19
La. Rev. Stat. § 40:2883.....	19
(A)(vi)(d).....	44
Miss. Code § 75-24-5.....	19
Mo. Rev. Stat. § 407.020 <i>et seq.</i>	22, 57
Mo. Rev. Stat. § 407.020	
(3).....	57
(4).....	57
Mo. Rev. Stat. § 407.025(1).....	57
Mo. Rev. Stat. § 407.095	22

TABLE OF AUTHORITIES—Continued

	<u>Page(s)</u>
Mo. Rev. Stat. § 407.110	22
Mo. Rev. Stat. § 407.130	22
N.D. Cent. Code § 43-15.3-08	19
Neb. L.B. 168, § 3(1) (2025)	19, 44
N.M. H.B. 78 (2025)	19
§ 1(A)(4)	44
S.B. 154 (S.D. 2025)	19
S.B. 28 (Kan. 2024)	19
S.B. 69 (Utah 2025)	19
S.B. 751, Mo. Rev. Stat. § 376.414	57
(1)(a)	29
(2)	21
(3)	22, 29, 57
S.B. 751, Mo. Rev. Stat. § 376.414.2	34, 47
S.B. 1414 (Tenn. 2025)	19
W. Va. Code § 60A-8-6a	19
 REGULATIONS:	
340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (Jan. 5, 2017).....	11
42 C.F.R. Part 1003.....	10
61 Fed. Reg. 43,549 (Aug. 23, 1996)	12
75 Fed. Reg. 10,272 (Mar. 5, 2010).....	13
Final Rule, 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28,643 (Apr. 19, 2024)	11

TABLE OF AUTHORITIES—Continued

Page(s)

EXECUTIVE MATERIAL:

HHS OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 4, 2014) 14

OTHER AUTHORITIES:

Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2020 Update* (June 2022)..... 15

11A Charles A. Wright & Arthur R. Miller, Fed. Prac. & Proc. Civ. § 2949 (3d ed. 2025 update).....46, 47

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INTRODUCTION

The federal 340B Drug Pricing Program requires pharmaceutical manufacturers to ensure that a specified list of hospitals and clinics known as “covered entities” can buy the manufacturers’ drugs at a capped, steeply discounted price. Manufacturers must participate in the 340B Program, and its price controls, as a condition for having Medicare Part B and Medicaid pay for their therapies. Importantly, the 340B Program governs only the price that *covered entities* pay to purchase the drug; covered entities turn around and charge full price to *patients* when the drug is dispensed. Simple math says that the more product a covered entity can buy low and sell high, the more lucrative the 340B Program is for that covered entity’s bottom line. The covered entities’ response to this incentive structure—combined with a well-established lack of transparency—has led to the current dispute.

Certain categories of covered entities sometimes lack an in-house pharmacy and therefore originally could not take advantage of 340B drug pricing. Accordingly, in the early years of the 340B Program, the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services, which administers the 340B Program, issued guidance allowing such covered entities to contract with a single third-party pharmacy for this purpose. The separate pharmacy—known as a “contract pharmacy”—would dispense drugs

to the covered entity's patients as though the drug had been dispensed in-house by the covered entity itself.

The lucrative nature of this program led covered entities to lobby HRSA for expansion of contract pharmacy use. HRSA acceded and issued guidance purporting to authorize *any* covered entity (even those with an in-house pharmacy) to designate an *unlimited number* of contract pharmacies, rather than just one. Again, because these discounts are generally not passed along to patients, this funding stream simply became a new way for covered entities to increase profits.

As a result, the 340B Program ballooned over the ensuing years to cover \$54 billion in discounted drug sales. Covered entities, seeking to maximize these profits, hired for-profit third-party administrators to cull through the claims data of the thousands of contract pharmacies after the fact to identify whether any of the patients may have some purported connection, however tenuous, to a covered entity. The algorithm used is deliberately opaque and many of the newly claimed discounts—which manufacturers cannot verify—violate the diversion and duplicate-discount obligations that the statute imposes on covered entities. Covered entities then claim retroactive rebates for these prescriptions. The covered entities, contract pharmacies—which are largely major for-profit chains such as Walmart and CVS—and the third-party administrators then divvy up the spread (the money Congress intended to help vulnerable patients) between them.

Manufacturers challenged this radical expansion of the 340B Program. Several courts, including one in a case that Novartis brought, ruled that the federal 340B law permits manufacturers to put reasonable guardrails in place to protect against these abusive practices, including by recognizing only a *single* contract pharmacy per covered entity lacking an in-house pharmacy—which was the common pre-2010 practice. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024); *see also Sanofi Aventis U.S. LLC v. United States Dep’t of Health & Human Servs.*, 58 F.4th 696, 705 (3d Cir. 2023).

Missouri is one of several states that then enacted a state law to expand the volume of drugs that receive the discounted 340B price and circumvent the reasonable limitations on the use of contract pharmacies that Congress allowed in enacting the federal program. Senate Bill No. 751 (“S.B. 751”) makes it unlawful for a drug manufacturer to directly or indirectly restrict the delivery or acquisition of a “340B drug” by *any contract pharmacies* that a Missouri covered entity designates.

While the State claims that the statute regulates only drug delivery, make no mistake: S.B. 751 is a drug-*pricing* statute. The District Court focused on the word “delivery” in S.B. 751, but the statute has no impact on whether or how a drug is delivered in Missouri. The same drugs at issue were already being delivered to the very same pharmacies at issue before the statute. It is actually

undisputed that S.B. 751 does not affect the quality or quantity of drugs delivered to Missouri covered entities and their contract pharmacies, how those drugs are delivered, or to where they are delivered. The key term instead is “340B drug,” which is the object of the new law’s obligations. S.B. 751 defines that term to mean a unit of drug *subject to the 340B price*, thereby requiring only the extension of 340B pricing to the same drugs already being sold and delivered to those same pharmacies in state.

S.B. 751’s pricing regulation also applies solely to drug manufacturers, which operate almost entirely outside of Missouri. This is critical context for Novartis’s Dormant Commerce Clause challenge. S.B. 751 triggers a chain of reimbursement requests that ultimately require an out-of-state drug manufacturer to reimburse an out-of-state wholesaler for the 340B discount that the new law now mandates be made available to an unlimited range of pharmacies in Missouri. To comply with S.B. 751, the manufacturer must now require that its wholesalers charge no more than the 340B price when shipping an order to a contract pharmacy. The wholesaler, which purchased the product from the manufacturer at a commercial price, needs to be made whole for fronting that 340B discount. The result: S.B. 751 requires a direct cash transfer, or subsidy, from (almost-entirely) out-of-state drug manufacturers to an (entirely) in-state group of hospitals and clinics and their third-party pharmacy partners.

This inter-state dynamic violates the Dormant Commerce Clause in three independent ways. *First*, it regulates the price that out-of-state drug manufacturers may charge out-of-state wholesalers in an *entirely out-of-state transaction*—violating one of the Dormant Commerce Clause’s core pillars. *Styczinski v. Arnold*, 46 F.4th 907, 913 (8th Cir. 2022). *Second*, S.B. 751 discriminates against “out-of-State economic interests” by requiring the out-of-state drug industry to finance in-state hospitals and clinics. *Oregon Waste Sys., Inc. v. Department of Env’t Quality of State of Or.*, 511 U.S. 93, 99 (1994). And *third*, it creates massive “incidental burdens” on interstate commerce by imposing millions of dollars of discounts on drug manufacturers on out-of-state sales simply because their drugs later cross Missouri state lines and are sold to a Missouri covered entity’s contract pharmacy. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Those costs clearly outweigh the local benefit, which is simply to “financ[e]” local industry—an illegitimate interest under the Dormant Commerce Clause. *C&A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 394 (1994).

S.B. 751 also is preempted under the federal 340B statute, which intentionally preserves the right of drug manufacturers to limit delivery of 340B drugs to a *single* contract pharmacy. *See Novartis*, 102 F.4th at 454. S.B. 751 erects an obstacle to the federal law by giving covered entities the right to

designate unlimited numbers of contract pharmacies to receive delivery of 340B drugs.

The District Court believed *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024) likely foreclosed Novartis's obstacle-preemption claim. But *McClain* never considered this theory, nor ruled on its merit. *McClain* held that the federal 340B law did not prohibit covered entities from using *any* contract pharmacies. 95 F.4th at 1144. Novartis's obstacle-preemption theory, by contrast, is that the federal law gives manufacturers the right to place reasonable guardrails around the use of contract pharmacies, including restricting delivery to a *single* contract pharmacy. That theory is both outside *McClain* and meritorious.

A preliminary injunction should have issued. Novartis has a likelihood of success on its Dormant Commerce Clause and preemption claims; it faces irreparable harm absent a preliminary injunction; and the balance of the equities and public interest both weigh in favor of granting Novartis's requested relief. This Court should reverse the District Court's denial of Novartis's request for a preliminary injunction and order the District Court to enter it on remand.

JURISDICTIONAL STATEMENT

The District Court had federal question jurisdiction over this case under 28 U.S.C. Section 1331 and entered a final order denying Novartis's motion for a preliminary injunction on February 24, 2025. App.316-329(R._Doc._78).

Novartis filed a notice of appeal thirty days later, on March 26, 2025. App.330-333(R._Doc._84). This Court has appellate jurisdiction under 28 U.S.C. Section 1292(a)(1).

STATEMENT OF ISSUES

1. Whether the District Court erred in concluding that Novartis was unlikely to succeed on its Dormant Commerce Clause claim, even though S.B. 751 regulates wholly out-of-state transactions; discriminates against out-of-state economic interests; and imposes burdens on interstate commerce that clearly outweigh local benefits.

Most Apposite Cases: *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330 (2007); *C&A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383 (1994); *Styczinski v. Arnold*, 46 F.4th 907 (8th Cir. 2022).

2. Whether the District Court erred in concluding that Novartis was unlikely to succeed on its obstacle-preemption theory, even though S.B. 751 gives Missouri hospitals and clinics the right to designate *unlimited* contract pharmacies, while the federal 340B carefully balances the interests of covered entities and manufacturers to preserve manufacturers’ right to limit delivery to a *single* contract pharmacy.

Most Apposite Case: *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000).

3. Whether this Court, sitting en banc, should find preemption based on the preemption theories addressed in *Pharmaceutical Research & Manufacturers of America v. McClain*, 95 F.4th 1136 (8th Cir. 2024) and conclude that panel's decision was contrary to Supreme Court case law.

Most Apposite Cases: *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

4. Whether the District Court incorrectly ruled that the remaining preliminary injunction factors—irreparable harm, balance of the equities, and public interest—weigh against a preliminary injunction.

Most Apposite Cases: *Abbott v. Perez*, 585 U.S. 579 (2018); *Iowa Utilities Bd. v. F.C.C.*, 109 F.3d 418 (8th Cir. 1996).

STATEMENT OF THE CASE

A. Legal And Factual Background.

1. *Federal 340B Program And The Emergence Of Contract Pharmacies.*

In 1992, Congress created the 340B Drug Pricing Program, which requires participating pharmaceutical manufacturers like Novartis to deeply discount their covered outpatient drugs for qualifying hospitals and clinics. 42 U.S.C. § 256b(a);

App.8-9(R._Doc._1, at 8-9 ¶ 27). Federal law defines qualifying hospitals and clinics, known as “covered entities,” as 15 specified types of nonprofit hospitals and federal grantees. *See* 42 U.S.C. § 256b(a)(4); App.9(R._Doc._1, at 9 ¶ 31). A manufacturer must agree to participate in the 340B Program to receive payment under Medicaid and Medicare Part B for its drugs. 42 U.S.C. § 1396r-8(a)(1). The subagency responsible for overseeing and enforcing the 340B Program is the Health Resources and Services Administration (HRSA).

At its core, the 340B Program requires a participating pharmaceutical manufacturer to ensure a covered entity is ultimately charged no more than the 340B ceiling price—a heavily discounted price calculated under a prescribed statutory formula—for each unit of the manufacturer’s covered outpatient drugs dispensed by the covered entity. 42 U.S.C. §§ 256b(a)(1), (a)(4), (b)(1).

Specifically, Section 256b(a)(1) states that a participating manufacturer shall “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.” Notably, whether the 340B discount applies is dependent on the *hospital or clinic’s* status as a covered entity, not the economic status of the individual patient receiving the drug. So, for example, if a hospital qualifies as a “covered entity” by virtue of serving “low income individuals,” 42 U.S.C. § 256b(a)(4)(L)(i), the 340B

discount would equally apply to drugs the hospital dispenses to its high-income patients.

Congress carefully calibrated the program to protect drug manufacturers, given the size of the mandatory price reductions being imposed. First, the statute prohibits “duplicate discounts”—a manufacturer cannot be required to both pay a Medicaid rebate and provide a 340B discount on the same unit of drug. 42 U.S.C. § 256b(a)(5)(A). Second, the statute prohibits what is known as “diversion”; 340B drugs may not be resold or otherwise transferred to “a person who is not a patient of the entity.” *Id.* § 256b(a)(5)(B).

The federal 340B statute also lays out two exclusive enforcement remedies. App.11-12(R._Doc._1, at 11-12 ¶ 37). First, the Department of Health and Human Services (HHS) is given direct enforcement powers, including the ability to mandate payment of the discount, seek civil fines for non-compliance, and kick covered entities out of the program. 42 U.S.C. §§ 256b(d)(1)(B)(vi), (d)(2)(B)(v)(I)-(II); *see also* 42 C.F.R. Part 1003 (rules governing Secretary’s imposition of civil monetary penalties). And second, the statute requires the HHS Secretary to promulgate regulations establishing an Administrative Dispute Resolution (ADR) process, allowing covered entities and manufacturers to resolve 340B disputes arising under two claim categories: (1) “claims by covered entities that they have been overcharged for drugs purchased under this section,” and (2)

claims by manufacturers relating to duplicate discounts and drug diversion. 42 U.S.C. § 256b(d)(3)(A); Final Rule, 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28,643 (Apr. 19, 2024); *see also* App.12(R._Doc._1, at 12 ¶ 38).

Critically, covered entities are not required to pass any portion of the 340B discount to patients and they generally do not. App.11, 13-14(R._Doc._1, at 11, 13-14 ¶¶ 35, 44). Nor are they even required to use the funds to provide charity care or otherwise benefit low-income patients. As a result, covered entities can charge patients (or their insurers) the same amount they otherwise would regardless of whether the covered entity received a 340B discount on the drug at issue. App.11(R._Doc._1, at 11 ¶ 35). That means covered entities are legally permitted to—and generally do—pocket the 340B discounts or use them to invest in unrelated facilities that serve high-income populations. App.13-14(R._Doc._1, at 13-14 ¶ 44).

The financial benefits to covered entities are massive. The 340B price that a manufacturer may charge for a drug is steeply discounted—“as low as one penny—calculated under a prescribed statutory formula.” App.9(R._Doc._1, at 9 ¶ 30) (quoting 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1214-15 (Jan. 5, 2017)); 42 U.S.C. § 256b(a)(2)); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456

(D.C. Cir. 2024) (the 340B discounted price is “strikingly generous to purchasers”). Meanwhile, the “insurance reimbursement rate” that covered entities receive when dispensing a 340B drug is calculated based on the drug’s *non-discounted* price. App.10-11(R._Doc._1, at 10-11 ¶ 34). As a hypothetical, a covered entity may receive an insurance reimbursement of \$50 for dispensing a given drug to a patient. That rate is calculated based on the non-discounted commercial price of the drug. If that drug is tagged for inclusion in the 340B Program, the hospital may pay as low as \$0.01 for it, leaving the covered entity with an extra \$49.99 to spend however it chooses.

Covered entities thus have a huge incentive to claim as many 340B drugs as possible. App.10-11(R._Doc._1, at 10-11 ¶ 34). This dynamic has made “the section 340B Program vulnerable to abuse—at great cost to [drug] manufacturers.” App.11(R._Doc._1, at 11 ¶ 36) (citing *Novartis*, 102 F.4th at 455).

That’s where “contract pharmacies” come in. When the 340B Program was first enacted, covered entities—which were much fewer in number—directly purchased drugs at the 340B price, dispensed those drugs at their own *in-house* pharmacies, and enjoyed savings from the discount. App.12(R._Doc._1, at 12 ¶ 41). In 1996, HRSA issued guidance announcing that the agency would not preclude covered entities lacking an in-house pharmacy from entering into a *single* contract-pharmacy relationship. *Id.* (citing 61 Fed. Reg. 43,549 (Aug. 23, 1996));

see also Sanofi Aventis U.S. LLC v. United States Dep't of Health & Human Servs., 58 F.4th 696, 705 (3d Cir. 2023) (“Congress might have expected that a covered entity without its own in-house pharmacy could instead use one contract pharmacy.”).

In 2010, HRSA heeded the calls from the covered-entity lobby to expand contract-pharmacy access. Its revised guidance stated that covered entities could use “multiple pharmacy arrangements”—with no cap on the number of contract pharmacies or their physical locations, and even if the covered entity had its own in-house pharmacy. App.12-13(R._Doc._1, at 12-13 ¶ 42) (citing 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010)). If a covered entity satisfied a few conditions, all monitored by the covered entity itself on the honor system, it could enter into limitless contract-pharmacy arrangements with pharmacies located across the United States. 75 Fed. Reg. 10,272, 10,274, 10,277 (outlining these requirements).

Seeing this potential for a massive windfall, individual covered entities began entering into “multiple pharmacy arrangements,” without regard to geographic proximity to the hospital or even whether the hospital already had an in-house pharmacy. App.12-13(R._Doc._1, at 12-13 ¶ 42). Over the ensuing years, the number of contract pharmacies receiving and distributing 340B drugs grew rapidly. App.13(R._Doc._1, at 13 ¶ 43) (citing government reports about the dramatic increase in use—and abuse—of 340B discounts through covered entities’

contract pharmacy relationships). The more contract pharmacies a covered entity designates, the more chances the covered entity can claim to be owed a 340B discounted price.

To supercharge their 340B savings, covered entities hired for-profit third-party administrators to implement what they call the “replenishment model.” App.10(R._Doc._1, at 10 ¶ 33). In this model, third-party administrators cull through pharmacy claims data—i.e., data for commercially priced drugs that have already been dispensed—to identify whether any of those individuals may have some purported connection, however tenuous, to a covered entity. *Id.* Anytime the third-party administrator flags that a pharmacy customer was (or may have been) a patient at the covered entity at some prior point in time, the covered entity places an order for a 340B priced unit to be delivered to the pharmacy to “replenish” the commercially priced unit previously dispensed to that customer. The new unit is then dispensed to the next pharmacy customer that walks in the door. *Id.* The pharmacy treats the 340B replenishment unit as if it had been purchased at the commercial price—and is available for dispensing to anyone, regardless of whether they qualify as a “patient” of the covered entity—even though it has in fact been purchased at the 340B price. *Id.* (citing *Novartis*, 102 F.4th at 461-463; HHS OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 at 5 (Feb. 4, 2014)).

How a third-party administrator determines the number of 340B drugs to replenish—and whether or not those drugs actually tie back to a patient of the covered entity—remains a mystery. *Id.* The contracts that covered entities enter into with third-party administrators are not publicly available.

What *is* widely known is that third-party administrators often receive a per-drug fee and are thus highly motivated to identify as many drugs as possible for “replenishment” at the 340B discounted price. App.10-11(R._Doc._1, at 10-11 ¶ 34) (citing *Novartis*, 102 F.4th at 454). Each player gets a cut: “The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate.” *Id.*

As a result of these lucrative arrangements, manufacturers have faced skyrocketing sales of drugs for which covered entities demand the steeply discounted 340B pricing, with little to no transparency as to whether these requests are legitimate 340B prescriptions. By 2020, sales of 340B units constituted an estimated 17% of all total U.S. branded outpatient drug sales. App.13-14(R._Doc._1, at 13-14 ¶ 44) (citing Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments* (Oct. 14, 2021); Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2020 Update* (June 2022). And in 2022, discounted purchases under the 340B Program hit a record high of approximately \$54 billion—a more than 22% year-over-year

increase. *Id.* (citing Adam J. Fein, *The 340B Program Reached \$54 Billion in 2022—Up 22% vs. 2021*, *Drug Channels* (Sept. 24, 2023)).

2. *Manufacturers Sue To Enforce The 340B Statute.*

The number of contract pharmacies ballooned from 1,300 in 2010 to nearly 20,000 in 2017. App.13(R._Doc._1, at 13 ¶ 43). That dramatic growth became unsustainable for drug manufacturers, who believed that contract pharmacies were driving up duplicate discounting and diversion. *See Sanofi*, 58 F.4th at 700-701. In November 2020, Novartis notified HRSA that it would recognize all contract pharmacies within 40 miles of a covered entity—an area of more than 5,000 square miles—and allow covered entities to seek exemptions based on individual circumstances. App.14(R._Doc._1, at 14 ¶ 45). But, barring an exemption, it would not offer 340B discounts for drugs that a covered entity’s patient bought more than 40 miles away from the covered entity. *Id.* Novartis imposed this (generous) geographic limitation in an attempt to make 340B pricing available only for the drugs associated with treatment that a patient actually received at the covered entity claiming the discount.

HRSA saw things differently. In 2021, it issued Novartis an enforcement letter, asserting that Novartis’s policy violated the federal 340B statute. App.14(R._Doc._1, at 14 ¶ 46). HRSA demanded immediate compliance with its view that a covered entity can unilaterally direct a manufacturer to deliver 340B

drugs to any contract pharmacy, on pain of an enforcement action for civil monetary penalties under Section 256b(d)(1)(B)(vi). *Id.*

Novartis challenged HRSA's letter in the U.S. District Court for the District of Columbia. App.14-15(R._Doc._1, at 14-15 ¶ 47). Novartis's challenge was heard alongside a separate case brought by United Therapeutics; HHS had issued a similar enforcement letter prohibiting United Therapeutics's policy of delivering 340B drugs to only one contract pharmacy designated or previously used by the covered entity—consistent with HRSA's pre-2010 position. *Id.*; *see also Novartis*, 102 F.4th at 452.

The district court sided with Novartis and United Therapeutics and vacated HRSA's enforcement letters. *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479-DLF, 2021 WL 5161783, at *8-9 (D.D.C. Nov. 5, 2021). HRSA appealed to the D.C. Circuit, which affirmed. The D.C. Circuit held that in enacting the 340B statute, Congress intended to provide drug manufacturers with the right to impose at least some "delivery conditions" on 340B drugs. *Novartis*, 102 F.4th at 460. For example, to ensure patient safety, manufacturers were entitled to limit the distribution of certain "specialty," or highly complex, 340B drugs to "specialized pharmacies" trained to handle such drugs. *Id.* at 461. The court noted that, in theory, some manufacturer-imposed delivery conditions may be unreasonable or otherwise violate specific provisions of the 340B statute. *Id.* at 462-463. But, the

court held, a delivery condition restricting 340B drugs to only one contract pharmacy designated by the covered entity was reasonable valid,¹ and Congress intentionally “preserve[d]” a drug manufacturer’s ability to impose it. *Id.* at 460, 463.

The Third Circuit heard a parallel lawsuit brought by other drug manufacturers and came to a similar conclusion. *See Sanofi*, 58 F.4th at 707. Like the D.C. Circuit, the Third Circuit upheld orders vacating HRSA’s enforcement letters against drug manufacturers that limited the delivery of 340B drugs to a single contract pharmacy that the covered entity designates. *Id.* at 701-706. The court held that the federal 340B statute intentionally provided “drug makers discretion on delivery.” *Id.* at 705. As part of that discretion, the drug makers’ policies of limiting each covered entity to a single contract pharmacy were authorized under Section 340B. *Id.* at 706.

3. *Recent State Laws Concerning “Delivery” Of 340B Drugs And This Court’s Decision In McClain.*

Responding to this litigation, several states wanted their in-state hospitals and other covered entities to retain and maximize the lucrative benefit of 340B pricing, App.29(R._Doc._1, at 29 ¶ 97), so they passed *state laws* requiring the

¹ Novartis had since discontinued its 40-mile condition in favor of a single-contract-pharmacy delivery condition similar to United Therapeutics. *See Novartis*, 102 F.4th at 463.

recognition of unlimited contract-pharmacy arrangements.² These laws also do not require any price discount be passed on to patients.

One of these laws has already come before this Court. In May 2021, the Arkansas General Assembly codified a right for a covered entity to have unlimited contract-pharmacy arrangements by prohibiting drug manufacturers “from interfering in a covered entity’s agreement with a contract pharmacy by denying the pharmacy access to a covered entity’s 340B drugs.” *PhRMA v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024). This Court rejected a preemption challenge to the Arkansas law brought by the trade group Pharmaceutical Research and Manufacturers of America (“PhRMA”). *Id.*

PhRMA argued four preemption theories. The first was a field preemption theory—namely that the federal 340B statute “preempts the field” on 340B drug pricing, meaning that Congress left “no room for state action.” *Id.* This Court

² Currently, state laws ostensibly protecting the “delivery” of 340B drugs have been enacted in: Kansas (S.B. 28 (2024), Kan. Stat. § 65-483); Louisiana (La. Rev. Stat. § 40:2883); Nebraska (Neb. L.B. 168, § 3(1) (2025)); Mississippi (H.B. 728 (2024), Miss. Code § 75-24-5); Maryland (H.B. 1056 (2024)); Minnesota (H.F. 4991 (2024)); New Mexico (N.M. H.B. 78 (2025)); North Dakota (N.D. Cent. Code § 43-15.3-08); South Dakota (S.B. 154 (2025)); Tennessee (S.B. 1414 (2025)); Utah (S.B. 69 (2025)); and West Virginia (W. Va. Code § 60A-8-6a).

disagreed, relying in part on the “presumption” that Congress does not preempt state laws regarding health and safety. *Id.* at 1140, 1143-44.

The second was that the federal 340B statute creates a “closed system” whereby contract pharmacies are not eligible for 340B pricing *at all* because contract pharmacies are not one of the statute’s 15 specifically-designated covered entities. *Id.* at 1144. This Court rejected that as well, holding that dispensing by contract pharmacies was not *per se* invalid under the federal 340B statute. *Id.*

PhRMA next contended that the Arkansas statute “contravene[d] HHS’s exclusive 340B jurisdiction” for oversight and enforcement of the federal 340B statute. *Id.* And finally, PhRMA argued that the state law was “at odds with the FDCA’s Risk Evaluation and Mitigation Strategies (‘REMS’) Program.” *Id.* at 1145. This Court rejected these preemption theories as well.

4. *Missouri Enacts S.B. 751.*

In May 2024, Missouri enacted S.B. 751, which like Arkansas’s law, gives in-state hospitals and other covered entities the right to enter into unlimited contract-pharmacy arrangements to obtain 340B pricing. S.B. 751 provides that a 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.” S.B. 751, Mo. Rev. Stat. § 376.414(2).

To be clear: S.B. 751 regulates pricing and profits, not merely delivery, because in all cases the statute’s obligations apply to a “340B drug.” Novartis and its wholesalers were already delivering these exact same drugs to these exact same pharmacies before the law passed. App.19(R._Doc._1, at 19 ¶ 60). The *only* change the law makes is the price Novartis can charge for the deliveries to these same pharmacies for these same drugs. App.10, 18-19(R._Doc._1, at 10, 18-19 ¶¶ 33, 57-60). Because the drugs are being delivered anyway, and because 340B discounts are not passed onto patients, S.B. 751 also does not impact patient access to medication. App.3-4(R._Doc._1, at 3-4 ¶ 6).

Missouri’s law also regulates *out-of-state* transactions. Novartis, like most other large-scale drug companies, is headquartered outside Missouri. It typically sells its products to national wholesalers and distributors located around the country. App.28-29(R._Doc._1, at 28-29 ¶ 96). In turn, the wholesalers sell the products to national pharmacy chains, whose headquarters are also typically located outside Missouri. *Id.* Further down the distribution chain, the drugs cross the Missouri line and are dispensed to patients from an in-state pharmacy. *Id.* A covered entity wishing to claim a 340B discount typically does not request or receive the discount directly from the drug manufacturer. Instead, covered entities

buy from the (largely out-of-state) wholesalers and distributors, and obtain the 340B discount from them. *Id.* The national wholesalers then separately request a refund from the manufacturers for the difference between the commercial price at which the wholesaler purchased the drug from the manufacturer and the 340B price that the wholesaler must now extend under S.B. 751. That transaction typically takes place between two out-of-state entities. *Id.*

The Missouri Attorney General enforces violations of S.B. 751 and is empowered to seek numerous significant penalties. Mo. Rev. Stat. §§ 376.414(3), 407.130. A violation of S.B. 751 constitutes an unfair, abusive, or deceptive trade practice under the Missouri Merchandising Practices Act (MMPA), *id.* § 407.020 et seq., which allows a maximum \$5,000 fine per violation, *id.* § 407.110. The law also imposes criminal penalties: A person who knowingly and willfully violates an order prohibiting an MMPA violation is guilty of a Class E felony. *Id.* § 407.095.

B. Procedural History.

Novartis sued to enjoin S.B. 751 and sought a preliminary injunction. App.40-42(R._Doc._3). The State's preliminary-injunction opposition included a motion to dismiss the complaint for failure to state a claim. App.98-139(R._Doc._32). The Missouri Hospital Association and Missouri Primary Care Association intervened to defend S.B. 751. App.194-200(R._Doc._62).

As relevant here, Novartis’s preliminary-injunction motion raised three separate theories under the Dormant Commerce Clause— none of which were raised in *McClain*—and three federal preemption challenges—one of which was also never raised or passed upon in *McClain*.

Novartis explained that S.B. 751 violates the Dormant Commerce Clause because it regulates wholly out-of-state conduct; discriminates against out-of-state economic interests; and creates incidental burdens on interstate commerce that far outweigh any local benefit. The District Court denied Novartis’s preliminary-injunction motion, ruling that Novartis was unlikely to succeed on the merits of its Dormant Commerce Clause theories. App.322-325(R._Doc._78, at 7-10).

Separately, the District Court denied the State’s motion to dismiss these claims, ruling each was a plausible theory under the Dormant Commerce Clause.

App.309-315(R._Doc._77, at 9-15).

On preemption, Novartis raised three theories relevant to this appeal. First, Novartis explained that the federal 340B statute preempted the field, such that all state regulation of the 340B was invalid, App.70-73(R._Doc._9, at 27-30), and second, that S.B. 751’s standalone enforcement mechanisms conflicted with HHS’s exclusive jurisdiction over the 340B Program. App.74-76(R._Doc._9, at 31-33). The District Court ruled that Novartis was unlikely to succeed on the merits of these claims in light of *McClain*. App.321-322(R._Doc._78, at 6-7).

Novartis also brought a third preemption theory, contending that S.B. 751 conflicts with the federal 340B statute by requiring manufacturers to “honor unlimited contract pharmacy arrangements.” App.73-74(R._Doc._9, at 30-31). Novartis explained that Congress specifically intended that drug manufacturers retain the ability to limit delivery of 340B drugs to a *single* contract pharmacy and that S.B. 751 impermissibly overrode Congress’s determination. *Id.* (citing *Sanofi*, 58 F.4th at 703; *Novartis*, 102 F.4th at 462). This Court in *McClain* never considered this preemption theory. The District Court nevertheless rejected Novartis’s untested preemption claim solely on the basis of “Eighth Circuit precedent” in *McClain*. App.321-322(R._Doc._78, at 6-7).

Finally, the District Court evaluated the other preliminary injunction factors—irreparable harm, the balancing of the equities, and public interest—and ruled they did not support entry of a preliminary injunction. App.325-328(R._Doc._78, at 10-13).

Novartis timely appealed the denial of its motion for a preliminary injunction. App.330-332(R._Doc._84).

STANDARD OF REVIEW

When reviewing the denial of a preliminary injunction, this Court reviews the district court’s “factual findings for clear error, its legal conclusions de novo,

and the court’s equitable judgment” for an abuse of discretion. *Heartland Acad. Cmty. Church v. Waddle*, 335 F.3d 684, 690 (8th Cir. 2003).

The District Court’s order here, entered on the papers without a hearing, turned largely on its view that Novartis was unlikely to prevail on its Dormant Commerce Clause and federal preemption claims. The legal conclusions incorporated in that ruling are reviewed without deference. *Lankford v. Sherman*, 451 F.3d 496, 504 (8th Cir. 2006) (giving no deference to “erroneous legal conclusions”); *GLBT Youth in Iowa Task Force v. Reynolds*, 114 F.4th 660, 670 (8th Cir. 2024) (similar).

SUMMARY OF THE ARGUMENT

The District Court committed multiple legal errors in denying Novartis’s request for a preliminary injunction.

First, S.B. 751 likely violates the Dormant Commerce Clause in three separate ways. For starters, the statute regulates wholly out-of-state transactions by setting the price at which out-of-state drug manufacturers may sell their products to out-of-state wholesalers—violating one of the Dormant Commerce Clause’s distinct prohibitions. *Styczinski v. Arnold*, 46 F.4th 907, 913 (8th Cir. 2022). The District Court ruled that Novartis was unlikely to prevail on this theory because the Missouri legislature did not “purposely discriminate” against out-of-state economic interests. App.324(R._Doc._78, at 9). But the Supreme Court had

made clear that a state “statute that directly controls commerce occurring wholly outside” of the state “is invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature.” *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989).

Next, S.B. 751 likely violates the Dormant Commerce Clause because it discriminates against out-of-state economic interests by requiring an almost completely out-of-state industry to subsidize Missouri’s hospitals and clinics. The District Court ruled there was no “discrimination” because the in-state hospitals and pharmacies are not “substantially similar” to the out-of-state drug manufacturers. App.323(R._Doc._78, at 8). But substantial similarity between in-state and out-of-state entities is not always a prerequisite to prevailing on a discrimination theory. Rather, the Supreme Court regularly finds discrimination against interstate commerce when the “burden of state regulation falls on interests outside the State.” *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 345 (2007).

Finally, S.B. 751 likely violates the Dormant Commerce Clause because its burdens clearly outweigh any local benefits. The District Court rejected this theory because, in its view, S.B. 751 created significant “local benefits.” App.324(R._Doc._78, at 9). That was wrong: S.B. 751 uses out-of-state entities to effectively “financ[e]” local industry—an illegitimate interest under the Dormant

Commerce Clause. *C&A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 394 (1994).

Second, S.B. 751 is preempted by federal law. Novartis's obstacle-preemption theory is that S.B. 751 forces Novartis to give Missouri hospitals and clinics the right to use *unlimited* contract pharmacies, while the federal 340B statute preserves the right of drug manufacturers to limit delivery to a *single* contract pharmacy. The District Court was incorrect to treat this theory as controlled by *McClain*. App.321-322(R._Doc._78, at 6-7). *McClain* does not address or resolve Novartis's distinct preemption argument.

Novartis acknowledges that its field- and enforcement-preemption theories are similar to the field- and enforcement-preemption theories this Court rejected in *McClain*. See 95 F.4th at 1143-44. Novartis preserves its ability to seek en banc review of these issues because *McClain* conflicts with Supreme Court precedent in rejecting these theories.

Third, the District Court erred in its analysis of the other preliminary injunction factors. S.B. 751 irreparably harms Novartis by causing millions of dollars in financial losses and lost research opportunities, neither of which Novartis could recover through the federal statute's exclusive ADR process if the statute is later held unconstitutional. And because neither the State's interest nor the public

interest is served by enforcing an unconstitutional statute, these factors favor Novartis as well.

ARGUMENT

A motion for a preliminary injunction requires the consideration of four factors: “(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 movant will succeed on the merits; and (4) the public interest.” *Dataphase Sys., Inc. v. CL Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc). All four factors weigh in Novartis’s favor.

I. THE DISTRICT COURT ERRED IN RULING THAT NOVARTIS IS UNLIKELY TO SUCCEED ON THE MERITS

A. Novartis Is Likely To Prevail On Its Dormant Commerce Clause Claim.

S.B. 751 regulates the price that pharmaceutical manufacturers may charge their wholesalers for drugs that are later dispensed by a pharmacy in Missouri. Once the price regulation aspect of S.B. 751 is understood, the Dormant Commerce Clause violations naturally follow.

1. S.B. 751 Regulates Drug Prices.

S.B. 751 is a drug pricing statute. The state law prohibits drug manufacturers from restricting or prohibiting delivery of a “340B drug” to any contract pharmacy that a covered entity designates, and it defines a “340B drug” as including a “covered outpatient drug within the meaning of Section 340B of the

Public Health Service Act, 42 U.S.C. Section 256b.” S.B. 751 §§ 376.414(1)(a), 376.414(3). By using the term “within the meaning of Section 340B,” the Missouri statute mandates that the price of specific units of drugs be “at or below the applicable ceiling price” set by the federal 340B statute. 42 U.S.C. § 256b(a)(1); App.18(R._Doc._1, at 18 ¶ 58).

The District Court’s erred by resting its analysis exclusively on the statute’s use of the word “deliver,” App.320(R._Doc._78, at 5), without also considering the object of that mandate. The key question is delivery of *what*, and the answer is the same drugs the pharmacy is already receiving, but now at a discount. Even before the statute, these same drugs were already being delivered to these same Missouri pharmacies by the same wholesalers or regional distributors. S.B. 751 does not change when, where, or how the delivery occurs. It does not result in more or fewer units of drugs being sold in the state. And critically, it does not change whether and where the patients can access these drugs and at what price. The statute affects nothing about that delivery *other than the sales price that is paid* for the exact same unit of the exact same drug the pharmacy receives from the wholesaler. App.19(R._Doc._1, at 19 ¶ 60).

The details of the replenishment model used by contract pharmacies in Missouri underscore that S.B. 751 regulates prices. Using that model, a third-party administrator looks through claims data for dispenses by contract pharmacies long

after the prescription is filled to identify prescriptions that it claims were 340B eligible, without providing the algorithms or specifics of the claim or how the individual qualifies as a patient of the covered entity. When they purport to find such a sale, the third-party administrator retroactively designates the drug as 340B-eligible. App.2-3, 10(R._Doc._1, at 2-3, 10 ¶¶ 3, 4, 33). Again, manufacturers are unable to verify whether the 340B discount was warranted.

After the third-party administrator flags a *previous* transaction, the covered entity then seeks to “replenish” the dispensed unit by ordering a brand new drug to be delivered to the contract pharmacy at the 340B discounted price. That new unit is then available for dispensing (at a non-discounted price) to the next customer with a prescription. This is effectuated through a series of *ex post* discounts extending up the supply chain to the manufacturer, which must reimburse its wholesaler for the difference between the commercial price and the 340B price. App.28-29(R._Doc._1, at 28-29 ¶ 96). S.B. 751 has zero impact beyond price on any delivery of any product to any pharmacy. The only change is the price being charged.

S.B. 751 is also not about patients’ access to drugs. The replenishment model means that the 340B drug is not even identified until *after* the patient has already obtained a prescription and pays the retail price. Drugs subject to 340B pricing are thus accessible to patients at the same pharmacies and for the same

retail prices without regard to S.B. 751. App.3-4, 11(R._Doc._1, at 3-4, 11 ¶¶ 6, 35).

The State repeatedly insisted below that S.B. 751 is concerned with the “delivery” of drugs and “*does not cap or set the price of drugs.*” App.120(R._Doc._32, at 23) (emphasis in original); App.119(R._Doc._32, at 22) (“Nothing about S.B. 751 adjusts . . . the price at which Novartis must sell those drugs.”). But it is pure semantics to state that the statute does not regulate *price*, only *delivery of the drugs at a certain price*. The State has never identified any “delivery” requirement in S.B. 751 aside from the “delivery” of drugs at discounted 340B prices. Nor could it: S.B. 751 does not affect the quality of the drugs delivered, the amount delivered, how they are delivered, or where they are delivered.

A simple examination of how a manufacturer would violate S.B. 751 is illustrative. Say a covered entity orders 100 units of a given drug from a wholesaler for delivery to a contract pharmacy. The wholesaler already sells that same drug to the pharmacy at commercial prices. A manufacturer violates S.B. 751 if it refuses to offer the 340B discount on any of those new units. That is a pricing regulation, pure and simple. A statute advancing a state’s interest in drug delivery, in contrast, could involve how many units can be delivered at once;

whether there must be temperature-controlled trains or trucks involved; or whether the drugs are limited to specialized pharmacies. Nothing like that is present here.

A federal court in West Virginia understood this shell game. *PhRMA v. Morrisey*, ___ F. Supp.3d ___, 2024 WL 5147643 (S.D. W. Va. Dec. 17, 2024). The court explained that manufacturers risk violating West Virginia’s similar 340B “delivery” statute “not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering [their] drugs to those pharmacies.” *Id.* at *9 (citation omitted). The court also understood how the replenishment model factors into the analysis: “The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one”—thus, the state statute required “delivery *at a given price*,” not “delivery *per se*.” *Id.* at *8.

Contrary to the District Court’s understanding, App.321(R._Doc._78, at 6), *McClain* does not suggest otherwise. *McClain* addressed federal preemption claims and does not speak to the merits of the unrelated *Dormant Commerce Clause* claim at issue here. *See United States v. Green*, 691 F.3d 960, 964 n.5 (8th Cir. 2012) (implicit holdings of “an issue that was not raised or discussed is not binding precedent”); *Downs v. Holder*, 758 F.3d 994, 997-998 (8th Cir. 2014) (similar). What’s more, the facts as understood by this Court in *McClain*—the earliest case challenging a state 340B statute—do not square with the allegations in

Novartis’s complaint. *McClain* rested on the factual predicate that the covered entities in Arkansas maintain title to the 340B drugs that their contract pharmacies dispense. 95 F.4th at 1142. Novartis directly alleges the opposite here, App.17(R._Doc._1, at 17 ¶ 53), underscoring that S.B. 751 is not actually about the “delivery” of a covered entity’s 340B drugs, but the price that covered entities pay under the 340B Program *on units delivered to contract pharmacies*.

2. *S.B. 751 Likely Violates The Dormant Commerce Clause In Three Independent Ways.*

The Commerce Clause, U.S. Const. art. I, § 8, cl. 3, includes a “negative command, known as the dormant Commerce Clause,” which prohibits states from regulating or discriminating against interstate commerce. *Oklahoma Tax Comm’n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995). S.B. 751 violates that prohibition in three independent ways: It regulates wholly out-of-state conduct; it discriminates against out-of-state economic interests; and it creates incidental burdens on interstate commerce that far outweigh any local benefit. Each of these theories is sufficient to show a likelihood of success on the merits.

i. S.B. 751 unlawfully regulates wholly out-of-state transactions.

A state law that “directly control[s] wholly out-of-state commerce is invalid” under the Dormant Commerce Clause. *Styczinski*, 46 F.4th at 913; *see also Healy*, 491 U.S. at 336 (prohibiting state regulation of “commerce that takes place wholly

outside of the State’s borders” (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-643 (1982) (plurality opinion)). S.B. 751 runs afoul of that rule.

S.B. 751 provides that “pharmaceutical manufacturer[s]” shall not “indirectly” restrict delivery of a 340B drug to any and all contract pharmacies that a Missouri covered entity designates. § 376.414.2. Virtually all drug manufacturers subject to that sweeping command are located outside of Missouri and violate the statute by denying 340B discounts in out-of-state transactions with wholesalers. App.28-29(R._Doc._1, at 28-29 ¶ 96).

Novartis does not transact directly with *any* Missouri covered entities. It transacts with out-of-state wholesalers, and those wholesalers distribute Novartis’s drugs nationwide. App.28-29, 36(R._Doc._1, at 28-29, 36 ¶¶ 96, 122). Missouri’s covered entities—some of which even use out-of-state contract pharmacies—obtain the 340B discount from wholesalers, and the wholesalers then separately request a refund from Novartis. App.28-29(R._Doc._1, at 28-29 ¶ 96). S.B. 751 requires drug manufacturers *anywhere in the country* to honor the wholesaler’s refund request for units subject to that law, even when the drug manufacturer did “not conduct[] a single transaction in [Missouri]” or with a Missouri-based entity. *Styczinski*, 46 F.4th at 913. The statute thus regulates “commerce wholly outside” of Missouri, which is disallowed under the Dormant Commerce Clause. *Id.*; see also, e.g., *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 836 (7th Cir. 2017)

(Dormant Commerce Clause invalidates Indiana law regulating e-cigarette “sales by an out-of-state manufacturer to an out-of-state distributor” even where “the distributor resells the e-liquids to Indiana retailers” because the regulated upstream transaction took place “wholly outside” of Indiana).

The District Court’s reasoning in rejecting this theory does not hold up. App.324-325(R._Doc._78, at 9-10). For starters, the District Court “presum[ed]” that S.B. 751 does not operate extraterritorially because its “express text” does not address conduct outside of Missouri. App.325(R._Doc._78, at 10). But by mandating a discounted price be given by manufacturers—virtually all of which are effectuated out of state—the state law regulates purely extraterritorial conduct between manufacturers and wholesalers. *See Association for Accessible Meds. v. Ellison*, 704 F. Supp. 3d. 947, 953 (D. Minn. 2023) (ruling that price restrictions on “drugs . . . ‘delivered’ within the State” applies to the initial sale occurring outside of the state); *see also* App.157-158(R._Doc._35-1) (demanding that Novartis honor 340B discounts for drugs delivered to all of a Missouri covered entity’s contract pharmacies). Indeed, S.B. 751 even reaches drugs *dispensed by non-Missouri pharmacies outside of Missouri* as long as they contract with a Missouri-based covered-entity.

The District Court next rejected Novartis’s extraterritoriality challenge on the basis that S.B. 751 treats drug manufacturers the same “regardless of their in-

state or out-of-state operations.” App.325(R._Doc._78, at 10). But that conflates two distinct Dormant Commerce Clause theories: A state’s discriminatory treatment of out-of-state entities has no bearing on Novartis’s standalone theory that Missouri impermissibly regulates wholly out-of-state transactions. *Styczinski*, 46 F.4th at 912 (explaining that “extraterritorial control” of out-of-state transactions and “discriminat[ion] against interstate commerce” are separate theories).

The District Court was also mistaken in its view that S.B. 751 does not regulate wholly out-of-state transactions because the drugs are ultimately delivered or acquired by “contract pharmacies within the state.” App.325(R._Doc._78, at 10). Court after court has recognized the opposite (and obvious) truism: A drug manufacturer’s initial sale to “national wholesalers,” App.28-29(R._Doc._1, at 28-29 ¶ 96), is separate from a regional wholesaler’s or distributor’s later sale to an individual pharmacy.

And the Dormant Commerce Clause prohibits states from regulating the manufacturer’s initial sale, if that sale occurs out of state. In *Association for Accessible Medicines v. Frosh*, for example, the Fourth Circuit held that a Maryland state law prohibiting all drug manufacturers and wholesalers from engaging in price gouging did *not* regulate the Maryland retailers that ultimately sold the drugs to patients. 887 F.3d 664, 671-672 (4th Cir. 2018). The court

explained that the “lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug.*” *Id.* at 671 (emphasis in original). Because that upstream transaction took place outside of Maryland, the Dormant Commerce Clause prevented the state from regulating it. *Id.* at 671-672. Courts across the country have reached the same result. *See Ellison*, 704 F. Supp. 3d. at 953 (preventing liability for sales to wholesaler “that take place wholly outside of Minnesota”); *Healthcare Distrib. All. v. Zucker*, 353 F. Supp. 3d 235, 246, 261-262 (S.D.N.Y. 2018) (law prohibiting manufacturers from “pass[ing]-through” a regulatory fee impermissibly regulated transactions wholly outside of New York), *rev’d in part on other grounds sub nom. Association for Accessible Meds. v. James*, 974 F.3d 216, 219 (2d Cir. 2020); *PhRMA v. District of Columbia*, 406 F. Supp. 2d 56, 68 (D.D.C. 2005) (price restrictions on sales from manufacturers to wholesalers on drugs later sold in the District impermissibly regulate wholly out-of-state transactions), *aff’d sub. nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).

Finally, the District Court faulted Novartis for not alleging that the Missouri legislature *purposefully discriminated* against out-of-state economic interests. App.324-325(R._Doc._78, at 9-10) (citing *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023)). But the Supreme Court has explained that a state “statute that directly controls commerce occurring wholly outside” of the state “is

invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature.” *Healy*, 491 U.S. at 336. The Court has also emphasized that *Healy*’s no-intent-required rule prevents states from requiring out-of-state drug manufacturers to “sell their drugs to a wholesaler for a certain price.” *PhRMA v. Walsh*, 538 U.S. 644, 669 (2003); *see also Frosh*, 887 F.3d at 672 (holding *Walsh* prohibits state laws that “regulate[] the price of [] out-of-state transaction[s]”).

The Supreme Court’s recent decision in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), kept *Healy*’s rule intact. *Pork Producers* rejected a “per se” rule that the Dormant Commerce Clause forbids enforcement of state laws that have a “practical effect” of controlling commerce outside of the state, 598 U.S. at 371, 374—separate from the Dormant Commerce Clause’s rule that states may not regulate wholly out-of-state transactions. *Pork Producers*’s rejection of the per se “practical effects” rule stemmed from a state’s well-established right to exclude certain widely-available products from its territory, in that case, California’s right to prohibit the sale of pork meat derived from animals confined in a cruel manner. *Id.* at 369; *City of Philadelphia v. New Jersey*, 437 U.S. 617, 629 (1978) (states may “prevent[] traffic in noxious articles, whatever their origin”). That right of exclusion is valid, the Supreme Court explained, even though it has significant “practical effects” on interstate commerce. *Pork Producers*, 598 U.S. at 374

(providing examples of other state laws, such as those regulating taxes or the environment, that have permissible “practical effects” on interstate commerce).

The “practical effects” doctrine at issue in *Pork Producers* is not implicated here, as Missouri does not seek to regulate the nature or type of drugs that can be sold in-state or the conditions under which those products must be produced or delivered. Instead, Missouri purports to regulate *only* the price that drug manufacturers can charge wholesalers for drugs *in wholly out-of-state transactions*. See *National Pork Producers Council v. Ross*, 6 F.4th 1021, 1029 (9th Cir. 2019) (“A state law is not impermissibly extraterritorial unless it directly regulates conduct that is wholly out of state.”), *aff’d* 598 U.S. 356 (2023). Courts have consistently read *Pork Producers* and *Healy* to draw that critical distinction. See *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1324 (9th Cir. 2015) (en banc) (distinguishing between laws regulating “wholly out-of-state conduct” and those regulating “*in-state conduct* with allegedly significant out-of-state practical effects”); see also *Interlink Prods. Int’l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. 2023) (*Pork Producers* clarified that laws with mere “extraterritorial effects are not prohibited under the dormant Commerce Clause” and “distinguished them from those in which a law directly regulated out-of-state transactions”) (quotation marks omitted); *Ellison*, 704 F. Supp. at 953 (“*Pork Producers* did not change the rule that a state may not directly regulate transactions

that take place wholly outside the state and have no connection to it.”). Novartis is likely to prevail on this Dormant Commerce Clause theory.

ii. S.B. 751 discriminates against out-of-state economic interests.

Separately, a state law that “discriminates against out-of-state goods or nonresident economic actors” also violates the Dormant Commerce Clause.

Tennessee Wine & Spirits Retailers Ass’n v. Thomas, 588 U.S. 504, 518, 540 (2019). In this context, discrimination means “differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter.”

Oregon Waste Sys., Inc. v. Department of Env’t Quality of State of Or., 511 U.S. 93, 99 (1994). S.B. 751 violates this rule, too.

S.B. 751 requires out-of-state manufacturers to provide their products at 340B-discounted prices to Missouri-based hospitals and their contract pharmacies in a wide number of transactions that the federal program itself does not require. App.36(R._Doc._1, at 36 ¶ 124). That amounts to a direct cash transfer from the pockets of (almost entirely) out-of-state drug manufacturers to (entirely) in-state hospitals and clinics. The Dormant Commerce Clause prohibits such disfavored treatment of out-of-state “economic interests.” *Oregon Waste*, 511 U.S. at 99.

The District Court accepted the premise that S.B. 751 favors in-state hospitals and clinics at the expense of a drug-manufacturing industry located

almost entirely outside of Missouri. Regardless, it ruled that Novartis was unlikely to prevail on this theory because it had not shown “how in-state pharmacies are substantially similar to out-of-state manufacturers.” App.323(R._Doc._78, at 8) (citing *Department of Revenue of Ky. v. Davis*, 553 U.S. 328, 342 (2008)).

That was legal error. There 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. *See Frosh*, 887 F.3d at 673-674 (finding Dormant Commerce Clause violation where drug pricing statute alters the interstate activity between manufacturers, wholesalers, and retailers). To the contrary, state laws can impermissibly discriminate against interstate commerce where “the burden of state regulation falls on interests outside the state.” *Oneida-Herkimer*, 550 U.S. at 345; *see also Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263, 272-273 (1984) (states “may not ‘build up [their] domestic commerce by means of unequal and oppressive burdens upon the industry and business of other States.’ ” (quoting *Guy v. Baltimore*, 100 U.S. 434, 443 (1880))). Because such lopsided laws lack the “political restraints normally exerted when interests within the state are affected,” the Supreme Court’s “dormant Commerce Clause cases often find discrimination.” *Oneida-Herkimer*, 550 U.S. at 345.

The District Court’s contrary conclusion rested on the Supreme Court’s decision in *Department of Revenue of Kentucky v. Davis*, which stated that “any

notion of discrimination assumes a comparison of substantially similar entities.” App.323(R._Doc._78, at 8) (quoting 553 U.S. 328, 342 (2008)). But the principle that “favored and disfavored entities” must be substantially similar to show discrimination applies only when the two are “allegedly competing” with one another. *General Motors Corp. v. Tracy*, 519 U.S. 278, 299-300 (1997). Because drug manufacturers and covered entities are not in direct competition, *Davis*’s statement does not apply.

In fact, *Davis* has no bearing on Novartis’s discrimination theory at all. In *Davis*, the Supreme Court upheld Kentucky’s law providing tax-exempt status to in-state municipal bonds but not out-of-state municipal bonds because the out-of-state bond issuers were “properly treated” as “private entit[ies].” *Id.* at 343. And Kentucky was under no obligation to apply the same tax treatment to public and private entities that operate in the same market. *Id.* at 343 & n.13. That case sheds no light on the question here: Whether Missouri discriminates against interstate commerce when it enacts laws propping up an exclusively in-state hospital and clinic industry at the expense of an almost-exclusively out-of-state drug manufacturing industry.

The answer is yes. Novartis is likely to succeed on the merits of showing that S.B. 751 improperly discriminates against out-of-state economic interests.

iii. S.B. 751 fails the Pike balancing test.

S.B. 751 further, and independently, violates the Dormant Commerce Clause because the incidental “burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits.” *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); *see also Pork Producers*, 598 U.S. at 403 (Kavanaugh, J., concurring) (“six Justices of this Court affirmatively retain the longstanding *Pike* balancing test”).

On one side of the scale, S.B. 751 harms interstate commerce by reducing the revenues that national drug manufacturers receive on drugs that are later sold in Missouri (or at least, sold by contract pharmacies used by Missouri-based covered entities). Drugs unconnected to a Missouri covered entity or its contract pharmacies, by contrast, are not subject to S.B. 751’s price controls—effectively stratifying the national market for prescription drugs. *See General Motors Corp.*, 519 U.S. at 287 (Dormant Commerce Clause exists to protect “free private trade in the national marketplace”).

The burdens that out-of-state manufacturers must bear when their drugs eventually cross over the Missouri state line are significant. Novartis anticipates that complying with S.B. 751 will cost it millions of dollars per year in forced discounts. App.92(R._Doc._9-1, at 4 ¶ 12). Those costs will only multiply, as more states follow Arkansas’s and Missouri’s lead. *See Healy*, 491 U.S. at 336

(the state statute’s interstate burdens must consider how the law “may interact with the legitimate regulatory regimes of other States”); *Frosh*, 887 F.3d at 670 (holding Maryland statute violated Dormant Commerce Clause, in part, because “if similarly enacted by other states, [it] would impose a significant burden on interstate commerce involving prescription drugs”). Comparable statutes have been adopted by Kansas, Louisiana, Nebraska, Mississippi, Maryland, Minnesota, New Mexico, North Dakota, South Dakota, Tennessee, Utah, and West Virginia—and more are sure to come. App.31(R._Doc._1, at 31 ¶ 102); *see supra* n.2.

These laws are not identical. *See CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 88 (1987) (invalidating state “statutes that may adversely affect interstate commerce by subjecting activities to inconsistent regulations”); *Healy*, 491 U.S. at 337 (Dormant Commerce Clause “preclude[s]” “competing and interlocking local economic regulation”). New Mexico, for example, requires manufacturers to honor unlimited contract pharmacies only for covered entities that “receive federal grant funding.” N.M. H.B. 78, § 1(A)(4). Nebraska, meanwhile, requires discounts for covered drugs delivered to “any location” that the covered entities authorize. Neb. L.B. 168, § 3(1). And Louisiana requires 340B discounts to be honored at a pharmacy of the “patient’s choice.” La. Rev. Stat. § 40:2883(A)(vi)(d). Novartis must now contend with a patchwork of state laws carving out their own regimes for the federal 340B system,

App.94(R._Doc._9-1, at 6 ¶ 18), “balkaniz[ing]” the national market for pharmaceutical drugs and undercutting the foundations of the Dormant Commerce Clause. *Fulton Corp. v. Faulkner*, 516 U.S. 325, 333 n.3 (1996).

On the other side of the scale, no “local benefits” justify these immense burdens on interstate commerce. *Pike*, 397 U.S. at 142. Again, S.B. 751 effectively amounts to a direct cash transfer from out-of-state drug manufacturers to in-state hospitals and clinics, and for-profit pharmacies. And “financing,” or enriching, local industry—especially when it burdens out-of-state actors—is not a valid interest under the Dormant Commerce Clause. *C&A Carbone*, 511 U.S. at 394.

Even if Missouri could identify a legitimate local purpose, it could achieve that purpose with “a lesser impact on interstate activities.” *Pike*, 397 U.S. at 90. Most obviously, Missouri could directly “subsidize” its local hospitals, clinics, and pharmacies “through general taxes” or bonds. *C&A Carbone*, 511 U.S. at 394.

The District Court rejected Novartis’s *Pike*-based argument because, in its view, S.B. 751 provides local benefits through “pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level.” App.324(R._Doc._78, at 9). That is wrong three times over. First, the 340B Program does not provide pricing discounts to individuals or families whose income falls below the federal poverty level. The discount is for a

hospital's or clinic's purchase based on its covered-entity status; it applies to drugs dispensed to their high-income and low-income patients alike; and the discount is not applicable to *patient* purchases. *See supra* 9-10; 42 U.S.C. § 256b(a)(1).

Second, the District Court ignored Novartis's evidence that covered entities, contract pharmacies, and their third-party administrators frequently "pocket the discount themselves," rather than pass them onto their patients. App.13-14(R._Doc._1, at 13-14 ¶ 44); *see also* App.83(R._Doc._9, at 40); App.60(R._Doc._9, at 6). Novartis presented a 2022 study published by the Food & Drug Law Institute that found that contract pharmacies reach an "astounding 72%" average profit margin when dispensing common 340B drugs, compared to 22% for non-340B drugs. App.83(R._Doc._9, at 40) (citing Peter J. Pitts & Robert Popovian, *340B and the Warped Rhetoric of Healthcare Compassion*, (FDLI Fall 2022));³ *see also* 11A Charles A. Wright & Arthur R. Miller, *Fed. Prac. & Proc. Civ.* § 2949 (3d ed. 2025 update) ("hearsay evidence also may be considered" on a preliminary injunction motion). It also highlighted that major pharmacy retailers retain 340B discounts—instead of passing them onto customers—at such a level that those discounts are material to their financial outlook. App.299(R._Doc._72, at 14) (citing CVS Health Corp., Annual Report (SEC Form 10-K), at 22 (Feb. 8,

³ <https://www.fdpi.org/2022/09/340b-and-the-warpedrhetoric-of-healthcare-compassion/>

2023), <https://bit.ly/3Sh3Dl1>; Walgreens Boots Alliance, Inc., Annual Report (SEC Form 10-K), at 28 (Oct. 13, 2022), <http://bit.ly/3kflVXh>). By contrast, neither the State nor intervenors put forth any conflicting evidence or studies to show that S.B. 751 generally decreases costs for needy patients.

Notably, the District Court *denied* the State’s motion to dismiss Novartis’s *Pike* theory, ruling that S.B. 751’s purported local benefits “may warrant further scrutiny.” App.314(R._Doc._77, at 14). Yet for the preliminary injunction motion, the District Court accepted the State’s contested (and flimsy) assertion that S.B. 751 generally creates savings and increases access for low-income patients, App.324(R._Doc._78, at 9), *without holding a hearing*. See *Wright & Miller* § 2949 (“[W]here there are factual disputes . . . a live hearing is more likely needed.”).

Third, the District Court violated the Supreme Court’s command to closely scrutinize a state’s asserted interest when the statute “bears disproportionately on out-of-state residents and businesses.” *Kassel v. Consolidated Freightways Corp. of Del.*, 450 U.S. 662, 676 (1981); see also *Clover-Green Spring Dairies Inc. v. Pennsylvania Milk Marketing Bd.*, 298 F.3d 201, 215-216 & n.18 (3d Cir. 2002). S.B. 751 is directed at “pharmaceutical manufacturer[s],” § 376.414.2, nearly all of which operate outside of the state and do not represent any “major in-state interests.” *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 473 & n. 17

(1981). Because there is “reason to suspect” that S.B. 751’s “gainers will be [in-state] firms” and its “losers out-of-state firms,” this Court should closely examine any justification the State puts forth to support S.B. 751’s grossly uneven burdens. *Id.* at 473.

B. Novartis Is Likely To Prevail On Its Claim That S.B. 751 Conflicts With The Federal 340B Statute, And *McClain* Does Not Hold Otherwise.

Novartis is also likely to prevail on its claims for injunctive relief based on federal preemption. S.B. 751 grants Missouri covered entities the right to use an *unlimited* number of contract pharmacies. That conflicts with the federal 340B statute, which Congress drafted to preserve a manufacturer’s right to limit distribution to a *single* contract pharmacy at the covered entity’s choosing. *Novartis*, 102 F.4th at 463; *see also Sanofi*, 58 F.4th at 706 (“Congress’s purposes” was not for covered entities to “use an unlimited number of contract pharmacies”).⁴

The Constitution’s Supremacy Clause, U.S. Const. Art. VI, § 2, prohibits states from enacting laws that “stand[] as an obstacle to the accomplishment and

⁴ Following the parties’ briefing, the D.C. and Third Circuits discussed a manufacturer’s limitation to distribute to a single contract pharmacy in terms of being a “delivery condition,” without considering whether such conditions are actually about *price*, because that was not at issue in those cases. The question in those cases was whether a manufacturer makes an “offer” under Section 256b(a)(1) if it places certain conditions on that offer. Moreover, because *Novartis* and *Sanofi* did not involve state laws, there was no Dormant Commerce Clause analysis to conduct.

execution of the full purposes and objectives of Congress.” *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 152-153 (1982) (internal quotation marks and citation omitted). S.B. 751 conflicts with the federal 340B statute, and thus violates that rule.

The federal 340B statute requires manufacturers to “offer each covered entity covered outpatient drugs for purchase” at or below the statutory ceiling “price.” 42 U.S.C. § 256b(a)(1). Using this specific language, Congress “merely require[d] manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount.” *Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703 (“Even if drug makers limit where they will deliver drugs, they still present the drugs for covered entities’ acceptance.”). By limiting the statute’s reach, Congress *intentionally* “preserve[d]” a manufacturer’s pre-existing ability to “impose at least some delivery conditions.” *Novartis*, 102 F.4th at 460; *see also Sanofi*, 58 F.4th at 705 (Congress intended to grant “drug makers discretion on delivery”). That includes manufacturers’ right to limit distribution of 340B drugs to a *single* “contract pharmacy designated or previously used” by a covered entity. *Novartis*, 102 F.4th at 463. Congress authorized manufacturers to implement this limited delivery policy because, with it, the manufacturer is still making a bona fide and reasonable “offer” to covered entities at the statute’s ceiling “price”—the core, and balanced, requirements that Congress imposed on manufacturers. *Id.*; *see*

also *Rodriguez v. United States*, 480 U.S. 522, 525-526 (1987) (“Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice.”).

S.B. 751, by contrast, permits covered entities to use an *unlimited* number of contract pharmacies. That “frustrate[s]” the federal 340B statute’s “natural effect”—which, again, was to preserve a manufacturer’s right to limit delivery to *one* contract pharmacy—and thus cannot stand. *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 373 (2000) (applying “obstacle” preemption).

The Supreme Court’s decision in *Geier v. American Honda Motor Co.*, underscores that state laws may not limit the range of options that Congress intended to provide regulated entities. 529 U.S. 861 (2000); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (“The purpose of Congress is the ultimate touchstone in every preemption case.”) (internal quotation marks omitted). In *Geier*, an injured driver claimed that the car he was driving was negligently and defectively designed because it lacked a driver’s side airbag. 518 U.S. at 865. While federal safety standards at the time provided car manufacturers with a range of options for passive restraint devices, *id.* at 874-875, the driver’s lawsuit would have required auto manufacturers to install an airbag. *Id.* at 881. Because that outcome would undermine Congress’s decision to permit a variety of devices, the state law “stood as an obstacle” to the execution of “federal objectives” and was

thus preempted. *Id.* (internal quotation marks omitted); *see also de la Cuesta*, 458 U.S. at 156 (state law limiting the availability of an option considered essential to a federal scheme was conflict preempted).

Novartis presented this obstacle-preemption theory to the District Court. *See* App.73-74(R._Doc._9, at 30-31); App.24-25(R._Doc._1, at 24-25 ¶ 83); App.91(R._Doc._9-1, at 3 ¶ 8). The District Court rejected it “[g]iven the Eighth Circuit precedent” in *McClain*. App.321-322(R._Doc._78, at 6-7). But, critically, *McClain* never considered this obstacle-preemption theory and offers no guidance on how to resolve that issue. In *McClain*, PhRMA contended that the Arkansas statute was preempted because the federal 340B statute created a “closed system” that forbid *any* contract pharmacies from obtaining drugs at 340B prices. *McClain*, 95 F.4th at 1144; Appellant’s Opening Brief, *PhRMA v. McClain*, No. 22-3675, 2023 WL 2337833, at *43 (8th Cir. Feb. 22, 2023) (“Act 1103 is conflict preempted because it frustrates . . . Congress’s intent to operate the federal 340B program as a closed system.”); Complaint, *PhRMA v. McClain*, Case 4:21-cv-00864-BRW, Dkt. 1 ¶ 69 (E.D. Ark. Sept. 29, 2021) (alleging conflict preemption because “[n]either contract pharmacies nor ‘community pharmacies’ are among the [federal 340B statute’s] fifteen enumerated covered entities”). *McClain* rejected that preemption theory, 95 F.4th at 1144, but was not presented with and did not pass upon Novartis’s theory here: That S.B. 751 is obstacle preempted because it

requires manufacturers to recognize an *unlimited* number of contract pharmacies. Novartis is likely to prevail on this untested obstacle-preemption theory.

C. Novartis Preserves An Argument That *McClain* Was Wrongly Decided.

Novartis contended that S.B. 751 is both field preempted and enforcement preempted. While the District Court ruled that those arguments are foreclosed under *McClain*, Novartis preserves for further review that *McClain*'s holdings on these points conflict with Supreme Court decisions and implicate matters of exceptional importance.

1. *McClain's Field Preemption Holding Conflicts With Supreme Court Case Law.*

State laws are preempted where the federal regulation is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.” *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990). The federal 340B statute establishes such a scheme.

Congress's expansive delegation of power to HRSA to administer the 340B Program makes clear that it intended to exclusively occupy the entire field of 340B transactions. It is the Secretary's exclusive duty to provide for compliance improvements, 42 U.S.C. § 256b(d)(1)(A), by establishing “a *single, universal, and standardized identification system* [] for purposes of facilitating the *ordering, purchasing, and delivery* of covered outpatient drugs[,] including the processing of

chargebacks for such drugs,” *id.* § 256b(d)(2)(B)(iv) (emphasis added). Congress implemented a “single integrated and all-embracing” federal system, thus occupying the field. *Hines v. Davidowitz*, 312 U.S. 52, 74 (1941); *American Ins. Ass’n v. Garamendi*, 539 U.S. 396, 419 n.11 (2003).

McClain held that the federal 340B statute does not occupy the field in part because “the practice of pharmacy is an area traditionally left to state regulation.” 95 F.4th at 1143. That presumption against preemption flows from the “historic primacy of state regulation of matters of health and safety.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001). But because the contours and administration of the national 340B Program represent “uniquely federal” interests, the presumption against preemption does not attach. *Boyle v. United Techs. Corp.*, 487 U.S. 500, 507-508 (1988); *see also Buckman*, 531 U.S. at 348 (similar).

2. *McClain’s Enforcement Preemption Holding Conflicts With Supreme Court Case Law.*

The federal 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).

State laws are preempted when they “involve[] a conflict in the method of enforcement” that Congress created. *Arizona v. United States*, 567 U.S. 387, 406 (2010). S.B. 751 is preempted under that theory as well. The federal 340B statute

provides two, detailed methods of enforcement. *See supra* 10-11 (describing HHS’s direct enforcement authority and the parallel ADR process).

The Supreme Court held in *Astra* that those mechanisms were exclusive. 563 U.S. at 117, 120. In *Astra*, county-operated 340B facilities brought state-law third-party beneficiary claims for breach of contract against drug manufacturers, claiming they were changing prices beyond the 340B cap. *Id.* at 117. The Supreme Court rejected those claims, concluding that additional enforcement mechanisms would “undermine the agency’s efforts to “administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis.” *Id.* at 120. That precedent applies here: S.B. 751 is preempted because its grant of authority to the Missouri Attorney General to bring suit threatens “a multitude of dispersed and uncoordinated lawsuits.” *Astra*, 563 U.S. at 120; *see also Morrisey*, 2024 WL 5147643, at *12 (ruling West Virginia 340B law was preempted because its enforcement provisions “much like the county in *Astra*, operate as a means of ‘enforcing the [340B] statute.’ ” (quoting *Astra*, 563 U.S. at 118)).⁵

McClain rejected this enforcement-preemption theory on the basis that the 340B enforcement mechanisms dealt with price, while the state-law enforcement

⁵ S.B. 751’s separate set of civil and criminal penalties, *see supra* 22, underscore that the statute is enforcement preempted. *See Wisconsin Dep’t of Indus., Lab. & Hum. Rels. v. Gould Inc.*, 475 U.S. 282, 286, 288 (1986) (“ ‘[C]onflict is imminent’ whenever ‘two separate remedies are brought to bear on the same activity.’ ”) (citation omitted).

mechanisms dealt with delivery. 95 F.4th at 1144. As described above, the purported price/delivery dichotomy is false. *See supra* 28-33. But regardless, S.B. 751 is still preempted. If S.B. 751 relates to non-pricing “delivery” conditions—which it does not—then so would the conditions at issue in *Novartis* and *Sanofi*. Those cases reviewed conditions that limited the provision of 340B drugs to a single contract pharmacy, *see Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703, regulating the same activity as S.B. 751, which requires delivery to an unlimited number of contract pharmacies.

And in *Novartis* and *Sanofi*, HRSA sought to halt manufacturers from imposing the reasonable condition of limiting covered entities to using a single-contract-pharmacy by issuing Section 256b(d)(1) *enforcement letters* under its carefully prescribed statutory authority. *See Novartis*, 102 F.4th at 458; *Sanofi*, 58 F.4th at 701-703 (describing similar “violation letters”). Disputes surrounding conditions of this nature are thus channeled through the federal 340B statute’s dual enforcement mechanisms, which Congress designed to be exclusive. *See Astra*, 563 U.S. at 117. *McClain*’s contrary holding is incorrect.

II. THE DISTRICT COURT ERRED IN RULING THAT NOVARTIS FAILED TO SATISFY THE REMAINING PRELIMINARY INJUNCTION FACTORS.

A. Novartis Has Established Irreparable Harm.

Novartis is stuck between a rock and a hard place: comply with S.B. 751 and incur millions of dollars in irrecoverable, forced discounts or violate Missouri law and subject itself to significant civil and criminal liability. Novartis suffers irreparable harm either way.

Irrecoverable Financial Losses. Unrecoverable monetary loss qualifies as irreparable harm. *Iowa Utilities Bd. v. F.C.C.*, 109 F.3d 418, 426 (8th Cir. 1996). And complying with S.B. 751 costs Novartis millions of dollars annually in the form of lost revenues. App.92(R._Doc._9-1, at 4 ¶ 12). These funds cannot be recovered should S.B. 751 ultimately be found unconstitutional. The federal 340B statute's ADR process—the *sole* legal process that manufacturers may initiate under the federal 340B Program—is limited to claims for prohibited drug resales or duplicative discounts. 42 U.S.C. § 256b(d)(3)(A). Neither this process nor any state process allows recovery for a 340B discount provided on account of an unconstitutional state law—thus establishing irreparable harm. *General Motors Corp. v. Harry Brown's, LLC*, 563 F.3d 312, 319 (8th Cir. 2009).

That irreparable harm compounds as the lost revenue will force Novartis to forgo research and development for new drugs. Novartis uses the revenues

generated from drugs already on the market to fund its research efforts for future drugs. App.91-92(R._Doc._9-1, at 3-4 ¶¶ 9-11). S.B. 751 disrupts this cycle. It decreases the funds available for Novartis’s innovative research, creating an irreparable harm unto itself. App.91-92(R._Doc._9-1, at 4-5 ¶ 14); *see also Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1011 (Fed. Cir. 2009) (lost research opportunities constitutes irreparable harm).

Civil and Criminal Penalties. If Novartis chooses instead to *not* comply with S.B. 751, it risks an immediate and unconstitutional state enforcement action with severe civil and criminal penalties. *See* Mo. Rev. Stat. § 376.414; *id.* § 407.020 *et seq.* That, too, constitutes irreparable harm. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992). Violations of S.B. 751 are considered unfair, abusive, or deceptive trade practices under the MMPA, Mo. Rev. Stat. § 376.414; *id.* § 407.020 *et seq.*, which subjects manufacturers to civil suit, punitive damages, attorneys’ fees, or other “such equitable relief” a court deems necessary, *id.* at § 407.025(1).

Noncompliance also risks criminal punishment. *Id.* §§ 376.414(3), 407.020(3-4). Apart from the debilitating effects of felony conviction, the collateral consequences of a criminal *adjudication* would irreparably harm Novartis’s reputation and goodwill with its clients. *Medicine Shoppe Intern., Inc.*

v. S.B.S. Pill Dr., Inc., 336 F.3d 801, 805 (8th Cir. 2003) (“Loss of intangible assets such as reputation and goodwill can constitute irreparable injury.”).

The District Court rejected these arguments, ruling that if “S.B. 751 is constitutional than Plaintiff will not suffer any irreparable harm.”

App.326(R._Doc._78, at 11). But S.B. 751 is not constitutional: It violates both the Commerce Clause, *see supra* 28-48, and the Supremacy Clause, *supra* 48-52. Novartis has demonstrated irreparable harm, weighing heavily in favor of granting a preliminary injunction.

B. The Balance Of The Equities And Public Interest Favor Granting An Injunction.

The equities also weigh heavily in Novartis’s favor, as Novartis’s likely harm outweighs any injury to the State from delaying S.B. 751’s enforcement. *Dataphase Sys., Inc.*, 640 F.2d at 113 (evaluating the balances of harm to parties if injunction is granted).

The State would suffer no harm from a preliminary injunction. States have an interest in enforcing their laws— “[u]nless that statute is unconstitutional.” *Abbott v. Perez*, 585 U.S. 579, 602 (2018). Because courts evaluate the relative harms as if the movant were successful, *Chicago, B. & Q. R. Co. v. Chicago Great W. R. Co.*, 190 F.2d 361, 363 (8th Cir. 1951) (per curiam) (evaluating the equities as if “the final determination is in [the movant’s] favor”), Missouri simply has “no interest” in enforcing an unconstitutional statute, *Dakotans for Health v. Noem*, 52

F.4th 381, 392 (8th Cir. 2022). Finally, a preliminary injunction serves the public interest by “enjoining the enforcement of the invalid provisions of state law.”

Bank One, Utah v. Guttau, 190 F.3d 844, 848 (8th Cir. 1999).

Contrary to the District Court’s understanding, injunctive relief would not impair the public’s access to affordable drugs. App.328(R._Doc._78, at 13).

Under the replenishment model, the 340B discount is split between “[t]he covered entity, the pharmacy, and the third-party administrator” involved, not passed onto the patient. *Novartis*, 102 F.4th at 457-458; *see also supra* 30-31, 46-47. By and large, patients have the same access to drugs at the same prices with or without S.B. 751. App.11(R._Doc._1, at 11 ¶ 35).

CONCLUSION

For the foregoing reasons, this Court should reverse the District Court’s denial of Novartis’s motion for a preliminary injunction and order that the District Court enter the preliminary injunction that Novartis requested.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32 and Eighth Circuit Rule 28A because it contains 12,980 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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/s/ Jessica L. Ellsworth
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I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the Court's CM/ECF system on May 15, 2025. All counsel of record are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

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