

No. 26-____

IN THE
Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,

Petitioner,

v.

LYNN FITCH,

in her official capacity as Attorney General of the
State of Mississippi,

Respondent.

On Petition for Writ of Certiorari to the United
States Court of Appeals for the Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In Section 340B of the Public Health Service Act, Congress used its spending power to create a program that requires drug manufacturers to “offer” to sell their “covered outpatient drugs” to a set of healthcare providers called “covered entities” at a steep discount as a condition of having their drugs covered by Medicare Part B and Medicaid. 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5).

Congress assigned sole responsibility to the U.S. Department of Health and Human Services (HHS) to administer this 340B Program “on a uniform, nationwide basis.” *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 120 (2011); see 42 U.S.C. § 256b(a)(5)(D), (d). The program terms are memorialized in an agreement signed by the HHS Secretary and the participating drug manufacturer. Congress directed HHS to administer a dispute resolution process, which allows covered entities to assert claims that a manufacturer improperly limited their purchases of drugs at the 340B discounted price.

Unlike cooperative federalism programs, Congress assigned states no role. Yet more than twenty states have enacted laws in the last few years mandating that manufacturers who participate in the 340B Program provide 340B-priced drugs on more expansive terms than federal law requires, and face state enforcement actions. Mississippi’s law, H.B. 728, is one of them.

The question presented is:

Whether state laws imposing different and more expansive program terms on drug manufacturers who participate in the federal 340B Program violate the Supremacy Clause?

PARTIES TO THE PROCEEDING

Petitioner is Novartis Pharmaceuticals Corporation.

Respondent is Lynn Fitch, in her official capacity as Attorney General of the State of Mississippi.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, the undersigned counsel certifies the following:

Novartis Pharmaceuticals Corporation hereby states that it is an indirect wholly-owned subsidiary of Novartis AG (NYSE: NVS). No publicly held corporation owns 10% or more of the stock of Novartis AG.

STATEMENT OF RELATED PROCEEDINGS

U.S. Supreme Court:

Novartis Pharms. Corp. v. Fitch, 26A127

U.S. Court of Appeals for the Fifth Circuit:

Novartis Pharms. Corp. v. Fitch, No. 24-60342 (5th Cir. 2026) (not reported but available at 2026 WL 963504) (rehearing denied May 5, 2026)

U.S. District Court for the Southern District of Mississippi:

Novartis Pharms. Corp. v. Fitch, No. 24-cv-164-HSO-BWR (reported at 738 F. Supp. 3d 737)

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OPINIONS BELOW

The Fifth Circuit's opinion (App. 1a-7a) is unreported but is available at 2026 WL 963504. The Fifth Circuit's order denying rehearing en banc (App. 37a-38a) is unreported. The District Court's denial of preliminary injunctive relief (App. 10a-36a) is reported at 738 F. Supp. 3d 737.

JURISDICTION

The Fifth Circuit entered judgment on April 9, 2026. App. 8a-9a. The court denied rehearing on May 5, 2026. App. 37a-38a. Novartis received two

extensions of time to file this petition, making the deadline October 2, 2026. Novartis timely filed this petition. *See* Sup. Ct. R. 13.1, 13.3. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

Relevant constitutional, statutory, and regulatory provisions are reproduced in the petition appendix. App. 82a-115a.

INTRODUCTION

Mississippi is one of twenty-two states that, in the last few years, have enacted state laws imposing new, additional obligations solely on drug manufacturers who voluntarily participate in an entirely federal program called the 340B Program. Congress enacted this discount-drug program decades ago, after a different statutory enactment had inadvertently made it prohibitively expensive for drug manufacturers to continue offering discounted prices to certain types of health care providers.

The once little-known 340B Program is today the second-largest federal drug-pricing program in the country, behind only Medicare Part D. And if other states follow Mississippi and its twenty-one sister states, the 340B Program's exponential growth will continue skyrocketing. As the United States has now told lower court after lower court, this expansion presents serious risks to the uniform, nationwide program that Congress intended the federal government alone to oversee, with the wide-angle lens that only a federal agency has to offer.

For decades, manufacturers participated in the program in Mississippi the same way they did in Wisconsin, Massachusetts, Texas, and everywhere else. That makes sense because the 340B Program is not a cooperative federalism program and Congress assigned states no role in its administration. Instead, at Congress's direction, a participating drug manufacturer and the federal government enter into a two-party agreement called a Pharmaceutical Pricing Agreement (PPA). The PPA lists the requirements for participating in the program and states that the agreement is to be "construed in accordance with Federal common law." HHS, *Example Pharmaceutical Pricing Agreement*, OMB No. 0915-0327, § VII(g), <https://perma.cc/2DPM-JR2J> (hereinafter Example PPA). States are not party to that agreement, and the agreement does not authorize states to rewrite the terms.

The 340B Program is a subsidy for certain types of hospitals that Congress created by conditioning reimbursement for drug manufacturers' products in Medicare Part B and Medicaid on their agreement to offer steeply discounted drugs to specified categories of hospitals and clinics (known as "covered entities"). The 340B Program operates as a subsidy because covered entities, after buying the drugs at steep discounts, can dispense them at full price to patients and keep the spread. That subsidy inures to a covered entity's bottom line; it need not, and almost never does, pass the discount to patients. And the Program imposes no limitations on how covered entities may spend the money, from renovating the cafeteria to building a

new facility in a wealthy neighborhood to paying for stadium naming rights.

Starting a few years ago, several—and now over twenty—states decided the covered-entity subsidy generated by 340B sales should be larger in their states than Congress had made it. So, they enacted state laws changing the rules of 340B Program participation for manufacturers. The state laws require manufacturers to sell more 340B-priced drugs on different terms to covered entities than the federal program requires.

The Supremacy Clause prevents a state from taking a federal program to which it is not a party, altering participants' obligations, creating alternative state enforcement authority, and saddling participants with more obligations than Congress chose to enact. State laws specifically focused on changing the terms of wholly federal programs are rarely enacted—and never like this, where manufacturers now face nearly two dozen versions of 340B Program obligations, despite having signed a single agreement with a single regulator: the federal government.

In upholding this state commandeering of a federal program, the Fifth Circuit deviated from bedrock precedents of this Court related specifically to the 340B Program, state authority to rewrite federal law, and the limitations against adding new terms to a Spending Clause bargain between the federal government and private parties. Two federal courts of appeals—the D.C. and Third Circuits—have recognized that Congress intended to preserve manufacturers' rights to impose commercially reasonable terms on

their participation; two other circuits—the Fifth and Eighth Circuits, with some dissenters in the latter—take the position that Congress only intended to prevent the *federal* government from imposing new rules, while allowing *states* to do whatever they want.

This Court’s intervention is warranted now, before the situation worsens more than it already has. The question presented is important and recurring, and there are serious, irreparable costs to delaying resolution of this issue on a nationwide basis. This Court should grant certiorari.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. Congress enacts the 340B Program.

The 340B statute provides that participating drug manufacturers “shall * * * offer” certain “covered outpatient drugs” at or below a substantially discounted “ceiling price” to specific “covered entities” to ensure coverage for their drugs under Medicare Part B and Medicaid. 42 U.S.C. §§ 256b(a)(1), (5), 1396r-8(a)(1), (5).

Congress enacted the 340B statute to fix a problem that developed after it enacted the Medicaid Drug Rebate Program (MDRP) in 1990. The MDRP is a bargain between drug manufacturers, states, and the federal government that requires manufacturers to give state Medicaid plans the “best price” given to any other purchaser. H.R. Rep. No. 102-384, pt. II at *9-10 (1992). This design inadvertently punished drug manufacturers for their longstanding practices of offering discounts to charitable hospitals because

these discounts would reduce the “best price” to the point that manufacturers would lose money on *all* Medicaid sales of that product. *Id.*; *see also* Milt Freudenheim, *Big Costs Imposed on Drug Makers*, N.Y. Times, Nov. 6, 1990, at D2, <https://perma.cc/VGM7-S95K>.

Two years later, in 1992, Congress created the 340B Program to address that disincentive. H.R. Rep. No. 102-384 II at *12. The program works as follows: Manufacturers who want to participate in Medicaid and Medicare Part B must agree to offer deeply discounted covered outpatient drugs to specific categories of non-profit hospitals and federal grantees known as “covered entities.” 42 U.S.C. § 256b(a); *id.* § 1396r-8(a)(1), (a)(5)(A). Congress enacted a statutory formula that sets the discounted price at which manufacturers must offer their drugs for purchase by those covered entities, *id.* § 256b(a)(1)-(2), and those discounts can be as low as a penny per unit, 82 Fed. Reg. 1,210, 1,215 (Jan. 5, 2017).

The 340B Program’s mandated subsidy from manufacturers to covered entities thus serves as the “price of admission” to Medicaid and Medicare Part B while rectifying the MDRP’s prior disincentive to offer discounted prices. *AbbVie, Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1273 (W.D. Okla. 2025), *appeal docketed*, No. 25-6182 (10th Cir. Nov. 13, 2025).

In setting this price of admission, Congress balanced the benefit that manufacturers would gain from participating (access to Medicaid and Medicare Part B) with the burden they would take on (the magnitude of 340B discounts). After all, if

Congress required deeply discounted pricing on too many transactions, manufacturers might decline to participate, which would also mean those manufacturers would withdraw from Medicaid and Medicare Part B—making their drugs unavailable nationwide to individuals enrolled in those programs. *See* App. 80a-81a.

Congress’s balance also matters to the federal fisc. Transactions at the 340B price are not subject to a Medicaid rebate—a particular type of rebate manufacturers pay to states that is then shared with the federal government—which means that more 340B-priced sales directly reduces the federal government’s share of Medicaid rebates. 42 U.S.C. § 256b(a)(5)(A). In 2024 alone, the 340B Program resulted in the federal government receiving \$4.2 billion less in Medicaid rebates. Eleanor Blalock & Carlee Launsbach, *The Financial Impact to Medicaid from the 340B Drug Pricing Program 2* (July 2025), <https://perma.cc/4LHY-HK24>.

2. *The federal government and a participating drug manufacturer enter into a PPA setting out the agreed terms of participation.*

Because Congress created the 340B Program with its spending power, Congress was constitutionally obligated to explicitly set out all of the Program’s limits and conditions in advance—so manufacturers could know what they are consenting to do by participating. *See, e.g., Landor v. Louisiana Dep’t of Corr. & Pub. Safety*, 609 U.S. 59, 69 (2026) (Spending power legislation requires Congress to “clearly and unambiguously alert a grant recipient to any condition on federal funds.”) (citing *Pennhurst State Sch. & Hosp. v.*

Halderman, 451 U.S. 1, 17 (1981)); *Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 219 (2022) (“Spending Clause legislation operates based on consent[.]”).

The federal government and a participating manufacturer enter into a PPA, which “recite[s] the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS.” *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). The PPA states seven specific “responsibilities” that a participating manufacturer agrees to meet to satisfy its end of the bargain. *See* Example PPA, § II. States are not parties to the PPA, and the PPA does not tell manufacturers that they could be subject to unidentified, additional state-law obligations or enforcement mechanisms as a result of participating.

3. *Congress charges HHS with administering the 340B Program and enforcing its requirements.*

Congress put both administrative and enforcement power for the program solely in the hands of HHS, which could administer 340B “with an eye towards any implications for” Medicaid. *Astra*, 563 U.S. at 120. It is HHS’s responsibility to “administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis.” *Id.* HHS administers 340B through its subagency, the Health Resources and Services Administration (HRSA).

HRSA operates an Administrative Dispute Resolution (ADR) system that Congress directed HHS to create for adjudicating specific categories

of 340B disputes between covered entities and manufacturers. 42 U.S.C. § 256b(d)(3). These disputes include claims by a manufacturer that a covered entity has diverted 340B-priced drugs to non-patients or claimed discounts that duplicate MDRP rebates, *id.*, and claims by covered entities that a manufacturer overcharged the entity or unduly “limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price,” 42 C.F.R. § 10.21(a)(1).

In addition to its administrative responsibilities, HHS also has direct enforcement power created by the 340B statute. If a manufacturer “knowingly and intentionally” fails to provide 340B pricing when due, HHS may impose “civil monetary penalties,” 42 U.S.C. § 256b(d)(1)(B)(vi), or terminate the PPA. *See* Example PPA, § IV(c).

B. Procedural History

1. Mississippi enacted H.B. 728 in April 2024 to prohibit 340B-participating manufacturers from engaging in conduct permitted under federal law and to impose state enforcement mechanisms. In June 2024, Novartis sued to enjoin H.B. 728 in the U.S. District Court for the Southern District of Mississippi. Novartis explained that the federal 340B program is an “integrated federal regulatory scheme” “in which Congress has set out * * * an exclusively federal framework for enforcement.” App. 56a-57a. H.B. 728 “tinker[s]” with that scheme, which “undermine[s] Congressional objectives.” App. 40a. For that reason, Novartis argued that H.B. 728 is both field and conflict preempted.

Novartis filed a request for a preliminary injunction, accompanied by a verified complaint and affidavit providing concrete evidence of the irreparable harm H.B. 728 is causing and will cause Novartis. App. 75a-81a. The district court denied Novartis's motion for a preliminary injunction. App. 35a-36a. It subsequently stayed the case pending resolution of Novartis's appeal. Order Granting Joint Mot. to Stay, ECF 37, *Novartis Pharms. Corp. v. Fitch*, No. 1:24-cv-164 (S.D. Miss. July 29, 2025).

2. Novartis appealed to the United States Court of Appeals for the Fifth Circuit. While Novartis's appeal was pending, another panel of the Fifth Circuit heard a separate challenge to H.B. 728 brought by other drug manufacturers, and it affirmed denial of preliminary injunctive relief there. *See AbbVie, Inc. v. Fitch*, 152 F.4th 635, 639 (5th Cir. 2025) (per curiam) ("*Fitch*"). A third panel heard a challenge to a virtually identical Louisiana law brought by other manufacturers, and affirmed the grant of summary judgment in the state's favor. *See AbbVie, Inc. v. Murrill*, 166 F.4th 528 (5th Cir. 2026), *opinion withdrawn and superseded on reh'g*, 180 F.4th 747 (5th Cir. 2026) ("*Murrill*"). The manufacturers sought rehearing en banc in *Murrill*, and the United States filed an amicus brief in support to explain the federal government's significant interest in ensuring the 340B Program operates as Congress intended. U.S. Amicus Br., ECF 205, *AbbVie, Inc. v. Murrill*, No. 24-30645 (5th Cir. filed April 1, 2026).

In *Murrill* and *Fitch*, the Fifth Circuit rejected arguments that the federal 340B statute preempts

state laws that regulate participation in the 340B Program. The court incorrectly viewed the federal statute as only regulating the *price* for drug units sold through the 340B Program and the state laws as regulating *delivery* of those drugs. In its view, the federal statute’s “silence” on where 340B-priced drugs are delivered permits states to “supplement[]” the 340B Program by prohibiting manufacturer limitations that are allowed by federal law. *Murrill*, 180 F.4th at 758, 760; *Fitch*, 152 F.4th at 646. The Fifth Circuit followed the Eighth Circuit in rejecting preemption challenges to state 340B laws. *See Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024).

Considering itself bound by the earlier decision in *Fitch*, 152 F.4th 635, the panel below reasoned that H.B. 728 “regulates areas traditionally governed by the states” and applied the presumption against preemption. App. 5a. It concluded that the state statute covers an area that “remain[s] subject to state regulation” because the 340B statute did not explicitly address distribution. App. 6a.

Novartis sought rehearing en banc, which the Fifth Circuit denied. App. 37a-38a. This petition follows.

C. Factual Background

A covered entity profits from buying 340B-priced drugs because, after buying drug units at a steep discount, the covered entity can sell those units to patients (or their insurers) at a non-discounted price and pocket the difference. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452,

455 (D.C. Cir. 2024) (“*Novartis*”). Covered entities keep this spread—between the 340B price and the drug’s commercial price—to spend however they want; they are not required to pass the discounted 340B price to patients, and rarely do. This dynamic has “left the section 340B program vulnerable to abuse—at great cost to the manufacturers.” *Id.*

1. *Covered entities seek to expand their 340B purchases—and thus their profits—through “contract pharmacies.”*

Although the 340B statute’s text suggests that Congress “had in mind one-to-one transactions between a covered entity and a drug maker,” *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 704 (3d Cir. 2023), some covered entities had no in-house pharmacy and so they turned to a “contract pharmacy” as a way to participate in the 340B Program. A 1996 HRSA guidance document endorsed a covered entity accessing 340B pricing through use of a single contract pharmacy when it lacked an in-house pharmacy, to avoid being shut out of the program. 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996).

In 2010, however, HRSA issued a new guidance document stating that covered entities “may contract with an unlimited number of outside pharmacies,” “regardless of whether the entities have in-house pharmacies.” *Novartis*, 102 F.4th at 457 (citing 75 Fed. Reg. 10,272, 10,272-73 (Mar. 5, 2010)). Many covered entities began to contract with hundreds of these generally for-profit pharmacies located all over the country, often large chain companies like CVS and Walgreens. S. Comm. on Health, Educ., Lab. & Pensions,

Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program 3 (Apr. 2025), <https://perma.cc/QK5P-HSV7> (hereinafter HELP Report) (noting five major chains account for 75% of 340B contract-pharmacy relationships).

Covered entities and contract pharmacies also began using a “replenishment model” to increase 340B purchases. This back-end accounting gambit works as follows: Sometime after a pharmacy has dispensed a drug to a customer who came to fill a prescription, the covered entity and contract pharmacy hire a “third-party administrator” to compare pharmacy- and patient-data. This administrator looks for pharmacy customers who may have been treated at a covered entity in the past. If a purported match is found, the covered entity retroactively claims that the drug unit the pharmacy previously dispensed was eligible for 340B pricing. The covered entity then buys a new, 340B-priced unit to “replenish” the already-dispensed unit, and requests delivery of the new unit to the pharmacy—where it can be dispensed to anyone in the future. App. 45a-46a.

It bears emphasis that contract-pharmacy arrangements do not change where a person can fill a prescription; pharmacies—contract or not—have the same drugs available to dispense to customers. Nor does it affect the price someone pays to walk out of the pharmacy with drugs in hand; pharmacies—contract or not—charge patients (and their insurers) the same amount and patients generally have no idea whether the pharmacy and covered entity later claimed a 340B discount from the manufacturer. The only change

a contract-pharmacy arrangement brings is that, after-the-fact, the covered entity, for-profit pharmacy, and third-party administrator can “divvy up the spread” created by 340B pricing. *Novartis*, 102 F.4th at 457.

2. *Covered entity purchases at 340B prices expand fifteen-fold after HRSA’s 2010 guidance document.*

HRSA’s 2010 guidance document had dramatic consequences. Since 2010, the value of 340B-priced sales has rocketed to *over fifteen times* its former size—going from about \$6.6 billion to *over \$100 billion* in 2025. HRSA, *2025 340B Covered Entity Purchases* (last reviewed July 2026), <https://perma.cc/39XU-98U9>; Rebecca Sachs & Joshua Varcie, Congressional Budget Off., *Spending in the 340B Drug Pricing Program, 2010 to 2021 2* (June 17, 2024), <https://perma.cc/GJF3-SUVN>. It is now the second-largest federal drug-pricing program (behind only Medicare Part D). Ashley Flint et al., *340B Purchase Data Highlights Continued Program Growth*, Avalere Health (Oct. 24, 2024), <https://perma.cc/H48X-VKHM>. This is a result of the number of contract pharmacy arrangements exploding from around 1,300 in 2010 to around 35,000 today. Adam J. Fein & Greis Kapexhiu, *The 340B Contract Pharmacy Market in 2026: A Maturing Industry Dominated by Big Chains and PBMs*, Drug Channel Institute (June 2, 2026), <https://perma.cc/FXL9-BNTE>; Milena Sullivan et al., *Contract Pharmacy Trends May Help Inform 340B Reform Debate*, Avalere Health (June 10, 2024), <https://perma.cc/8ECG-4XXC>.

The relentlessly swelling dollar value of covered entity purchases is directly attributable to covered entities leveraging higher and higher numbers of contract pharmacy arrangements through which they claim 340B sales. A Senate committee recently examined the data and found “significant increases in 340B sales to contract pharmacies compared to direct sales to [covered entities].” HELP Report at 32-33.

Contract pharmacies today earn so much revenue from their partnerships with covered entities that it materially affects their bottom line, as they have told the SEC. *See* CVS Health, *2025 Annual Report* 22 (Feb. 10, 2026) (“A reduction in Covered Entities’ participation in contract pharmacy arrangements * * * could materially and adversely affect the Company.”), <https://perma.cc/8LER-UHND>; Walgreens Boots Alliance, *2024 Annual Report* 35 (Oct. 15, 2024) (similar), <https://perma.cc/UEN3-9FUJ>.

Patients feel little to no benefit when a covered entity demands 340B pricing from a manufacturer for itself. *See* HELP Report at 2 (noting studies that “suggest[] that the 340B benefit does not translate into increased charity care or lower costs for vulnerable populations”). Covered entities have used the portion of 340B profit they keep after paying contract pharmacies and third-party administrators to make “deals with minor-league and college sports teams for naming rights,” to launch “a film company,” and to fuel industry consolidation that “has increased prices and insurance premiums.” The Editorial Board, *A Good*

Idea to Cut Drug Costs, Wall St. J., Sept. 21, 2025, <https://perma.cc/Q77P-SPW5>.

3. *Novartis imposes commercially reasonable limitations on its 340B-mandated offer, as permitted by the 340B statute.*

Concerned about this seemingly endless expansion, Novartis notified HRSA in 2020 that it would begin limiting use of contract pharmacies in its offer to sell drugs to covered entities at the 340B price. App. 49a-50a. HRSA told Novartis that such a limitation violated federal law because the 340B statute required recognizing unlimited contract pharmacy arrangements for any covered entity. App. 50a. Novartis challenged HRSA's position in federal court as unlawful under the Administrative Procedure Act. App. 50a.

Novartis won. The district court vacated HRSA's violation letter, concluding the agency's argument "rest[ed] upon an erroneous reading of Section 340B." *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021). A unanimous panel of the D.C. Circuit affirmed. It pointed out that the federal statute says nothing about contract pharmacies, and concluded that this "silence preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Novartis*, 102 F.4th at 460.¹

Novartis's current policy recognizes that a covered entity without an in-house pharmacy may use one contract pharmacy, but otherwise provides

¹ The Third Circuit reached a similar conclusion regarding other manufacturers' policies. *See infra* pp. 28-29.

340B pricing only on covered entities' direct purchases. App. 77a.

4. *H.B. 728 overrides the discretion Congress gave manufacturers to include commercially reasonable offer limitations, including on contract pharmacies.*

Covered entities and national pharmacy chains that profit from contract pharmacy arrangements began lobbying state legislatures to prohibit manufacturers who choose to participate in the 340B Program from limiting use of contract pharmacies *as a matter of state law*. The 340B Program is not a cooperative federalism program, and Congress gave states no role in setting the 340B Program's terms or administering it, in contrast to a program like Medicaid. Nevertheless, twenty-two states have enacted laws that add new obligations onto a manufacturer's participation in the 340B Program. One of those new obligations is that 340B participating manufacturers must recognize unlimited contract pharmacy arrangements for a covered entity, overriding Congress's decision to give manufacturers discretion.

Mississippi is part of that group. In April 2024, Mississippi enacted H.B. 728, which makes it illegal for a manufacturer to

deny, restrict, prohibit, or otherwise interfere with, 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 a 340B entity and is authorized under such contract to

receive and dispense 340B drugs on behalf of the covered entity.

H.B. 728 § 4(1).

The law says the quiet part out loud: It is changing the terms of the 340B Program. It defines a “340B drug” as a covered outpatient drug that “has been subject to any offer for reduced prices by a manufacturer pursuant to [the federal 340B statute].” *Id.* § 2(a).

Mississippi’s statute establishes state-law enforcement mechanisms under the Mississippi Consumer Protection Act (MCPA), *see* Miss. Code Ann. 75-24-1 § *et seq.*, including enforcement actions, fines, and criminal liability. Three or more violations of H.B. 728 result in a felony offense. And, by tying H.B. 728’s enforcement mechanism directly to the MCPA, Mississippi gave its Attorney General broad authority to issue cease and desist orders, conduct investigatory hearings, and compel document production—all necessarily related to the 340B program.

REASONS FOR GRANTING THE PETITION

Rather than operate as the uniform, nationwide program that Congress intended, manufacturers who participate in the 340B Program now face a crazyquilt patchwork of obligations and enforcement mechanisms that vary across twenty-two states. That is deeply wrong, conflicts with this Court’s precedents, and has already led to a circuit split over whether Congress intended participating manufacturers to retain discretion over the terms on which they offer discounted drugs for purchase. This Court should intervene

now, before even more states try their hand at rebalancing Congress's interests.

I. CERTIORARI IS WARRANTED.

A. The Fifth Circuit's Ruling Conflicts With This Court's Precedents In Several Ways.

Congress intended for the federal 340B Program to operate with a "unitary administrative and enforcement scheme." *Astra*, 563 U.S. at 120-121. And it gave manufacturers discretion to impose reasonable conditions on "offers" to covered entities, including through limitations on contract-pharmacy arrangements. The Fifth Circuit's decision that a state can unilaterally attach new conditions to the 340B program's bargain between manufacturers and the federal government runs afoul of several lines of this Court's precedents.

1. In *Astra*, this Court held that third parties could not sue drug manufacturers over how the manufacturers participated in the 340B Program because Congress intended "centralized enforcement" of the 340B Program in the federal government. 563 U.S. at 119. The Court rejected Santa Clara's argument that its private suit would help HRSA by "spreading the enforcement burden" amongst interested parties. *Id.* The Court explained that third-party enforcement actions were "incompatible with" the 340B statutory regime. *Id.* at 113; *see id.* at 118. Even parallel enforcement "would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 120. The Court was explicit that HHS "h[e]ld the control rein" over the 340B Program—and the

statute would not tolerate attempts for others to do so in the federal government's stead. *Id.*

Astra expressly noted that states' interests and federal interests in how the 340B Program operates may conflict, given the intertwined nature of the 340B Program and Medicaid. *Id.* at 120 n.6. At oral argument, several Justices discussed that Congress knew how to create a jointly run federal-state program, like it did in the Medicaid statute—but did not create such a program in the 340B statute. Tr. of Oral Arg. at 24-25, *Astra*, 563 U.S. 110 (No. 09-1273).

Although *Astra* is not itself a preemption case, the principles the Court articulated in rejecting Santa Clara's claims are equally applicable to answering whether H.B. 728 violates the Supremacy Clause. Congress created a statutory scheme to be uniformly applied nationwide. By greenlighting every state to come up with its own version of what 340B participation requires, the Fifth Circuit "interferes with Congress's design for the 340B Program." U.S. *Murrill* Amicus Br., *supra*, at 9.

2. In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court held that a presumption against preemption was inapplicable to state-law fraud claims premised on inaccurate submissions to the Food and Drug Administration, because the relationship between FDA and an FDA-regulated entity was "inherently federal in character." *Id.* at 347. There, as with the 340B Program, the relationship that the state sought to regulate "originates from, is governed by, and terminates according to federal law," which meant

the relationship could “hardly” be said to fall within the traditional scope of state involvement. *Id.* at 347. As *Buckman* recognized, in such “inherently federal” relationships, “[t]he balance sought by the [federal government] can be skewed by allowing” state laws into the picture. *Id.* at 347-348. There, as here, the state’s attempts to enforce compliance “inevitably conflict with the [federal government’s] responsibility” to do the same. *Id.* at 350.

This Court has made a similar point repeatedly. In *United States v. Locke*, 529 U.S. 89 (2000), this Court underscored that “[n]o artificial presumption” against preemption applies “in an area where there has been a history of significant federal presence.” *Id.* at 108. There has been *nothing but* a history of significant federal presence when it comes to the obligations attached to a manufacturer’s participation in the 340B Program until these laws began sprouting a few years ago. Indeed, Mississippi’s law is entirely parasitic to the federal regime: If Congress repealed the 340B Program, Mississippi’s law would have no effect. *See id.* at 99 (Washington law preempted because the state could not “enact[] legislation in an area where the federal interest has been manifest * * * and is now well established”).

Similarly, in *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 638-639 (1973), this Court held that a city ordinance on airport noise was preempted where Congress had directed two federal agencies to implement “a delicate balance” between the interdependent factors of safety,

efficiency, and protecting people on the ground; the fact that states had historic police powers over noise control did not detract from the “pervasive control vested” in those federal agencies by Congress. There had to be “a uniform and exclusive system of federal regulation if the congressional objectives underlying the Federal Aviation Act [were] to be fulfilled”—not “fractionalized control.” *Id.* at 639.

By incorrectly holding a presumption against preemption applicable here, on the basis that states can regulate “pharmacies,” App. 5a, the ruling below conflicts with these cases. Regardless of whether Mississippi can regulate “pharmacies” at some general level, the challenged law regulates whether 340B-participating manufacturers must allow 340B covered entities to purchase “340B drugs” where federal law does not require manufacturers to do so. *See Buckman*, 531 U.S. at 353 (“[T]he existence of these federal enactments is a critical element in [the petitioners’] case,” because their claims would not exist without them). The relationships between manufacturers, covered entities, and contract pharmacies “originate[] from, [are] governed by, and terminate[] according to” the federal 340B statute. *Id.* at 347-348.

3. In *Arizona v. United States*, 567 U.S. 387 (2012), this Court rejected the argument that a state could invoke the consequences of unlawful immigration on areas of traditional State control, such as crime, to override the “comprehensive and unified” federal law setting out alien-registration requirements. *Id.* at 397-398, 401-402. Regardless

of the State's "historic * * * powers" to police crime, it could not "do so in a field * * * that has been occupied by federal law." *Id.* at 400-402. Were it otherwise, "every State could give itself independent authority to prosecute federal * * * violations, 'diminishing the Federal Government's control over enforcement' and 'detracting from the integrated scheme of regulation created by Congress.'" *Id.* at 402 (cleaned up).

Arizona rejected the notion that states could use state law to augment a federal enforcement regime. Where "federal law str[i]k[es] a careful balance" between policy objectives, that balance indicates "Congress intended the federal plan * * * to be a 'single integrated and all-embracing system.'" *Id.* at 400 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 74 (1941)). While Congress did not explicitly say that states had no role, Congress's dominant interest in alien-registration requirements "reflects a congressional decision to foreclose any state regulation in the area, even if it is parallel to federal standards." *Id.* at 401.

By declining to recognize Congress's dominant interest in the workings of the 340B Program, and the balancing of competing interests underlying the Program, the decision below conflicts with *Arizona*.

4. This Court has also held that state laws "frustrate[]" federal law when they "limit[] the availability of an option that the federal [government] consider[s] essential to ensure its ultimate objectives." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873, 882 (2000) (citations omitted).

In *Geier*, an injured driver claimed that his car was negligently and defectively designed because it lacked a driver’s side airbag. *Id.* 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 manufacturers to install one particular restraint—an airbag, *id.* at 881. Because that outcome would undermine Congress’s decision to permit manufacturers to choose from a variety of devices, the state law “stood as an obstacle” to the execution of “federal objectives” and was thus preempted. *Id.* at 881.

The Fifth Circuit decision conflicts with *Geier* because federal law gives manufacturers a “range of choices” when it comes to whether to impose commercially reasonable conditions on an offer to sell 340B-priced drugs to covered entities—and Mississippi overrides that congressionally granted discretion. *Id.* at 875.

5. Finally, an additional strand of this Court’s precedent is triggered by Congress’s enactment of the 340B Program under its spending power authority. “[T]he ‘legitimacy of Congress’ power’ to enact Spending Clause legislation rests not on its sovereign authority to enact binding laws, but on ‘whether the [recipient] voluntarily and knowingly accepts the terms of th[at] ‘contract.’” *Cummings*, 596 U.S. at 219 (quoting *Barnes v. Gorman*, 536 U.S. 181, 186 (2002)); accord *Landor*, 609 U.S. at 68 (emphasizing that “our precedents have stressed the centrality of consent” to any conditions a party must meet to satisfy its obligations under Spending Clause legislation).

As this Court has explained, this notice requirement means that for Spending Clause legislation, “statutory silence” is not “a license to freely supply remedies we cannot be sure Congress would have chosen to make available.” *Cummings*, 596 U.S. at 226. Instead, silence represents Congress’s decision not to impose a particular condition. *See, e.g., Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 699. If “statutory silence” left a gap in the program that could later be filled by any state, it would be impossible for funding recipients ever to receive the requisite “clear notice” of their obligations. *Cummings*, 596 U.S. at 220, 226 (citation omitted).

The Fifth Circuit’s decision conflicts with these precedents. Manufacturers agreed with the federal government to meet a set of conditions in order to obtain a benefit from the federal government; but now twenty-two states have added new conditions that manufacturers must *additionally* meet to get the benefit of their bargain with the federal government. Nowhere did manufacturers somehow unambiguously agree to *states* unilaterally imposing broader obligations and additional penalties on their bargain with the federal government.² Holding Mississippi’s law

² The Fifth Circuit suggested that *Moyle v. United States*, 603 U.S. 324 (2024), supports its approach. *Murrill*, 180 F.4th at 762 n.68. That is wrong. Leaving aside the lack of a binding opinion in *Moyle*, the Spending Clause issue raised for the first time in this Court was whether “Congress, in reliance on the Spending Clause, can obligate recipients of federal funds to violate state criminal law.” *Moyle*, 603 U.S. at 336 (Barrett, J., concurring). The answer to that question has no bearing on this case, which asks whether states can impose

permissible conflicts with this Court’s Spending Clause caselaw.

B. The Circuits Are Split On Congress’s Intent.

The courts of appeals are divided on whether Congress intended to permit manufacturers to impose commercially reasonable conditions when offering 340B-priced drugs for sale to covered entities. After careful consideration of 340B’s text and structure, the D.C. and Third Circuits answered that question affirmatively. Applying ordinary contract-law principles to the statutory term “offer,” these courts held that Congress “preserve[d]—rather than abrogate[d]—the ability of [manufacturers] to impose at least some delivery conditions” on their covered-entity offers. *Novartis*, 102 F.4th at 460; *see also Sanofi*, 58 F.4th at 703-704. The Fifth and Eighth Circuits, however, disagree. As those courts see it, Congress intended to permit states to prohibit manufacturer conditions on offers to sell “340B drugs.” H.B. 728 § 2(a); *Fitch*, 152 F.4th at 646; *McClain*, 95 F.4th at 1144; App. 6a.

1. *The D.C. and Third Circuits hold that Congress intentionally preserved manufacturers’ right to include commercially reasonable limits in 340B-mandated offers of discounted pricing.*

Both the D.C. Circuit and the Third Circuit have recognized that, in the 340B statutory framework,

additional obligations on a Spending Clause bargain that exists solely between the federal government and a regulated party.

Congress affirmatively preserved manufacturers' authority to impose reasonable conditions when making the statutorily mandated offer to sell drugs to covered entities at a steep discount. Where Congress intended to preserve that flexibility for manufacturers, HRSA could not contravene Congress's intent by eliminating that discretion.

In *Novartis*, a unanimous panel of the D.C. Circuit held that the 340B statute gave manufacturers discretion to impose "reasonable conditions" on the terms of their offer to sell 340B drugs, including a one-contract pharmacy policy, and it reversed HRSA's actions that would have interfered with that discretion. 102 F.4th at 461. That holding flowed from careful textual analysis. The 340B statute provides that manufacturers must "offer each covered entity covered outpatient drugs for purchase" at or below a specified ceiling "price." 42 U.S.C. § 256b(a)(1). As the D.C. Circuit recognized, this language invokes well-established contract-law principles that govern what an "offer" requires.

The court applied ordinary contract interpretation principles in concluding that Congress must have intended to "preserve[]—rather than abrogate[]—the ability of [manufacturers] to impose at least some delivery conditions" on their covered-entity offers. *Novartis*, 102 F.4th at 460. After all, an "offer" can "contain both price and non-price terms." *Id.* (citing Restatement (Second) of Contracts § 33 cmt. a (A.L.I. 1981); 1 Williston on Contracts § 4:22 (4th ed. 2023)). Non-price terms "typically include

provisions about the place or manner of delivery.” *Id.* (citing U.C.C. §§ 2-307, 2-308, 2-503). And because such delivery conditions are standard features of contracts like the ones between drug manufacturers and covered entities, “including such terms is fully consistent with making an ‘offer’ at a specified ‘price.’” *Id.*

Because Congress intended to preserve manufacturer discretion on non-price terms, HRSA could not prohibit those terms so long as they were commercially reasonable and amounted to a “bona fide” offer. *Id.* at 463. As Judge Katsas put it, “statutory silence implies that private parties may act freely,” and manufacturers are entitled to make offers that include “reasonable conditions” so long as those offers remain “bona fide.” *Id.* at 460-462.

The Third Circuit—also unanimously—reached the same conclusion in a suit brought by another drug manufacturer. *Sanofi*, 58 F.4th at 699. Judge Bibas, writing for the court, likewise applied contract-law principles to the statutory term “offer,” explaining that “[o]ffer” means to “present[] something for acceptance.” *Id.* at 703 (quoting Offer, Black’s Law Dictionary (11th ed. 2019)). “Even if drug makers limit where they will deliver drugs, they still present the drugs for covered entities’ acceptance.” *Id.* The court held that the 340B program “impose[d] only a price term for drug sales to covered entities, leaving all other terms blank.” *Id.* at 704. And “when Congress’s words run out, covered entities may not pick up the pen.” *Id.*

Carefully parsing the statutory text and structure, the court noted that Congress had “expressly contemplate[d] drug makers selling discounted drugs through contract pharmacies” in a “neighboring provision” of the same statute. *Id.* at 704-705. Indeed, that neighboring provision—which addresses a separate “prime vendor” program for drug distribution—appears “on the very page of the Act where Section 340B ended.” *Id.* at 704-705. Congress’s choice to “add[] that specific language there but not [in the 340B statute]” was a classic, telltale sign that Congress intentionally declined to subject 340B participants to the same restriction. *Id.*

2. *The Fifth and Eighth Circuits hold that Congress did not intend to preserve manufacturers’ right to include commercially reasonable limits in 340B-mandated offers of discounted pricing.*

The Fifth and Eighth Circuits reached a different conclusion—that Congress did *not* intend to preserve the rights of participating 340B manufacturers to include commercially reasonable limitations on their 340B-mandated offers to covered entities. Under these courts’ approach, Congress did not intend to preserve manufacturer discretion; it intended only *for the federal government not to limit manufacturer discretion* while leaving it up to each of the fifty states to decide for itself whether to do so—even as Congress gave the states no role in the 340B Program.

In rejecting the manufacturers’ arguments in *Fitch*, the Fifth Circuit concluded the 340B statute

only addressed “pricing” and not “delivery,” and therefore, Congress left it up to states whether to regulate the terms of delivery of 340B-priced drugs. 152 F.4th at 646; *see Murrill*, 180 F.4th at 759 (same). The per curiam opinion did not engage with the D.C. and Third Circuits’ interpretation of the statutory term “offer” under background contract-law principles, nor did it address those courts’ holdings that 340B’s structure affirmatively preserved manufacturers’ authority to impose reasonable delivery conditions on their statutory offers. *See* App. 5a-7a.

Instead, the court characterized H.B. 728 as a regulation of “the distribution of drugs to patients” and “the role of pharmacies in this distribution.” *Fitch*, 152 F.4th at 646. The court then reasoned that the federal 340B statute did not speak to those topics, so “there is no dominant federal interest in the area regulated by H.B. 728.” *Id.* That reasoning treated 340B’s silence not as part of Congress’s bargain, but as an invitation for supplementary state regulation—the inverse of the D.C. and Third Circuits’ conclusions. The court never discussed or analyzed the D.C. and Third Circuits’ conclusion that Congress preserved manufacturers’ right to include reasonable non-price terms, including delivery conditions, in the “offers” that 340B requires them to make.

The Fifth Circuit’s decisions followed the same path the Eighth Circuit took a couple years earlier. There, the Eighth Circuit upheld Arkansas’s regulation of 340B Program participants against a preemption challenge. It characterized Arkansas’s law as regulating only “the practice of

pharmacy”—an area traditionally left to state regulation—and likewise relied on “Congress’s decision not to legislate the issue of pharmacy distribution” as the basis for rejecting field preemption. *McClain*, 95 F.4th at 1143-44. Applying the presumption against preemption, the court reasoned that because the 340B statute was silent on whether an offer could include delivery terms, Congress meant to endorse state supplementation of manufacturers’ 340B Program obligations. *Id.* The court held that by adding its own compliance mechanisms, Arkansas was “assist[ing] in fulfilling the purpose of 340B,” which did not “create an obstacle for pharmaceutical manufacturers to comply” with the federal statute. *Id.* at 1144-45.

The Eighth Circuit drew a distinction between the concepts of regulating pricing and regulating delivery—even though the price and any delivery terms are all part of the congressionally mandated “offer” that a manufacturer has to make, as the D.C. and Third Circuits emphasized. Congress required only that the “offer” include a specific price term, but chose to leave all other aspects of the offer available for a manufacturer to address however it wanted so long as the offer remained bona fide. *See Novartis*, 102 F.4th at 460 (explaining that “offer,” within the 340B statute, “contain[ed] both price and non-price terms” and that non-price terms “typically include provisions about the place or manner of delivery”).

In a second decision from the Eighth Circuit, the court rejected Novartis’ preemption challenge to Missouri’s law regulating 340B Program

participation. There, Novartis sought rehearing en banc based in part on *McClain* being wrongly decided. With three members of the court recused, five judges voted to deny rehearing en banc and three judges “would grant the petition for rehearing en banc.” *Novartis Pharms. Corp. v. Hanaway*, No. 25-1619, 2026 WL 2729618, at *1 (8th Cir. Sept. 16, 2026). As Judge Traynor (writing for himself and Judge Smith) explained in his dissent from the denial of rehearing en banc, a law like Missouri’s 340B law “directly undermines one of the most important conditions of the bargain the federal government struck with manufacturers to incentivize them to participate in the 340B program,” which is “that manufacturers would not be forced to distribute drugs to an unlimited number of contract pharmacies for lower prices.” *Id.* (Traynor, J., dissenting).

Neither the Fifth nor the Eighth Circuit attempted to explain why it would make sense for Congress to have intended to preclude the federal agency to which it assigned responsibility for overseeing the 340B Program in a uniform, nationwide way from eliminating manufacturer discretion on non-price offer terms—but wanted a patchwork of states to be able to do so.

II. FURTHER PERCOLATION IS UNWARRANTED.

1. State 340B laws present an unprecedented commandeering of a federal program on a massive scale. These laws have been enacted in twenty-two states, forcing manufacturers to contend with many versions of their federal 340B Program obligations and an equally large number of

enforcers and compliance regimes—the opposite of the “uniform, nationwide” 340B Program this Court described in *Astra*. 563 U.S. at 119-120. The Fifth and Eighth Circuits alone encompass ten states, where such laws are currently greenlighted.

Drug manufacturers have been litigating challenges to state laws around the country, and those challenges are currently pending in the First, Fourth, Sixth, Ninth, and Tenth Circuits, and several district courts. The United States has filed amicus briefs in case after case explaining that these state laws are invalid under multiple Supremacy Clause doctrines and present serious risk to the federal government’s overarching, intertwined, and competing interests at stake across the 340B Program, Medicaid, and Medicare Part B. These pending cases are not a reason to wait for further percolation.

As the number of transactions at 340B-pricing spirals upward, manufacturers are disincentivized from participating in the 340B Program, which—as the United States has repeatedly noted—jeopardizes the availability of drugs in Medicaid and Medicare Part B. This Court’s intervention is urgently needed to return the 340B Program to the singular and federally implemented design that existed for decades prior to states’ uninvited commands for a different design and different balancing of interests.

2. A Fourth Circuit panel, in two decisions since vacated by the granting of West Virginia’s and Maryland’s petitions for rehearing en banc, *see* 176

F.4th 830 (4th Cir. 2026), precisely captured the legal issues at stake.

First, in *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, Judge Richardson, writing for himself and Judge Rushing, upheld a preliminary injunction issued by a district court in West Virginia against that State’s 340B law. 171 F.4th 675, 697 (4th Cir. 2026). The court recognized that West Virginia’s law reflected that the state is “[d]issatisfied with the scale of drug discounts required by Congress in the 340B program,” so it seeks “to reshape the *contractual* bargain Congress made with private manufacturers.” *Id.* at 682. The court explained that state 340B laws are “anything but a traditional health-and-safety regulation.” *Id.* at 689. The point of these laws is to “inject[] the State into ‘the relationship between a federal agency and the entity it regulates.’” *Id.* (quoting *Buckman*, 531 U.S. at 347). The court distinguished the 340B Program from a cooperative federalism program that “*invit[es]* States to supplement federal conditions with state laws that address local variations and fill gaps.” *Id.* Here, however, “[t]he substantive provisions [of West Virginia’s 340B law] interfere at a high level with Congress’s exercise of its spending power and at an operational level with HHS’s enforcement authority.” *Id.* at 695.

Second, in *AbbVie, Inc. v. Brown*, the court addressed Maryland’s 340B law, which “imposes obligations on drug manufacturers solely by virtue of their participation in the federal 340B program and does not regulate manufacturers outside that program.” No. 24-1939, 2026 WL 1005576, at *1

(4th Cir. Apr. 14, 2026). The court vacated the district court's order denying a preliminary injunction "in light of th[e] Court's decision in *PhRMA* [v. *McCuskey*]." *Id.*

In both decisions, Judge Benjamin dissented. *Id.* at *1 (Benjamin, J., dissenting); *McCuskey*, 171 F.4th at 697 (Benjamin, J., dissenting).

3. There is no further information for this Court to glean from waiting for further ventilation in the courts of appeal. The opinions from the D.C. and Third Circuit have considered Congress' intent in examining federal agency authority over the 340B program. The Fourth, Fifth, and Eighth Circuit decisions have debated the significance of any purported statutory silence in challenges to state 340B laws from six states. *Compare, e.g., McCuskey*, 171 F.4th at 692 ("Section 340B did not merely set a floor to which States may add additional obligations."), with *McClain*, 95 F.4th at 1143-44 (silence permits the states to strip away that discretion); *see also Novartis*, 102 F.4th at 460 (silence evinces Congress' intent to preserve manufacturer discretion to set non-price terms).

These courts have debated the 340B statute's context, including its relationship to Medicaid and Medicare Part B. They have debated the purpose of the statute, and whether the purpose of the state laws is some sort of general regulation of "pharmacies" or a forced entry by states into a bargain between the federal government and drug manufacturers. *Compare, e.g., McCuskey*, 171 F.4th at 692 (state law "directly changes the terms of drug manufacturers' federally created 340B relationships with covered entities") with *Fitch*,

152 F.4th at 646 (concluding that 340B “does not ‘provide a full set of standards governing’ discounted drugs for needy patients”). And they have debated the practical consequences of adopting one interpretation over the other. *Compare, e.g., Fitch*, 152 F.4th at 648 (recognizing that state 340B laws could “have the effect of allowing covered entities and contract pharmacies to engage in illicit activities” but upholding the state law anyway) with *Hanaway*, 2026 WL 2729618, at *1 (Traynor, J., dissenting from denial of rehearing en banc) (“[T]hese state laws risk disincentivizing participation in and ultimately uprooting the federal 340B program.”).

The issues are well ventilated. Further percolation would not aid this Court’s review.

4. Two years ago, this Court denied certiorari review of the Eighth Circuit’s *McClain* decision. 145 S. Ct. 768 (2024). The legal landscape has shifted significantly since then. The Fifth Circuit followed the Eighth Circuit’s reasoning, App. 4a-7a, and the Eighth Circuit has declined to rehear the issue en banc by a single vote, *supra* pp. 30-32—even after the United States told those courts that they “erred” in their analysis, *e.g.*, U.S. *Murrill* Amicus Br., *supra*, at 11; U.S. Amicus Br. in Supp. of Reh’g En Banc at 10, *Novartis Pharms. Corp. v. Hanaway*, No. 25-1619 (8th Cir. filed July 23, 2026); *see also Hanaway*, 2026 WL 2729618, at *1 (Traynor, J., dissenting from denial of rehearing en banc) (emphasizing that “the United States filed additional briefing in this case that warrants reconsidering the precedential value of the court’s decision in *McClain*”). Repeatedly, the United

States has explained its significant interest in the 340B Program and its concerns about states disincentivizing participation across federal programs. Such state laws “facially violate [the Supremacy Clause’s] constitutional stricture by imposing additional burdens on manufacturers who participate in the 340B Program.” United States Br. at 14, ECF 178-1, *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, No. 25-1054 (4th Cir. filed July 10, 2026).

The number of state 340B laws has tripled since certiorari was denied in *McClain*. Pet. for Writ of Certiorari, *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 2024 WL 3654711, at *14 (July 31, 2024) (eight state laws). That number will continue growing if this Court denies certiorari again.

5. This petition is a good vehicle for resolving the question presented. Whether Mississippi’s law is unconstitutional under the Supremacy Clause, and specifically whether it is preempted by federal law, was pressed and passed upon by the court of appeals below. The Fifth Circuit—in three different opinions—has considered and analyzed the merits of Supremacy Clause challenges to state 340B laws. And Mississippi has not challenged Novartis’s view of the facts, including the expansive growth of the 340B program and the operation of contract-pharmacy arrangements.

6. This Court should grant review now because Novartis is suffering irreparable harm. H.B. 728 and other state laws like it affect billions of dollars of transactions industry-wide, and inflict extensive financial injury on drug manufacturers, who depend on sales of their products at commercial

prices to support their research and development efforts. *See* App. 76a, 78a-80a. Once lost, those drug development research opportunities can never be fully regained. App. 79a-80a. Preliminary injunctive relief is warranted when a party like Novartis must choose between “expos[ing] itself to potentially huge liability” or “suffer[ing] the injury of obeying the law during the pendency of the proceedings.” *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992).

III. THIS COURT SHOULD CALL FOR THE VIEWS OF THE SOLICITOR GENERAL.

The United States has an interest in the proper enforcement and operation of the 340B Program. It has protected that interest by filing amicus briefs in support of Novartis and other drug manufacturers in seven courts of appeals reviewing more than a dozen state laws.³

³ *E.g.*, U.S. Amicus Br., *Pharm. Rsch. & Mfrs. of Am. v. Neronha*, No. 26-1039 (1st Cir. filed Feb. 27, 2026); U.S. Amicus Br., *Pharm. Rsch. & Mfrs. of Am. v. Frey*, No. 26-1099 (1st Cir. filed Mar. 9, 2026); U.S. Amicus Br., ECF 178-1, *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, No. 25-1054 (4th Cir. filed July 10, 2026); U.S. Amicus Br., ECF 118-1, *AbbVie Inc. v. Brown*, No. 24-1939 (4th Cir. filed July 10, 2026); U.S. *Murrill* Amicus Br., *supra*, at 10; U.S. *Hanaway* Amicus Br., *supra*, at 33; U.S. Amicus Br., ECF 16, *Pharm. Rsch. & Mfrs. of Am. v. Skrmetti*, No. 26-5275 (6th Cir. filed June 9, 2026); U.S. Amicus Br., *Pharm. Rsch. & Mfrs. of Am. v. Wrigley*, No. 26-1860 (8th Cir. filed Aug. 21, 2026); U.S. Amicus Br., ECF 29.1, *AbbVie Inc. v. Brown*, No. 26-3712 (9th Cir. filed July 14, 2026); U.S. Amicus Br., ECF 15, *AstraZeneca Pharms., LP v. Lopez*, No. 26-1172 (9th Cir. filed Apr. 3, 2026); U.S. Amicus Br., ECF 67, *Novartis Pharms. Corp. v. Drummond*, No. 25-6182 (10th Cir. filed Mar. 30, 2026).

Each time, the United States has explained that state laws like H.B. 728 violate the Supremacy Clause “by arrogating to the State enforcement authority that properly belongs to the federal government alone.” *E.g., McCuskey* United States Br. at 16. And it has warned that “[o]nly the federal government can determine the extent to which it will tolerate the risk of manufacturer withdrawal.” *Id.* at 21.

The United States’s view on this matter will benefit the Court. Indeed, it already has: The Court looked to the United States’ interpretation of the scope of the federal 340B program in *Astra*, where it also participated as amicus. *E.g.*, 563 U.S. at 120. To the extent this Court has any doubt regarding whether to grant certiorari, this Court should call for the views of the Solicitor General.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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October 2026