No. 25A___

IN THE

Supreme Court of the United States

JANSSEN PHARMACEUTICALS INC.,

Applicant,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services; 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 Samuel A. Alito, Jr., Associate Justice of the Supreme Court of the United States and Circuit Justice for the United States Court of Appeals for the Third Circuit:

Applicant Janssen Pharmaceuticals, Inc. respectfully requests a 16-day extension of time, to and including December 19, 2025, to file a petition for a writ of certiorari in the above-captioned proceeding. *See* S. Ct. R. 13.5, 30.2; 28 U.S.C. § 2101(c). The U.S. Court of Appeals for the Third Circuit, over a dissent by Judge Thomas M. Hardiman, issued its judgment and opinion in this case on September 4, 2025. *See* Appendix ("App.") 1a–96a. Absent an extension, a petition for a writ of certiorari would be due on December 3, 2025, and this Application is being filed at least ten days before that date. Janssen will invoke this Court's jurisdiction under 28 U.S.C. § 1254(1).

1. This case concerns the "Medicare Drug Price Negotiation Program" ("Program"), which Congress established in 2022. Under the Program, the Centers for Medicare and Medicaid Services ("CMS") selects prescription drugs that account for the largest share of Medicare spending, "negotiates" with manufacturers to establish a "maximum fair price" for each selected drug, and requires manufacturers to provide Medicare beneficiaries "access" to the selected drugs at those prices. *See* 42 U.S.C. §§ 1320f–1320f-6. While designed to look like an arms-length negotiation, the Program actually involves forced transfers on terms dictated by CMS. If a manufacturer does not sign an agreement to "negotiate" with CMS, or fails to agree to CMS's price after those negotiations, the noncompliant manufacturer must pay a 1900% excise tax on all domestic sales of the selected drug or withdraw all its drugs (not just the selected drug) from Medicare and Medicaid. *See id.* § 1320f-6; 26 U.S.C. § 5000D. In other words, the Program makes manufacturers "offer[s] they [can't] refuse" by threatening them with "enterprise-crippling" penalties if they do not "agree" to turn over their drugs at highly discounted prices set by CMS. App. 78a, 81a–82a (Hardiman, J., dissenting) (cleaned up).

2. For the first year of the Program, CMS selected Janssen's Xarelto® (rivoroxaban), which millions of Americans rely upon to prevent blood clots and reduce the risk of stroke. *See* App. 20a. Had Janssen not participated, it would have faced more than $90 billion in excise tax penalties in the first year alone—more than triple the 2022 adjusted net earnings of Janssen's parent company, Johnson &

Johnson. *See* JA796.[1] Had Janssen attempted to avoid the Program by withdrawing its drug portfolio from Medicare and Medicaid, millions of patients would have lost coverage for Xarelto® and 20 other medications, and Janssen would have lost 65% of its gross sales—crippling the company's ability to continue developing innovative treatments. *See* JA796–97. Accordingly, Janssen took the only viable step: it complied with the Program's requirements. *See* App. 20a.

That compliance started by signing (under protest) an agreement drafted by CMS, expressing Janssen's assent to participate in negotiations with CMS. *See* 42 U.S.C. § 1320f-2; App. 16a–18a, 20a. Janssen then signed an addendum drafted by CMS (again under protest), attesting that the company had "negotiated" with CMS and expressing "agree[ment]" that the resulting price—a 62% reduction in the market-based price[2]—was the "maximum fair price" for Xarelto®. *See* App. 18a, 20a. As a result, Janssen became obligated (under pain of additional monetary penalties) to provide Medicare beneficiaries "access" to Xarelto® on CMS's terms starting January 1, 2026, and continuing until CMS determines that generic competition has entered the market. *See* 42 U.S.C. §§ 1320f(b)(1), 1320f-2(b), 1320f-6.

3. Janssen filed a lawsuit alleging that the Program violates the First Amendment by compelling Janssen to express the Government's disputed messages about drug pricing, effects a *per se* taking under the Fifth Amendment by forcing Janssen to transfer Xarelto® to Medicare beneficiaries on CMS's terms, and imposes unconstitutional conditions on participation in Medicare and Medicaid.

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[1] Joint Appendix, *Janssen Pharms. Inc. v. Sec'y of HHS*, No. 24-1821, ECF 30-3 (3d Cir. Jul. 12, 2024).

[2] *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/8VRC-PLKC.

4. The District Court (Quraishi, J.) granted the Government summary judgment, *see* 2024 WL 1855054 (D.N.J. Apr. 29, 2024), and a divided panel of the Third Circuit (Hardiman, Phipps, Freeman, JJ.) affirmed, *see* 2025 WL 2537005 (3d Cir. Sep. 4, 2025). The Third Circuit rejected Janssen's takings claim, concluding that the Program does not appropriate property because it is "voluntary," App. 21a–36a, and that the unconstitutional conditions doctrine does not apply to exactions outside the land-use context, App. 36a–38a. The Third Circuit then rejected Janssen's compelled-speech claim because, among other things, Janssen retains the ability to engage in counterspeech outside the Program, App. 45a–52a.

Judge Hardiman dissented. He explained that the Program is not voluntary because manufacturers cannot opt out without incurring "enterprise-crippling" penalties. App. 63a–78a, 82–83a. Thus, while the Program is voluntary in theory, it is mandatory in fact. Judge Hardiman then concluded that the Program's "access" requirement effects a taking by "forcing [Janssen] to turn over physical doses of [Xarelto®] to Medicare beneficiaries." App. 78a–81a. The Program likewise violates the First Amendment, Judge Hardiman explained, by forcing Janssen to state in writing that the price set by CMS is not only the agreed-upon product of a negotiation, but also the "maximum fair price" for Xarelto®. App. 86a–87a.

Judge Hardiman also underscored the ways in which the majority's decision contradicts this Court's precedents and splits with decisions from other circuits. *See, e.g.*, App. 90a–91a (citing precedent contradicting the majority's First Amendment holding); App. 87a n.13 (noting split with *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518 (D.C. Cir. 2015)). Judge Hardiman concluded by emphasizing that the questions

presented by this case are "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." App. 95a.

5. There is good cause to grant a 16-day extension. *First*, this extension would promote the Court's ability to consider this case together with several others that present similar constitutional challenges to the Program. Following the decision in this case, the Third Circuit decided two other cases that presented overlapping constitutional challenges to the Program. *See Novartis Pharms. Corp. v. Sec'y of HHS*, 2025 WL 2619133 (3d Cir. Sep. 11, 2025); *Novo Nordisk, Inc. v. Sec'y of HHS*, 2025 WL 2825979 (3d Cir. Oct. 6, 2025). Petitions for writs of certiorari in those cases are due on December 10 and January 5, respectively. The Court also recently extended the petition deadline in *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 25A357, another case presenting constitutional challenges to the Program, to January 5, 2026. Extending Janssen's filing deadline by 16 days will facilitate coordinated action on these cases by the parties, the Government, and the Court.

Second, Janssen's counsel have obligations in other matters that will make filing a petition within the current timeframe challenging, including reply briefs due on November 5 in *Amazon.com, Inc. v. CPSC*, No. 8:25-cv-00853 (D. Md.), and on November 20 in *Baxley v. Driscoll*, No. 24-5104 (D.C. Cir.); an intervenor-appellee response brief due on November 10 in *Outsourcing Facilities Ass'n v. FDA*, No. 25-10758 (5th Cir.); and an amicus brief due on December 22 in *KalshiEx LLC v. Martin*, No. 25-1892 (4th Cir.).

Finally, no meaningful prejudice would arise from the requested extension. Janssen is authorized to state that Respondents consent to this request.

Respectfully submitted,

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Applicant makes the following disclosures: Janssen Pharmaceuticals Inc. is a wholly owned subsidiary of Johnson & Johnson (NYSE: JNJ). No other publicly held corporation owns 10% or more of Janssen's or Johnson & Johnson's stock.