No. 26A___

IN THE

Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,

Applicant,

v.

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

Respondent.

APPLICATION FOR AN EXTENSION OF TIME TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Novartis Pharmaceuticals Corporation hereby states that it is a wholly-owned subsidiary of Novartis AG (NYSE: NVS). No publicly held corporation owns 10% or more of the stock of Novartis AG.

APPLICATION

To the Honorable Samuel A. Alito, Associate Justice of the United States Supreme Court and Circuit Justice for the United States Court of Appeals for the Fifth Circuit:

1. Pursuant to Rule 13.5 of the Rules of this Court and 28 U.S.C. § 2101(c), Petitioner Novartis Pharmaceuticals Corporation respectfully requests a 30-day extension of time, up to and including September 2, 2026, within which to file a petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit.

2. The Fifth Circuit entered judgment on April 9, 2026, and denied Applicant's timely petition for rehearing on May 5, 2026. *See* App. 7a-8a, 34a. Unless extended, the time to file a petition for a writ of certiorari will expire on August 3, 2026. This application is being filed more than ten days before a petition is currently due. *See* Sup. Ct. R. 13.5. This Court has jurisdiction under 28 U.S.C. § 1254(1).

3. This case raises an important question that courts and state legislatures are grappling with around the country: Is it constitutionally permissible for a State to enact a law that interferes with the federal 340B Drug Pricing Program—a wholly federal program enacted by Congress in 1992 under its Spending Clause authority—by adding state-law requirements onto the terms of drug manufacturers' participation in that exclusively federal program? Or, as Novartis asserts, is such a state law preempted by federal law, which sets out the terms, administration, and enforcement of the 340B Program without inviting state participation? Counsel for

Petitioner Novartis has substantial briefing and argument obligations over the next few weeks and requests an extension of time to accommodate these obligations and to prepare a petition that fully addresses the important issues raised by the decision below.

4. Congress enacted the 340B Program in 1992 under the Spending Clause, offering drug manufacturers a bargain: The federal government would allow manufacturers to participate in Medicaid and Medicare Part B if they agree to offer to sell their drugs to certain specified categories of health-care providers (called "covered entities") at far-below-market prices. *See* 42 U.S.C. §§ 256b(a)(1), (a)(4), 1396r-8(a)(1), (a)(4), (a)(5)(A). Congress placed exclusive authority for administering and enforcing the 340B Program in the United States Department of Health and Human Services (HHS) and did not invite States to play any role, unlike in cooperative federalism programs like Medicaid. Nor did Congress provide any notice to manufacturers that choosing to participate meant being subject to state-law alterations of the Program's terms, administration, or enforcement.

5. Participating manufacturers must "offer" their drugs to covered entities at deeply discounted prices set by statutory formula. 42 U.S.C. §§ 256b(a)(1)-(2); 82 Fed. Reg. 1,210, 1,215 (Jan. 5, 2017). The Program thus subsidizes covered entities, who can buy drugs cheaply while charging patients (and their insurers) the drug's full commercial price. The Program does not require that *patients* receive any discount, which makes sense because passing on the discount to patients would reduce or eliminate the subsidy to covered entities. Covered entities may not engage

in "diversion" by reselling a 340B-priced drug "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Congress, by requiring only that manufacturers make a bona fide "offer" to covered entities to sell their drugs at discounted prices, preserved manufacturers' right to include commercially reasonable terms as part of their offer. *Novartis Pharm. Corp.* v. *Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (holding the 340B statute "preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions").

6. Congress delegated centralized oversight of both Medicaid and the 340B Program to one federal agency, HHS, in order to ensure uniform administration nationwide and allow for balancing of both programs' goals. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 119-120 (2011). HHS's oversight and enforcement authority is exclusive. *Id.*

7. Mississippi is one of twenty-two States to enact laws in the last few years that target manufacturers who choose to participate in the 340B Program for additional burdens. *See* Miss. H.B. 728, codified at Miss. Code Ann. § 41–149–7 (2024). These state laws create a patchwork of new obligations for manufacturers, including various prohibitions on including commercially reasonable terms in their offers to sell discount-priced drugs to covered entities as part of the 340B Program and establish new state-level enforcement mechanisms of various kinds, including attorney general and pharmacy board proceedings, private rights of action, and criminal prosecutions.

8. Mississippi's law says that drug manufacturers cannot "deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition … or delivery of" 340B priced drugs to contract pharmacies. App. 17a (citing Miss. Code Ann. § 41–149–7 (2024)). It is designed to force manufacturers to provide 340B-discounted pricing to covered entities for units of drugs dispensed at an unlimited number of "contract pharmacies." Contract pharmacies are for-profit pharmacies like CVS or Walgreens that are not eligible to purchase Novartis's drugs at the 340B price; they regularly buy drugs at commercial prices. The 340B discount is so lucrative that covered entities and contract pharmacies have started working together in huge numbers to try to increase the number of units of drugs on which a covered entity can try to claim a 340B discount; the covered entities and their contract-pharmacy partners then "divvy up the spread" between the 340B-discounted price paid to acquire the drug and the commercial price paid by pharmacy customers or their insurers when it is dispensed. *Novartis*, 102 F.4th at 457.

9. Contract-pharmacy arrangements do not make drugs more available or less expensive to patients or change the total number of units of any drug dispensed. Covered entities partner with contract pharmacies for one reason: to "access[] 340B pricing." 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). By using multiple contract pharmacies, a covered entity can sharply increase the number of drug units that it buys at the 340B-discounted price and thereby correspondingly increase its profits from the Program. To make this work, contract pharmacies hire third-party administrators to sift through pharmacy data looking for purported matches between

pharmacy customers and covered-entity patients. When a purported match is found, the covered entity orders a new 340B-priced unit of the drug from the wholesaler to replace the already-dispensed pharmacy unit, and the wholesaler, in turn, requests a refund from the manufacturer for that unit.

10. Novartis implemented policies to limit the use of contract pharmacies and improve transparency in the contract-pharmacy process. The limitations it chose are ones that the D.C. and Third Circuit have already held manufacturers may include in their 340B-offer terms. *Novartis*, 102 F.4th at 460; *Sanofi Aventis U.S. LLC* v. *HHS*, 58 F.4th 696, 704-706 (3d Cir. 2023). But Mississippi's law would override federal law and require Novartis to change the terms of its 340B offer to covered entities in Mississippi.

11. Novartis sued to enjoin Mississippi's law as preempted. The district court held that Novartis was unlikely to succeed on the merits of its preemption claim and denied preliminary relief. App. 9a-33a. It characterized Mississippi's law as a "health and safety regulation" that triggered the presumption against preemption, App. 22a, even though this is not a law of general applicability; it affects only the acquisition price for certain units of drug already sitting on a pharmacy shelf, and does not change where any Mississippian can obtain a Novartis drug, or at what cost. The district court also held that Mississippi's law was unlikely to conflict with federal law, even though it recognized that federal law *permitted* Novartis's contract-pharmacy policy, because it did not view Congress as having "intended to *preclude states* from enacting their own public health regulations." App. 25a. Again,

Mississippi's law is not a public health regulation. It does not apply to all manufacturers, all health care providers, all pharmacies, or all drug sales. And it does not change the availability of any drug at any pharmacy to any individual with a prescription, or mandate pharmacies charge lower prices when dispensing the drug. Finally, and for the same reason, the court held that the 340B statute did not occupy the field of drug manufacturers' obligations under the Program but left "room for states to impose their own regulations on delivery of Section 340B drugs." App. 29a.

12. The Fifth Circuit affirmed. App.1a-6a. The court's decision relied on two prior Fifth Circuit decisions that had considered other plaintiffs' challenges to the state 340B laws enacted by Mississippi and Louisiana. App.4a-6a; *see AbbVie, Inc.* v. *Murrill*, 166 F.4th 528 (5th Cir. 2026), *opinion withdrawn and superseded on reh'g,* No. 24-30645, 2026 WL 1947948, at *1 (5th Cir. July 6, 2026) ("*Murrill*"); *AbbVie, Inc.* v. *Fitch*, 152 F.4th 635, 639 (5th Cir. 2025) (per curiam) ("*Fitch*"). Both *Murrill* and *Fitch* rejected arguments that the federal 340B statute preempts state 340B laws, reasoning that federal law regulates drug *pricing* while the state laws regulate drug *delivery*, and that federal "silence" concerning the latter permits states to use state laws to "supplement[]" the 340B Program by prohibiting federally-permissible limitations on contract pharmacies. *Murrill*, 2026 WL 1947948, at *5; *Fitch*, 152 F.4th at 646. *Murrill* and *Fitch* also held that there is no conflict preemption. *Murrill*, 2026 WL 1947948, at *7; *Fitch*, 152 F.4th at 647. The Fifth Circuit followed the Eighth Circuit in rejecting preemption challenges to state 340B

laws. *See Pharm. Rsch. and Mfrs. of Am.* v. *McClain*, 95 F.4th 1136 (8th Cir. 2024), *cert. denied*, 145 S. Ct. 768 (2024).

13. A divided panel of the Fourth Circuit disagreed and held that such laws *are* likely preempted. It affirmed an injunction against a similar West Virginia law, *see Pharm. Rsch. and Mfrs. of Am.* v. *McCuskey*, 171 F.4th 675 (4th Cir. 2026), *reh'g en banc granted,* 176 F.4th 830 (4th Cir. 2026), and reversed the denial of an injunction against a similar Maryland law, *see AbbVie v. Brown*, No. 24-1939, 2026 WL 1005576 (4th Cir. Apr. 14, 2026), *reh'g en banc granted*, 176 F.4th 830 (4th Cir. 2026). Those decisions will be heard en banc by the Fourth Circuit in a hearing anticipated to be set for this fall.

14. In the Fourth Circuit panel decision, Judges Richardson and Rushing explained how West Virginia's 340B law, just like Mississippi's, intrudes upon the federal field of 340B program requirements—a field "Congress has ousted the States from." *McCuskey*, 171 F.4th at 692. The court further explained that 340B statute "did not merely set a floor to which States may add additional obligations," but instead "struck a careful bargain" ensuring the "the upside of Medicaid market access outweighed the downside of selling drugs for a lower price." *Id.* By "directly chang[ing] the terms of drug manufacturers' federally created 340B relationships with covered entities," West Virginia had "alter[ed] the 340B program's fundamental bargain" between manufacturers and the federal government, and intruded upon the federal field. *Id.* The court also held that West Virginia's law was likely conflict preempted because it "interferes operationally with multiple aspects of the 340B

program," including by "intrud[ing] on HHS's enforcement authority." *Id.* at 693-694.

15. The First, Eighth, Ninth, and Tenth Circuits are currently considering challenges brought by Novartis to similar state laws. *See Novartis Pharms. Corp.* v. *Frey,* No. 25-1908 (1st Cir.) (challenging Maine 340B law; argued June 2, 2026 and pending decision); *Novartis Pharms. Corp.* v. *Neronha,* No. 25-1941, (1st Cir.) (challenging Rhode Island 340B law; argued June 3, 2026 and pending decision); *Novartis Pharms. Corp.* v. *Hanaway*, No. 25-1619 (8th Cir.) (challenging Missouri 340B law; pending decision on petition for rehearing en banc); *AbbVie Inc., et al.* v. *Brown*, No. 26-3712 (9th Cir.) (challenging Washington 340B law; briefing to be complete August 25, 2026); *Novartis Pharms. Corp.* v. *Drummond*, No. 25-6182 (10th Cir.) (seeking affirmance of preliminary injunction against Oklahoma's 340B law; oral argument scheduled for September 17, 2026).

16. The question presented is recurring and important. The Mississippi law that Novartis challenged here has analogs in nearly two dozen States. This issue has generated numerous opinions in the federal courts of appeals. And this case is a good vehicle to resolve the circuit split. The legal issues are clearly presented and do not depend on further factual development.

17. Good cause exists for the 30-day extension of time to file a certiorari petition. Lead counsel for Novartis, Jessica L. Ellsworth, has a number of upcoming briefing and argument deadlines, including: a brief in opposition in *United Biologics, LLC* v. *Amerigroup Tennessee, Inc.*, No. 25-1388 (U.S.) due August 17, 2026; a reply brief in *Flynn-Murphy* v. *Jaguar Land Rover N. Am. LLC*, No. 26-1195 (3d Cir.) due

July 27, 2026; a supplemental brief in *Pharmaceutical Research and Manufacturers of America* v. *McCuskey*, No. 25-1054 (L) (4th Cir.) due July 31, 2026; a supplemental brief in *AbbVie* v. *Brown*, No. 24-01939 (L) (4th Cir.) due July 31, 2026; an opening brief in *Ford Motor Co.* v. *Mikhov*, No. 26-2317 (9th Cir.) due August 3, 2026; a response brief in *Njoku* v. *Amgen, Inc.*, No. A174810 (Cal. Ct. App.) due August 13; a reply brief in *Louisiana* v. *FDA*, No. 26-30203 (5th Cir.) due August 19, 2026; a response brief in *Hurley* v. *Google LLC*, No. 26-2193 (9th Cir.) due August 19, 2026; and a reply brief in *AbbVie* v. *Brown*, No. 26-03712 (9th Cir.) due August 25, 2026; oral argument in *Louisiana* v. *FDA,* No. 26-30203 (5th Cir.) on September 7, 2026; and oral argument in *Novartis Pharmaceuticals* v. *Drummond*, No. 25-06182 (10th Cir) on September 17, 2026.

18. For the foregoing reasons, Novartis Pharmaceuticals Corporation respectfully requests that the Court extend the time to file a certiorari petition to and including September 2, 2026.

Respectfully Submitted,

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