In the Supreme Court of the United States

No. 25A___

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
Applicant,
v.
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, CENTERS FOR MEDICARE AND MEDICAID SERVICES, MEHMET OZ, in his official capacity as Administrator of Centers for Medicare and Medicaid Services,
Respondents.

APPLICATION FOR AN EXTENSION OF TIME TO FILE A PETITION FOR A WRIT OF CERTIORARI

To the Honorable Sonia Sotomayor,
Associate Justice of the Supreme Court of the United States and
Circuit Justice for the United States Court of Appeals for the Second Circuit

Applicant Boehringer Ingelheim Pharmaceuticals, Inc. respectfully requests a 60-day extension of time, to and including January 4, 2026, within which to file a petition for a writ of certiorari. *See* S. Ct. R. 13.5, 30.2; 28 U.S.C. § 2101(c). The U.S. Court of Appeals for the Second Circuit issued its judgment and opinion on August 7, 2025. *See* Appendix ("App.") 1a–50a. Absent an extension, a petition for a writ of certiorari would be due on November 5, 2025, and this Application is being filed at least ten days before that date. Boehringer will invoke this Court's jurisdiction under 28 U.S.C. § 1254(1).

1. This case concerns a federal program that takes unprecedented steps to reduce Medicare spending. In 2022, Congress created the "Medicare Drug Price Negotiation Program" as part of the Inflation Reduction Act. Under this Program, the Centers for Medicare and Medicaid Services ("CMS") sets a highly discounted

"maximum fair price" for a defined set of prescription drugs and requires manufacturers to provide "access" to the drugs at that price. *See* 42 U.S.C. §§ 1320f–1320f-4.

But Congress knew that top-down government price setting was politically unpopular and thus characterized the Program as involving negotiations between CMS and manufacturers. Under the Program, a manufacturer must not only grant Medicare beneficiaries access to a covered drug on CMS's terms, but also sign documents attesting that it "negotiate[d]" and "agree[s]" to the "maximum fair price" prescribed by CMS. 42 U.S.C. § 1320f-2(a). Failure to sign these "agreements" subjects the manufacturer to a 1900% excise tax penalty (amounting to billions of dollars per year in Boehringer's case); failure to provide access to the drug according to the "agreements" results in millions of dollars in additional penalties per day. *See* 26 U.S.C. § 5000D; 42 U.S.C. § 1320f-6(a); Marsh Decl. ¶ 16, *Boehringer Ingelheim Pharm, Inc. v. HHS*, No. 24-2092, ECF 47, at 89 (2d Cir. Nov. 4, 2024). A manufacturer cannot avoid the Program or its penalties unless it withdraws *all* its drugs (not just the selected drug) from *both* Medicare *and* Medicaid, which collectively make up nearly half the U.S. drug market.

In short, Congress created a program designed to compel one outcome: compliance. As Judge Hardiman recently observed in a related case, Congress had several constitutionally permissible options at its disposal to reduce Medicare spending on prescription drugs. "Instead of" exercising those options, however, Congress "made [manufacturers] an offer they couldn't refuse," thus "compel[ling] manufacturers to subject themselves to prices set by CMS" and "misrepresent that

they agreed to such prices." *Bristol Myers Squibb Co. v. Sec'y of HHS*, 2025 WL 2537005, *25, *33 (3d Cir. Sept. 4, 2025) (dissenting opinion, cleaned up) ("*BMS*").

2. Boehringer's Jardiance® was among the first group of drugs selected for the Program. App. 21a. Jardiance® is widely prescribed to reduce the risk of cardiovascular death, lower blood sugar in adults with type 2 diabetes, and prevent chronic kidney disease from worsening. It is one of many innovative lifesaving and life-improving treatments that Boehringer and its affiliates have spent years of effort and billions of dollars to develop, benefitting millions of patients worldwide. When CMS selected Jardiance® for the Program, Boehringer had no choice but to comply: the excise tax liability for failing to participate in the Program would have been hundreds of millions of dollars *per week* initially, quickly increasing to billions per week; and withdrawing Boehringer's entire portfolio (more than 20 drugs) from Medicare and Medicaid would have eliminated more than half the company's net domestic sales, depriving Boehringer of the ability to continue developing innovative medicines. *See* Marsh Decl., *supra*, ¶¶ 7, 17–19. Boehringer thus made the only viable choice and signed (under protest) an agreement drafted by CMS, purportedly expressing Boehringer's assent to participate in "negotiation[s]" with the agency. *Id.* ¶¶ 11–14; App. 21a. Once that "negotiation" process was complete, Boehringer signed (again, under protest) an addendum drafted by CMS expressing "agreement" that the price set by CMS—a 66% reduction below market value[1]—was the "maximum fair

[1] *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/8VRC-PLKC; *see also* 42 U.S.C. § 1320f-2.

price" for Jardiance®. App. 22a. Boehringer's obligation to provide "access" to Jardiance® on those terms begins on January 1, 2026, and will remain in effect until the drug is subject to generic competition. *See* 42 U.S.C. §§ 1320f(b)(1), 1320f-2(b).

3. In parallel, Boehringer sought redress from the courts, alleging, among other things, that the Program—whether directly or as an unconstitutional condition on Medicare and Medicaid participation—(1) violates the Fifth Amendment by effecting a physical taking by forcing Boehringer to provide access to Jardiance® products on CMS's terms; (2) violates the First Amendment by compelling Boehringer to express the Government's messages regarding the Program; and (3) violates the Fifth Amendment by depriving Boehringer of its property rights without due process.

4. The District Court (Shea, C.J.) granted the Government summary judgment on Boehringer's claims, *see Boehringer Ingelheim Pharms., Inc. v. HHS*, 2024 WL 3292657 (D. Conn. July 3, 2024), and the Second Circuit (Leval, Bianco, Nardini, JJ.) affirmed, *see Boehringer Ingelheim Pharms. v. HHS*, 2025 WL 2248727 (2d Cir. Aug. 7, 2025), *reproduced at* App. 2a–50a. In doing so, the panel split with other courts of appeals and contravened this Court's precedent.

First, the panel held that a federal program is constitutional so long as participation is not "legally compelled" (i.e., required by law) and the conditions it imposes on participants relate to the program's goals. *See* App. 26a–31a, 43a–48a. That rationale conflicts with this Court's unconstitutional conditions cases, which prohibit the Government from putting program participants to an illusory choice between retaining their constitutional rights and suffering disproportionate

penalties.[2] *Second*, the panel rejected Boehringer's takings claim because participation in the Program is not legally compelled. *See* App. 32a. But as Judge Hardiman recently explained, manufacturers are "compelled … to participate" under threat of "unavoidable, enterprise-crippling tax liabilities if they refuse to sell drugs at prices set by CMS," effecting a taking of their property under *Horne*. *BMS*, 2025 WL 2537005, at *15 (dissenting opinion). *Third*, the panel rejected Boehringer's First Amendment claim because, in the court's view, no speech was "actual[ly] comp[elled]." App. 42a. But as Judge Hardiman also reasoned, manufacturers are "force[d] … to convey the government's message about the Program" "by the threat of a direct punishment." *BMS*, 2025 WL 2537005, at *27–28 (dissenting opinion, cleaned up). These issues are "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." *Id.* at *33.

5. There is good cause to grant a 60-day extension. *See* S. Ct. R. 13.5. *First*, an extension would allow Boehringer to evaluate and address developments in other cases challenging the same Program. For example, the Fifth Circuit recently expedited *National Infusion Center Association v. Kennedy*, No. 25-50661, which presents similar constitutional challenges to the Program, so that the appeal will be fully briefed on September 24, 2025, and will be argued on October 7, 2025. Similarly, *Novo Nordisk Inc. v. Kennedy*, No. 24-2510, presents overlapping constitutional challenges to the Program and remains pending before the Third Circuit (following

[2] *See, e.g.*, *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214–15, 218–19 (2013); *Horne v. Dep't of Agriculture*, 576 U.S. 350, 365–66 (2015); *United States v. Butler*, 297 U.S. 1, 70–71 (1936).

oral argument in April 2025). Extending the deadline in this case to January 4, 2026, may thus allow Boehringer to address the decisions in these cases.

Second, Boehringer's counsel have obligations in other matters that will make filing a petition within the current timeframe challenging, including reply briefs due on October 16 in *Baxley v. Driscoll*, No. 24-5104 (D.C. Cir.), on October 20 in *Novo Nordisk Inc. v. WellHealth Inc.*, No. 25-10681 (11th Cir.), on October 27 in *United States ex rel. Penelow v. Janssen Prods. L.P.*, No. 25-1818 (3d. Cir.), and on November 5, 2025 in *Amazon.com, Inc. v. CPSC*, No. 8:25-cv-00853 (D. Md.); an opening brief due on October 31 in *Novo Nordisk Inc. v. Brooksville Pharms. Inc.*, No. 25-12617 (11th Cir.); an intervenor-appellee response brief due on November 10 in *Outsourcing Facilities Ass'n v. FDA*, No. 25-10758 (5th Cir.); and a petition for writ of certiorari due on October 1 in *Tobien v. Nat'l General Ins. Co.*, 133 F.4th 613 (6th Circ. 2025).

Finally, no meaningful prejudice would arise from the requested extension. Boehringer is authorized to state that Respondents do not oppose this request.

Respectfully submitted,

/s/Kevin F. King

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Applicant makes the following disclosures: Applicant Boehringer Ingelheim Pharmaceuticals, Inc. is a nongovernmental corporation that is wholly owned by Boehringer Ingelheim USA Corp. Both corporations are privately owned, and no publicly held company owns 10% or more of those corporations' stock.