Nos. 25-749 and 25-751

In the Supreme Court of the United States

JANSSEN PHARMACEUTICALS, INC., PETITIONER

v.

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

BRISTOL MYERS SQUIBB COMPANY, PETITIONER

v.

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

ON PETITIONS FOR WRITS 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 government commits a physical taking when, pursuant to statute, a federal agency negotiates the price that Medicare will pay for certain prescription drugs.

2. Whether the government compels speech when participants in a government program must memorialize their decisions to participate in the program (as well as certain negotiated terms) in a contract.

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

ADDITIONAL RELATED PROCEEDINGS

Supreme Court of the United States:

Janssen Pharm., Inc. v. *Kennedy*, No. 25A514 (Nov. 5, 2025)

Bristol Myers Squibb Co. v. *Kennedy*, No. 25A519 (Nov. 6, 2025)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-86a)[1] is reported at 155 F.4th 245. The opinion of the district court (Pet. App. 87a-118a) is available at 2024 WL 1855054.

[1] Citations to "Pet. App." refer to the appendix to the petition in No. 25-749.

JURISDICTION

The judgment of the court of appeals was entered on September 4, 2025. On November 5, 2025 Justice Sotomayor extended the time within which to file a petition for a writ of certiorari in *Janssen Pharmaceuticals, Inc.* to and including December 19, 2025, and the petition was filed on that date. On November 6, 2025 Justice Alito extended the time within which to file a petition for a writ of certiorari in *Bristol Myers Squibb Co.* to and including December 19, 2025 and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Congress created Medicare in 1965. Health Insurance for the Aged Act, Pub. L. No. 89-97, 79 Stat. 286. Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. See *Becerra* v. *Empire Health Found.*, 597 U.S. 424, 428 (2022); 42 U.S.C. 1395 *et seq.* The Centers for Medicare & Medicaid Services (CMS) administers Medicare on behalf of the Secretary of the Department of Health and Human Services (HHS).

Medicare is divided into "Parts," which establish the terms under which Medicare pays for specific benefits. See Pet. App. 11a. As relevant here, Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. See *id.* at 12a n.5. CMS generally pays Part B providers at a rate of 106% of the average sales price for most drugs or biologicals. See 42 U.S.C. 1395w-3a(b)(1); see also *American Hosp. Ass'n* v. *Becerra*, 596 U.S. 724, 729 (2022).

Pharmaceutical manufacturers opt into participating in Medicare (and Medicaid). See 42 U.S.C. 1395cc.

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

For nearly four decades, Medicare did not cover the cost of prescription drugs unless they were administered by medical professionals. That changed in 2003, when Congress enacted Medicare Part D to provide "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *AstraZeneca Pharm. LP* v. *HHS*, 137 F.4th 116, 120 (3d Cir. 2025) (citation omitted); see 42 U.S.C. 1395w-101 *et seq.* Under Part D, CMS enters into contracts with private entities, known as "sponsors," 42 U.S.C. 1395w-112, and makes payments to them to provide prescription drug plans to Part D eligible individuals, see 42 U.S.C. 1395w-115. On average, the government subsidizes 74.5% of the expected cost of Part D benefits. See 42 U.S.C. 1395w-115(a).

In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise becoming involved in the arrangements between drug manufacturers and insurance plans. Congress thus expressly provided that CMS may not "interfer[e] with the negotiations between drug manufacturers and pharmacies and . . . sponsors" and may not "institut[e] a

price structure for the reimbursement of covered part D drugs." Pet. App. 11a. (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). Conse-

quently, 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) (Revised Guidance), https://perma.cc/K6QB-C3MM; 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).[2] To ensure that negotiated prices could be implemented by that date, Congress established interim deadlines to govern the process. 42 U.S.C. 1320f(d).

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[2] 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).

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/37ELGRUW. 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.[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 *ibid.*; 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, *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

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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.

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 has withdrawn from the Negotiation Program, and the manufacturers have been responsible for effectuating the negotiated prices since January 1, 2026.

3. Petitioners Janssen Pharmaceuticals Inc. (Janssen) and Bristol Myers Squibb Company (BMS) manufacture pharmaceuticals, including the blood thinners Eliquis and Xarelto. See Pet. App. 15a, 90a. Eliquis and Xarelto were two of the drugs selected for the first round of the Negotiation Program. See *Selected Drugs for IPAY 2026*, *supra*. In 2023, more than 3.9 million Medicare Part D enrollees used Eliquis and more than 1.3 million used Xarelto; that year, CMS covered more than $24.5 billion in costs for those two drugs combined. *Negotiated Prices for IPAY 2026*, *supra*. Petitioners entered into Manufacturer Agreements and ultimately agreed to negotiated prices for those drugs with CMS. See *ibid.*

Petitioners sued separately in the United States District Court for the District of New Jersey to challenge the Negotiation Program. Pet. App. 90a. They alleged that the Negotiation Program effectuates a taking of their property without just compensation in violation of the Fifth Amendment, that it compels them to speak in violation of the First Amendment, and that it is an

unconstitutional condition on Medicare and Medicaid participation. *Id.* at 90a-91a. The matters were briefed through coordinated dispositive motions. *Id.* at 91a. The district court denied petitioners' motions for summary judgment and granted the government's cross-motions for summary judgment. *Id.* at 87a-118a.

The district court first held that the Negotiation Program did not effect a physical taking of petitioners' drugs because "there is no physical appropriation taking place," Pet. App. 99a, and "there can be no taking when participating in Medicare is voluntary," *id.* at 108a.

The district court then rejected petitioners' compelled-speech claims. Pet. App. 109a-117a. The court again emphasized that petitioners "are not being compelled or forced to participate in the [Negotiation] Program," *id.* at 111a, and explained that the "Program regulates conduct, not speech, and [petitioners] are not engaging in expressive conduct by participating in the Program or by signing the agreements," *id.* at 116a.

Finally, the district court found the unconstitutional-conditions doctrine inapplicable because petitioners had failed to identify a "constitutional right in danger of being trampled," given the court's rejection of petitioners' takings and compelled-speech claims. Pet. App. 117a (citation omitted); see *id.* at 117a-118a.

4. The court of appeals affirmed. Pet. App. 1a-44a. On petitioners' takings claims, the court held that petitioners' "participation in the Program is voluntary, and there is no physical taking." *Id.* at 16a-17a; see *id.* at 16a-32a. The court rejected petitioners' claims that opting out was an "illusory" choice because of the size of the Medicare and Medicaid programs, holding that "'economic hardship is not equivalent to legal compulsion for purposes of takings analysis.'" *Id.* at 20a

(quoting *Baker Cnty. Med. Servs., Inc.* v. *U.S. Attorney Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014), cert. denied, 575 U.S. 1008 (2015)). The court likewise rejected petitioners' "practical objection to withdrawal"—*i.e.*, that they were not permitted "to withdraw in time to suspend the excise taxes." *Id.* at 25a. The court explained that CMS had announced that it would use its "good cause" authority to terminate within 30 days the agreement of any manufacturer that chose not to participate in the Negotiation Program. *Id.* at 26a-27a (quoting 42 U.S.C. 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i)).

The court of appeals then rejected petitioners' compelled-speech claims "for two independent reasons: (1) The Program permissibly regulates conduct, with only an incidental effect on speech, and (2) participation in the Program is voluntary, so [petitioners] are not compelled to speak at all." Pet. App. 32a; see *id.* 32a-44a. The court also held that the Program "does not impose an unconstitutional condition on participation." *Id.* at 43a; see *id.* at 41a-44a. It explained that "[a]ny 'compelled' speech is squarely within the scope of the Program" and that petitioners "remain free to criticize the Program in any forum or instrument other than the contracts needed to effectuate the Program." *Id.* at 43a-44a.

The court of appeals also rejected petitioners' theory that the Negotiation Program "amounts to extortion" under "the *Nollan-Dolan* test" because "the Supreme Court has not expanded [that] test beyond conditions on land-use permitting" and even if the test applied, the Program would "withstand scrutiny." Pet. App. 30a-31a & n.21.

Judge Hardiman dissented as to the takings and compelled-speech claims. Pet. App. 44a-86a. In his view,

manufacturers did not have the option to exit Medicare and Medicaid before they would have been obligated to sign the Manufacturer Agreements because, under his reading of the relevant provisions, such terminations may occur only on 11-23 months' notice. *Id.* at 58a-69a. And because he believed that manufacturers must participate in the Negotiation Program, he believed that that the Program "effects a per se taking" by "forc[ing] [petitioners] to turn over their drugs to Medicare beneficiaries." *Id.* at 72a; see *id.* at 69a-72a. He likewise opined that the Act unconstitutionally "compels [petitioners] to attest that they agreed to negotiate a 'maximum fair price' for their drugs even though they were compelled to participate in the Program." *Id.* at 72a; see *id.* at 72a-82a.

ARGUMENT

These petitions do not warrant further review. The court of appeals correctly rejected petitioners' constitutional challenges, which all rest on mistaken premises about the involuntariness of the Negotiation Program. See, *e.g.*, Janssen Pet. 1-2, 14; BMS Pet. 1-3, 14. That fundamental misconception of the program—which every court of appeals to consider the issue has rejected—dooms these constitutional claims, all of which also fail for many other reasons. Petitioners' contrary view would risk exposing government contracts and federal-benefit programs to constitutional challenges based on purportedly unequal bargaining power and the imposition of mandatory conditions. The absence of any conflict with any decision of this Court or of any other court of appeals further counsels against review.

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

a. ***Takings Clause.*** Petitioners err in claiming that the Negotiation Program effects a physical taking of

their drugs by "coerc[ing] manufacturers to transfer doses of those products to Medicare beneficiaries at a cut-rate discount to CMS." BMS Pet. 14; see *id.* at 14-17; Janssen Pet. 23-29.[4]

i. The Fifth Amendment provides that private property shall not "be taken for public use, without just compensation." U.S. Const. Amend. V. A "physical appropriation[]" occurs when the government "physically takes" or "occupies property." *Cedar Point Nursery* v. *Hassid*, 594 U.S. 139, 147-148 (2021). The "essential question" in physical takings cases is "whether the government has physically taken property for itself or someone else." *Id.* at 149.

Horne v. *Department of Agriculture*, 576 U.S. 350 (2015), is illustrative. That case concerned a requirement that raisin growers "physical[ly] surrender" a percentage of their raisin crop to the government as a condition of selling raisins on the open market. *Id.* at 364; see *id.* at 355. The Court deemed that requirement a physical taking because it required the transfer of "[a]ctual raisins" from the growers to the government, *id.* at 361, and growers lost "any right to control the[] disposition" of the raisins, *id.* at 364.

By contrast, there is no physical taking when a law prohibits selling a product but does not "'compel the surrender'" of property, or impose any "'physical invasion or restraint upon'" it, and the owner "retain[s] the rights to possess, donate, and devise" the property. *Horne*, 576 U.S. at 364 (citation omitted). In *Andrus* v. *Allard*, 444 U.S. 51 (1979), for example, this Court upheld a law prohibiting the sale of bald eagle feathers against a Takings Clause challenge. The Court explained

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[4] Petitioners do not allege that the Negotiation Program effects a regulatory taking. Pet. App. 17a n.9.

that it was "not dispositive" that the law "prevent[s] the most profitable use of [the] property." *Id.* at 66. Rather, "loss of future profits—unaccompanied by any physical property restriction—provides a slender reed upon which to rest a takings claim." *Ibid.*

ii. Under those precedents, there is no taking here because the Negotiation Program does not physically appropriate or otherwise compel the transfer of petitioners' property and petitioners' loss of some profitability for their selected drugs does not support a takings claim. Unlike in *Horne*, the government is not "sen[ding] trucks to [petitioners'] facilit[ies]" to haul away their products. 576 U.S. at 356. Nor do petitioners plausibly contend that they must physically transfer their drugs to the government. Rather, petitioners contend that it is not feasible to withdraw from Medicare and Medicaid; that if they continue to participate in Medicare and Medicaid yet refuse to comply with the Act, they will be subject to excise taxes; and that if they do comply with the Act, the government is driving so hard a bargain that a de facto forced transfer is happening and the compensation that petitioners undisputedly receive under the Negotiation Program does not provide just compensation. See, *e.g.*, Janssen Pet. 3-4, 25, 28; BMS Pet. 1-2, 14-16.

That is not a viable theory because the Negotiation Program simply alters what Medicare will offer to pay for certain drugs. No manufacturer must accept the terms the government is presently offering; manufacturers are subject to the negotiated price only if they choose to sell their drugs to Medicare beneficiaries. See Revised Guidance 120-121; see also 26 U.S.C. 5000D(c)(1). And manufacturers may always free themselves from the excise tax either by selling at the negotiated price

or withdrawing from the Program. See pp. 8-9, *supra*. As the court of appeals recognized, "[i]f [petitioners] dislike the prices the government is willing to pay, they are free to stop doing business with the government." Pet. App. 16a.

Courts have thus "uniformly" rejected "takings claims about Medicare or Medicaid" due to medical providers' "ability to stop participating in those programs." Pet. App. 18a-19a & n.10 (collecting cases). And "economic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Id.* at 20a (quoting *Baker Cnty. Med. Servs., Inc.* v. *U.S. Attorney Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014), cert. denied, 575 U.S. 1008 (2015)); see *id.* at 20a-21a (collecting additional cases). Even where "business realities" create "strong financial inducement to participate," the decision to participate in the program "is nonetheless voluntary." *Minnesota Ass'n of Health Care Facilities, Inc.* v. *Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), cert. denied, 469 U.S. 1215 (1985). Similarly here, the financial incentives of obtaining revenue from Medicare and Medicaid participation or of avoiding the excise taxes do not render participation in the Negotiation Program involuntary.

Were the law otherwise, claims like petitioners' would constitutionalize countless government-contracting settings where the government exercises considerable market power. Indeed, in some circumstances, such as defense spending, "the government may be the only purchaser," Pet. App. 21a, such that defense companies may view the government as effectively setting the terms for programs where defense companies feel that they have no other commercially viable choice but to participate. But the government's significant leverage

in heavily regulated programs does not transform the government's bargaining terms into matters of constitutional concern. Cf. *Perkins* v. *Lukens Steel Co.*, 310 U.S. 113, 127-128 (1940) ("Judicial restraint of those who administer the Government's purchasing would constitute a break with settled judicial practice and a departure into fields hitherto" entrusted to coordinate branches).

Here, petitioners' objections ring particularly hollow because asymmetries in bargaining within the Medicare and Medicaid systems are longstanding and pervasive. For example, as a condition on their participation in Medicaid, petitioners have long been required to enter into agreements giving the Department of War, the Department of Veterans Affairs, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceilings. See 38 U.S.C. 8126(a)-(h). They have likewise been required to enter into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. See *Astra USA, Inc.* v. *Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (describing requirements under Section 340B of the Public Health Service Act). Under petitioners' view, because the "government is a major purchaser in our Nation's economy," "contracts delineat[ing] the terms of many government purchases" would regularly "give rise to takings claims." Pet. App. 18a. That would be an untenable sea change in Takings Clause jurisprudence at odds with the history of government contracting.

In all events, the Negotiation Program entails a real negotiation in which manufacturers are in a position to bargain with the government. For the first year of the Program, CMS outright accepted four manufacturer counteroffers. See *Negotiated Prices for IPAY 2026*,

supra. Manufacturers achieved that result because they are "not without leverage in these negotiations"; their ability to walk away and prevent Medicare and Medicaid from purchasing any of their drugs affords them bargaining power. *Boehringer Ingelheim Pharm., Inc.* v. *HHS*, 150 F.4th 76, 92 n.11 (2d Cir. 2025).

iii. Petitioners also claim to be coerced into forfeiting much of the value of their drugs based on their "practical objection to withdrawal," Pet. App. 25a—*i.e.*, that they could not have withdrawn from the Medicare and Medicaid in time to avoid participating in the Negotiation Program or facing excise taxes. That objection also lacks merit. CMS's Revised Guidance expressly provides that if a manufacturer "decides not to participate in the Negotiation Program," CMS will "facilitate an expeditious termination of" the manufacturer's Medicare agreements before the manufacturer incurs liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days before that tax would otherwise begin to accrue. Revised Guidance 33-34. CMS has authority to facilitate such a withdrawal because Congress permitted it to terminate any manufacturer's Medicare agreements for "good cause." See 42 U.S.C. 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i).

Judge Hardiman disagreed with that understanding of CMS's authority because he believed it would render the manufacturer's unilateral termination option superfluous and because a manufacturer might not send the right type of termination notice to CMS. See Pet. App. 61a-66a. But, as the majority persuasively explained, CMS may terminate a manufacturer on 30 days' notice only if CMS finds "good cause"—"'a uniquely flexible and capacious concept, meaning simply a legally sufficient

reason'"—and CMS may permissibly find good cause when a manufacturer decides not to participate in the Negotiation Program. *Id.* at 28a (citation omitted); see *id.* at 28a-29a. To the extent there were constitutional concerns under the Takings Clause and the Court considered the good-cause provision ambiguous, constitutional-avoidance principles would further underscore the correctness of the court of appeals' reading. See *United States* v. *Hansen*, 599 U.S. 762, 781 (2023).

b. ***Compelled Speech.*** Petitioners further contend (Janssen Pet 15-23; BMS Pet. 17-20) that the Negotiation Program compels them to speak in violation of the First Amendment by requiring that participants sign a Manufacturer Agreement memorializing their decision to negotiate and—if negotiations succeed—the maximum amount that Medicare will pay for a selected drug. Petitioners' exact challenge is hard to pin down. Sometimes, they suggest the entire negotiating process is a "charade," "sham," and "kabuki" for "political deception." BMS Pet. 17; see Janssen Pet. 1-2. Elsewhere, they focus on the Manufacturer Agreement as the relevant speech and compare "parroting" the message to a "forced confession" that they previously charged more than the "'maximum fair price.'" BMS Pet. 19 (citation omitted); see Janssen Pet. 16-17. Ultimately, they appear to object most that the Manufacturer Agreement "compel[s] speech" by using the term "'maximum fair price,'" and terms like "'agree' and 'negotiate' to describe their participation in the Program" when "they are acting under duress." Pet. App. 32a. The court of appeals correctly rejected this claim as well. See *id.* at 32a-41a.

i. This claim fails at the outset for similar reasons as the Takings Clause claim: the government is not

actually compelling petitioners' speech. "A violation of the First Amendment right against compelled speech occurs 'only in the context of actual compulsion.'" *Miller* v. *Mitchell*, 598 F.3d 139, 152 (3d Cir. 2010) (citation omitted); see *Wilkins* v. *Daniels*, 744 F.3d 409, 415 (6th Cir. 2014); *Boehringer Ingelheim*, 150 F.4th at 95. Petitioners face no "actual compulsion" to engage in speech because—as explained—their participation in the Negotiation Program and in ensuing contracts memorializing specific terms, like their participation in Medicare and Medicaid, is voluntary. See Pet. App. 39a-41a; see also pp. 16-19, *supra*. The voluntariness of the Negotiation Program and any attendant "speech" requirements is fatal to these claims. See, *e.g.*, *C.N.* v. *Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005) (rejecting compelled-speech claim absent "the compulsion necessary to establish a First Amendment violation").

Petitioners' First Amendment claims independently fail because, as the court of appeals below held, the Negotiation Program regulates non-expressive conduct, "with only an incidental effect on speech." Pet. App. 39a; see *id.* at 35a-39a. Specifically, "the Program regulates the price at which [petitioners] will be reimbursed," then enshrines those terms in contracts. *Id.* at 36a n.23; see *id.* at 35a. Although First Amendment protections extend beyond "the spoken or written word," *Texas* v. *Johnson*, 491 U.S. 397, 404 (1989), the Court has "rejected the view that 'conduct can be labeled "speech" whenever the person engaging in the conduct intends thereby to express an idea,'" *Rumsfeld* v. *Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 65-66 (2006) (*FAIR*) (quoting *United States* v. *O'Brien*, 391 U.S. 367, 376 (1968)). First Amendment protections

for conduct cover only "inherently expressive" conduct. *Id.* at 66.

Thus, "the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech." *Sorrell* v. *IMS Health Inc.*, 564 U.S. 552, 567 (2011). A "typical price regulation" is a classic example. *Expressions Hair Design* v. *Schneiderman*, 581 U.S. 37, 47 (2017). Such a "law—by determining the amount charged—would indirectly dictate the content" of speech about the product's price, but poses no First Amendment problem because any "effect on speech would be only incidental to its primary effect on conduct." *Ibid.* The same is true for commercial conduct executed through written contracts. "[I]t has never been deemed an abridgment of freedom of speech" to regulate conduct "merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *FAIR*, 547 U.S. at 62 (quoting *Giboney* v. *Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)).

In requiring the parties to sign documents memorializing their intent to negotiate and their agreement upon the maximum price that Medicare will pay for selected drugs, the Negotiation Program regulates only non-expressive, commercial conduct, and any effects on speech are "plainly incidental." *FAIR*, 547 U.S. at 62. Manufacturers that choose to participate in the Program engage in negotiations with the government and agree to make any negotiated prices available when Medicare beneficiaries purchase selected drugs; the Manufacturer Agreement memorializes those terms. See Revised Guidance 118-120.

That is unremarkable: Healthcare providers and other entities regularly execute similar agreements with the

government to memorialize their acceptance of the terms of participation across a range of federal healthcare programs. See, *e.g.*, 42 U.S.C. 1395cc, 1396r-8(b) and (c), 1395w-102(b)(1). Because the Negotiation Program "simply regulate[s] the amount that a [manufacturer] c[an] collect" when selling drugs within the Program, its effect on speech is the same as an ordinary commercial contract. *Expressions Hair Design*, 581 U.S. at 47. Thus, petitioners' reliance on cases concerning expressive speech are inapposite. See, *e.g.*, Janssen Pet. 18-19 (citing *Miami Herald Publ'g Co.* v. *Tornillo*, 418 U.S. 241 (1974); *Hurley* v. *Irish-American Gay, Lesbian, & Bisexual Grp. of Boston*, 515 U.S. 557 (1995); *Agency for Int'l Dev.* v. *Alliance for Open Soc'y Int'l, Inc.*, 570 U.S. 205 (2013)).

ii. Petitioners' main objection is that the Manufacturer Agreement's use of terms like "maximum fair price," "agree," and "negotiate" purportedly forces petitioners to promote a "false narrative." BMS Pet. 17; see Janssen Pet. 15. But terms like "'agree'" and "'negotiate'" merely "describe the parties' dealings in the Program." Pet. App. 37a. As the court of appeals recognized, "it is difficult to imagine how any contract could effectuate the Program without using" those terms "or equivalents that would draw the same objections from [petitioners]." *Id.* at 37a-38a.

Further, the Agreement's use of defined terms, like "maximum fair price," 42 U.S.C. 1320f(c)(3), ensures a consistent understanding of the parties' obligations by referring to the statute; it is not a means of compelling manufacturers to express a view about the value of their drugs. Indeed, the Agreement states explicitly that a manufacturer's signature reflects neither an "endorsement of CMS'[s] views" nor a representation of

the manufacturers' views concerning the fairness of prices. Pet. App. 186a. And the Agreement explains that the "[u]se of the term 'maximum fair price' and other statutory terms throughout th[e] Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." *Id.* at 186a-187a. Petitioners do not plausibly explain why using such defined terms in a contract that expressly disclaims that those terms reflect petitioners' own views would nonetheless mislead others as to petitioners' views or force petitioners to contradict themselves.

Petitioner Janssen's reliance (Pet. 2, 18) on *Pacific Gas & Electric Co.* v. *Public Utilities Commission*, 475 U.S. 1 (1986) (plurality opinion), is misplaced. *Pacific Gas* involved a challenge to a rule requiring "a privately owned utility company to include in its billing envelopes speech of a third party with which the utility disagree[d]." *Id.* at 4. The Court explained that, while a disclaimer stating that the third-party speech did not represent the views of the utility was ineffective to avoid First Amendment harms, it served "to avoid giving readers the mistaken impression that [the third party's] words are really those of [the utility]." *Id.* at 15 n.11. Here too, the statute's disclaimer confirms the absence of any intent in the Manufacturer Agreement to convey a particular message.

Moreover, the Negotiation Program's use of the term "fair" in the Agreements is not unique. Contra Janssen Pet. 16-17. Government contracting is premised on the government obtaining a "fair and reasonable price." 48 C.F.R. 15.402(a). Every government contractor entering a fixed-price contract implicitly agrees that the

price is fair; were it otherwise, the contractor could never defend its contract award against a bid protest. Nor is the Program alone in requiring a contractor to agree expressly that a price is "fair." See, *e.g.*, *United States* v. *General Dynamics Corp.*, 19 F.3d 770, 771 (2d Cir. 1994) (statute requires that, to obtain a federal subsidy, "the proposed ship purchaser and the shipyard submit backup cost details and evidence that the negotiated price is fair and reasonable"); *Air Borealis Ltd. P'ship* v. *United States*, 167 Fed. Cl. 370, 389 (2023) (contractor allowed to certify that price is "fair and reasonable" in lieu of providing cost data to government purchaser) (citation omitted); *Sea-Land Serv., Inc.* v. *United States*, 493 F.2d 1357, 1360 (Ct. Cl.) (agreement to sell ships to purchaser at "fair and reasonable values"), cert. denied, 419 U.S. 840 (1974). Any of these agreements could be framed as forcing a counterparty to "carry political water," BMS Pet. 20, but that limitless standard is no part of First Amendment doctrine.

Petitioners miss the mark (BMS Pet. 20) in framing the Manufacturer Agreements as fundamentally different from ordinary government contracting. "Like any other private party seeking to leverage its purchasing power to get a better bargain, the government through the Negotiation Program forces pharmaceutical manufacturers to decide whether to do business according to its terms." *Boehringer Ingelheim*, 150 F.4th at 92 n.11. And the Manufacturer Agreements resemble the types of agreements which CMS regularly uses to memorialize program conditions when entities opt-in to voluntary programs. See, *e.g.*, *Astra USA*, 563 U.S. at 113, 115.

Finally, petitioners' characterization of the negotiation process as a "sham," BMS Pet. 17, is incorrect. As

explained, manufacturers are not without leverage in negotiating with the government. See pp. 18-19, *supra*. The Program entails real negotiations, and it is telling that in the first round of the Negotiation Program, the government outright accepted four manufacturer counteroffers. See *ibid.*

c. ***Unconstitutional Coercion.*** Finally, petitioners err in arguing (Janssen Pet. 18-19, 25-26, 29-33; BMS Pet. 21-27) that the Negotiation Program is unconstitutionally coercive under *National Federation of Independent Business* v. *Sebelius*, 567 U.S. 519 (2012) (*NFIB*), and violates the unconstitutional conditions doctrine. The panel below unanimously rejected this claim for good reason. As with petitioners' other claims, this argument falters both on doctrine and on their exaggeration of the degree of coercion involved.

i. As relevant here, *NFIB* considered the constitutionality of statutory provisions requiring States to expand Medicaid eligibility or risk losing all of their existing Medicaid funding. See 567 U.S. at 575 (plurality opinion). The Court held that the threat to withdraw all existing Medicaid funding was so coercive as to "violate[ ] the basic principle that the 'Federal Government may not compel the States to enact or administer a federal regulatory program.'" *Ibid.* (quoting *New York* v. *United States*, 505 U.S. 144, 188 (1992)); see *id.* at 580. The Medicaid expansion thus exceeded "Congress's power under the Spending Clause to secure state compliance with federal objectives." *Id.* at 576; see *id.* at 576-585.

Petitioners err in attempting to analogize the federal assistance provided to States in *NFIB* to their history of profitable sales to the government through Medicare and Medicaid. Janssen Pet. 30-31; BMS Pet. 23. Both

before and after *NFIB*, courts have uniformly rejected the idea that the lucrative nature of Medicare and Medicaid coerces private parties. See p. 17, *supra*; see also Pet. App. 18a-21a & n.10. And rightly so: The *NFIB* "coercion" framework addresses—and is derived from cases analyzing—how *federalism* principles inform what conditions Congress may attach to money it grants to *States*. See *NFIB*, 567 U.S. at 579-581 (plurality opinion) (discussing, *inter alia*, *South Dakota* v. *Dole*, 483 U.S. 203 (1987)). As the Chief Justice's opinion emphasizes, those principles protect "the status of the States as independent sovereigns in our federal system." *Id.* at 577; see *id.* at 579-581 (discussing "coercion" as a limit on Congress's ability to induce States to adopt policy changes).

Petitioners' reliance (Janssen Pet. 31-33; BMS Pet. 13, 22) on *United States* v. *Butler*, 297 U.S. 1 (1936), is similarly misplaced. *Butler* held that an agricultural program violated the Tenth Amendment because the Court, at the time, viewed the program as improperly regulating an area of exclusive state control. *Id.* at 68, 74-75. Those federalism principles animated the Court's concerns about potential coercion by the federal government, exactly as in *NFIB*. Such principles are absent here. And where "no federalism concerns are implicated, the presence or absence of coercion is wholly irrelevant." *Nevada* v. *Skinner*, 884 F.2d 445, 450 (9th Cir. 1989), cert. denied, 493 U.S. 1070 (1990).

Petitioners' concerns are more appropriately addressed to the general rule that "Spending Clause legislation operates based on consent" and that, accordingly, recipients must "'voluntarily and knowingly accept the terms'" of the funding contract. *Cummings* v. *Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 219

(2022) (citation omitted); accord *Medina* v. *Planned Parenthood S. Atl.*, 606 U.S. 357, 376 (2025). But petitioners overstate the voluntariness that this Court's Spending Clause cases require. As explained, when private actors participate in Medicare and Medicaid, they must follow numerous requirements, including that they must provide drugs to certain providers subject to price limits. See p. 18, *supra*. Petitioners need not be able to negotiate every term of every requirement to which they are subject for that spending contract to be voluntary. They need only have notice of the conditions and voluntarily agree to participate in the programs, as petitioners have done here.

ii. Petitioners fare no better relying on the unconstitutional conditions doctrine. See Janssen Pet. 18-19, 25-26; BMS Pet. 24-27. That doctrine prevents the government from requiring a person to give up a constitutional right in order to receive an unrelated benefit. See *Rust* v. *Sullivan*, 500 U.S. 173, 196-198 (1991). But the government may condition the receipt of federal funds on compliance with program-specific requirements without violating the unconstitutional conditions doctrine, so long as the conditions are relevant to the program's purpose and "leave the grantee unfettered in its other activities." *Id.* at 196. The "'unconstitutional conditions' cases involve situations in which the Government has placed a condition on the recipient of the subsidy rather than on a particular program or service, thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally funded program." *Id.* at 197 (emphasis omitted). The cases have thus consistently distinguished between provisions that set the terms of and define the scope of

government programs and provisions that impose external conditions on beneficiaries. See *id.* at 197-198.

In *Rust*, the Court upheld regulations that prohibited the use of federal funds for abortion-related activities, emphasizing that the conditions were directly connected to the purpose of the funding and did not prevent recipients from engaging in protected speech through affiliates funded by non-federal sources. 500 U.S. at 196-198. Conversely, in *Agency for International Development*, the Court struck down a condition that required non-governmental organizations receiving federal HIV/AIDS funding to adopt a policy announcing their opposition to prostitution and sex trafficking that extended beyond the scope of the funded program. 570 U.S. at 208, 218-219.

Those cases confirm the permissibility of the Negotiation Program. The Act 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. The government has a substantial interest in curbing the rising costs of public spending on prescription drugs, see *Lyng* v. *International Union*, 485 U.S. 360, 373 (1988), and the Negotiation Program furthers that interest by promoting the long-term fiscal integrity of government programs. The terms that petitioners challenge—agreeing to participate in price negotiations, signing contracts reflecting agreed-upon prices, and ultimately selling drugs within Medicare at such prices—are integral to the functioning of this drug-payment program, and do not impede petitioners' ability to exercise their rights outside of the government's prescription drug spending.

Finally, petitioners' reliance (Janssen Pet. 25-29; BMS Pet. 24-26) on the nexus-and-proportionality test

from *Dolan* v. *City of Tigard*, 512 U.S. 374, 391 (1994), and *Nollan* v. *California Coastal Commission*, 483 U.S. 825, 834-837 (1987), is misplaced. As this Court has recognized, while the *Nollan-Dolan* test is "modeled on the unconstitutional conditions doctrine," it "address[es] * * * potential abuse of the permitting process." *Sheetz* v. *County of El Dorado*, 601 U.S. 267, 275 (2024). This Court "has not expanded the * * * test beyond conditions on land-use permitting." Pet. App. 30a-31a; see *Koontz* v. *St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (*Nollan* and *Dolan* concern the "'special application' of * * * land-use permits") (citation omitted); *Lingle* v. *Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005) (noting the "special context of land-use exactions").

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); *Novo Nordisk Inc.* v. *HHS*, 154 F.4th 105 (3d Cir. 2025); *AstraZeneca Pharm. LP* v. *HHS*, 137 F.4th 116, 120 (3d Cir. 2025); *Boehringer Ingelheim*, 150 F.4th 76. Thus, BMS correctly does not even attempt to allege a circuit conflict. For its part, Janssen discusses only two cases with which the Third Circuit's decision allegedly conflicts, but even that purported conflict is illusory. See Janssen Pet. 20-23.

Janssen's alleged conflict rests on a misreading of the court of appeals' citation of *Meese* v. *Keene,* 481 U.S. 465 (1987). Contrary to Janssen's contentions, the court of appeals did not "extend[ ] *Meese*" to the compelled-speech context, Janssen Pet. 21, nor rely on it to hold

that "the Government c[an] require regulated parties to recite normatively charged terms as long as it defines them in a way that obscures their ordinary meaning," *id.* at 22. Instead, the court of appeals cited *Meese* to explain that where parties to a contract intend to incorporate by reference a statutory definition, the rules for construing terms defined by statute apply—a principle for which it could have cited any number of other cases. See Pet. App. 37a; see also *id.* 115a-116a (district court relying on *Meese* for the same principle).

Thus, *National Ass'n of Manufacturers* v. *SEC*, 800 F.3d 518 (D.C. Cir. 2015) (*NAM*), in which the D.C. Circuit held unconstitutional a statute and regulation requiring companies to make certain disclosures relating to their use of "conflict minerals" originating in the Democratic Republic of the Congo, is irrelevant here. *Id.* at 522, 530; see 15 U.S.C. 78m(p). *NAM* explained that *Meese* would not permit "Congress to force filmmakers to label their own films as 'political propaganda'—or not 'propaganda free'—however the term was defined." 800 F.3d at 529 (citation omitted). The court of appeals never disputed that proposition. Janssen's reliance (Pet. 22-23) on *Entertainment Software Ass'n* v. *Blagojevich*, 469 F.3d 641 (7th Cir. 2006), is misplaced for the same reasons. The court of appeals did not hold that regulated parties may be required to speak "merely because a statute defines [the government's] message in a non-expressive way." Janssen Pet. 23.

3. Petitioners urge this Court's review by invoking "far-reaching legal ramifications" of the decision below. BMS Pet. 28; see Janssen Pet. 36-38. Specifically, they suggest that, if the Negotiation Program stands, "Congress can accrue monopsony power in *any* area of the economy" and would be "free to extort property, compel

speech, or infringe other rights enjoyed by any individual or business that finds itself operating in a federally dominated market." BMS Pet. 28-29.

Again, that parade of horribles misapprehends the nature of this program. And that parade is hardly materializing now, despite numerous existing contexts where the nature of the government program or the government's bargaining power could equally be characterized as unfairly coercive or as placing unconstitutional conditions on government benefits. See, *e.g.*, BMS Pet. 22-25. The Constitution offers robust protections for constitutional rights, but it does not forbid the federal government from conditioning the availability of subsidies for prescription drug purchases on the drugs costing a reasonable amount.

Moreover, many of petitioners' hypotheticals are easily dismissed and underscore the weakness of their principal arguments. BMS Pet. 30; see Janssen Pet. 37-38. BMS, for example, suggests that "the government could condition access to federal contracts or licenses on discriminatory hiring practices." BMS Pet. 30. That is obviously incorrect given that such racial classifications would be subject to strict scrutiny, see *Adarand Constructors, Inc.* v. *Pena*, 515 U.S. 200, 235 (1995), and would not survive, see *Students for Fair Admissions, Inc.* v. *President & Fellows of Harvard Coll.*, 600 U.S. 181, 218-219 (2023).

Petitioners' arguments about unequal bargaining power also lack limiting principles. Given its scale, the government often has dominant purchasing power. Petitioners' attempt to locate a constitutional right to government payments above and beyond those authorized by Congress runs counter to decades of precedent rejecting takings claims by physicians and hospitals

dissatisfied with reimbursement rates. See, *e.g.*, *Managed Pharmacy Care* v. *Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013), cert. denied, 571 U.S. 1125 (2014); p. 17, *supra*. Such an approach would also have sweeping implications outside of Medicare, giving manufacturers a constitutional right to dictate the government's expenditures. Just as a defense contractor cannot force the Pentagon to buy an aircraft carrier at the contractor's preferred price, pharmaceutical companies cannot force Medicare drug sales at prices the government is unwilling to pay.

Petitioners separately suggest that review is warranted because the "Program will inflict serious harm." BMS Pet. 31. They primarily focus (Janssen Pet. 34-36; BMS Pet. 31-33) on alleged harms to manufacturers, but 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. The Program is a critical tool to achieve the government's policy of "optimiz[ing]" "Federal health care programs[] * * * to provide access to prescription drugs at lower costs to American patients and taxpayers." *Lowering Drug Prices by Once Again Putting Americans First*, Exec. Order No. 14,273, 90 Fed. Reg. 16,441, 16,442, § 2 (Apr. 18, 2025); see *id.* at 16,442, § 3 (directing HHS to improve Negotiation Program). Ballooning drug prices burden American families. The first year of the Negotiation Program is estimated to save seniors $1.5 billion, providing meaningful relief from unaffordable medical expenses. See *Negotiated Prices for IPAY 2026*, *supra*. For example, more than 3.9 million patients previously obtained BMS's drug Elliquis at the $521 list price. *Ibid.* Under the Negotiation Program, a senior with a standard 25%

copay has seen her monthly out-of-pocket cost decrease from $130.25 to $57.75. See *ibid.* Petitioners seek to reimpose higher costs on seniors and the fisc alike.

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. 30, *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. argument scheduled for May 5, 2026); *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). 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); *Novo Nordisk Inc.* v. *Kennedy*, petition for cert. pending, No. 25-761 (filed Dec. 22, 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 petitions for writs of certiorari should be denied.

Respectfully submitted.

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