Nos. 24-1820 & 24-1821

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRISTOL MYERS SQUIBB CO,
Plaintiff-Appellant,
v.
XAVIER BECERRA, *et al.*,
Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,
Plaintiff-Appellant,
v.
XAVIER BECERRA, *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey

BRIEF FOR APPELLEES

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INTRODUCTION

For more than 30 years, Congress has established limits on the amounts that federal agencies will pay for prescription drugs. Manufacturers that wish to sell their drugs to the Departments of Defense and Veterans Affairs, for example, do so subject to statutorily defined ceiling prices, and both agencies have authority to negotiate prices below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). In the Inflation Reduction Act of 2022 (IRA), Pub. L. No. 117-169, 136 Stat. 1818, Congress gave the Secretary of Health and Human Services (HHS) similar authority to address the extraordinary and unsustainable increase in the prices that Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses. 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). Under the IRA's Drug Price Negotiation Program, the Centers for Medicare & Medicaid Services (CMS) can now negotiate the prices that Medicare will pay for a select group of drugs manufactured by pharmaceutical companies that choose to sell drugs to Medicare and Medicaid.

Plaintiffs Bristol Myers Squibb (BMS) and Janssen Pharmaceuticals each challenged the Negotiation Program as effecting a physical taking of

their drugs in violation of the Fifth Amendment, as compelling their speech in violation of the First Amendment, and as otherwise compelling waivers of these First and Fifth Amendment rights. The district court correctly rejected each of these claims, recognizing that Congress has broad authority to set the terms of the government's offer to purchase drugs, and that it acted well within this authority in establishing a framework for negotiating the prices that Medicare pays for certain high-expenditure drugs.

First, the Negotiation Program does not physically take plaintiffs' drugs. Plaintiffs are under no obligation to provide drugs to the government or to any third party *at all*, let alone on terms they find unfavorable. Rather, as the district court explained, "[s]elling to Medicare is a choice Plaintiffs can accept or not accept," just like "any negotiation between a purchaser and a seller." JA17. Plaintiffs have the option not to sell their drugs on the terms offered by the government. If they do so anyway because the alternative is less profitable, they cannot complain that a taking has occurred.

Second, the Negotiation Program does not violate the First Amendment by compelling speech in the form of contractual agreements.

Plaintiffs object that any manufacturer that participates in the Program must sign an agreement to negotiate, and, if negotiations prove successful, an agreement to honor the negotiated price. These agreements, the district court explained, are not speech; they are commercial contracts governing the negotiation process and the parties' associated conduct. In any event, plaintiffs are not compelled to sign these agreements because participation in Medicare (and the Negotiation Program, by extension) is voluntary.

Finally, the Negotiation Program is not unconstitutionally coercive under *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519 (2012), nor does it violate the unconstitutional conditions doctrine. *NFIB* addressed federalism-based limits on Congress's ability to secure *State* compliance with federal objectives, and these federalism concerns do not arise when the government offers to buy drugs from private parties. Plaintiffs' recourse to the unconstitutional conditions doctrine is equally unavailing, because that doctrine does not operate as a constraint on the government's broad discretion to set the commercial terms of its offers to purchase goods. Even if it did, the Supreme Court has long recognized that the government may establish the parameters and mechanisms through which its programs operate and the terms on which it disburses

money. Congress implemented the Negotiation Program to curb the unsustainable rise in public spending on prescription drugs, and the requirements plaintiffs challenge are integral parts of the Program's operation—not extrinsic conditions preventing plaintiffs from exercising their constitutional rights beyond the scope of government prescription drug spending.

STATEMENT OF JURISDICTION

Plaintiffs in these consolidated cases invoked the district court's jurisdiction under 28 U.S.C. §§ 1331 and 1346. JA4, 436. On April 29, 2024, the district court issued an order granting the government's motion for summary judgment. JA26. BMS filed its timely notice of appeal on April 29, 2024, and Janssen filed its timely notice of appeal on April 30, 2024. JA29-30, 31-32; *see* Fed. R. App. P. 4(a)(3). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

The district court rejected plaintiffs' constitutional challenges to the IRA's Drug Negotiation Program. The questions presented are:

1. Whether the district court correctly rejected plaintiffs' claims that the Negotiation Program effects a physical taking of plaintiffs' drugs.

2. Whether the district court correctly rejected plaintiffs' compelled speech claims, both because the Negotiation Program involves no compulsion and because the challenged provisions regulate conduct rather than speech.

3. Whether the district court correctly rejected plaintiffs' unconstitutional conditions arguments, because the doctrine does not prevent the government from using its purchasing power to negotiate the prices it pays for high-cost items.

STATEMENT OF THE CASE

A. Medicare and the Escalating Cost of Prescription Drug Coverage

Medicare provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. 42 U.S.C. § 1395 *et seq.* CMS administers Medicare on behalf of the Secretary of Health and Human Services.

Medicare is divided into "Parts" that set forth the terms by which Medicare will pay for specific benefits. *See Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Medicare Part B covers outpatient care as well as the cost of drugs administered as part of that care. *Cares Cmty.*

Health v. HHS, 944 F.3d 950, 953 (D.C. Cir. 2019). Medicare Part D, which Congress added in 2003, provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. § 1395w-101 *et seq.* In enacting Part D, Congress initially barred CMS from negotiating Part D drug prices or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42 U.S.C. § 1395w-111(i). But that model led to skyrocketing drug prices that saddled beneficiaries with unaffordable copays and threatened the long-term solvency of the program.

The cost to the federal government of providing 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 these programs. *See* 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. That figure has risen dramatically over the last decade and is "projected to continue rising during the coming decade, 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 HHS Report to Congress). Medicare Part D spending in particular "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019).

In addition to its effects on the federal treasury, the high cost of prescription drug coverage directly burdens Medicare beneficiaries by affecting their premiums and out-of-pocket payments. Because Part B premiums are automatically set to cover 25% of aggregate Part B spending, higher total spending on prescription drug coverage results in higher premiums for individual enrollees. *See* 2020 HHS Report to Congress, at 11. Beneficiaries also pay 20% of their Part B prescription drug costs out of pocket. Part D premiums are similarly based on a plan's anticipated costs, and many Part D plans likewise require beneficiaries to pay additional cost-sharing amounts.

A "relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, 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 . . . Part D." 2020 HHS Report to Congress, *supra*, at 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.

These rising costs are in large part attributable to manufacturers' considerable latitude in dictating the prices that Medicare pays for the most expensive drugs. Because formulas for drug prices under Medicare Part B and Part D were tied to the price manufacturers charged private buyers, *see* 42 U.S.C. §§ 1395w-3a(b), 1395w-101 *et seq.*, 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. Drug companies' substantial leeway in this respect was compounded by the significant legal and practical obstacles to market entry faced by generic competitors, along with the practice of many manufacturers of protecting their market share by entering into "settlements" with generic manufacturers to limit generic marketing. *See, e.g.*, Sarah M.E. Gabriele &

William B. Feldman, *The Problem of Limited-Supply Agreements for Medicare Price Negotiation,* 330 JAMA 1223 (2023). As a result of these factors, there are in many instances "no market forces to apply downward pressure to provide lowered prices to the millions who have coverage for such medicines under Medicare." H.R. Rep. No. 116-324, pt. 2, at 37-38.

Other federal agencies, including the Departments of Defense and Veterans Affairs, operate their drug benefit programs differently and have not been subject to skyrocketing costs. 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). As a consequence, 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 (Feb. 2021), https://perma.cc/YY2E-GM97. "[I]f Medicare had received the same discounts as the Departments of Defense and Veterans Affairs, taxpayers would have saved" billions. Staff of H. Comm. on Oversight & Reform, *Drug Pricing Investigation: AbbVie – Humira and Imbruvica* 13-15 (May 2021), https://perma.cc/Z2KG-ZKW3.

B. The IRA's Drug Price Negotiation Program

Through the IRA's Drug Price Negotiation Program, Congress empowered the HHS Secretary, acting through CMS, to negotiate the prices Medicare pays for certain drugs, just as the Departments of Defense and Veterans Affairs have done for decades. *See* IRA §§ 11001-11003, 136 Stat. at 1833-64 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). 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* 42 U.S.C. § 1320f-1(b), (d). The Program does not apply to 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. *See* 42 U.S.C. § 1320f-1(d), (e). For the first negotiation cycle, CMS selects 10 of these drugs with the highest Medicare expenditures for negotiations. *Id.* § 1320f-1(a). Additional drugs are to be selected for future negotiation cycles.

After selecting the drugs, CMS signs agreements with those manufacturers that are willing to engage in the negotiation process. 42 U.S.C. § 1320f-2. The object of the negotiations is to reach agreement on what the IRA terms a "maximum fair price" that Medicare will pay for each selected drug. *Id.* § 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, *id.* § 1320f-3(c), and directed CMS to "aim[] to achieve the lowest maximum fair price" that the manufacturer will accept, *id.* § 1320f-3(b)(1). If negotiations prove successful, the manufacturer signs an addendum to the negotiation agreement establishing the maximum price at which the drug will be made available to Medicare beneficiaries. *Id*. § 1320f-3.

In enacting the Negotiation Program, Congress altered the terms of its offer to continue purchasing drugs for Medicare and Medicaid. A drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because "participation in the Medicare program is a voluntary undertaking," JA15 (quotation marks omitted), the manufacturer can withdraw from Medicare and Medicaid, and thus not be subject to any of the Negotiation Program's requirements. 26 U.S.C. § 5000D(c)(1); *see also*

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 120-21 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). 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 131-32. A manufacturer that pursues neither of these 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(a)-(h); *see also* Internal Revenue Service Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P.

C. The Negotiation Program's Implementation

In addition to the statutory requirements set out above, Congress instructed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" for the first few negotiation cycles. IRA § 11001(c), 136 Stat. at 1854. In June 2023, CMS published a Revised Guidance that explains, among other things, how CMS determines which drugs may be selected for negotiation, and the procedures for participating in the negotiation process. *See* Revised

Guidance 91-92. It also sets out procedures for manufacturers to follow if they decide not to participate in the Negotiation Program. *Id.* at 118-20, 129-31; *see infra* p. 39 n.4.

In August 2023, CMS published the list of drugs selected for the first negotiation cycle. *See* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The 10 drugs selected accounted for more than $50 billion of gross Medicare Part D spending 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* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94. BMS's drug Eliquis and Janssen's drug Xarelto were among the drugs selected for negotiation. *Id.* Both BMS and Janssen executed agreements to negotiate the price of their respective drugs, 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 BMS, Janssen, and the other manufacturers of selected drugs with initial offers by February 1, 2024. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/6MVG-BZP8. Each participating manufacturer responded to the initial offer with a counteroffer by March 2. *Id.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Id.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright. *Id.* All in all, 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 July 15. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the 10 selected drugs. *Id.* Assuming that none of the 10 manufacturers withdraws from Medicare and Medicaid by December 2025, these prices will take effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

D. Prior Proceedings

BMS and Janssen filed these lawsuits in the summer of 2023, before CMS had published the list of selected drugs. They asserted claims under the Takings Clause of the Fifth Amendment, the compelled speech doctrine of the First Amendment, and the unconstitutional conditions doctrine. JA74-80; JA467-73. The matters were briefed on a coordinated schedule in district court, and the parties filed cross-motions for summary judgment.

After oral argument, the district court granted summary judgment to the government on all of plaintiffs' claims. The court held that the Negotiation Program did not effect a physical taking of plaintiffs' drugs: Fundamentally, the government is "not taking drugs from Plaintiffs"; rather, "BMS and Janssen want to sell their drugs to Medicare." JA18. "Selling to Medicare is a choice Plaintiffs can accept or not accept," just like "any negotiation between a purchaser and a seller." JA17. If plaintiffs are dissatisfied with the terms offered by the government, they can "exit[] from sales to Medicare" and "continue to sell their drugs to any purchaser other than the federal government." JA17.

The district court rejected plaintiffs' attempts to analogize the Negotiation Program to regulatory programs in which courts have found

takings based on the physical appropriation of property. For instance, in *Horne v. Department of Agriculture*, 576 U.S. 350 (2015), the Supreme Court considered a requirement that raisin growers "physical[ly] surrender" a percentage of their raisin crop to the government as a condition of selling raisins to anyone. *Id.* at 364. This regulation, the Court concluded, constituted a physical taking because it required that "[a]ctual raisins" be transferred from the growers to the government, and the growers lost "any right to control [the] disposition" of the raisins. *Id.* at 361, 364.

The regime in *Horne*, the district court explained, is "markedly different" from the Negotiation Program, which "applies solely to sales to Medicare." JA11-12. Unlike in *Horne*, "[t]here is no statutory provision that imposes a requirement that pharmaceutical manufacturers must set aside, keep, or otherwise reserve any of their drugs for the government's use, for the use of Medicare beneficiaries, or any other entity's use." JA12. "Nor, as Plaintiffs conceded at oral argument, does the Program require a manufacturer to physically transmit or transport drugs at the agreed price." JA12. In attempting to "distort their position to liken it to the passive role of the raisin growers" in *Horne*, the court explained, plaintiffs "strategically overlook[] the obvious point that the only way for raisin

growers to avoid the reserve requirement was to stop selling raisins altogether." JA11.

The district court also rejected plaintiffs' compelled speech claims. To participate in the Negotiation Program, a drug manufacturer must sign an agreement to negotiate and, if negotiations are successful, an agreement reflecting the drug's negotiated price. The district court held that these requirements do not amount to compelled speech. First, plaintiffs "are not being compelled or forced to participate in the Program," JA20, and they are therefore not "compelled" to sign any agreements they find objectionable, JA19. In any event, "the Program regulates conduct, not speech." JA20. The court explained that the agreements are "incidental mechanisms the government is using" to negotiate the prices that "manufacturers may charge for those specific drugs they choose to sell to Medicare." JA22. And the agreements' use of statutorily defined terms—like "maximum fair price"—does not render them expressive activity; the agreements "are ordinary commercial contracts" that "do not express views or convey beliefs." JA22-23 (quotation marks omitted). Accordingly, "a manufacturer's signature does not convey any message beyond its agreement . . . to the terms of the contract." JA23.

The district court also rejected plaintiffs' unconstitutional conditions arguments. The court noted that plaintiffs had failed to identify a "constitutional right in danger of being trampled," and thus concluded that the unconstitutional conditions doctrine "does not apply under these circumstances." JA25-26 (quotation marks omitted). Having rejected each of plaintiffs' claims, the court entered judgment in favor of the government.

Other drug manufacturers and interest groups have filed related suits across the country challenging the constitutionality and implementation of the Negotiation Program. To date, district courts in three other cases have considered such claims on the merits, and all have rejected them. *See Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *appeal pending*, No. 24-2510 (3d Cir.); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 23-01103, 2024 WL 3292657 (D. Conn. July 3, 2024), *appeal pending*, No. 24-2092 (2d Cir.); *AstraZeneca Pharm. LP v. Becerra*, No. 23-931, 2024 WL 895036 (D. Del. Mar. 1, 2024), *appeal pending*, No. 24-1819 (3d Cir.). Courts rejected two other challenges on threshold grounds. *Dayton Area Chamber of Commerce v. Becerra*, No. 3:23-cv-156, 2024 WL 3741510 (S.D. Ohio Aug. 8, 2024); *National Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024), *appeal pending*, No. 24-50180 (5th Cir.).

Two other district court cases raising related issues are pending. *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C. June 6, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. Sept. 1, 2023).

SUMMARY OF ARGUMENT

I. Courts have long recognized that government action that adjusts economic relationships, without a physical invasion or appropriation of property, does not amount to a *per se*, physical taking—and this is the only type of taking either plaintiff asserts. To establish a physical takings claim, a plaintiff must show that the government has forcibly appropriated or otherwise compelled the transfer of private property. When there is neither a physical appropriation nor any legal compulsion to provide property to the government, there is no deprivation that could give rise to a physical takings claim.

In the Inflation Reduction Act, Congress established a framework for voluntary negotiations over the prices that Medicare will pay for certain drugs. Contrary to plaintiffs' contention, the Negotiation Program simply adjusts the terms of the government's offer to purchase drugs for beneficiaries. It does not physically appropriate any manufacturer's drugs or otherwise compel their surrender. Because the Negotiation Program

does not compel plaintiffs to provide their drugs to the government or to anyone else, it does not effect a physical taking under the Fifth Amendment.

Plaintiffs err in asserting that the Negotiation Program "forces" them to sell their drugs to the government at below-market value. Plaintiffs are not legally required to make any such sales, but they argue that they have no choice because they cannot afford to forgo the profits they have long enjoyed from sales through Medicare. The courts of appeals have uniformly held that the economic pressures on the healthcare industry to participate in Medicare and Medicaid do not make such participation involuntary. This widespread recognition that economic incentives to do business with the government do not raise Takings Clause concerns is unsurprising: The fundamental question in a takings case is whether the government has "taken" private property. When a company retains the option not to sell products or services on the offered terms—but chooses to anyway because the alternative is less profitable—no "taking" has occurred.

II. The Negotiation Program does not compel speech in violation of the First Amendment by requiring participating manufacturers to enter

into agreements to negotiate and to honor any agreed-upon prices. As the district court explained, plaintiffs' compelled speech claims suffer from two independent defects. First, participation in the Negotiation Program, like participation in Medicare generally, is voluntary, and plaintiffs are thus not compelled to sign these agreements. Second, the challenged agreements implicate only non-expressive commercial conduct, not plaintiffs' speech. The agreements are the mechanisms by which the government sets the terms of the negotiation process and memorializes the outcomes of the price negotiations. Plaintiffs themselves acknowledge that "most government contracts are unlikely to violate the First Amendment," Janssen Br. 42; *see* JA23, and the agreements here are no different.

III. The Negotiation Program is not unconstitutionally coercive under *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519 (2012), nor does it violate the unconstitutional conditions doctrine. In *NFIB*, the Supreme Court held that Congress's threat to withdraw all existing Medicaid funding from States 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." *Id.* at 575 (plurality opinion) (quotation marks omitted). This federalism-based limit on

securing state compliance with federal objectives does not prevent the government from using its purchasing power as a market participant to bargain with private sellers for lower drug prices.

The unconstitutional conditions doctrine likewise does not restrict Congress's ability to establish a program to negotiate lower prices for prescription drugs. The Supreme Court has long recognized that the government may set the parameters and mechanisms through which its programs operate without infringing on participants' constitutional rights, as long as those conditions leave participants free to exercise their constitutional rights outside the scope of the government spending. Plaintiffs complain that a manufacturer that participates in the Negotiation Program must (1) enter into price-negotiation agreements, and (2) abide by the agreed-upon prices in sales of the selected drugs to Medicare beneficiaries. But these are integral parts of the Negotiation Program's operation, and they do not impede plaintiffs' ability to exercise their rights outside the scope of government spending on prescription drugs.

STANDARD OF REVIEW

This Court "review[s] the grant or denial of summary judgment de novo." *Canada v. Samuel Grossi & Sons, Inc.*, 49 F.4th 340, 345 (3d Cir. 2022) (quotation marks omitted).

ARGUMENT

I. The Negotiation Program does not effect a physical taking.

Courts have long recognized that government actions that adjust economic relationships, without a physical invasion or appropriation of property, do not amount to a physical taking under the Fifth Amendment. In the Inflation Reduction Act, Congress established a framework for voluntary negotiations over certain drug prices that fits squarely within this well-established precedent. The Negotiation Program adjusts the terms of the government's offer to purchase drugs for beneficiaries, but it does not physically appropriate any manufacturer's drugs or otherwise compel their surrender. If plaintiffs prefer not to sell selected drugs to the government on the terms that Congress has authorized CMS to pay for them, they are under no obligation to sell drugs to the government at all.

A. The government effects a physical taking only where it appropriates or compels the transfer of property.

1. 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 authorizes "possession of property." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147-48 (2021). The government can also effect a "regulatory taking[]" by, for example, imposing a regulation so burdensome that it effectively deprives the owner of the property's economic use. *See Lingle v. Chevron USA Inc.*, 544 U.S. 528, 537 (2005). Plaintiffs in these cases allege only the first type of taking—a physical appropriation of their personal property.[1]

To establish a physical takings claim, a plaintiff must show that the government has forcibly appropriated or otherwise compelled the transfer of private property. The Supreme Court analyzed one such claim in *Horne v. Department of Agriculture*, 576 U.S. 350, 364 (2015), which concerned a requirement that raisin growers "physical[ly] surrender" a percentage of

[1] *See* Janssen Br. 23 n.14 ("Janssen asserts only a physical takings claim," not "a regulatory takings claim."); BMS Br. 1, 10-11, 15-17.

their raisin crop to the government as a condition of selling raisins on the open market. The Court held that the requirement constituted a physical taking because it required the transfer of "[a]ctual raisins" from the growers to the government, and growers lost "any right to control the[] disposition" of the raisins as a result. *Id.* at 361, 364.

The Supreme Court distinguished this direct, physical appropriation of personal property from laws that merely restricted the use or limited the value of such property, and which therefore did not effect a *physical* taking. A regulation limiting the production of raisins, for instance, might well have "the same economic impact" on a farmer as a requirement to surrender raisins, but it would not amount to a physical taking. *Horne*, 576 U.S. at 362. The Court observed that this analytical "distinction flows naturally from the settled difference in [its] takings jurisprudence between appropriation and regulation," despite the similar economic consequences for the grower. *Id.* Similarly, the Court explained, a law prohibiting the sale of eagle feathers did not effect a taking, even though the law sapped the feathers of their commercial value, because the feather owners "retained the rights to possess, donate, and devise their property." *Id.* at 364 (describing the holding in *Andrus v. Allard*, 444 U.S. 51 (1979)). The

eagle-feather law neither "compel[led] the surrender of the artifacts'" nor resulted in any "physical invasion or restraint upon them," unlike the "physical appropriation" at issue in *Horne*. *Id.* (quoting *Andrus*, 444 U.S. at 65-66).

The Supreme Court recently reiterated that a physical appropriation is an essential element of a physical takings claim in *Cedar Point*, 594 U.S. 139. The plaintiffs in that case challenged a regulation "grant[ing] union organizers a right to physically enter and occupy" private farmland for up to three hours per day, 120 days a year. *Id.* at 149. In determining whether the challenged action was a physical taking, the Court explained that the "essential question" is "whether the government has physically taken property for itself or someone else." *Id.* Because the challenged provision granted third parties a right to "literally," "physically invade the growers' property," the Court held that this government-authorized physical occupation amounted to a physical taking. *Id.* at 152.

2. When there is no mandate to provide property to the government or to any third party, there is no government deprivation that could give rise to a physical takings claim. *See Lingle*, 544 U.S. at 539; *Bowles v. Willingham*, 321 U.S. 503, 517-18 (1944). Accordingly, when an entity

"voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide" goods or services, "and thus there can be no taking." *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (citing cases); *see Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009).

Applying these general principles, the courts of appeals have uniformly rejected takings challenges to pricing restrictions in Medicare, on the grounds that "participation in the Medicare program is a voluntary undertaking." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991). Unlike public utilities, which "generally are compelled" by statute "to employ their property to provide services to the public," *Garelick*, 987 F.2d at 916, no statute or regulation requires entities to sell their products or services to Medicare. As a result, whether addressing regulations limiting physician fees, nursing-home payments, or hospital reimbursements, courts have been unequivocal: Because providers are not required to offer services to Medicare beneficiaries, the government deprives them of no property interest for purposes of the Fifth Amendment when it limits the amount it will pay for such services. *See Southeast Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) ("[Plaintiff] voluntarily chose to participate in the Medicare hospice program. 'This

voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation.'" (alteration omitted) (quoting *Minnesota Ass'n of Health Care Facilities v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984))).[2]

B. The Negotiation Program does not physically appropriate or otherwise compel the transfer of plaintiffs' property.

1. In contending that the Negotiation Program effects a physical taking of property, plaintiffs characterize their asserted property interest in two ways. They point to the physical doses of their medicines, Eliquis and Xarelto, *see, e.g.*, BMS Br. 15, 17; Janssen Br. 18, 53, and to a more abstract "right[] to control the disposition of, and set the terms of access to," these

[2] *See also Garelick*, 987 F.2d at 916; *Franklin Mem'l Hosp.*, 575 F.3d at 129; *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991) (rejecting takings challenge to reimbursement under Medicare because "[o]nly hospitals that voluntarily participate in the federal government's Medicare program must comply"); *Baptist Hosp. East v. HHS*, 802 F.2d 860, 869-70 (6th Cir. 1986); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875-76 (7th Cir. 1983) (per curiam); *see also Baker Cty. Med. Servs., Inc. v. U.S. Attorney Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014) (rejecting hospital's "challenge [to] its rate of compensation in a regulated industry for an obligation it voluntarily undertook . . . when it opted into Medicare").

medicines, Janssen Br. 23, 25; *see also* BMS Br. 16. The Negotiation Program takes neither.

With respect to the physical doses, there can be no serious argument that the Negotiation Program mandates any direct, physical appropriation of this property. Plaintiffs do not allege that CMS will "sen[d] trucks to [Janssen's or BMS's] facility at eight o'clock one morning" to haul away their products—like the Department of Agriculture did in *Horne*. 576 U.S. at 356. "Nor, as Plaintiffs conceded at oral argument, does the Program require a manufacturer to physically transmit or transport drugs" at the agreed-upon price. JA12 (citing Oral Arg. Tr. 58:12-13). Finally, as the district court observed, there is "no statutory provision" requiring manufacturers to "set aside, keep, or otherwise reserve any of their drugs for the government's use, for the use of Medicare beneficiaries, or any other entity's use." JA12. Because the Negotiation Program in no way forces manufacturers to surrender their drugs—to the government or to anyone else—it bears no resemblance to a classic or "physical" taking. *See Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982).

Pointing to the Supreme Court's use of the word "access" in takings cases concerning access to real property, plaintiffs alternatively cast their

property interest in terms of "access" to the drugs, arguing that the Negotiation Program effects a physical taking by requiring them to "grant[] Medicare participants access to [their drugs] over [their] objection." Janssen Br. 23; *see* BMS Br. 16 ("That special 'access' requirement [in the Negotiation Program] amounts to a taking."); *see also Cedar Point*, 594 U.S. at 152 (discussing a "regulation [that] appropriates a right to physically invade the growers' property—to literally 'take access'"). For the reasons explained below, the Negotiation Program does not require plaintiffs to provide Medicare beneficiaries "access" to any drugs at all: Sales to Medicare are voluntary. If plaintiffs object to the terms of the government's offer, they can refuse the offer and instead sell their drugs to other buyers. *See infra* pp. 32-36.

In any case, a regulation concerning the "terms of access" to personal property short of physical appropriation does not give rise to a physical takings claim. Here, there is no physical appropriation to speak of. If a manufacturer chooses to participate in the Negotiation Program, and if it agrees to a negotiated price for a selected drug, the manufacturer may not charge Medicare beneficiaries more than the negotiated price for the selected drug. Under the Negotiation Program framework, manufacturers

thus agree to provide "access" to that price to Medicare beneficiaries who are dispensed, furnished, or administered the selected drug. 42 U.S.C. § 1320f-2(a)(1), (3). But the statute does not require the manufacturer to make any sales of the drug to Medicare in the first instance, and it does not require the manufacturer to provide any party with physical access to the drugs over the manufacturer's objection.[3]

Finally, to the extent plaintiffs assert instead that the Negotiation Program *interferes* with their purported "rights to . . . set the terms of access to" their drugs, Janssen Br. 25—meaning the amount they will be paid by the government for Medicare sales—they again allege no physical appropriation. And plaintiffs have no constitutionally protected property interest in selling their drugs to Medicare at any particular price. "[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). Plaintiffs' attempt to locate a constitutional

[3] Plaintiffs cite *Cedar Point* for the proposition that an "access" requirement can amount to a physical taking, but as discussed above, *Cedar Point* underscores that physical takings arise from "Government action that physically appropriates property," as by granting access to private farmland in that case. 594 U.S. at 149.

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 Medicare reimbursement rates. *See, e.g.*, *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013); *Garelick*, 987 F.2d at 917 (collecting cases). 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.

2. While the government has the "right to decide how it will spend taxpayer money," plaintiffs, too, have the "right to decide whether . . . to sell their drug[s]" on the terms the government is offering. JA18. The Negotiation Program does not abridge that right because it "neither requires nor forces Plaintiffs to give or sell their drugs" to the government or to any third party. JA13. Thus, if plaintiffs are dissatisfied with the terms of the government's offer, they can refuse to sell. If they choose

instead to accept the offer, they cannot then complain that the government has taken their property without just compensation.

The Negotiation Program altered the terms on which the government is willing to purchase drugs, but it does not require any pharmaceutical company to accept those terms. Instead, it gives companies a choice whether to continue doing business with the government on the terms the government is presently offering. As CMS noted, "the IRA 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; *see also* 26 U.S.C. § 5000D(c)(1). Thus, as with other restrictions on Medicare spending, providers may choose whether to accept participation on these terms. As the district court put it, "[s]elling to Medicare is a choice Plaintiffs can accept or not accept." JA17; *see also, e.g.*, *Southeast Ark. Hospice*, 815 F.3d at 450.

It makes no difference that the government spends significant money on drugs for Medicare and Medicaid, and that this money translates into substantial, but tightly controlled, commercial opportunities for pharmaceutical companies. The government exercises considerable market

power across a range of contexts—indeed, in some circumstances, such as defense spending, it may be the only market participant—but that basic reality has never been understood to elevate the government's bargaining terms into matters of constitutional concern. *Cf. Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127-28 (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 other branches of government.). Accordingly, the government has for decades offered to purchase drugs subject to an extensive set of statutory and regulatory requirements that plaintiffs have previously accepted. For example, as a condition on their participation in Medicaid, plaintiffs have long been required to enter into agreements that give the Department of Defense, 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). Pursuant to another condition on Medicaid participation, plaintiffs have likewise 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 Services Act).

For each of these programs, providers must choose whether to do business with the government on the terms that the government is offering, and these choices are voluntary. The Negotiation Program works the same way. Any company that rejects the government's offer "can continue to sell [its] drugs to any purchaser other than the federal government," JA17, including to private insurance plans and to buyers in international markets. Because the Negotiation Program does not restrict plaintiffs' ability to possess, use, and dispose of their drugs as they choose, there is no basis for a takings claim.

C. There is no merit to the suggestion that the profitability of Medicare and Medicaid participation renders such participation involuntary.

1. Plaintiffs' takings argument rests on the erroneous assertion that they are "forced" to sell their drugs to the government because they cannot afford to forgo the profits they have long enjoyed from sales through Medicare and Medicaid. But the courts of appeals have uniformly held that the economic pressures on the healthcare industry to participate in Medicare and Medicaid do not make such participation involuntary. Economic or other practical "hardship is not equivalent to legal compulsion for purposes of [a] takings analysis." *Garelick*, 987 F.2d at 917.

Even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicaid provides the vast majority of a nursing home's revenue—courts have emphasized that the decision to participate in the program "is nonetheless voluntary." *Minnesota Ass'n*, 742 F.2d at 446; *see also St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"); *Whitney v. Heckler*, 780 F.2d 963, 972 n.12 (11th Cir. 1986) (same).

Indeed, although courts have consistently recognized that forgoing the opportunity to sell drugs and services to Medicare can come at a high cost, plaintiffs have admitted to finding no "case law in this circuit or any other that holds that the participation in the Medicare system is not voluntary." JA14 (quotation marks omitted). This widespread recognition that economic incentives to do business with the government, regardless of their magnitude, do not raise Takings Clause concerns is unsurprising: The fundamental question in a takings case is whether the government has "taken" private property. When a company retains the option not to sell products or services on the offered terms—but chooses to anyway because the alternative is less profitable—no "taking" has occurred.

2. Plaintiffs contend that their ability to withdraw from Medicare and Medicaid (and thus avoid the terms of the Negotiation Program) is no different from the option of the farmers in *Horne* to withdraw from the raisin market (and thus avoid the requirement to turn over raisins to the government). They therefore conclude that, "under *Horne*, [the] ability to exit Medicare and Medicaid to avoid the [Negotiation] Program is irrelevant to the takings analysis." Janssen Br. 33. This attempted analogy fails.

The *Horne* Court held that there was no voluntary exchange because (1) the government was not actually offering anything in exchange for the raisins, and (2) the farmers were legally compelled to transfer the raisins to the government unless they stopped selling raisins altogether. The Court explained that "[s]elling produce in interstate commerce" is a "basic and familiar use[] of property" that people already enjoy, not something the government gave to the farmers as part of an exchange. *Horne*, 576 U.S. at 366; *see also id.* (distinguishing *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984), in which the Court held that an EPA requirement to disclose certain information that included trade secrets in exchange for a license to sell hazardous chemicals was not a taking). The farmers' only options,

besides turning over their raisins, were to sacrifice their preexisting ability to engage in the ordinary commercial activity of selling produce on the open market, or to pay a fine equivalent to the fair market value of the raisins that they were otherwise obligated to turn over.

An offer from the government to pay for drugs for Medicare beneficiaries, which plaintiffs can take or leave, bears no resemblance to the demand for raisins in *Horne*. Here, the government is not demanding plaintiffs' drugs; it is making an offer to *purchase* them, and plaintiffs can reject this offer or accept it. The government is thus proposing a transaction and offering something of value to which plaintiffs have no pre-existing right—unlike the raisin farmers' ability to "sell produce in interstate commerce," which is not a thing of value provided by the government. And unlike in *Horne*, the plaintiff drug companies here may reject the government's offer without prejudice to any pre-existing property interest, including their ability to sell their drugs to other buyers.

Plaintiffs also err in describing the excise tax as a penalty akin to the fine assessed for failure to comply with the raisin requirement in *Horne*. If plaintiffs choose not to sell their drugs to the government through Medicare, they will face no excise tax nor any restriction on their ability to

sell their drugs to any willing buyer. The plaintiffs in *Horne* were not given a similar choice. While the excise tax provision gives pharmaceutical companies that do not wish to participate in the Negotiation Program an option other than withdrawing from Medicare and Medicaid—*i.e.*, continuing to sell their drugs to Medicare at non-negotiated prices and paying an excise tax on those sales, 26 U.S.C. § 5000D—they are not limited to that option. A manufacturer may instead opt out of business with the government by withdrawing from Medicare and Medicaid, in which case it would not be subject to any excise tax, and it would retain its ability to sell its drugs to other buyers. The existence of the excise tax option does not negate plaintiffs' fundamental ability to walk away from any deal with the government (and pay no excise tax) if they are dissatisfied with the terms on which the government is willing to do business. *See* JA17 ("There are alternatives for Plaintiffs to explore should they choose, including exiting from sales to Medicare in the first instance.").[4]

[4] Janssen makes a passing reference to the perceived difficulty of the withdrawal process. *See* Janssen Br. 50 n.29. But 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

Continued on next page.

The same is true for any other alternative, including the possibility that a manufacturer may divest its interest in the selected drug or end sales of a selected drug but continue to sell its other drugs to Medicare. Plaintiffs disagree that these are satisfactory alternatives. *See* BMS Br. 19-24. But plaintiffs' satisfaction with these options has no bearing on their ability to reject the government's offer to purchase drugs for Medicare and Medicaid in the first place.

3. Plaintiffs are incorrect in suggesting that *NFIB*, 567 U.S. 519 (2012), recognized an independent limit on the government's ability to set the terms of procurement offers. Plaintiffs cite no authority to support this reading, and for good reason.

In *NFIB*, the Court determined that Congress exceeded the "limits on [its] power under the Spending Clause to secure state compliance with federal objectives," thus "violat[ing] the basic principle that the 'Federal

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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. In any event, Janssen's complaints are purely academic. Neither Janssen nor BMS has indicated that it wishes to withdraw from the Negotiation Program or from Medicare and Medicaid; rather, both companies have successfully negotiated prices for each of their selected drugs.

Government may not compel the States to enact or administer a federal regulatory program.'" 567 U.S. at 575-76 (plurality opinion) (quoting *New York v. United States*, 505 U.S. 144, 188 (1992)). It did so by threatening to withhold existing grants of Medicaid funding as a means of "coerc[ing] a State to adopt a federal regulatory system as its own." *Id.* at 578.

As explained in greater detail below, *infra* pp. 52-56, *NFIB* thus addresses federalism-based limits on the conditions that Congress may attach to money it grants to States. *See NFIB*, 567 U.S. at 579 (plurality opinion). These limits on Congress's ability to "encourage a State to regulate in a particular way," *id.* at 576 (quotation marks omitted), do not similarly restrict the government's ability to procure goods from private companies.

II. The Negotiation Program does not compel manufacturers' speech.

The district court also correctly rejected plaintiffs' claims that the Negotiation Program compels speech in violation of the First Amendment. As the district court recognized, plaintiffs' compelled speech claims suffer two independent defects. First, because participation in the Negotiation Program is voluntary, nothing compels manufacturers to engage in the

conduct that plaintiffs describe as compelled speech. And second, the Negotiation Program implicates only non-expressive, commercial conduct; any effects on manufacturers' speech are incidental at best.

A. The voluntary Negotiation Program does not compel speech.

Plaintiffs' compelled speech claims fail at the first hurdle because the Negotiation Program does not compel drug manufacturers to do anything, much less engage in protected speech. This Court has made clear that "[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) (quoting *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005)). Plaintiffs face no "actual compulsion" to engage in any speech because their participation in the Negotiation Program, like their participation in Medicare and Medicaid, is voluntary.

As explained above, manufacturers are subject to the Negotiation Program's terms—including any requirement to sign a negotiation agreement—only if they choose to do business with the government by selling their drugs to Medicare and Medicaid. Just as nothing compels plaintiffs to participate in Medicare and Medicaid in the first instance,

nothing compels them to engage in any form of protected speech. The voluntariness of the Negotiation Program and any attendant "speech" requirements is fatal to plaintiffs' claims. *See, e.g.*, *C.N.*, 430 F.3d at 189 (rejecting compelled speech claim in the absence of "the compulsion necessary to establish a First Amendment violation").

If a manufacturer does choose to participate in the Program, the IRA leaves participants at liberty to say what they wish about the Negotiation Program. As the district court explained, "nothing in the statute prevents Plaintiffs from publicly criticizing the Program or the final drug prices." JA24. Indeed, manufacturers have not been shy in doing so. *See, e.g.*, PhRMA, *Inflation Reduction Act's Unintended Consequences*, https://perma.cc/JXL4-DNND. Manufacturers are free to voice those objections without penalty, whether or not they choose to participate in the Negotiation Program. *Cf. Rumsfeld v. Forum for Acad. & Institutional Rights, Inc. (FAIR)*, 547 U.S. 47, 60 (2006). The IRA thus "neither limits what [drug manufacturers] may say nor requires them to say anything." *Id.*

B. The Negotiation Program regulates conduct, not speech.

Plaintiffs' First Amendment claims also fail for the independent reason that the Negotiation Program does not regulate plaintiffs' constitutionally protected speech.

1. The First Amendment guarantees the right to "freedom of expression." *Texas v. Johnson*, 491 U.S. 397, 406 (1989) (quotation marks omitted). Although the right extends beyond the "the spoken or written word," *id.* at 404, the Supreme Court has "rejected the view that 'conduct can be labeled "speech" whenever the person engaging in the conduct intends thereby to express an idea,'" *FAIR*, 547 U.S. at 65-66 (quoting *United States v. O'Brien*, 391 U.S. 367, 376 (1968)). The Court instead "has limited First Amendment protections to what it has called 'inherently expressive' conduct." *Falcone v. Dickstein*, 92 F.4th 193, 206 (3d Cir. 2024) (quoting *FAIR*, 547 U.S. at 66). "It is possible to find some kernel of expression in almost every activity a person undertakes—for example, walking down the street or meeting one's friends at a shopping mall—but such a kernel is not sufficient to bring the activity within the protection of the First Amendment." *City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989).

To the contrary, it is well established that "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 one such 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, but the price regulation poses no First Amendment problem because any "effect on speech would be only incidental to its primary effect on conduct." *Id.*; *see also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality opinion) (minimum prices or taxes would not restrict speech); *id.* at 524 (Thomas, J., concurring in part and concurring in the judgment); *id.* at 530 (O'Connor, J., concurring in the judgment); *Nicopure Labs, LLC v. Food & Drug Admin.*, 944 F.3d 267, 292 (D.C. Cir. 2019) (reiterating that "ordinary price regulation does not implicate constitutionally protected speech").

This principle holds true when commercial conduct is carried out 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 G*iboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)); *see also Lowe v. SEC*, 472 U.S. 181, 232 (1985) (White, J., concurring in the result) ("[O]ffer and acceptance are communications incidental to the regulable transaction called a contract . . ."). There is no dispute on this point; rather, plaintiffs rightly acknowledge that "most government contracts are unlikely to violate the First Amendment." Janssen Br. 42; *see also* JA23 ("Plaintiffs acknowledge that 'many contracts do not express views or convey beliefs.'" (quoting BMS's Memorandum of Law in Support of Plaintiff's Motion for Summary Judgment, Dkt. No. 36-3, at 25 (No. 3:23-cv-03335))).

The Negotiation Program regulates only non-expressive, commercial conduct, and any effects on speech are "plainly incidental." *FAIR*, 547 U.S. at 62. As the district court explained, the Negotiation Program exists to "determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare." JA22. Manufacturers that choose to participate thus engage in negotiations with the government and agree to make any negotiated prices available when Medicare beneficiaries purchase selected drugs. *See* Revised Guidance 118-20. Because the Negotiation Program "simply regulate[s] the amount that a [manufacturer]

c[an] collect" when selling drugs to Medicare, its effect on speech is the same as an ordinary commercial contract. *Expressions Hair Design*, 581 U.S. at 47. There is no dispute that such commercial arrangements between government as buyer and private party as seller raise no First Amendment concerns, and the Negotiation Program is no different.

Any speech implicated by the agreements themselves is similarly incidental to this regulation of conduct. *FAIR*, 547 U.S. at 65. The "agreements are ordinary commercial contracts" that the "government is using to set" agreed-upon prices. JA22-23. Healthcare providers and other entities execute similar agreements to memorialize their acceptance of the terms for participation across a range of federal healthcare programs. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b), (c), 1395w-102(b)(1); *see also* CMS, Form CMS-460, *Medicare Participating Physician or Supplier Agreement*, https://perma.cc/WG64-ZNPL. Such agreements are "not directed at the communication of information," and any incidental effect on speech "is imposed 'for reasons unrelated to the communication of ideas.'" *Nicopure Labs*, 944 F.3d at 291 (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001)).

Plaintiffs' objection to the agreements' use of "statutory terms of art that are defined in the [Negotiation] Program's statutory text" fails for similar reasons. JA23. The use of statutory terms in these agreements promotes consistency and clarity. For example, the IRA defines the term "maximum fair price," 42 U.S.C. § 1320f(c)(3), and "[w]hen 'maximum fair price' is used in the agreements, its meaning reflects its statutorily defined definition." JA24 (citing *Meese v. Keene*, 481 U.S. 465, 484 (1987)). These terms of art accurately describe the operation of the Program and do not convey or require plaintiffs to endorse any view regarding the value of their drugs. Indeed, the agreements state explicitly that a manufacturer's signature reflects neither an "endorsement of CMS' views" nor a representation of the manufacturers' views concerning the fairness of prices. JA680. And they explain that the use "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.* This language confirms that the agreements use statutory terms as a way of ensuring a consistent understanding of the Program terms and the parties' obligations by reference to the statute, not

as a means of compelling manufacturers to express a view about the value of their drugs.

2. Recognizing that commercial and contractual arrangements raise no First Amendment concerns even when they have incidental effects on speech, plaintiffs attempt to recharacterize the Negotiation Program as a "speech mandate" that Congress devised for the *purpose* of deceiving the public. BMS Br. 33. Plaintiffs' arguments in this respect are premised on unsubstantiated accusations that Congress designed the negotiation process for the purpose of forcing drug manufacturers to amplify the government's allegedly deceitful message about drug prices. *See* BMS Br. 33 (declaring that the negotiation and agreement process has "*zero* conduct-based justification," and that Congress "rout[ed] the IRA's mandates through 'agreements'" for the purpose of "deceiv[ing] the public for political ends"); BMS Br. 2, 27; Janssen Br. 2, 4, 21, 39, 46.

Plaintiffs are incorrect. Congress employed the negotiation and agreement process as familiar mechanisms for arriving at an agreed-upon price and committing the parties to a shared understanding of their contractual obligations. It is simply not true, as plaintiffs insist, that "a direct price regulation would have equally served Congress's economic

goals," and that "[t]he only marginal benefit of an intervening 'agreement' is to deceive the public for political ends." BMS Br. 33. Instead, by establishing a framework for negotiation, Congress made clear that it wanted CMS to hear from manufacturers. And CMS did so. The negotiations did not entail a one-sided imposition of a government price. Rather, CMS made opening offers for each drug, and "[d]uring the course of the negotiation process" that followed, "CMS revised its offers for each of the drugs upward in response to" discussions with manufacturers. CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, *supra*. In four instances, CMS directly accepted counteroffers proffered by manufacturers in connection with the negotiations. *See id.* These results would not have been possible but for the genuine negotiation process designed by and carried out through the Negotiation Program.

III. The Negotiation Program is neither unconstitutionally coercive under *NFIB*, nor does it violate the unconstitutional conditions doctrine.

As explained above, plaintiffs' constitutional objections to the Negotiation Program fail for the fundamental reason that their participation in Medicare and Medicaid is voluntary: The government

neither compels them to sell their drugs nor requires them to sign contractual agreements and accept the government's offered price. Despite decades of precedent confirming the voluntariness of Medicare participation, plaintiffs contend that their participation is coerced, citing *NFIB* and the unconstitutional conditions doctrine for the proposition that the Constitution limits Congress's ability to negotiate the prices the government pays for goods from private parties in the market. But plaintiffs' arguments rest on a mischaracterization of the relationship between Congress and pharmaceutical companies, coupled with a misreading of the relevant case law. These decisions confirm that the government may use its leverage as a market participant to negotiate the prices that it will pay for high-cost drugs.

A. *NFIB* does not restrict the government's ability to set the commercial terms under which it will purchase drugs.

Plaintiffs rely heavily on the Supreme Court's decision in *NFIB* for the proposition that Congress cannot use its economic leverage to dictate the terms according to which it will pay for goods sold by private parties. But *NFIB* does not limit the government's ability to bargain for lower prices as a market participant, and plaintiffs cite no authority to the contrary.

In *NFIB*, the Court reviewed the constitutionality of a statutory provision requiring States to expand Medicaid eligibility or risk losing all of their existing Medicaid funding. 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.'" *NFIB*, 567 U.S. at 575-76 (plurality opinion) (quoting *New York*, 505 U.S. at 188). The Medicaid expansion thus exceeded Congress's legislative powers under the Spending Clause "to secure state compliance with federal objectives." *Id.* at 576-78.

Plaintiffs 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. Both before and after *NFIB*, courts have uniformly rejected the idea that the lucrative nature of Medicare and Medicaid coerces private parties. *See, e.g.*, *Baker Cty. Med. Servs., Inc. v. U.S. Attorney Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014); *Garelick*, 987 F.2d at 917; *Minnesota Ass'n*, 742 F.2d at 446; *St. Francis Hosp.*, 714 F.2d at 875. And rightly so: The *NFIB* "coercion" framework addresses—and is derived exclusively from cases analyzing—how *federalism* principles inform what conditions Congress may attach to money

it grants to *States*. *See NFIB*, 567 U.S. at 579-81 (plurality opinion) (discussing, *inter alia*, *South Dakota v. Dole*, 483 U.S. 203 (1987)). As the lead opinion in *NFIB* emphasizes, those principles protect "the status of the States as independent sovereigns in our federal system." *Id.* at 577; *see id.* at 579-81 (discussing "coercion" as a limit on Congress's ability to induce States to adopt policy changes); *see also Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (explaining that the *NFIB* "coercion" inquiry "describe[s] the federal government's limited constitutional authority under the Spending Clause to regulate the states, not a federal agency's ability to regulate [private] facilities' use of federal funding" (citation omitted)), *cert. denied*, 143 S. Ct. 294 (2022).

The same analysis does not apply when, rather than using grant conditions to "encourage[]" States to regulate, Congress sets terms for how the federal government will pay for goods sold by private parties. *NFIB*, 567 U.S. at 579-81 (plurality opinion) (quoting *New York*, 505 U.S. at 175). It "has long been recognized that the government, like private individuals and businesses, has the power 'to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.'" *Ray Baillie Trash Hauling, Inc. v. Kleppe*, 477 F.2d 696, 709 (5th

Cir. 1973) (quoting *Perkins*, 310 U.S. at 127). Any downward "pressure" on prices that Congress may exert through the terms of its procurement offers is analogous to the leverage of any well-funded market participant, which is of no constitutional import.

Indeed, courts have long distinguished, for constitutional purposes, between the government acting "as a regulator" and the government acting as "a market participant" vindicating a "legitimate proprietary interest." *Chamber of Commerce v. Brown*, 554 U.S. 60, 70-71 (2008); *see also Building & Constr. Trades Council of the Metro. Dist. v. Associated Builders & Contractors of Mass./R.I., Inc.* (*Boston Harbor*), 507 U.S. 218, 229 (1993) (discussing the "conceptual distinction between regulator and purchaser"). This distinction reflects "the principle that a government, just like any other party participating in an economic market, is free to engage in the efficient procurement and sale of goods and services." *Associated Builders & Contractors Inc. N.J. Chapter v. City of Jersey City*, 836 F.3d 412, 417-18 (3d Cir. 2016) (citing *Chamber of Commerce*, 554 U.S. at 70; *Boston Harbor*, 507 U.S. at 228-30; *Reeves, Inc. v. Stake*, 447 U.S. 429, 437-40 (1980)); *see also Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006) (confirming that the

government can be a market participant even when it regulates "the specific market in which it participates").

This principle applies similarly to other terms that the government imposes in the context of voluntary programs. As the Supreme Court recently observed in upholding a COVID-19 vaccination requirement for workers in facilities funded by Medicare or Medicaid, "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions." *Biden v. Missouri*, 595 U.S. 87, 94 (2022) (per curiam). Such conditions have not been held to be coercive under *NFIB*; indeed, the Supreme Court upheld the vaccination requirement against that very argument. *See* Response to Application for a Stay Pending Appeal at 27, *Becerra v. Louisiana*, Nos. 21A240, 21A241, WL 8939385, at *27 (U.S. Dec. 30, 2021) (arguing that the vaccination "condition was impermissibly coercive because the consequence of opting out would be the loss of *all* Medicare and Medicaid funds" (citing *NFIB*, 567 U.S. at 580-81 (plurality opinion))).

In procuring drugs for beneficiaries, Congress has legitimate interests in achieving the best prices it can for American taxpayers and ensuring the financial integrity of public prescription drug programs for years to come.

The Negotiation Program vindicates these interests, and any potential effect on plaintiffs' profits does not raise constitutional "coercion" concerns.

B. The Negotiation Program does not leverage a discretionary benefit to compel waivers of constitutional rights.

As a final recourse, plaintiffs invoke the unconstitutional conditions doctrine, which provides that the government may not require 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).[5] Contrary to plaintiffs' contention, the government acted well within its authority in modifying the terms of its offer to include the Negotiation Program provisions. The unconstitutional conditions doctrine does not operate as a constraint on the government's broad discretion to set the commercial terms of its offers to purchase goods. In any case, the challenged provisions do not set unrelated, external conditions on the eligibility for a government benefit,

[5] Plaintiffs' complaints take slightly different approaches to the unconstitutional conditions argument. BMS invokes the doctrine as an ancillary argument in support of its First and Fifth Amendment claims, JA77-80, whereas Janssen asserts violations of the unconstitutional conditions doctrine as a standalone claim, JA471-72. Both versions of the argument fail for largely the same reasons.

and they do not impede plaintiffs' ability to exercise their rights outside the scope of government spending on prescription drugs.[6]

1. As an initial matter, plaintiffs err in attempting to export the principles of the unconstitutional conditions doctrine to the context of government procurement. As plaintiffs repeatedly acknowledge, this doctrine concerns the provision of government benefits, such as federal financial assistance to universities and other nonprofits, welfare benefits, or land-use permits. *See* Janssen Br. 52 (explaining that the doctrine "specifically applies when a person . . . 'has *no* "right" to a valuable governmental benefit'"); *see also* BMS Br. 43-45, 47. The doctrine was developed in light of an understanding that, in many such contexts, the recipient is entirely dependent on the government's grace in continuing to

[6] During their discussion of unconstitutional conditions, plaintiffs observe that the Supreme Court has developed a special framework for analyzing the constitutionality of land-use exactions in *Nollan v. California Coastal Commission*, 483 U.S. 825, 834-37 (1987), and *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994). The Supreme Court has made clear that the *Nollan and Dolan* test is reserved for the "'special application' of . . . land-use permits." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013); *see also Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005) (noting the "special context of land-use exactions"). Indeed, plaintiffs recognize that this framework applies "in the context of real property," which is not at issue here. BMS Br. 43.

grant certain "privilege[s] which may be vital" for daily living. *Frost v. Railroad Comm'n*, 271 U.S. 583, 593 (1926) (striking down a condition on the use of state highways). Consistent with that history, the Supreme Court's unconstitutional conditions cases all arise in the context of the government's conferral of a benefit. *See, e.g.*, *Agency for Int'l Dev. v. Alliance for Open Soc'y Int'l, Inc.* (*AID*), 570 U.S. 205 (2013) (federal grants to nongovernmental organizations to combat HIV/AIDS); *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013) (land-use permits); *FAIR*, 547 U.S. 47 (federal funding for universities); *United States v. American Library Ass'n*, 539 U.S. 194 (2003) (federal assistance to public libraries); *Legal Servs. Corp. v. Velazquez*, 531 U.S. 533 (2001) (funding to organizations providing legal representation to indigent clients); *FCC v. League of Women Voters of Cal.*, 468 U.S. 364 (1984) (financial assistance to educational public broadcasters); *Memorial Hosp. v. Maricopa County,* 415 U.S. 250 (1974) (free medical care for the needy); *Shapiro v. Thompson*, 394 U.S. 618 (1969) (welfare benefits).

The conferral of a discretionary government benefit is materially different from a bargained-for exchange, like an agreement to purchase goods at a negotiated price. In the context of a commercial transaction,

each party comes to the table with something to offer, and thus with some bargaining power. A beneficiary has no such leverage: If the government chooses to withhold a benefit, it can do so without giving anything up in return. The latter circumstance can create opportunities for constitutionally suspect government coercion, and the unconstitutional conditions doctrine exists to address that concern. *Cf. Hannegan v. Esquire, Inc.*, 327 U.S. 146, 155–56 (1946) (explaining that, although Congress has broad latitude in regulating the postal service, "grave constitutional questions are immediately raised once it is said that the use of the mails is a privilege which may be extended or withheld on any grounds whatsoever").

Plaintiffs are not similarly situated to recipients of federal benefits, and their reliance on these unconstitutional conditions "cases is unavailing, . . . because here the Government is not denying a benefit to anyone." *Rust v. Sullivan*, 500 U.S. 173, 196 (1991). While Medicare is a government benefits program, plaintiffs are not in any sense beneficiaries. They are commercial suppliers of drugs that the government purchases for beneficiaries, and plaintiffs receive billions of dollars annually in exchange for the goods they provide. Moreover, plaintiffs have substantial leverage

in negotiating the terms of these sales. Plaintiffs produce lifesaving medications, many of which cannot be sourced from other suppliers, and the government has a strong interest in facilitating beneficiaries' access to these drugs.

Plaintiffs nonetheless seek to invoke the unconstitutional conditions doctrine as a constraint on the government's ability to negotiate the commercial terms under which it will purchase goods. They cite no judicial decision applying their broad conception of the unconstitutional conditions doctrine in this context, and they offer no justification for doing so. Instead, they merely assert, without elaboration, that the doctrine must also apply "whenever the government buys or sells things." BMS Br. 48. But the government has long enjoyed broad discretion to "fix the terms and conditions upon which it will make needed purchases," *Perkins*, 310 U.S. at 127, and the unconstitutional conditions doctrine does not limit this ability to set the commercial terms of such offers.[7]

[7] While the unconstitutional conditions doctrine does not govern the commercial terms of procurement decisions, such decisions are of course not free from constitutional scrutiny. For instance, a procurement program might still violate the equal protection component of the Fifth Amendment by relying on impermissible race-based classifications. *Cf. Adarand*

Continued on next page.

2. In any event, the Negotiation Program does not require plaintiffs to relinquish a constitutional right, much less one that extends beyond the government's purchase of drugs. As the Supreme Court explained in *Rust*, the government may condition the receipt of federal funds on compliance with program-specific regulations 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." 500 U.S. at 196; *see id.* at 197 ("[O]ur '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."). This jurisprudence has consistently distinguished between provisions that impose external conditions on the *recipient* of a government benefit, on the one hand, and

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Constructors, Inc. v. Peña, 515 U.S. 200 (1995). And a program could violate the Due Process Clause if it is not rationally related to a legitimate state interest. But no such concerns are present here. "It is clear that protection of the fiscal integrity of the fund is a legitimate concern of the State," *Ohio Bureau of Emp't Servs. v. Hodory*, 431 U.S. 471, 493 (1977), and there is no doubt that the negotiation of prices is rationally related to the government's control of rising public spending on prescription drugs.

provisions that set the terms of and define the scope of government *program*s, on the other. *See id.*

In *Rust*, the Court upheld regulations that prohibited the use of federal funds for abortion counseling, emphasizing that the conditions were directly connected to the purpose of the funding, and that they did not prevent recipients from engaging in protected speech through affiliates funded by non-federal sources. *See* 500 U.S. at 196-98. Conversely, in *AID*, 570 U.S. 205, 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. This condition violated the unconstitutional conditions doctrine because it forced organizations to adopt a viewpoint well outside the scope of the funded program.

These cases underscore the permissibility of the Program terms. The IRA does not set an *external* "condition" on eligibility to sell drugs to the government; it sets the commercial terms of the government's offer to purchase these drugs. The government has a substantial interest in curbing the rising costs of public spending on prescription drugs, and the establishment of the Negotiation Program furthers that interest and

promotes the long-term fiscal integrity of the government's drug-procurement program. The terms that plaintiffs challenge—agreeing to participate in price negotiations, signing contracts reflecting agreed-upon prices, and ultimately selling drugs to Medicare at such prices—are integral to the functioning of this drug-purchasing program as structured by Congress, and they do not compel plaintiffs to surrender any rights beyond the scope of the government's spending on prescription drugs.

Under the Supreme Court's precedents, the requirements plaintiffs challenge are constitutionally permissible because they define the terms of CMS's offer to purchase drugs, and they do not impede plaintiffs' ability to exercise their rights outside of the government's prescription drug spending. For example, plaintiffs raise First Amendment objections to the Negotiation Program's alleged "speech conditions"—that is, the requirement that participating manufacturers sign (1) an agreement to negotiate, and (2) a contractual commitment after a deal is reached. Such negotiations and agreements are the mechanisms by which the government and manufacturers establish prices for the selected drugs, as well as the source of the enforceable obligation for both parties to honor those terms. *See* Revised Guidance 118-20. In this way, the agreements "define the

federal program" and do not "reach outside it." *AID*, 570 U.S. at 217. Thus, even if the agreements implicated plaintiffs' speech interests, there is no serious argument that Congress has impermissibly leveraged its spending "to regulate speech outside the contours of the program itself." *Id.* at 214-15.

Plaintiffs' Fifth Amendment objections likewise fail. Plaintiffs argue that they cannot be "mandate[d] to turn over property" as a condition of selling their drugs to Medicare and Medicaid. BMS Br. 48. As explained above, the IRA imposes no such mandate. *See supra* pp. 29-31. In any event, the unconstitutional conditions doctrine is not implicated by conditions that "govern the scope of the [federal] *project's* activities, and leave the grantee unfettered in its other activities." *Rust*, 500 U.S. at 196. Here, the negotiation of prices is the central point of Congress's decision to adjust the terms of its drug-procurement program; it thus cannot reasonably be described as an extrinsic condition imposed on the manufacturers themselves. And because plaintiffs remain free to sell their drugs to other purchasers at any price they choose, this requirement does not infringe on plaintiffs' rights "outside the scope of the federally funded program." *Id.* at 197.

Despite plaintiffs' objections, the Negotiation Program and its mechanisms of operation plainly withstand constitutional scrutiny. The program itself furthers the government's legitimate interest in "protecting the fiscal integrity of Government programs, and of the Government as a whole," *Lyng v. International Union, United Auto., Aerospace & Agric. Implement Workers of Am.*, 485 U.S. 360, 373 (1988). The challenged requirements are amply justified in light of this purpose, and they leave any participating manufacturers free to exercise constitutional rights outside the scope of CMS's prescription drug spending.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.

2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,930 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Book Antiqua 14-point font, a proportionally spaced typeface.

3. On September 9, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

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