No. 25-761

In the Supreme Court of the United States

NOVO NORDISK INC., ET AL., PETITIONERS

v.

ROBERT F. KENNEDY, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Inflation Reduction Act's Drug Price Negotiation Program (26 U.S.C. 5000D, 42 U.S.C. 1320f to 1320f-7) violates the nondelegation doctrine because of a purported lack of procedural constraints on pricing and rulemaking and because Congress precluded judicial review of certain agency actions.

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.

3. Whether, under the Due Process Clause of the Fifth Amendment, a pharmaceutical manufacturer has a protected property interest in setting the prices it charges for drugs within the confines of a government-run healthcare program.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-17) is reported at 154 F.4th 105. The opinion of the district court (Pet. App. 18-40) is available at 2024 WL 3594413.

JURISDICTION

The judgment of the court of appeals was entered on October 6, 2025. This petition was filed on December 22, 2025. 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 *AstraZeneca Pharm. LP* v. *HHS*, 137 F.4th 116, 120 (3d Cir. 2025). As relevant here, Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. See *ibid.* 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).

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*, 137 F.4th at 120 (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(b), 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." 42 U.S.C. 1395w-111(i)(1) and (3).

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 imple-

[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).

mented 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 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.

The Revised Guidance explains how CMS determines what constitutes a "[q]ualifying single source drug" that may be selected for negotiation. 42 U.S.C. 1320f-1(e). The Act "directs CMS to establish procedures 'to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.'" Revised Guidance 99 (quoting 42 U.S.C. 1320f-5(a)(2)). The Revised Guidance explains that CMS will consider a qualifying single source drug to include "all dosage forms and strengths of [a] biological product with the same active ingredient and the same holder of a Biologics License Application (BLA), inclusive of products that are marketed pursuant to different BLAs."[2] *Ibid.* (footnote omitted). This means that if one manufacturer holds BLAs for several forms of a drug with the same active ingredient (or same fixed combination of active ingredients), these various forms will be considered collectively under the provisions of the Act that require aggregation across dosage forms, package types, and formulations. *Id.* at 99-100 (citing 42 U.S.C. 1320f-1(d)(3)(B)).

CMS acknowledged that some commenters had suggested that a qualifying single source drug must be defined "in reference to a distinct * * * BLA," such that products licensed under different applications could never be considered together as one negotiation-eligible drug. Revised Guidance 11. In responding to this comment, CMS observed that the Act "necessarily establish[es] that the statutory negotiation procedures apply

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[2] Where there are differences in treatment of drug products and biological products, see, *e.g.*, 42 U.S.C. 1320f-1(e)(1), this brief describes the policies with respect to biological products, which are at issue in this litigation.

more broadly than to a distinct * * * BLA," because it requires CMS to aggregate data "'across dosage forms and strengths of the drug, including new formulations of the drug.'" *Ibid.* (quoting 42 U.S.C. 1320f-1(d)(3)(B)).

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.[3] 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. 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 (*Manufacturer Agreements for IPAY 2026*).

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[3] 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.

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 company to discuss the offers and relevant evidence. *Ibid.* Many companies 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. *Ibid.* 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. *Ibid.*

3. Petitioner Novo Nordisk, Inc.[4] manufactures and sells pharmaceuticals, including a synthetic insulin called insulin aspart. Pet. App. 10. Petitioner sells this drug in two different formulations—one faster acting than the other—each of which is available in different package types (or "presentations"), such as vials, disposable insulin pens, and reusable insulin pens. See C.A. App. 109, 111. Consistent with the statutory command to select drugs according to the total Medicare

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[4] There are two petitioners, Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. See Pet. ii. For ease of reference, this brief refers to "Novo Nordisk" or "petitioner."

spending on the drug overall, inclusive of formulations with adjusted absorption rates, 42 U.S.C. 1320f-1(d)(3)(B), CMS grouped these different forms of the drug together in the selection and negotiation process. See *Manufacturer Agreements for IPAY 2026*, *supra*.

Petitioner's insulin aspart was one of the drugs CMS selected for the first round of the Negotiation Program. See *Selected Drugs for IPAY 2026*, *supra*. In 2023, approximately 785,000 Medicare Part D enrollees used petitioner's insulin aspart, which accounted for more than $2.6 billion in covered prescription drug costs. See *Negotiated Prices for IPAY 2026*, *supra*. Petitioner entered into a Manufacturer Agreement and ultimately agreed to a negotiated price for that drug with CMS. See *ibid.*

Petitioner sued in the United States District Court for the District of New Jersey to challenge the Negotiation Program. Petitioner argued that "CMS violated the Act by treating its six products as one 'negotiation-eligible drug' and by imposing legislative rules without following notice and comment procedures." Pet. App. 8. Petitioner further asserted that the Negotiation Program "violated the nondelegation doctrine, the Fifth Amendment's Due Process Clause, the First Amendment, and the unconstitutional conditions doctrine." *Ibid.*

The district court denied petitioner's motion for summary judgment and granted the government's cross-motion for summary judgment. Pet. App. 18-40. The court rejected petitioner's statutory arguments for lack of jurisdiction, holding that the Act's judicial-review bar, 42 U.S.C. 1320f-7, divested the court of "jurisdiction to consider challenges under the APA" to the selection of drugs for negotiation, Pet. App. 24, and that

petitioner lacked standing to argue that CMS violated the Act by purportedly selecting more than ten drugs for the initial drug-pricing period, *id.* at 26.

The district court then rejected petitioner's constitutional challenges on the merits. The court explained that petitioner's "participation in the program is voluntary," that the program "does not compel [petitioner's] speech," and that the Program "does not violate the unconstitutional conditions doctrine given the Due Process Clause does not protect [petitioner's] desired, but not inherent, right to continue selling its drugs to Medicare at a 'fair market value.'" Pet. App. 29-30. The court further rejected petitioner's nondelegation argument because the Act "conveys a specific, delineated task to CMS, and it explains the scope and parameters of the delegation throughout the statute." *Id.* at 38.

4. The court of appeals affirmed in an opinion authored by Judge Hardiman and joined by Judges Phipps and Freeman. Pet. App. 1-17.

The court of appeals held that it "lack[ed] jurisdiction to reach the merits of [petitioner's] statutory claim" that CMS violated the Act by treating six of its products as one drug due to the Act's judicial-review bar. Pet. App. 9; see *id.* at 9-13. That bar also precluded petitioner's argument that CMS selected more than ten drugs for negotiation. See *id.* at 12. Further, based on its ruling in *Bristol Myers Squibb Co.* v. *Secretary*, 155 F.4th 245 (3d Cir. 2025), the court held that the Act "expressly permits CMS to promulgate legislative rules by issuing guidance." Pet. App. 14.

The court of appeals then rejected petitioner's constitutional claims. Pet. App. 15-17. The court concluded that the Negotiation Program complies with the nondelegation doctrine because "[t]he Act contains detailed

rules governing which products may be subject to price controls," "limits the number of products that may be selected and grants CMS only narrow discretion to determine whether certain products should be excepted." *Id.* at 15. The Act also "constrains CMS's pricing determinations" by "set[ting] a price ceiling that the agency cannot exceed," and requiring CMS to "'justif[y]'" prices "based on certain factors identified in the statute." *Id.* at 16 (citation omitted). The Act, the court concluded, "provides CMS with detailed guidance and restrains its discretion at many turns," and "clears the 'intelligible principle' hurdle." *Ibid.*

The court of appeals then held that petitioner's due-process and compelled-speech arguments failed due to circuit precedent. Pet. App. 16-17 (citing *AstraZeneca*, 137 F.4th at 125-126, and *Bristol Myers Squibb*, 155 F.4th at 263-269).

The court of appeals also rejected petitioner's invitation "to take a 'holistic[]' view of its due process and nondelegation arguments," Pet. App. 17 n.3 (citation omitted; brackets in original), explaining that "'[t]wo wrong claims do not make one that is right'" and that the court's "conclusion about each individual argument resolves [petitioner's] 'combination claim' as well," *ibid.* (quoting *FCC* v. *Consumers' Research*, 606 U.S. 656, 697 (2025)) (first set of brackets in original).

ARGUMENT

This petition presents another set of challenges to the Medicare Drug Price Negotiation Program.[5] Though

[5] 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); *Boehringer Ingelheim Pharm., Inc.* v.

petitioner now recasts its arguments in abstract separation-of-powers terms regarding the need for legislative "*guidance* and *constraints*," Pet. 1, petitioner at bottom reasserts contentions that the Negotiation Program violates the nondelegation doctrine, the unconstitutional conditions doctrine, and the Due Process Clause. Pet. 15-22, 25-30.

The Program complies with the nondelegation doctrine; petitioner's unconstitutional conditions arguments fail for the same reasons as the government explained in *Janssen* and *BMS*, see Br. in Opp. at 26-30, *Janssen Pharm. Inc.* v. *HHS*, Nos. 25-749 and 25-751 (filed Mar. 25, 2026) (*Janssen/BMS* Br. in Opp.); and petitioner's due-process arguments fail for the same reasons as the government explained in *AstraZeneca*, see Br. in Opp. at 14-22, *AstraZeneca* v. *HHS*, No. 25-348 (filed Jan. 2, 2026) (*AstraZeneca* Br. in Opp.). The court of appeals thus correctly rejected those claims. Pet. App. 15-17.[6] That decision does 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. ***Nondelegation.*** Petitioner errs (Pet. 15) in claiming that the Negotiation Program "[v]iolates the [s]eparation of [p]owers" based on a purported lack of intelligible principles to constrain CMS's discretion. Petitioner posits nondelegation problems with the Program

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HHS, petition for cert. pending, No. 25-799 (filed Jan. 5, 2026); *Novartis Pharm. Corp.* v. *Kennedy*, petition for cert. pending, No. 25-902 (filed Jan. 23, 2026).

[6] The decision below did not expressly analyze petitioner's unconstitutional conditions claim, but the Third Circuit had previously rejected such a claim in *Bristol Myers Squibb Co.* v. *Secretary*, 155 F.4th 245 (3d Cir. 2025).

by claiming that CMS possesses unbridled discretion over price-setting and rulemaking decisions and because the Act precludes judicial review of certain agency actions. See Pet. 20-21; 42 U.S.C. 1320f-7. As the court of appeals held, that theory is incorrect.

i. Congress does not impermissibly delegate legislative power when Congress "'vest[s] discretion' in executive agencies to implement and apply the laws it has enacted—for example, by deciding on 'the details of [their] execution.'" *FCC* v. *Consumers' Research*, 606 U.S. 656, 672 (2025) (citation omitted; second set of brackets in original); see *J. W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394, 406 (1928). When Congress leaves implementation of a statute to an agency, it must supply an "intelligible principle," *Hampton*, 276 U.S. at 409, meaning that Congress must "ma[k]e clear both 'the general policy' that the agency must pursue and 'the boundaries of [its] delegated authority,'" *Consumers' Research*, 606 U.S. at 673 (citation omitted; second set of brackets in original). Under the intelligible-principle test, "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Ibid.* (quoting *Whitman* v. *American Trucking Ass'ns, Inc.*, 531 U.S. 457, 475 (2001)). Where that test is satisfied, courts "will not disturb [Congress's] grant of authority." *Ibid.*

ii. As the court of appeals correctly held, the Negotiation Program readily satisfies the intelligible-principle test. Congress "provide[d] CMS with detailed guidance and restrain[ed] its discretion at many turns." Pet. App. 16.

Congress provided CMS with a general goal in negotiating with manufacturers: CMS must "aim[] to achieve the lowest maximum fair price for each selected drug"

that the manufacturer will agree to. 42 U.S.C. 1320f-3(b)(1). And Congress told CMS how to go about achieving that goal by providing both "detailed rules governing which products may be subject to price controls," Pet. App. 15, and constraints on "CMS's pricing determinations," *id.* at 16.

Specifically, the statute outlines how negotiation-eligible drugs are identified, ranked, and selected, see 42 U.S.C 1320f-1(b), (d), and (e), and requires the agency to consider in "determining the offers and counteroffers" during the negotiation a set of nine enumerated factors, see 42 U.S.C 1320f-3(e). On top of that guidance, "Congress restricted [CMS]'s discretion by making many of the key regulatory decisions itself." *Big Time Vapes, Inc.* v. *FDA*, 963 F.3d 436, 445 (5th Cir. 2020), cert. denied, 141 S. Ct. 2746 (2021); see, *e.g.*, 42 U.S.C. 1320f-1(a) (number of drugs), 1320f-3(c) (ceiling price). Nothing more was required.[7]

Indeed, the Negotiation Program's requirements are analogous to the "determinate standards for operating the universal-service program" that this Court considered and upheld in *Consumers' Research*. 606 U.S. at 684. This Court acknowledged that the Federal Communications Commission (FCC) would "still have to strike balances in addressing th[e statutory] criteria,

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[7] Although petitioner argues (Pet. 21) that the obligation to consider specified factors does not sufficiently constrain the agency, this Court reached the opposite conclusion in *Hampton*, rejecting a nondelegation challenge to a statute that required "the President, in so far as he finds it practicable, [to] take into consideration" four factors in setting customs duties. 276 U.S. at 401 (citation omitted). The Act provides even further constraints than the statute at issue in *Hampton*, imposing an affirmative obligation on the agency to consider statutory factors, whether or not practicable. 42 U.S.C. 1320f-3(e) (the agency "shall consider" nine factors).

along with the statute's other provisions," but held that the "conditions, each alone and together, have bite, creating a bounded program." *Id.* at 685, 688; see, *e.g.*, *American Trucking Ass'ns*, 531 U.S. at 472 (rejecting challenge to agency's authority to set air quality standards at a level "requisite to protect the public health") (citation omitted). So too here.

The context of this particular grant of authority underscores the lack of a nondelegation problem. CMS is engaged in a price negotiation affecting the prices that the government will pay within a government benefits program. In that context especially, courts heed "the traditional principle of leaving purchases necessary to the operation of our Government to administration by the executive branch of Government, with adequate range of discretion free from vexatious and dilatory restraints at the suits of prospective or potential sellers." *Perkins* v. *Lukens Steel Co.*, 310 U.S. 113, 127 (1940). In areas of traditional executive authority, like this one, the constraints of the nondelegation doctrine are even more relaxed. See *Loving* v. *United States*, 517 U.S. 748, 772-773 (1996) (ordinary "limitations on delegation do not apply 'where the entity exercising the delegated authority itself possesses independent authority over the subject matter'") (citation omitted). Indeed, agencies ordinarily exercise leeway in federal contracting; were Congress to dictate terms with the specificity that petitioner apparently wishes, it would defeat the point of contractual bargaining.

iii. Petitioner concedes that the intelligible-principle test applies to its claim. See Pet. 15. But petitioner primarily renews a contention that the Third Circuit rejected in a footnote: that "a confluence of issues with the Act," including allegedly insufficient "procedural

rights" and the lack of "judicial review of CMS's pricing decisions," "work together to violate the separation of powers." Pet. App. 17 n.3; see Pet. 16-19. As the court of appeals correctly held, "[t]wo wrong claims do not make one that is right." Pet. App. 17 n.3 (quoting *Consumers' Research*, 606 U.S. at 697).

In *Consumers' Research*, this Court rejected a similar "combination" theory in the context of a nondelegation challenge. 606 U.S. at 696-698. There, the Court addressed a statute in which (1) Congress granted authority to the FCC to determine what level of fees would be sufficient to support a program, and (2) the FCC relied on a private body to perform calculations and financial projections to set those fees. See *id.* at 666-670. The Court explained that the first element implicated the traditional nondelegation doctrine, while the second element implicated the "private nondelegation doctrine." *Id.* at 697; see *Carter* v. *Carter Coal Co.*, 298 U.S. 238, 310-311 (1936). Because "[t]hose doctrines do not operate on the same axis (save if it is defined impossibly broadly)," "a measure implicating (but not violating) one does not compound a measure implicating (but not violating) the other, in a way that pushes the combination over a constitutional line." *Consumers' Research*, 606 U.S. at 697.

The same logic governs here. Congress provided an intelligible principle to CMS, so it did not violate the nondelegation doctrine. See pp. 16-18, *supra*. There has been no deprivation of a property interest here, so petitioner's due-process claim fails. See p. 22, *infra*. And Congress may undoubtedly prohibit judicial review of agency actions. See *Briscoe* v. *Bell*, 432 U.S. 404, 414-415 (1977); see *Sheldon* v. *Sill*, 49 U.S. (8 How.) 441, 448-449 (1850). Petitioner does not appear to go so far

as saying the nondelegation doctrine requires judicial review to be available, and that contention would be without merit in any event. Congress has "plenary" control over the jurisdiction of the lower federal courts, *Patchak* v. *Zinke*, 583 U.S. 244, 252 (2018) (plurality opinion) (citation omitted), and Congress has exercised that power to bar judicial review in at least 190 extant statutes, Laura E. Dolbow, *Barring Judicial Review*, 77 Vand. L. Rev. 307, 380-400 (2024). And this Court has repeatedly upheld statutes barring judicial review of nonconstitutional claims. See, *e.g.*, *Briscoe*, 432 U.S. at 414-415. The purported lack of procedural protections and the Act's limitation on judicial review are irrelevant to petitioner's nondelegation claim and do not create a novel constitutional problem.

b. ***Unconstitutional Conditions.*** While petitioner's second question presented is difficult to pin down, petitioner appears to renew its contention that the Negotiation Program violates the unconstitutional conditions doctrine because it forces a manufacturer to "relinquish its constitutional rights as a condition of selling is products into a regulated market." Pet. 25; see Pet. 29 (citing unconstitutional conditions arguments made below).[8] The argument fails.

As explained more fully in the government's brief in opposition in *Janssen Pharmaceuticals* v. *Kennedy*, and *Bristol Myers Squibb Co.* v. *Kennedy*, the unconstitutional conditions doctrine "prevents the government

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[8] Petitioner's first or second question presented could be construed to raise due-process arguments, which the government addresses separately. See p. 22, *infra*. To the extent petitioner seeks to raise a different constitutional challenge, it has forfeited it by failing to present that argument below. See *Ohio* v. *EPA*, 603 U.S. 279, 298 (2024).

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.

To the extent petitioner argues (Pet. 28-29) that the Negotiation Program is unconstitutionally coercive under *National Federation of Independent Business* v. *Sebelius*, 567 U.S. 519 (2012) (*NFIB*), the government has also explained why that argument is without merit. *Janssen/BMS* Br. in Opp. at 26-27. *NFIB* addressed the special context of the federal government attaching conditions to funds on money granted to States. See *ibid.* And "courts have uniformly rejected the idea that the lucrative nature of Medicare and Medicaid coerces private parties." *Id.* at 27. While the Spending Clause generally requires that funding recipients knowingly and voluntarily accept the terms on government funding, petitioner had notice of the conditions here and voluntarily agreed to participate in the Program. See *id.* at 27-28; see Pet. App. 7 (reiterating prior holding that "participation in the Program is * * * voluntary").

Finally, petitioner errs in suggesting (Pet. 27) that the Negotiation Program violates the special application of the unconstitutional conditions doctrine in *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)) (alteration and brackets in original). The test has not been expanded beyond that specialized context. See *ibid.*

c. ***Due Process.*** To the extent petitioner separately argues that the Act violates the Due Process Clause, see, *e.g.*, Pet. 25 (suggesting that the Act "fails to protect manufacturers' due process rights"), that argument fails.

As explained more fully in the government's brief in opposition in *AstraZeneca*, a pharmaceutical manufacturer lacks a protected property interest in selling drugs within the Medicare program at a particular price. See *AstraZeneca* Br. in Opp. at 14-22. While petitioner alludes to the lack of "hearing or other procedural protections," Pet. 25, it fails to grapple with that dispositive basis on which the Third Circuit rejected its due-process argument. See Pet. App. 16-17 (citing *AstraZeneca Pharm. LP* v. *HHS*, 137 F.4th 116, 125-126 (3d Cir. 2025)).

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 courts of appeals have uniformly upheld the constitutionality of the Negotiation Program. See *Novartis Pharm. Corp.* v. *Secretary*, 155 F.4th 223 (3d Cir. 2025); *Bristol Myers Squibb Co.* v. *Secretary*, 155 F.4th 245 (3d Cir. 2025); *AstraZeneca*, 137 F.4th 116; *Boehringer Ingelheim Pharm., Inc.* v. *HHS*, 150 F.4th 76 (2d Cir. 2025).

While petitioner tries to manufacture circuit conflicts, see Pet. 22-24, 30-34, it fails to identify any court of appeals decision suggesting this case would have been resolved differently in another circuit.

a. Petitioner alleges that the court of appeals' nondelegation analysis conflicts with the "reasoning" from decisions from the Eighth, Ninth, and D.C. Circuits, which, in petitioner's view, "have interpreted this Court's separation-of-powers cases to require an analysis of relevant constraints, like judicial review and notice-and-comment procedures." Pet. 22; see Pet. 22-24. But there is no conflict warranting this Court's review.

The Eighth Circuit's decision in *United States* v. *Garfinkel*, 29 F.3d 451 (8th Cir. 1994), does not conflict with the decision below. Contra Pet. 22. To start, while that decision reasons that the *availability* of "[j]udicial review is a factor weighing in favor of *upholding* a statute against a nondelegation challenge," 29 F.3d at 459 (emphasis added; citation omitted), it in no way holds that *preclusion* of judicial review creates a nondelegation problem. Accord *Beall Constr. Co.* v. *OSHA*, 507 F.2d 1041, 1045 (8th Cir. 1974) (judicial review available). Indeed, *Garfinkel* noted that judicial review offered an additional safeguard only after explaining that the challenged statute supplied "significant guidelines," which "more than satisfy" the intelligible-principle requirement. 29 F.3d at 458. The same is true here. See pp. 16-18, *supra*.

Petitioner is likewise wrong (Pet. 22-23) that the decision below conflicts with *United States* v. *Bozarov*, 974 F.2d 1037 (9th Cir. 1992), cert. denied, 507 U.S. 917 (1993). As petitioner candidly acknowledges, that decision actually "recognized that judicial review is not 'always constitutionally required,'" Pet. 23 (quoting

Bozarov, 974 F.2d at 1042); indeed, it explicitly held that "the [Act's] preclusion of judicial review does not violate the nondelegation doctrine." *Bozarov*, 974 F.2d at 1045. That decision is thus fully consistent with the Third Circuit's holding that the Act comports with the nondelegation doctrine because it supplies an intelligible principle, regardless of whether it precludes judicial review of certain questions. See Pet. App. 17 n.3.

To the extent petitioner contends (Pet. 23) that the decision below split from "the Ninth Circuit's approach" because the Ninth Circuit considered the availability of judicial review while the decision below did not, petitioner still fails to show that its case would have come out differently under *Bozarov*. Here, the court of appeals concluded that the nondelegation doctrine was satisfied because "the Act provides CMS with detailed guidance and restrains its discretion at many turns." Pet. App. 16. The same considerations drove the Ninth Circuit's decision in *Bozarov*. See 974 F.2d at 1042. Moreover, *Bozarov* rejected the argument advanced by petitioner here (Pet. 17) that "the purpose of requiring an intelligible principle is to permit a court to ascertain whether the will of Congress has been obeyed," instead accepting the government's argument that "the purpose of an intelligible principle is simply to channel the discretion of the executive and to permit Congress to determine whether its will is being obeyed." 974 F.2d at 1041.

Nor is the Third Circuit's decision "in tension with" D.C. Circuit precedents recognizing that the APA's "procedural and judicial review requirements" are "important to protecting the separation of powers." Pet. 23. The APA is, to be sure, an important check on how agencies carry out their statutory duties. See *State of*

N. J., Dep't of Envtl. Prot. v. *EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980); Pet. 23. But the Constitution mandates neither the procedures of the APA, see, *e.g.*, *Marcello* v. *Bonds*, 349 U.S. 302, 310-311 (1955), nor judicial review, see, *e.g.*, *Briscoe*, 432 U.S. at 414-415. And the D.C. Circuit itself has recognized that a lack of judicial review does not create a nondelegation problem. See *Michigan Gambling Opposition* v. *Kempthorne*, 525 F.3d 23, 33 n.8 (D.C. Cir. 2008) ("Nor are we concerned, for purposes of the non-delegation doctrine, that the Secretary's decision * * * might be unreviewable in a court of law. [T]he [Act] intelligibly guides the Secretary's exercise of discretion, and that is all that the non-delegation doctrine requires.") (citations omitted), cert. denied, 555 U.S. 1137 (2009).

b. Petitioner fares no better in arguing that the decision below conflicts with the decisions of other circuits because the Third Circuit "declin[ed] to apply" the unconstitutional conditions doctrine. Pet. 34; see Pet. 32-34.

Lebron v. *Secretary of Florida Department of Children & Families*, 772 F.3d 1352 (11th Cir. 2014), has no application here. Contra Pet. 32-33. That case concerned a Fourth Amendment challenge to a Florida statute requiring "suspicionless drug testing of all applicants" for certain welfare benefits. *Lebron*, 772 F.3d at 1355. The court of appeals held the statute unconstitutional under the Fourth Amendment, concluding that the searches were unreasonable and that no "special needs" justified the drug-testing scheme. *Id.* at 1374. The court's analysis drew an analogy to the nexus-and-proportionality standard "[i]n the area of unconstitutional conditions," suggesting that "[a] *similar* germaneness analysis might justify a special need for

suspicionless drug testing when essential to the implementation of a voluntary government benefits program." *Id.* at 1365 (citing *Dolan*, 512 U.S. at 386) (emphasis added). But the Eleventh Circuit did not hold that the nexus-and-proportionality test applies to all invocations of the unconstitutional conditions doctrine. Indeed, the court rejected Florida's effort to analogize to *Agency for International Development* v. *Alliance for Open Society International, Inc.*, 570 U.S. 205, 213 (2013), and *Koontz* v. *St. Johns River Water Management District*, 570 U.S. 595 (2013), explaining that those cases "involved significantly different constitutional rights" and arose in different contexts. *Lebron*, 772 F.3d at 1375; see *id.* at 1376.

Petitioner's reliance (Pet. 33) on *Litman* v. *George Mason University*, 186 F.3d 544 (4th Cir. 1999), cert. denied, 528 U.S. 1181 (2000), is even further afield. That case involved a Spending Clause challenge, and the Fourth Circuit explained that one limit on Congress's spending power is that "any conditions imposed must 'bear some relationship to the purpose of the federal spending' so that a reasonable nexus exists between the two." *Id.* at 552-553 (quoting *New York* v. *United States*, 505 U.S. 144, 167 (1992)). That federalism-based doctrine derives from the Tenth Amendment, not the unconstitutional conditions doctrine, see *South Dakota* v. *Dole*, 483 U.S. 203, 207-208 (1987), and certainly is not the same as the *Nollan-Dolan* framework.

Petitioner's other cases simply illustrate principles of the unconstitutional conditions doctrine. For example, the Government may define the limits of its own programs but may not leverage a program to regulate outside conduct it could not otherwise reach. See *Agency for Int'l Dev.*, 570 U.S. at 214-215. Thus, in

National Amusements, Inc. v. *Town of Dedham*, 43 F.3d 731 (1st Cir.), cert. denied, 515 U.S. 1103 (1995) the First Circuit held that when issuing an entertainment license, a town could impose conditions to "preserve the nighttime tranquility of the community." *Id.* at 748. Such a restriction, the court of appeals held, is not equivalent to "arbitrarily conditioning the grant of a benefit on the surrender of a constitutional right." *Id.* at 747. And as *Stavrianoudakis* v. *United States Fish & Wildlife Service*, 108 F.4th 1128 (9th Cir. 2024), explained, for purposes of establishing standing in an unconstitutional conditions case, a plaintiff need only show that he was forced to give up a constitutional right in exchange for a benefit, not that he was denied the benefit too. *Id.* at 1137 (citing *Koontz*, 570 U.S. at 606-607, and *Dolan*, 512 U.S. at 379). None of these cases conflict with the decision below.

c. Petitioner also errs in asserting a circuit split regarding whether the Negotiation Program "implicates due-process concerns." Pet. 30; see Pet. 30-32.

The decision below does not conflict with *National Infusion Centers Ass'n* v. *Becerra*, 116 F.4th 488 (5th Cir. 2024) (*NICA I*). As the government has previously explained, *NICA I* addressed only a question of standing to raise a due-process claim in reviewing the grant of a motion to dismiss for improper venue. See *AstraZeneca* Br. in Opp. at 23-24. And in considering standing, a court must "accept as valid the merits of [the plaintiff's] legal claims." *FEC* v. *Ted Cruz for Senate*, 596 U.S. 289, 298 (2022). *NICA I*, therefore, did not purport to resolve the due-process merits question, which is presently pending before the Fifth Circuit for the first time following the district court's entry of summary judgment in the government's favor on remand.

See *National Infusion Ctr. Ass'n* v. *Kennedy*, 798 F. Supp. 3d 748, 765-769 (W.D. Tex. 2025), appeal pending, No. 25-50661 (5th Cir. argued Oct. 7, 2025).

3. Petitioner stresses (Pet. 34-37) the importance of the questions presented, relying on the size of the government programs at issue 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. And "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. 22, *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*, 798 F. Supp. 3d at 765-769, 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); *Boehringer Ingelheim Pharm., Inc.* v. *HHS*, petition for cert. pending, No. 25-799 (filed Jan. 5, 2026); *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.

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