No. 25-799

In the Supreme Court of the United States

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
PETITIONER

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

D. JOHN SAUER
Solicitor General
Counsel of Record
ERIC J. HAMILTON
Deputy Assistant Attorney General
MICHAEL S. RAAB
MAXWELL A. BALDI
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTIONS PRESENTED

1. Whether the court of appeals correctly held that petitioner's takings, due-process, and compelled-speech claims fail because petitioner's participation in the Medicare Drug Price Negotiation Program (26 U.S.C. 5000D, 42 U.S.C. 1320f to 1320f-7) is voluntary.

2. Whether the government violates the unconstitutional-conditions doctrine when it defines the scope of and sets the terms for participating in a voluntary federal program.

ADDITIONAL RELATED PROCEEDINGS

Supreme Court of the United States:

Boehringer Ingelheim Pharm., Inc. v. *HHS*, No. 25A357 (Sept. 29, 2025)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-46a) is reported at 150 F.4th 76. The opinion of the district court (Pet. App. 47a-104a) is available at 2024 WL 3292657.

JURISDICTION

The judgment of the court of appeals was entered on August 7, 2025. On September 29, 2025, Justice Sotomayor extended the time within which to file a petition for a writ of certiorari to and including January 5, 2026, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Congress created Medicare in 1965. Health Insurance for the Aged Act, Pub. L. No. 89-97, 79 Stat. 286. Medicare provides federally funded health coverage for

individuals who are 65 or older or who have certain disabilities or medical conditions. See *Becerra* v. *Empire Health Found.*, 597 U.S. 424, 428 (2022); 42 U.S.C. 1395 *et seq.* The Centers for Medicare & Medicaid Services (CMS) administers Medicare on behalf of the Secretary of the Department of Health and Human Services (HHS).

Medicare is divided into "Parts," which establish the terms under which Medicare pays for specific benefits. See Pet. App. 8a. As relevant here, Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. See *id.* at 8a-9a. CMS generally pays Part B providers at a rate of 106% of the average sales price for most drugs or biologicals. See 42 U.S.C. 1395w-3a(b)(1); see also *American Hosp. Ass'n* v. *Becerra*, 596 U.S. 724, 729 (2022).

Pharmaceutical manufacturers opt into participating in Medicare (and Medicaid). See 42 U.S.C. 1395cc. Their participation may also be terminated by one of two statutory procedures. If a manufacturer chooses to withdraw unilaterally, it may terminate its agreements "for any reason" after providing 11 to 23 months' notice. 42 U.S.C. 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). Alternatively, CMS may terminate its agreements with a manufacturer "for a knowing and willful violation of the requirements of the agreement or other good cause shown" with only 30 days' notice. 42 U.S.C. 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i).

For nearly four decades, Medicare did not cover the cost of prescription drugs unless they were administered by medical professionals. That changed in 2003, when Congress enacted Medicare Part D to provide "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription

drug insurance premiums for Medicare enrollees." *AstraZeneca Pharm. LP* v. *HHS*, 137 F.4th 116, 120 (3d Cir. 2025) (citation omitted); see 42 U.S.C. 1395w-101 *et seq.* Under Part D, CMS enters into contracts with private entities, known as "sponsors," 42 U.S.C. 1395w-112, and makes payments to them to provide prescription drug plans to Part D eligible individuals, see 42 U.S.C. 1395w-115. On average, the government subsidizes 74.5% of the expected cost of Part D benefits. See 42 U.S.C. 1395w-115(a).

In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise becoming involved in the arrangements between drug manufacturers and insurance plans. Congress thus expressly provided that CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and . . . sponsors" and "may not . . . institute a price structure for the reimbursement of covered part D drugs." Pet. App. 9a (citation omitted).

The cost to the federal government of subsidizing prescription drug coverage under Medicare Parts B and D is immense. In 2021 alone, the federal government spent more than $250 billion on drugs covered by those programs. See News Release, KFF, *10 Prescription Drugs Accounted for $48 Billion in Medicare Part D Spending in 2021, or More Than One-Fifth of Part D Spending That Year* (July 12, 2023), https://perma.cc/4CYL-KYRM. "Prescription drug expenditures" were "projected to continue rising during the" 2020s, "placing increasing fiscal pressure[]" on the federal budget. Office of the Assistant Sec'y for Planning & Evaluation, HHS, *Report To Congress: Prescription Drug Pricing* 8 (May 20, 2020), https://perma.cc/5GEN-LZ7F (2020 Report). Medicare Part D spending in particular was

"projected to increase faster than any other category of health spending." S. Rep. No. 120, 116th Cong., 1st Sess. 4 (2019).

The high cost of prescription drugs and thus drug coverage also burdens Medicare beneficiaries by affecting their out-of-pocket payments and premiums. Beneficiaries generally pay 20% of their Part B prescription drug costs out of pocket after their deductible. See 42 U.S.C. 1395*l*(a)(1) and (b). And because Part B premiums are automatically set to cover 25% of aggregate Part B spending, see 2020 Report 11, higher total spending on prescription drug coverage results in higher premiums for individual enrollees. Many Part D plans likewise require beneficiaries to pay cost-sharing amounts, *e.g.*, 42 C.F.R. 423.104(d)(2), and Part D premiums are similarly based on a plan's anticipated costs, see 42 C.F.R. 423.286.

A "relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 324, 116th Cong., 1st Sess. Pt. 2, at 37 (2019). In 2018, "the top ten highest-cost drugs by total spending accounted for 46 percent of spending in Medicare Part B" and "18 percent of spending in Medicare Part D." 2020 Report 7. By 2021, the top ten drugs by total spending accounted for 22% of spending under Part D. See Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (July 12, 2023), https://perma.cc/2PF2-336Z.

Those high costs are largely attributable to manufacturers' considerable latitude in dictating the prices that Medicare pays for the most expensive drugs. Congress originally tied drug prices under Medicare Part B and Part D to the price that manufacturers charged private

buyers. See 42 U.S.C. 1395w-3a(b), 1395w-111(i)(1) and (3). As a result, manufacturers of drugs with no generic competition could "effectively set[ ] [their] own Medicare payment rate[s]" by dictating sales prices in the broader market. Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2022), https://perma.cc/5X4R-KCHC.

Other federal agencies, including the Departments of War and Veterans Affairs, operate their drug benefit programs differently and have not been subject to skyrocketing costs. As a condition on Medicaid participation, manufacturers that wish to sell drugs to the government through these programs have long been required to negotiate with the government and reach agreements subject to statutorily defined ceiling prices. See 38 U.S.C. 8126(a)-(h); 42 U.S.C. 1396r-8(a)(1) and (6). Consequently, manufacturers often sell drugs to these agencies for roughly half as much as they charge Medicare Part D. See Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 16, 18 (Feb. 2021), https://perma.cc/YY2E-GM97.

b. In the Inflation Reduction Act of 2022 (Act), Pub. L. No. 117-169, §§ 11001-11003, 136 Stat. 1833-1864 (26 U.S.C. 5000D, 42 U.S.C. 1320f to 1320f-7), Congress empowered the HHS Secretary, acting through CMS, to negotiate the prices Medicare pays for certain drugs, as the Department of War, the Department of Veterans Affairs, and other agencies have done for decades. The Negotiation Program applies only to manufacturers that choose to participate in Medicare and Medicaid, and even then, it governs only the prices that Medicare pays for certain drugs. See CMS, *Medicare Drug Price*

Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, at 120-121 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance); see also 26 U.S.C. 5000D(c)(1); 42 U.S.C. 1320f-1(b) and (d). The Program does not dictate the prices paid by other buyers of those drugs.

By statute, only certain drugs are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years (or 11 years, for biological products). See 42 U.S.C. 1320f-1(d) and (e). After selecting the drugs, CMS signs a Manufacturer Agreement with each manufacturer that is willing to engage in the negotiation process. See 42 U.S.C. 1320f-2.

The object of the negotiations is to reach an agreement on what the Act calls a "maximum fair price" that Medicare will pay for each selected drug. See 42 U.S.C. 1320f-3. To guide the negotiation process, Congress imposed a "[c]eiling for [the] maximum fair price," which is based on specified pricing data for each drug, 42 U.S.C. 1320f-3(c), and directed CMS to "aim[] to achieve the lowest maximum fair price" that the manufacturer will accept, 42 U.S.C. 1320f-3(b)(1). The statute requires CMS to "consider several factors during negotiations, including the manufacturer's production and distribution costs, the manufacturer's research and development costs (and the extent to which those costs have been recouped), federal funding for the drug's development, patent rights and statutory exclusivities, FDA product approvals, sales data, and alternative treatments." *AstraZeneca*, 137 F.4th at 121 (citing 42 U.S.C. 1320f-3(e)). If negotiations prove successful, the

manufacturer signs an addendum to the Manufacturer Agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. 42 U.S.C. 1320f-3; see 42 U.S.C. 1320f-2; Revised Guidance 159. CMS must then publish the maximum fair price. See 42 U.S.C. 1320f-4(a)(1).

Congress specified that, for drugs selected for the first negotiation cycle, any negotiated prices take effect for Part D on January 1, 2026. 42 U.S.C. 1320f(b)(1) and (2).[1] To ensure that negotiated prices could be implemented by that date, Congress established interim deadlines to govern the process. 42 U.S.C. 1320f(d). And to ensure that litigation would not disrupt negotiations, Congress expressly prohibited judicial review of certain agency decisions, including the selection of drugs for negotiation and the determination of a maximum fair price. 42 U.S.C. 1320f-7.

A drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because participation in the Medicare program is voluntary, the manufacturer can withdraw from Medicare and Medicaid, and thus not be subject to any of the Negotiation Program's requirements. See 26 U.S.C. 5000D(c); Revised Guidance 120-121. Alternatively, a manufacturer can transfer its ownership of the selected drug to another entity and continue to sell other drugs to Medicare and Medicaid. See Revised Guidance 131-132. A manufacturer that pursues neither of those options may also continue to sell the selected drug to Medicare beneficiaries at non-negotiated prices

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[1] The prices negotiated for the first two years of the Negotiation Program apply only to drugs covered by Part D; for Medicare Part B, drug selection and negotiations occur later, and any negotiated prices will take effect in 2028. See 42 U.S.C. 1320f-1(a)(3).

subject to an excise tax. See 26 U.S.C. 5000D; see also *Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025); IRS, Notice 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice).

c. In addition to the statutory requirements detailed above, Congress instructed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" for the first three negotiation cycles. Act § 11001(c), 136 Stat. 1854; 42 U.S.C. 1320f note. In June 2023, "[a]fter receiving more than 7,500 public comments," CMS published a revised guidance document that applies for the 2026 drug-pricing period. *AstraZeneca*, 137 F.4th at 121. Among other things, that guidance explains how CMS determines which drugs may be selected for negotiation and the procedures for participating in the negotiation process. See Revised Guidance 94-96. And that guidance provides a process for manufacturers to contest putative errors made by CMS in certain calculations. See *id.* at 128-129.

The Revised Guidance also sets out procedures for manufacturers that choose not to participate in the Negotiation Program. See Revised Guidance 120-121, 129-131; accord CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, at 257-260 (Sept. 30, 2025), https://perma.cc/37EL-GRUW. In those circumstances, CMS will "facilitate an expeditious termination of" a manufacturer's Medicare agreement before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies the agency of its desire to withdraw at least 30 days

in advance of when the tax would otherwise begin to accrue. Revised Guidance 33-34. The Treasury Department and the Internal Revenue Service (IRS) issued a notice explaining that, when excise tax liability is triggered, the tax will be imposed only on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare"—*i.e.*, not on drugs dispensed, furnished, or administered outside of Medicare. IRS Notice 3. That interpretation took effect immediately. See *id.* at 5. The Treasury Department and the IRS have reiterated that understanding of the application of the tax in a proposed rule. See 90 Fed. Reg. at 32-34, 36.

2. In August 2023, CMS selected ten drugs with the highest Medicare expenditures for the first negotiation cycle. See 42 U.S.C. 1320f-1(a); HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z.[2] The ten drugs selected accounted for more than $50 billion of gross Medicare Part D prescription drug costs between June 2022 and May 2023, and Medicare beneficiaries paid a total of $3.4 billion in out-of-pocket costs for those drugs in 2022 alone. See *HHS Selects the First Drugs for Medicare Drug Price Negotiation*, *supra*; CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug.

[2] In January 2025, CMS selected 15 drugs for the second negotiation cycle in 2027. CMS, *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors* (Jan. 17, 2025), https://perma.cc/D4JH-AKFN. And in January 2026, CMS selected 15 drugs for the third negotiation cycle in 2028. CMS, *CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program, Including First-Ever Part B Drugs* (Jan. 27, 2026), https://perma.cc/687W-QKQL.

2023), https://perma.cc/X37F-RC94 (*Selected Drugs for IPAY 2026*). Each manufacturer of a selected drug executed a Manufacturer Agreement with CMS to negotiate the price of its drug, and negotiations proceeded over the spring and summer of 2024. See CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/3222-VPEE.

In accordance with the schedule established by Congress, CMS presented the manufacturers with initial offers. See CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8 (*Negotiated Prices for IPAY 2026*). The manufacturers responded with counteroffers. *Ibid.* CMS subsequently held three negotiation meetings with each manufacturer to discuss the offers and relevant evidence. *Ibid.* Many manufacturers proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright. *Ibid.* All told, CMS reached price agreements for five of the selected drugs in connection with these meetings. CMS sent final written offers to manufacturers of the five remaining drugs. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the ten selected drugs. *Ibid.* None of the ten manufacturers has withdrawn from the Negotiation Program, and the manufacturers have been responsible for effectuating the negotiated prices since January 1, 2026.

3. Petitioner Boehringer Ingelheim Pharmaceuticals, Inc. manufactures pharmaceuticals, including the glycemic-control drug Jardiance. See Pet. App. 18a.

Jardiance was one of the drugs selected for the first round of the Negotiation Program. See *Selected Drugs for IPAY 2026*, *supra*. In 2023, more than 1.8 million Medicare Part D enrollees used Jardiance; that year, CMS covered more than $8.8 billion in costs for that drug. *Negotiated Prices for IPAY 2026*, *supra*. Petitioner entered into a Manufacturer Agreement and ultimately agreed to a negotiated price for Jardiance with CMS. See *ibid.*

Petitioner sued in the United States District Court for the District of Connecticut to challenge the Negotiation Program. Pet. App. 59a. Petitioner raised five constitutional claims, specifically that the Program: (1) deprives petitioner of property without due process, in violation of the Fifth Amendment; (2) effects a per se physical taking without just compensation, in violation of the Fifth Amendment; (3) compels petitioner to speak, in violation of the First Amendment; (4) violates the Eighth Amendment's Excessive Fines Clause; and (5) is an unconstitutional condition on Medicare and Medicaid participation. *Id.* at 7a. Petitioner also argued that, in issuing the Manufacturer Agreement without notice and comment, CMS violated the Administrative Procedure Act (APA) and the Medicare statute. *Id.* at 7a-8a, 44a. The court denied petitioner's motion for summary judgment and granted the government's cross-motion for summary judgment. *Id.* at 47a-104a.

The district court first rejected petitioner's claims that the Negotiation Program effects a physical taking of property and deprives petitioner of due process. Pet. App. 62a-82a. The court explained that, because petitioner could "opt out of Medicare and Medicaid" without penalty before the maximum fair price was to take effect, participation in the Negotiation Program is

voluntary and does not deprive petitioner of its property. *Id.* at 63a; see *id.* at 63a-64a.

The district court next rejected the argument that the requirement to sign a Manufacturer Agreement impermissibly forces petitioner to speak or to engage in expressive conduct because the Agreement uses terms like "negotiation" and "maximum fair price." Pet. App. 83a (citation omitted); see *id.* at 83a-87a. The court reiterated that the Negotiation Program "d[oes] not 'compel' [petitioner] to do anything" because manufacturers can opt out of participation and avoid signing the Agreement. *Id.* at 84a.

The district court likewise rejected petitioner's argument that the Negotiation Program violated the unconstitutional-conditions doctrine. Pet. App. 87a-93a. The court explained that, "to the extent the unconstitutional condition[s] doctrine applies at all to claims such as these," the "core feature" of the doctrine "is a concern that the government will tie its own goals to unrelated benefits that flow from its regulatory and spending programs—and that feature is missing here" because the conditions imposed are "closely related to the government's goal of controlling spending in the Medicare program." *Id.* at 93a. The court also rejected petitioner's excessive-fines and APA/statutory challenges. *Id.* at 94a-104a.

4. The court of appeals unanimously affirmed. Pet. App. 1a-46a. On appeal, petitioner abandoned its arguments that the Negotiation Program violates the Eighth Amendment's Excessive Fines Clause and that CMS's issuance of the Manufacturer Agreement violated the Medicare statute, but renewed its other claims. *Id.* at 20a-21a & n.5.

The court of appeals explained that "participation in the Negotiation Program is voluntary." Pet. App. 22a. Relying on circuit precedent, see *Garelick* v. *Sullivan*, 987 F.2d 913 (2d Cir.), cert. denied, 510 U.S. 821 (1993), and noting the similar conclusions reached in other circuits, see Pet. App. 23a & n.7 (collecting cases), the court held that "[p]articipation in the Negotiation Program, like participation in Medicare as a whole, is voluntary" because no statute "compels pharmaceutical companies to offer products or services through Medicare, via the Negotiation Program or otherwise," *id.* at 25a. The court rejected petitioner's "economic hardship argument," explaining that "the choice to participate in a voluntary government program does not become involuntary simply because the alternatives to participation appear to entail worse, even substantially worse, economic outcomes." *Id.* at 25a-26a (citing *Garelick*, 987 F.2d at 917, and *St. Francis Hosp. Ctr.* v. *Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam), cert. denied, 465 U.S. 1022 (1984)).

Based on that conclusion, the court of appeals rejected petitioner's Fifth Amendment takings and due-process claims, holding that there can be no taking and no deprivation of a protected property interest when petitioner voluntarily agrees to sell products as part of a government program. Pet. App. 27a-35a. The court also rejected petitioner's compelled-speech claim because petitioner suffered no "actual compulsion" to sign the Manufacturer Agreement. *Id.* at 38a.

Turning to petitioner's unconstitutional-conditions claim, the court of appeals explained that "laws establishing conditions on spending under federally funded programs without implicating recipients' activity in the private market do not run afoul of the unconstitutional

conditions doctrine." Pet. App. 40a. Because the Negotiation Program "simply establishes a price structure to limit CMS's costs for certain high-expenditure drugs," without "regulat[ing] [petitioner's] sales of Jardiance in the private market," "the program is a lawful exercise of Congress's spending power." *Id.* at 43a-44a.

Like the district court, the court of appeals rejected petitioner's APA claim as well. Pet. App. 44a-45a.

ARGUMENT

This petition presents another set of challenges to the Medicare Drug Price Negotiation Program.[3] Though petitioner abandons some contentions it raised below, it renews its arguments that the Negotiation Program violates the Fifth Amendment's Takings and Due Process Clauses, compels it to speak in violation of the First Amendment, and is an unconstitutional condition on Medicare and Medicaid participation. See Pet. 14-28; Pet. App. 7a.

As the government has explained elsewhere, those claims fail. See Br. in Opp. at 14-22, *AstraZeneca* v. *HHS*, No. 25-348 (Jan. 2, 2026) (*AstraZeneca* Br. in Opp.) (due-process claim); Br. in Opp. at 14-30, *Janssen Pharm. Inc.* v. *HHS*, No. 25-749, and *Bristol Myers Squibb Co.* v. *Kennedy*, No. 25-751 (Mar. 25, 2026) (*Janssen/BMS* Br. in Opp.) (takings, compelled-speech, and unconstitutional-conditions claims). The court of

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[3] See *AstraZeneca Pharm. LP* v. *Kennedy*, petition for cert. pending, No. 25-348 (filed Sept. 19, 2025); *Janssen Pharm. Inc.* v. *Kennedy*, petition for cert. pending, No. 25-749 (filed Dec. 19, 2025); *Bristol Myers Squibb Co.* v. *Kennedy*, petition for cert. pending, No. 25-751 (filed Dec. 19, 2025); *Novo Nordisk Inc.* v. *Kennedy*, petition for cert. pending, No. 25-761 (filed Dec. 22, 2025); *Novartis Pharm. Corp.* v. *Kennedy*, petition for cert. pending, No. 25-902 (filed Jan. 23, 2026).

appeals correctly rejected petitioner's takings, due-process, and compelled-speech arguments for the "threshold" reason that petitioner's participation in the Negotiation Program is voluntary. Pet. App. 22a; see *id.* at 20a-39a. And the court correctly held that petitioner's unconstitutional-conditions claim fails because the Program is a lawful exercise of Congress's spending power. *Id.* at 39a-44a. Those holdings do not conflict with any decision of this Court or of any other court of appeals. The petition should be denied.

1. The decision of the court of appeals is correct.

a. ***Voluntariness.*** Petitioner first contends that the Second Circuit erred in holding that "participation in the [Negotiation] Program is 'voluntary' as a matter of law." Pet. 14. In petitioner's telling, the economic incentives to participate in the Program are sufficient to render its participation involuntary. See Pet. 15-18; Pet. App. 25a. As the court of appeals held, that theory is incorrect, and the voluntary nature of the Negotiation Program dooms petitioner's takings, due-process, and compelled-speech claims. See Pet. App. 22a-39a.

i. Participation in the Negotiation Program—as in all of Medicare—is voluntary. The Program simply alters what Medicare will offer to pay for certain drugs. No manufacturer must accept the terms the government is presently offering; manufacturers are subject to the negotiated price only if they choose to sell their drugs to Medicare beneficiaries. See Revised Guidance 120-121; see also 26 U.S.C. 5000D(c)(1). And manufacturers may always free themselves from the excise tax either by selling at the negotiated price or withdrawing from the Program. See pp. 7-9, *supra*. "If [petitioner] dislike[s] the prices the government is willing to pay, [it is] free to stop doing business with the government."

Bristol Myers Squibb Co. v. *Secretary*, 155 F.4th 245, 255 (3d Cir. 2025).

Courts have thus "recognized in various contexts that participation in Medicare and Medicaid is voluntary." Pet. App. 23a n.7 (collecting cases); see *Bristol Myers Squibb*, 155 F.4th at 256 & n.10 (similar). Importantly, that principle holds where "the alternatives to participation appear to entail worse, even substantially worse, economic outcomes." Pet. App. 26a (citing *Garelick* v. *Sullivan*, 987 F.2d 913, 917 (2d Cir.), cert. denied, 510 U.S. 821 (1993)). Even where "business realities" create "strong financial inducement to participate" in a government program, the decision to participate in the program "is nonetheless voluntary." *Minnesota Ass'n of Health Care Facilities, Inc.* v. *Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), cert. denied, 469 U.S. 1215 (1985); see *St. Francis Hosp. Ctr.* v. *Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"), cert. denied, 465 U.S. 1022 (1984); see also *Whitney* v. *Heckler*, 780 F.2d 963, 972 n.12 (11th Cir. 1986) (similar), cert. denied, 479 U.S. 813 (1986). That the government spends significant sums on drugs for Medicare and Medicaid, and that this money translates into substantial, but highly regulated, commercial opportunities for pharmaceutical companies, does not in any relevant sense mandate participation in those programs. Similarly here, the financial incentives of obtaining revenue from Medicare and Medicaid participation or of avoiding the excise taxes do not render participation in the Negotiation Program involuntary.

Were the law otherwise, Medicare could not function. To be sure, "Spending Clause legislation operates

based on consent" and, accordingly, recipients must "'voluntarily and knowingly accept[] the terms'" of the funding contract. *Cummings* v. *Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 219 (2022) (citation omitted); accord *Medina* v. *Planned Parenthood S. Atl.*, 606 U.S. 357, 376 (2025). But that principle does not invite manufacturers and providers to negotiate bespoke deals with CMS, no matter how dependent they may be on federal funds. For example, Medicare funds the vast majority of hospice care in the United States, such that many hospices likely could not operate without federal funding. And hospices are highly regulated to ensure they provide adequate and dignified palliative care to those approaching the ends of their lives. See 42 C.F.R. Pt. 418, Subpts. C and D. On petitioner's theory of economic coercion, the government could not require hospices to abide by some of the more unprofitable requirements of its Medicare participation, such as providing 24-hour nursing care, 42 C.F.R. 418.110(b), or housing no more than two patients in each room, 42 C.F.R. 418.110(g)(2) and (3)(iv).

Other longstanding conditions on participation in Medicaid would also be called into question. For example, as a condition on its participation in Medicaid, petitioner has long been required to enter into agreements giving the Department of War, the Department of Veterans Affairs, and other agencies the option to purchase drugs at negotiated prices at or below statutory ceilings. See p. 5, *supra*. Petitioner has likewise been required to enter into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. See *Astra USA, Inc.* v. *Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health Service Act). Under

petitioner's economic-coercion theory, all of these requirements are apparently constitutionally suspect.

Nor is petitioner's argument limited to the Medicare context. In some circumstances, such as defense spending, "the government may be the only purchaser," *Bristol Myers Squibb*, 155 F.4th at 257, such that defense companies may view the government as effectively setting the terms for programs where defense companies feel that they have no other commercially viable choice but to participate. But the government's significant leverage in heavily regulated programs does not transform the government's bargaining terms into matters of constitutional concern. Cf. *Perkins* v. *Lukens Steel Co.*, 310 U.S. 113, 127-128 (1940) ("Judicial restraint of those who administer the Government's purchasing would constitute a break with settled judicial practice and a departure into fields hitherto" entrusted to coordinate branches). Just as a defense contractor cannot force the Pentagon to buy an aircraft carrier at the contractor's preferred price, pharmaceutical companies cannot force Medicare drug sales at prices the government is unwilling to pay.

In all events, petitioner's arguments about economic coercion and unequal bargaining power are overstated. The Negotiation Program entails a real negotiation in which manufacturers are in a position to bargain with the government. For the first year of the Program, CMS outright accepted four manufacturer counteroffers. See *Negotiated Prices for IPAY 2026*, *supra*. Manufacturers achieved that result because they are "not without leverage in these negotiations"; their ability to walk away and prevent Medicare and Medicaid from purchasing any of their drugs affords them bargaining power. Pet. App. 31a n.11.

ii. As the court of appeals determined, because petitioner's participation in Medicare, and therefore the Negotiation Program, is voluntary, petitioner's takings, due-process, and compelled-speech claims fail. Pet. App. 27a-39a. Petitioner errs in claiming (Pet. 2) that the court of appeals "never engaged with the substance of [its] claims"; the court considered each of petitioner's constitutional arguments and correctly rejected them on the merits.

Takings. A voluntary exchange of property for a government benefit categorically does not constitute a taking. See *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 1007 (1984); see also *Valancourt Books, LLC* v. *Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023); *In re Financial Oversight & Mgmt. Bd.*, 54 F.4th 42, 60-61 (1st Cir. 2022). The reason for that rule is obvious: the Takings Clause protects against compelled surrender of property rights. See *Yee* v. *City of Escondido*, 503 U.S. 519, 527 (1992). Where a property owner voluntarily gives property to the government in exchange for a benefit, no physical taking has occurred. See *Horne* v. *Department of Agric.*, 576 U.S. 350, 366 (2015); see also *Mayor of New Orleans* v. *United States*, 35 U.S. 662, 712 (1836) ("That property may be dedicated to public use, is a well established principle of the common law.").

"Here, because [petitioner] voluntarily chose to participate in the Negotiation Program, no taking has occurred." Pet. App. 28a. As explained more fully in the government's brief in opposition in *Janssen* and *BMS*, "the Negotiation Program simply alters what Medicare will offer to pay for certain drugs," and "the financial incentives of obtaining revenue from Medicare and Medicaid participation or of avoiding the excise taxes do not render participation in the Negotiation Program

involuntary." *Janssen/BMS* Br. in Opp. at 16-17. Moreover, the "'essential question' in physical takings cases is 'whether the government has physically taken property for itself or someone else.'" *Id.* at 15 (quoting *Cedar Point Nursery* v. *Hassid*, 594 U.S. 139, 149 (2021)). Here, "there is no taking" because "the Negotiation Program does not physically appropriate or otherwise compel the transfer of petitioner['s] property and petitioner['s] loss of some profitability for [its] selected drugs does not support a takings claim." *Id.* at 16; see Pet. App. 30a-32a (distinguishing *Horne*).

Due Process. The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property. *American Mfrs. Mut. Ins. Co.* v. *Sullivan*, 526 U.S. 40, 59 (1999). "A company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program." Pet. App. 33a. The court of appeals correctly rejected petitioner's due-process claim on that basis.

But as explained more fully in the government's brief in opposition in *AstraZeneca*, petitioner's claim fails for the additional reason that a pharmaceutical manufacturer lacks a protected property interest in selling drugs to Medicare beneficiaries at a particular price. See *AstraZeneca* Br. in Opp. at 14-22. "Like private individuals and businesses, the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases." *Id.* at 15 (quoting *Perkins*, 310 U.S. at 127). "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-*

Delany Co. v. *Capital Dev. Bd.*, 616 F.2d 341, 342 (7th Cir. 1980) (per curiam).

Compelled Speech. "A violation of the First Amendment right against compelled speech occurs 'only in the context of actual compulsion.'" *Miller* v. *Mitchell*, 598 F.3d 139, 152 (3d Cir. 2010) (citation omitted); see Pet. App. 36a-37a. As the government explained more fully in *Janssen* and *BMS*, petitioner faces no "actual compulsion" to engage in speech because petitioner's "participation in the Negotiation Program and in ensuing contracts memorializing specific terms, like their participation in Medicare and Medicaid, is voluntary." *Janssen/BMS* Br. in Opp. at 20-21.

The court of appeals had no need to address the government's alternative argument that the Negotiation Program regulates only non-expressive conduct. See Pet. App. 39 n.13. But petitioner's claim "independently fail[s]" for that reason. *Janssen/BMS* Br. in Opp. at 21. "In requiring the parties to sign documents memorializing their intent to negotiate and their agreement upon the maximum price that Medicare will pay for selected drugs, the Negotiation Program regulates only non-expressive, commercial conduct, and any effects on speech are 'plainly incidental.'" *Id.* at 22 (citation omitted).

iii. Petitioner's arguments to the contrary lack merit. To support its freestanding economic-coercion theory, petitioner cites (Pet. 15-18) *National Federation of Independent Business* v. *Sebelius*, 567 U.S. 519 (2012) (*NFIB*), and *United States* v. *Butler*, 297 U.S. 1 (1936), for the proposition that the incentives to participate in the Negotiation Program are coercive. But that reliance is misplaced, as the government has previously explained. See *Janssen/BMS* Br. in Opp. at 26-27; Br. in Opp. at 21, *Novo Nordisk Inc.* v. *Kennedy*, No. 25-761

(Mar. 30, 2026). Both *NFIB* and *Butler* are rooted in enforcing the Tenth Amendment's limits on Congress's Spending Clause authority. See *NFIB*, 567 U.S. at 579-581 (plurality opinion); *Butler*, 297 U.S. at 68, 74-75. *NFIB*'s anti-coercion analysis derived from the Tenth Amendment to protect "the status of the States as independent sovereigns in our federal system." 567 U.S. at 577 (plurality opinion). And in *Butler*, the Court held that Congress could not "purchas[e] with federal funds submission to federal regulation of a subject reserved to the states." 297 U.S. at 72. Neither of those cases apply where, "as here, the federal government program at issue sets the terms for how the federal government will pay for goods sold by private parties." Pet. App. 27a.

Petitioner finds no more support for its economic-coercion theory in *Union Pacific Railroad* v. *Public Service Comm'n*, 248 U.S. 67 (1918), or *Carter* v. *Carter Coal Co.*, 298 U.S. 238 (1936). See Pet. 17-18. In *Union Pacific*, the railroad would have been wholly excluded from the State of Missouri—and thus effectively prevented from operating its interstate railroad—unless it submitted to an extortionate tax. 248 U.S. at 68-70. And in *Carter*, the mine would have been subject to a penalty if it produced or sold any coal at all. 298 U.S. at 288-289. The same analysis does not apply where a party can avoid regulation simply by forgoing sales to a government program, rather than exiting the industry altogether. It is well established that, when Congress spends money, it has wide latitude to require recipients to "agree to comply with federally imposed conditions." *Cummings*, 596 U.S. at 219 (quoting *Pennhurst State Sch. & Hosp.* v. *Halderman*, 451 U.S. 1, 17 (1981)).

Petitioner further contends (Pet. 19) that the decision below "conflicts with foundational cases addressing the substantive claims at issue here." Not so.

For its takings claim, petitioner seeks (Pet. 19-20) to rely on *Horne* v. *Department of Agriculture*, 576 U.S. 350 (2015). But "*Horne* is materially different from * * * this case." Pet. App. 30a. As explained in the government's brief in opposition in *Janssen/BMS*, "[u]nlike in *Horne*, the government is not 'sen[ding] trucks to [petitioner's] facilit[ies]' to haul away [its] products." *Janssen/BMS* Br. in Opp. at 16 (quoting *Horne*, 576 U.S. at 356). Instead, petitioner's takings claim hinges on its belief that it has "no real option" to withdraw from the Negotiation Program because the Program would impact petitioner's "domestic net sales." Pet. 15-16; see *Janssen/BMS* Br. in Opp. at 16. In other words, in petitioner's view, "the government is driving so hard a bargain that a de facto forced transfer is happening and the compensation that petitioners undisputedly receive under the Negotiation Program does not provide just compensation." *Janssen/BMS* Br. in Opp. at 16. "That is not a viable theory." *Ibid.* While the raisin growers in *Horne* would have had to exit the raisin market entirely to avoid turning over raisins to the government, see Pet. App. 32a, the manufacturers here do not face that same choice. Instead, they may choose whether to do business with the government on the terms the government is offering; and even if manufacturers choose not to participate in the Negotiation Program, they may sell their drugs to anyone who does not use Medicare benefits to pay for them.

For its due-process claim, petitioner turns (Pet. 20) to *Bowles* v. *Willingham*, 321 U.S. 503 (1944). But *Bowles* is inapposite, as well. *Bowles* involved a statute

of general applicability that regulated the price at which a landlord could rent his property to any buyer. See *id.* at 506-510, 519-521. By contrast, the Negotiation Program does not regulate the price at which petitioner may sell its drug in any context except for sales made through the Medicare program, which CMS subsidizes. See *United States ex rel. Spay* v. *CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017). "The Negotiation Program regulates the price only for those transactions in which a patient chooses to use Medicare benefits to pay for drugs and applies only because petitioners choose to participate in Medicare and Medicaid." *AstraZeneca* Br. in Opp. at 23.

For its compelled-speech claim, petitioner points (Pet. 20-21) to *Hurley* v. *Irish-American Gay, Lesbian & Bisexual Group*, 515 U.S. 557 (1995). There, this Court found a state law violated the First Amendment by requiring a parade organizer to allow a group of individuals to display a message against the parade organizer's wishes. *Id.* at 568-581. In petitioner's view (Pet. 20), *Hurley* supports its position because "[t]he group was under no legal obligation to organize the parade." But petitioner fails to acknowledge the context of the *Hurley* decision—"the inherent expressiveness of marching to make a point." 515 U.S. at 568. There are many limits on the government's regulation of core expressive speech like a parade. See *Chiles* v. *Salazar*, No. 24-539, 2026 WL 872307, at *7 (Mar. 31, 2026) ("[L]aws regulating speech based on its subject matter or 'communicative content' are 'presumptively unconstitutional.'") (citation omitted). But it does not follow that organizing a parade is in any way comparable to participating in a voluntary federal spending program. Because the Negotiation Program "simply regulate[s]

the amount that a [manufacturer] c[an] collect" when selling drugs within the Program, its effect on speech is the same as an ordinary commercial contract, *Expressions Hair Design* v. *Schneiderman*, 581 U.S. 37, 47 (2017), and cases like *Hurley* are inapposite. See *Janssen/BMS* Br. in Opp. 23.

b. ***Unconstitutional Conditions.*** Petitioner also errs in arguing that the decision below conflicts with this Court's "[u]nconstitutional [c]onditions [p]recedents." Pet. 21.

As explained more fully in the government's brief in opposition in *Janssen/BMS*, the unconstitutional-conditions doctrine "prevents the government from requiring a person to give up a constitutional right in order to receive an unrelated benefit," but does not prohibit the government from "condition[ing] the receipt of federal funds on compliance with program-specific requirements" so long as "the conditions are relevant to the program's purpose and 'leave the grantee unfettered in its other activities.'" *Janssen/BMS* Br. in Opp. at 28 (quoting *Rust* v. *Sullivan*, 500 U.S. 173, 196 (1991)). The Negotiation Program complies with that doctrine because it "sets the terms of the government's offer to pay for drugs for Medicare beneficiaries—not some external 'condition' on manufacturers' ability to sell drugs." *Id.* at 29.

Petitioner also errs in suggesting (Pet. 24) that the Second Circuit's approach "conflicts with this Court's precedents applying the unconstitutional conditions doctrine in the takings context." Petitioner appears to invoke the nexus-and-proportionality test from *Dolan* v. *City of Tigard*, 512 U.S. 374 (1994), and *Nollan* v. *California Coastal Commission*, 483 U.S. 825 (1987). As the government has explained, "while the *Nollan-Dolan*

test is 'modeled on the unconstitutional conditions doctrine,' it 'address[es] * * * potential abuse of the permitting process.'" *Janssen/BMS* Br. in Opp. at 30 (quoting *Sheetz* v. *County of El Dorado*, 601 U.S. 267, 275 (2024)) (asterisks and brackets in original). The test has not been expanded beyond that specialized context. See *ibid.*

2. Review is also unwarranted because the court of appeals' decision does not conflict with the decision of any other court of appeals. To the contrary, the Third Circuit—which is the only other circuit to have issued decisions regarding the constitutionality of the negotiation program—has upheld the Program in several decisions. See *AstraZeneca Pharm. LP* v. *HHS*, 137 F.4th 116 (2025); *Novo Nordisk Inc.* v. *HHS*, 154 F.4th 105 (2025); *Novartis Pharm. Corp.* v. *Secretary*, 155 F.4th 223 (2025); *Bristol Myers Squibb*, 155 F.4th 245. Petitioner thus rightly does not attempt to assert a conflict of authority in the courts of appeals on its claims.

3. Petitioner stresses (Pet. 28-33) the importance of the questions presented, relying on the "vast scale" and "economic effects" of the Negotiation Program, and the purported harms suffered by pharmaceutical manufacturers. But as explained elsewhere, petitioner's "parade of horribles misapprehends the nature of" the Negotiation Program. *Janssen/BMS* Br. in Opp. at 32. "The Constitution offers robust protections for constitutional rights, but it does not forbid the federal government from conditioning the availability of subsidies for prescription drug purchases on the drugs costing a reasonable amount." *Ibid.* Moreover, "whatever harms exist for drug manufacturers pale in comparison to the problems for everyday Americans' out-of-pocket prices that Congress designed the Negotiation Program to

address." *Id.* at 33. Petitioner's additional stated concerns do not support this Court's review.

4. The Court's review of the questions presented at this time would be premature. Courts have thus far unanimously rejected constitutional challenges to the Negotiation Program. See p. 26, *supra*. Further percolation is warranted because two other courts of appeals are poised to consider challenges to the Negotiation Program. See *Teva Pharm., USA, Inc.* v. *Kennedy*, No. 25-113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025), appeal pending, No. 25-5425 (D.C. Cir. oral argument scheduled for May 5, 2026); *National Infusion Ctr. Ass'n* v. *Kennedy*, 798 F. Supp. 3d 748 (W.D. Tex. 2025), appeal pending, No. 25-50661 (5th Cir. argued Oct. 7, 2025). If those courts of appeals were to deem the Negotiation Program unconstitutional, this Court could consider addressing those cases at a later juncture. And if the government continues to prevail across courts of appeals, there will continue to be no need for this Court's intervention.

At a minimum, the Court may wish to consider all pending petitions regarding the constitutionality of the Negotiation Program together, when they are fully briefed. See *AstraZeneca Pharm. LP* v. *Kennedy*, petition for cert. pending, No. 25-348 (filed Sept. 19, 2025); *Janssen Pharm. Inc.* v. *Kennedy*, petition for cert. pending, No. 25-749 (filed Dec. 19, 2025); *Bristol Myers Squibb Co.* v. *Kennedy*, petition for cert. pending, No. 25-751 (filed Dec. 19, 2025); *Novo Nordisk Inc.* v. *Kennedy*, No. 25-761 (filed Dec. 22, 2025); *Novartis Pharm. Corp.* v. *Kennedy*, petition for cert. pending, No. 25-902 (filed Jan. 23, 2026).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

D. JOHN SAUER
Solicitor General
ERIC J. HAMILTON
Deputy Assistant Attorney General
MICHAEL S. RAAB
MAXWELL A. BALDI
Attorneys

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