No. 25-348

In the Supreme Court of the United States

ASTRAZENECA PHARMACEUTICALS LP, 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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QUESTION PRESENTED

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.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Cases—Continued: Page

Constitution, statutes, and regulations:

Statutes and regulations—Continued: Page

Regulations—Continued: Page

Miscellaneous:

Miscellaneous—Continued: Page

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-19a) is reported at 137 F.4th 116. The opinion of the district court (Pet. App. 20a-56a) is reported at 719 F. Supp. 3d 377.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 2025. On July 28, 2025, Justice Alito extended the time within which to file a petition for a writ of certiorari to and including September 20, 2025, and the petition was filed on September 19, 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 Pet. App. 6a. 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." Pet. App. 6a (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." Pet. App. 6a (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 (the Act), Pub. L. No. 117-169, §§ 11001-11003, 136 Stat. 1833-1864 (26 U.S.C. 5000D, 42 U.S.C. 1320f-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." Pet. App. 8a (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 will take effect for Part D on January 1, 2026. 42 U.S.C. 1320f(b)(1)

and (2).[1] To ensure that negotiated prices can 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 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); I.R.S., 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

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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).

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. Pet. App. 9a. 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. 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.

In accordance with the schedule established by Congress, CMS presented the manufacturers with initial offers. See CMS Newsroom, *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. 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 have withdrawn from the Negotiation Program, and the manufacturers will be responsible for effectuating the negotiated prices starting on January 1, 2026.

3. Petitioners manufacture pharmaceuticals, including Farxiga, a drug used to treat diabetes, heart disease, and kidney disease. Pet. App. 10a-11a. Farxiga was one of the drugs selected for the first round of the Negotiation Program. See *Selected Drugs for IPAY 2026*, *supra*. "Between June 2022 and May 2023, approximately 799,000 Medicare Part D enrollees used Farxiga, and Farxiga accounted for approximately $3,268,329,000 of Part D's gross covered prescription drug costs during that 12-month period." Pet. App. 30a-31a (citing *Selected Drugs for IPAY 2026*, *supra*). Petitioner AstraZeneca AB entered into a Manufacturer Agreement and ultimately agreed to a negotiated price for that drug with CMS. See *Negotiated Prices for IPAY 2026*, *supra*.

Petitioners sued in the United States District Court for the District of Delaware to challenge the Negotiation Program. Petitioners asserted that aspects of the Revised Guidance violated the Administrative Procedure Act (APA) because the guidance conflicted with or exceeded the statute. See C.A. App. 91-93; Pet. App.

11a-12a. Petitioners also alleged that the Negotiation Program deprived petitioners of a protected property interest without adequate procedural protections, in violation of the Due Process Clause of the Fifth Amendment. C.A. App. 93-95.

The district court denied petitioners' motion for summary judgment and granted the government's cross-motion for summary judgment. Pet. App. 20a-56a. The court first determined that petitioners lacked standing to challenge the Revised Guidance under the APA. *Id.* at 34a-47a. The court noted that petitioners "d[id] not allege that CMS's selection of Farxiga for negotiation under the Program constitutes the injury for which it seeks redress" because Farxiga qualified for selection even under petitioners' interpretation of the statute. *Id.* at 35a. The court then rejected on various grounds each of four other harms that petitioners claimed. See *id.* at 36a-47a.[2]

The district court then rejected petitioners' due process claim on the merits. The court explained that the "first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty,'" and petitioners failed to identify such an interest. Pet. App. 50a, 55a (quoting *American Mfrs. Mut. Ins. Co.* v. *Sullivan*, 526 U.S. 40, 59 (1999)). The court determined that, while petitioners invoked a property interest in "the ability to sell [their] drugs to Medicare at prices above the ceiling prices and

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[2] Because the district court concluded that petitioners lacked standing, it did not reach the government's arguments that the Act "expressly precludes judicial review of CMS's selection of a drug for negotiation under the Program and its underlying determinations that a drug is a qualifying single source drug and a negotiation-eligible drug." Pet. App. 34a; see *id.* at 47a-48a; 42 U.S.C. 1320f-7.

negotiated maximum fair prices established by the [Act]," petitioners "ha[ve] no legitimate claim of entitlement to sell [their] drugs to the Government at any price other than what the Government is willing to pay." *Id.* at 50a, 54a. Participation in Medicare "'is a voluntary undertaking,'" and nothing in the Act or any other law "requires [petitioners] to sell [their] drugs to Medicare beneficiaries." *Id.* at 53a (quoting *Livingston Care Ctr., Inc.* v. *United States*, 934 F.2d 719, 720 (6th Cir.), cert. denied, 502 U.S. 1003 (1991)). The court reasoned that, although there are "powerful incentive[s]" to participate in Medicare, "it does not follow" that the government's exercise of its market power "requires a drug manufacturer to participate" in the Negotiation Program "or any other Medicare program." *Id.* at 55a.

4. The court of appeals unanimously affirmed. Pet. App. 4a-19a. The court first agreed with the district court that petitioners lacked standing to challenge the Revised Guidance under the APA. *Id.* at 16a. Specifically, the court rejected as not "concrete or particularized" petitioners' claims that the Guidance harms its "decision-making about research, development, and marketing" and created "difficulty valuing Farxiga in negotiations with CMS." *Id.* at 12a.

The court of appeals then rejected petitioners' due process claim, holding that petitioners had failed to "articulate a protected property interest." Pet. App. 19a; see *id.* at 16a-19a. The court explained that petitioners' patents did not "confer a right to sell at all," and thus did not "confer a right to sell at a particular price." *Id.* at 17a (citing *Biotechnology Indus. Org.* v. *District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007)). The court rejected petitioners' argument that they had a "protected property interest in selling goods to Medicare

beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs." *Ibid.* Such an "asserted interest does not 'resemble any traditional conception of property,'" and thus cannot support a due process claim. *Id.* at 17a-18a (quoting *Town of Castle Rock* v. *Gonzales*, 545 U.S. 748, 766 (2005)); see *id.* at 18a n.9 (citing A. M. Honoré, *Ownership*, *reprinted in* Oxford Essays in Jurisprudence 107 (A.G. Guest ed. 1961)) (noting that asserted interest "does not align with any of" the "eleven 'standard incidents' of property ownership") (citation omitted).

The court of appeals also rejected petitioners' argument that "the Negotiation Program violates the Due Process Clause by imposing price controls on private market transactions while barring judicial review of CMS's price-setting decisions." Pet. App. 18a. Petitioners had invoked *Bowles* v. *Willingham*, 321 U.S. 503 (1944), which upheld a wartime rent-control statute while noting that it provided for judicial review. But the court of appeals found *Bowles* distinguishable because "the Negotiation Program only sets prices for drugs *that CMS pays for* when it reimburses sponsors," Pet. App. 18a, and does not regulate "private market transactions, regardless of the private hands through which CMS's funds pass," *id.* at 19a.

ARGUMENT

The petition should be denied. Sometimes (*e.g.*, Pet. 3-4) the petition purports to mount an across-the-board attack on the Negotiation Program, including challenging the negotiation process itself and the adequacy of its procedures. But elsewhere—most notably in their question presented (Pet. i)—petitioners rightly acknowledge that the dispositive issue below was a

narrow one: whether petitioners "articulate[d] a protected property interest" at all in dictating the price at which they sell drugs within a government-run program. Pet. App. 19a. On that narrow question, the court of appeals correctly held that petitioners have no property interest in dictating the price at which they sell drugs within a government-run program and which the federal government pays for when it reimburses Medicare plan sponsors. See *id.* at 17a-18a. The court of appeals' decision does not conflict with any decision of this Court and does not implicate a circuit split. Indeed, petitioners acknowledge (Pet. 3) that while multiple lawsuits challenging the program are pending, the only other circuit to have addressed constitutional challenges to the program has rejected them. This case is also a poor vehicle to address the question presented because there are alternative grounds of affirmance.

1. The court of appeals correctly rejected petitioners' due process claim because petitioners lack a protected property interest in selling drugs to Medicare beneficiaries at a particular price.

The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. Amend. V. Therefore, 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). Property interests arise from an independent source, such as state or federal law. See *Board of Regents* v. *Roth*, 408 U.S. 564, 577 (1972). To have a constitutionally protected property interest, "a person clearly must have more than an abstract need or desire for it" and "more than a unilateral expectation of it." *Ibid.* Rather, he must have an

"individual entitlement" to the property, which "cannot be removed except 'for cause.'" *Logan* v. *Zimmerman Brush Co.*, 455 U.S. 422, 430 (1982) (quoting *Memphis Light, Gas & Water Div.* v. *Craft*, 436 U.S. 1, 11-12 (1978)).

The Negotiation Program does not implicate petitioners' due process rights. Petitioners assert (Pet. 15) that the Negotiation Program deprives them of their right to "offer access to [their] products to private parties at market prices" and of the right to "seek market-based profits" from their patents. But as the court of appeals properly held, those claims do not identify any constitutionally protected property interest threatened by the Negotiation Program. See Pet. App. 17a-18a. The federal government regularly negotiates the prices it pays for goods, and drug manufacturers have no property interest in forcing the government to pay for prescription drugs on specific terms.

Petitioners' assertion (Pet. 15) that they have a due-process right to sell their drugs to Medicare beneficiaries at their preferred price lacks merit. "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." *Perkins* v. *Lukens Steel Co.*, 310 U.S. 113, 127 (1940). "[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).

Pursuant to the government's power to determine the prices it will pay for goods and services, other federal agencies have long negotiated with drug manufacturers over the price paid for drugs in other government programs. *E.g.*, 38 U.S.C. 8126(a)-(h); see pp. 4-5,

supra. Similarly, as a condition of Medicaid participation, drug manufacturers have long entered into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. See *Astra USA, Inc.* v. *Santa Clara County*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health Service Act); see also 42 U.S.C. 1396r-8(a) and (b) (requiring participation in national drug rebate agreement to provide reduced drug prices to state Medicaid programs). And the government regularly negotiates the price it will pay for other goods. See, *e.g.*, 48 C.F.R. Pts. 15, 215. Just as military contractors have no right to sell their products to the Department of War at a certain price, "[t]here is no protected property interest in selling goods to Medicare beneficiaries (through sponsors or pharmacy benefit plans) at a price higher than what the government is willing to pay when it reimburses those costs." Pet. App. 17a.

Petitioners' position hinges on their argument (Pet. 17) that "CMS dictates the prices" for "*private* transactions to which the government is not a party," such as when Medicare beneficiaries obtain prescriptions from a pharmacy. Petitioners emphasize (Pet. 17-18) that the government "*never* buys or directly reimburses drugs" because it instead pays Medicare Part D sponsors "subsidy and reinsurance payments [that] do not directly turn on the prices paid by plan sponsors for individual drug sales." Petitioners obfuscate how the Medicare program works and thus, the federal government's role in subsidizing prescription drugs for beneficiaries.

Prices negotiated through the Drug Negotiation Program apply only within the confines of the Medicare Program. When Medicare beneficiaries pick up a prescription at the pharmacy, they obtain the drug at the

cost negotiated through the Negotiation Program; they would likely pay a cost-sharing amount and their Medicare Part D plan sponsor, a private insurer, would pay the rest. The federal government, in turn, reimburses the plan sponsor for the bulk of the costs of the beneficiaries' prescriptions. The government pays plan sponsors ex ante for the expected costs that they will incur in providing prescription drug coverage to Medicare beneficiaries during a given period. By statute, the government pays for 74.5% of the costs of the drugs. See 42 U.S.C. 1395w-115(a). If after-the-fact costs are significantly lower or higher, adjustments are to be made to the amounts CMS has paid.

That the federal government reimburses plan sponsors in this way—rather than "directly" reimbursing "individual drug sales," Pet. 17-18—does not change the simple and dispositive fact that the federal government subsidizes the bulk of prescription drug costs for Medicare beneficiaries. If prescription drug costs are higher, the federal government reimburses plan sponsors a higher amount; and if prescription drug costs are lower, the federal government reimburses plan sponsors a lower amount. That is why the court of appeals recognized that "the Negotiation Program only sets prices for drugs *that CMS pays for* when it reimburses sponsors" of Part D plans. Pet. App. 18a. And those "are not private market transactions, regardless of the private hands through which CMS's funds pass." *Id.* at 19a.

By contrast, the Negotiation Program does not control the price paid for a drug by any person who is not a Medicare beneficiary or by any private insurance plan. In those instances, when a person picks up a prescription at the pharmacy, they likely pay a co-pay and their private insurance plan pays the rest. The prices

negotiated through the Negotiation Program do not apply because the federal government does not reimburse for the prescription drug costs of persons who are not Medicare Part D beneficiaries. Nor does the Negotiation Program even control the price paid for Medicare beneficiaries who, for whatever reason, choose to purchase their drugs without using their Part B or D benefits—*e.g.*, who choose to pay cash when filling their prescriptions. See, *e.g.*, 42 C.F.R. 423.120(c)(3) (permitting an individual at an in-network pharmacy to request that the pharmacy not bill the individual's Part D plan); Revised Guidance 167 ("The [negotiated price] is not required to be made available to a Medicare beneficiary who uses other sources of prescription drug coverage, such as a plan that receives the Retiree Drug Subsidy, prescription drug discount cards, or cash.").

In negotiating the price that Medicare will pay for drugs, the government thus acts as a market participant. The Act sets the terms of the government's offer to pay for certain drugs. While manufacturers may use their market power to negotiate with the government, they have no right to force the government to pay for their drugs on specific terms. Petitioners' contrary view does not reflect how the Negotiation Program works, nor is it consistent with Congress's undoubted authority to control federal spending. The Program reflects Congress's judgment that American taxpayers have been spending too much on high-cost prescription drugs, and the government has a strong interest in controlling federal spending to promote the general welfare. Cf. *Sabri* v. *United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures * * * is bound up with congressional authority to spend in the first place.").

Even on its own terms, petitioners' argument that the Negotiation Program unlawfully regulates purely private transactions fails. Petitioners invoke *Old Dearborn Distributing Co.* v. *Seagram-Distillers Corp.*, 299 U.S. 183 (1936), to argue that they have a property interest in deciding "'the price at which [they] will sell' their products." Pet. 15 (quoting *Old Dearborn*, 299 U.S. at 192) (brackets in original). *Old Dearborn* noted a line of cases holding that legislatures generally may not impair "the right of the owner of property to fix the price at which he will sell" his property in the broader marketplace. 299 U.S. at 192. But this Court later clarified that the Constitution does not substantively constrain a legislature's ability to fix the price of goods, thus overruling cases on which *Old Dearborn* had relied. See *Olsen* v. *Nebraska ex rel. Western Reference & Bond Ass'n*, 313 U.S. 236, 244-245 (1941). Indeed, even before *Old Dearborn*, the Court upheld a New York statute fixing the price of milk against a due process challenge, explaining that "[t]he Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases." *Nebbia* v. *New York*, 291 U.S. 502, 527-528 (1934).

Petitioners fare no better in invoking (Pet. 15-16, 19) patent rights. Petitioners do not allege any actual deprivation of patent rights themselves. Instead, petitioners claim that patents "entitle [them] to seek market-based profits" and that the Negotiation Program "depriv[es] [them] of a key benefit of the bargain under which [they] obtained [their] patents." Pet. 15-16. But "federal patent laws do not create any affirmative right to * * * sell anything," *Biotechnology Indus. Org.* v. *District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (citation omitted), much less a right to command

a particular price, Pet. App. 17a. While a patentee may use its exclusive right to sell a drug as leverage in the marketplace, the freedom from competitive pressure conferred by the period of exclusivity does not entitle the patent holder to any particular revenue from any particular buyer. There is no overriding right inherent in a patent that entitles the holder to compel the government or anyone else to purchase a good or to pay more for a good than they are willing to pay.

Petitioners also assert (Pet. 4-5, 19-21) that, even if the Program sets prices only for government-purchased drugs, the Negotiation Program violates the Due Process Clause because it represents an arbitrary exercise of governmental power. Specifically, petitioners suggest that, if the court of appeals' decision were correct, "nothing would stop the government from choosing drugs for negotiation by a coinflip, or setting maximum fair prices by throwing darts at a dartboard." Pet. 21. But petitioners have forfeited any arbitrariness claim by failing to present it below. See *Ohio* v. *EPA*, 603 U.S. 279, 298 (2024); cf. C.A. App. 93-95 (pleading only deprivation of property rights without adequate safeguards). It was not pressed or passed upon below and is also outside the question presented, which concerns only whether petitioners have an "interest * * * that is protected by the Due Process Clause." Pet. i.

In any event, petitioners' argument is without merit. The "criteria to identify what is fatally arbitrary differ depending on whether it is legislation or a specific act of a governmental officer that is at issue." *County of Sacramento* v. *Lewis*, 523 U.S. 833, 846 (1998). Petitioners challenge legislation (the Act) on its face, so they must show that Congress's decision was "clearly wrong, a display of arbitrary power, not an exercise of

judgment." *Bowen* v. *Gilliard*, 483 U.S. 587, 598 (1987) (citation omitted); see *Lyng* v. *Castillo*, 477 U.S. 635, 639 (1986) (applying rational basis review). Petitioners cannot satisfy that showing because they do not even challenge the Act itself, but instead challenge particular, hypothetical drug selections or negotiated prices that are arbitrarily low. See Pet. 5, 21. And the government has an obvious interest in limiting the fiscal burdens of Medicare prescription drug coverage; by limiting the price it will pay to reimburse those drugs, the Negotiation Program is a permissible means of achieving that goal.

To the extent petitioners suggest that a general prohibition against arbitrary government action somehow gives them a "due process protection[ ]," Pet. 19, that does not follow. The fatal problem with petitioners' due process claim is that they have no protected property interest in forcing the government to pay a certain price for their products. Petitioners principally rely (Pet. 20-21) on *Goldberg* v. *Kelly*, 397 U.S. 254 (1970), but that decision does not help them because drug companies that sell to Medicare beneficiaries are not similarly situated to persons who have a "statutory entitlement" to "welfare benefits" that are terminated. *Id.* at 261-262. Whether the government must follow certain minimum procedures when terminating benefits to which a person has a "statutory entitlement" says nothing about whether the person has a property interest in the first place.

Finally, petitioners repeatedly invoke (Pet. 2, 3, 27) a dissenting opinion in a separate Third Circuit case, but that case concerned takings and compelled-speech claims that are before the Court in separate petitions for certiorari. See *Bristol Myers Squibb Co.* v. *Secretary*,

155 F.4th 245, 269 (3d Cir. 2025) (Hardiman, J., dissenting), petitions for cert. pending, Nos. 25-749 and 25-751 (filed Dec. 19, 2025). Moreover, in the course of that dissent, Judge Hardiman emphasized that the federal government "may offer whatever prices it deems proper" for goods and that pharmaceutical companies "have no constitutional right to sell their wares to the federal government or its designated beneficiaries." *Ibid.* And Judge Hardiman joined the opinion below rejecting petitioners' due process claim.

2. The decision of the court of appeals is consistent with decisions of this Court and does not implicate a circuit split warranting this Court's review.

Contrary to petitioners' suggestion (Pet. 22-23), the decision below does not conflict with this Court's decision in *Bowles* v. *Willingham*, 321 U.S. 503 (1944). As petitioners acknowledge, that case concerns "the procedures the government must follow when imposing price controls," Pet. 5, and whether certain procedures "satisfie[d] the requirements of due process," *Bowles*, 321 U.S. at 520; Pet. 22-23—not the threshold question here of whether there is a due-process interest in selling drugs at particular prices at all. See Pet. i. The challengers there mounted a due-process challenge to the Emergency Price Control Act of 1942, pursuant to which a maximum rent was set in certain geographic areas. Specifically, they argued that the Act violated the Fifth Amendment because "it ma[de] no provision for a hearing to landlords before the order or regulation fixing rents becomes effective." *Bowles*, 321 U.S. at 519.

Bowles is further distinguishable because it involved a statute of general applicability that regulated the price at which the landlord could rent his property to any buyer. See 321 U.S. at 506-510, 519-521. By contrast,

the Negotiation Program does not regulate the price at which petitioners may sell their 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.

Petitioners also misapprehend (Pet. 24-25) the Fifth Circuit's decision in *National Infusion Centers Ass'n* v. *Becerra*, 116 F.4th 488 (2024) (*NICA I*). There, the Fifth Circuit reversed an order dismissing a challenge to the Negotiation Program for lack of venue, disagreeing with the district court's conclusion that the only local plaintiff failed to establish subject-matter jurisdiction. *Id.* at 494. The Fifth Circuit held that the associational plaintiff's allegations had demonstrated standing, *id.* at 504, and that it "was not required to channel [its claims] through HHS," *id.* at 509. There can thus be no conflict between the decision below and *NICA I* because, as petitioners admit (Pet. 25), *NICA I* addressed only "the providers' standing to raise a due process claim, rather than the merits of that claim."

Petitioners instead assert (Pet. 24-25) that, because the Fifth Circuit found that at least one of the *NICA I* plaintiffs had pleaded sufficient facts to assert an injury for purposes of standing, it follows that the Fifth Circuit concluded that the plaintiff had a protected property interest. But 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). Thus, as the Second Circuit explained when considering

the impact of *NICA I*, "whether a party bringing a due process claim has a 'colorable claim' to a protected property interest for purposes of standing is a different question from whether, on consideration of the merits, the party in fact has a protected property interest." *Boehringer Ingelheim Pharm., Inc.* v. *HHS*, 150 F.4th 76, 94 n.12 (2025) (citation omitted); see, *e.g.*, *Booker-El* v. *Superintendent*, 668 F.3d 896, 899-901 (7th Cir.) (assuming that a state statute conferred a property interest to conclude that plaintiff had adequately pleaded an injury in fact based on "a substantial risk in losing benefits" but also holding that plaintiff lacked a property interest in those same benefits), cert. denied, 568 U.S. 836 (2012). *NICA I* 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 Ctrs. 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).

Finally, the Federal Circuit's decision in *Biotechnology Industry Organization*, *supra*, does not conflict with the court of appeals' judgment. Contra Pet. 25-26. In that case, the Federal Circuit held that federal law preempted a District of Columbia statute that set maximum prices for any sales of patented prescription drugs within the District, *Biotechnology Indus. Org.*, 496 F.3d at 1365-1366, because "[t]he underlying determination about the proper balance between innovators' profit and consumer access to medication * * * is exclusively one for Congress to make" in the patent laws, *id.* at 1374; see *id.* at 1371-1374. There is, of course, no conflict preemption issue here; *Congress* enacted the

Negotiation Program and cannot preempt itself. That explains why petitioners must resort (Pet. 26) to the "logic" of the Federal Circuit's decision to suggest a purported conflict. But even that does not help them because the Federal Circuit essentially rejected petitioners' claimed property interest here, recognizing that "the federal patent laws do not create any affirmative right to * * * sell anything." *Biotechnology Indus. Org.*, 496 F.3d at 1372 (citation omitted).

3. The Court should also deny review because alternative grounds of affirmance make this case a poor vehicle. The court of appeals rejected petitioners' due process claim because petitioners "d[id] not articulate a protected property interest." Pet. App. 19a. But petitioners' claim fails for the additional reason that they suffered no deprivation within the meaning of the Due Process Clause. Rather, petitioners voluntarily participate in the Negotiation Program by choosing to participate in Medicare and Medicaid.

The court of appeals below did not reach this ground, making this case an unattractive vehicle for addressing challenges to the Program. And this ground should alone be dispositive. As the Second Circuit recognized in rejecting a similar due process claim, "[a] company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program." *Boehringer Ingelheim*, 150 F.4th at 94. The terms of the Negotiation Program apply only to entities that choose to participate in Medicare and Medicaid, and the Program regulates only the prices the government will pay for certain drugs sold to Medicare beneficiaries. As the Revised Guidance explains, the Act "expressly connects a * * * [m]anufacturer's financial responsibilities under the voluntary Negotiation

Program to that manufacturer's voluntary participation" in Medicare and Medicaid. Revised Guidance 120-121; see 26 U.S.C. 5000D(c)(1) (making the applicability of the excise tax contingent on such participation). Drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices need not do so. See Revised Guidance 33-34, 120-121, 129-132. This alternative and independent ground—which the court of appeals had no occasion to address because the government prevailed on other arguments—further cautions against this Court's review.

Moreover, further percolation is appropriate because two other courts of appeals are poised to consider both the question presented and other arguments challenging the Negotiation Program. As petitioners concede (Pet. 3), courts have thus far unanimously rejected those challenges. See *Bristol Myers Squibb*, 155 F.4th 245; *Novartis Pharm. Corp.* v. *Secretary*, 155 F.4th 223 (3d Cir. 2025); *Novo Nordisk Inc.* v. *HHS*, 154 F.4th 105 (3d Cir. 2025); *Boehringer Ingelheim*, 150 F.4th 76; *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. docketed Nov. 30, 2025). The Second Circuit is the only other court of appeals that has addressed a due process challenge; that court rejected that challenge on the related, but distinct, ground that the manufacturer "had the choice to opt out of the Negotiation Program and withdraw from Medicare and Medicaid," and thus did not suffer a deprivation of a protected property interest. *Boehringer Ingelheim*, 150 F.4th at 93-94; see pp. 25-26, *supra*.

Other courts of appeals are considering or could consider the question presented shortly. The Fifth Circuit is currently considering a case presenting a similar due

process claim following the remand in *NICA I*. See pp. 23-24, *supra*. The D.C. Circuit likewise could address, on an expedited basis, a due process claim that was rejected by the district court. See *Teva Pharm.*, 2025 WL 3240267, at *14-*17. If those courts of appeals were to reach the opposite conclusion and deem the Negotiation Program unconstitutional, this Court could consider addressing those grounds 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 and soon-to-be filed petitions regarding the constitutionality of the Negotiation Program together. See, *e.g.*, *Bristol Myers Squibb* v. *Kennedy*, petition for cert. pending, No. 25-751 (filed Dec. 19, 2025) (concerning Takings Clause and First Amendment claims); *Janssen Pharmaceuticals Inc.* v. *Kennedy*, petition for cert. pending, No. 25-749 (filed Dec. 19, 2025) (same).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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