No. 24-2968

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

NOVARTIS PHARMACEUTICALS CORP,

Plaintiff-Appellant,

v.

SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *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, Pub. L. No. 117-169, 136 Stat. 1818 (IRA), 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 drugs 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 certain high-expenditure drugs. A manufacturer that disagrees with the program terms or with the price the government is willing to pay is under no legal obligation to participate in the program.

Plaintiff Novartis Pharmaceuticals challenged the Negotiation Program as violating the Eighth Amendment's prohibition on excessive fines, the Fifth Amendment's prohibition on takings without just compensation, and the First Amendment's prohibition on compelled speech. The district court correctly concluded that it lacked jurisdiction to review plaintiff's Eighth Amendment claim, because the Anti-Injunction Act prohibits pre-enforcement suits challenging, as relevant here, the constitutionality of a tax.

The district court also correctly rejected plaintiff's takings and compelled speech claims on the merits. The Negotiation Program does not give rise to a physical taking because it neither physically takes plaintiff's drugs nor mandates their sale. The government is instead offering to purchase drugs on terms that plaintiff is under no legal obligation to accept. Plaintiff retains the option not to sell its drugs on these terms; if it does so anyway because the alternative is less profitable, it cannot plausibly complain that a taking has occurred.

The Negotiation Program is also consistent with the First Amendment and does not compel plaintiff's speech. Plaintiff objects 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 are not compelled, and they are not speech; they are commercial contracts governing the negotiation process and the parties' associated conduct.

STATEMENT OF JURISDICTION

Plaintiff invoked the district court's jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346. JA41 (Complaint). The district court's jurisdiction over plaintiff's Eighth Amendment claim is contested. *See infra* pp. 21-34. On October 18, 2024, the district court granted the government's motion for summary judgment and entered a final judgment in the government's favor. JA10-11. Plaintiff filed a timely notice of appeal on October 21, 2024. JA12-13; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the district court correctly held that it lacks jurisdiction over plaintiff's claim that the IRA's excise tax violates the Eighth Amendment's prohibition on excessive fines.

2. Whether the district court correctly rejected plaintiff's claim that the Negotiation Program effects a physical taking of its drugs by setting the terms of Medicare's offer to pay.

3. Whether the district court correctly rejected plaintiff's compelled speech claim because the Negotiation Program involves no compulsion and because the challenged provisions regulate conduct rather than speech.

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. 42 U.S.C. § 1395 *et seq.* CMS administers Medicare on behalf of the HHS Secretary.

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 prices for drugs covered under Part D or otherwise interfering in the arrangements between drug manufacturers and insurance plans. 42 U.S.C. § 1395w-111(i). But, over time, 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 Part B and Part 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 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 7. By 2021, the top 10 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 drug prices under Medicare Part B and Part D were closely linked 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 often "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. Pharmaceutical companies that wish to sell drugs to these agencies 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). Agreement to do so is a condition of participation in Medicaid, even though these agency programs are part of a separate statutory framework that operates independently of Medicaid. 42 U.S.C. § 1396r-8(a)(1). As a result, manufacturers often sell drugs to the Departments of Defense and Veterans Affairs 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

In enacting the IRA, Congress empowered the HHS Secretary, acting through CMS, to negotiate the prices that 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 high-expenditure drugs. 42 U.S.C. § 1320f-1(b), (d). The program altered the terms of the government's offer to purchase drugs for Medicare; it does not apply to the prices paid by other buyers of those drugs.

By statute, the only drugs eligible for selection in the Negotiation Program are "qualifying single source drug[s]"—*i.e.*, those that have no generic or biosimilar competitors and that have been on the market for at least seven years (for drugs) and 11 years (for biologics). 42 U.S.C. § 1320f-1(e). The IRA directs the agency to rank the resulting set of drugs according to total Medicare expenditures and select the top 10 drugs on the list for the first negotiation cycle. *Id.* § 1320f-1(a)(1).

After selecting the negotiation-eligible drugs with the highest aggregate Medicare expenditures, CMS signs agreements with manufacturers willing to engage in the negotiation process. 42 U.S.C. § 1320f-2. The goal is to reach agreement on what the statute refers to as the "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 it directed the agency to "aim[] to achieve the lowest maximum fair price" that the manufacturer will accept, *id.* § 1320f-3(b)(1). If negotiations are 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. For drugs selected for the first negotiation cycle, any negotiated prices will take effect for Part D on January 1, 2026. *Id.* § 1320f(b)(1), (2). For Medicare Part B, any negotiated prices will take effect in 2028. *See id.* § 1320f-1(a)(3).

A drug manufacturer that does not wish to participate in the Negotiation Program has several options. Because participation in Medicare is voluntary, any manufacturer may withdraw from Medicare and Medicaid (with 30 days' notice to CMS) and thus not be subject to any of the Negotiation Program's requirements. 26 U.S.C. § 5000D(c)(1); *see also* JA383-84 (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 may transfer its ownership of the selected drug to another entity and continue to sell other drugs to Medicare. *See* JA394-95 (Revised Guidance 131-32). A manufacturer that pursues neither of these options may 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* JA501-05 (Internal Revenue Service Notice 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice)).

C. The Negotiation Program's Implementation

Congress instructed the agency 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 March 2023, CMS issued initial guidance explaining how it planned to implement certain aspects of the statute and soliciting public comment. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments* (Mar. 15, 2023), https://perma.cc/8X4K-CVD8. In June 2023, after considering thousands of comments, CMS published Revised Guidance that explains, among other things, how CMS determines which drugs may be selected for negotiation, and how the negotiation process works. *See* JA354-55 (Revised Guidance 91-92). It also sets out procedures for manufacturers to follow if they decide not to negotiate. JA381-83, 392-94 (Revised Guidance 118-20, 129-31). Specifically, it explains that a manufacturer can opt out of the Negotiation Program by notifying CMS of its decision to withdraw from Medicare and Medicaid. *Infra* pp. 55-56 (explaining that the withdrawal will become effective within 30 days of the notice).

Treasury and the Internal Revenue Service (IRS) have issued notices and rules outlining their interpretation of the Negotiation Program's excise-tax provision. *See* JA501-05 (IRS Notice). As the IRS explained, 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," not on drugs dispensed, furnished, or administered outside

Medicare. JA503 (IRS Notice 3). In January 2025, the IRS published a notice of proposed rulemaking consistent with the 2023 Notice's substantive interpretations of the tax. Excise Tax on Designated Drugs, 90 Fed. Reg. 31 (Jan. 2, 2025).

In August 2023, CMS published the list of drugs selected for the first negotiation cycle. *See* Press Release, 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. Plaintiff's drug Entresto was among the drugs selected for negotiation, and plaintiff executed an agreement to negotiate Entresto's price with CMS. *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.

Over the spring and summer of 2024, CMS engaged in robust negotiations with the manufacturers of each of the drugs selected for the first negotiation cycle. In accordance with the schedule established by Congress, CMS presented plaintiff 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 with a counteroffer by March 2, 2024. *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.* 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

Plaintiff filed this action in September 2023, JA32, challenging the IRA under the Excessive Fines Clause of the Eighth Amendment, the

Takings Clause of the Fifth Amendment, and the compelled speech doctrine of the First Amendment.

1. The district court dismissed plaintiff's Eighth Amendment challenge to the IRA's excise-tax provision for lack of jurisdiction under the Anti-Injunction Act, which provides that "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person." 26 U.S.C. § 7421(a). Because plaintiff sought a declaration that the tax violated the Eighth Amendment and therefore could not be assessed, the court held that the claim fell squarely within scope of this statutory bar. The court also determined that a narrow exception for cases involving irreparable injury and a "certainty of success on the merits" did not apply. JA7-8 (quoting *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974)). The court explained that plaintiff's alleged injury was not irreparable because the availability of a refund suit would adequately protect plaintiff's interests. JA8-9. And plaintiff fell well short of establishing a certainty of success on the claim given that no case "has ever held that a tax—lacking any connection to criminal conduct—was a fine for Excessive Fines Clause purposes." JA9.

2. The district court then rejected plaintiff's Fifth and First Amendment claims on the merits, relying largely on its analysis of materially identical claims in *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-3335, 23-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024); and *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024). With respect to the claim alleging a physical taking of plaintiff's drugs, the court emphasized that participation in the Negotiation Program is voluntary, such that plaintiff is under no requirement to provide drugs under the terms offered by the government. JA5. The district court also held that the Negotiation Program did not violate the First Amendment because "the Program regulates commercial conduct, not speech," JA6 and "[a]ny 'speech' aspects of the Program, such as the agreements and negotiations, are merely incidental mechanisms used during" the process for reaching a negotiated price, JA6 (quoting *Novo Nordisk*, 2024 WL 3594413, at *5).

3. Other drug manufacturers and interest groups have filed related suits challenging the constitutionality and implementation of the Negotiation Program. To date, district courts in four other cases have considered such claims on the merits, and all have rejected them. *Novo Nordisk*, 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. 23-1103, 2024 WL 3292657 (D. Conn. July 3, 2024), *appeal pending*, No. 24-2092 (2d Cir. Aug. 8, 2024); *Bristol Myers Squibb*, Nos. 23-3335, 23-3818 (D.N.J. Apr. 29, 2024), *argued*, Nos. 24-1820, 24-1821 (3d Cir. Oct. 30, 2024); *AstraZeneca Pharm. LP v. Becerra*, 719 F. Supp. 3d 377 (D. Del. 2024), *argued*, No. 24-1819 (3d Cir. Oct. 30, 2024); *see also Dayton Area Chamber of Commerce v. Becerra*, No. 23-156, 2024 WL 3741510 (S.D. Ohio Aug. 8, 2024), *appeal pending*, No. 24-3868 (6th Cir. Oct. 8, 2024). Three district court cases raising related issues remain pending. *Merck & Co. v. Becerra*, No. 23-1615 (D.D.C. filed June 6, 2023); *National Infusion Ctr. Ass'n v. Becerra*, No. 23-707 (W.D. Tex. filed June 21, 2023); *Teva Pharm. V. HHS*, No. 25-113 (D.D.C. filed January 15, 2025).

SUMMARY OF ARGUMENT

I. The district court correctly dismissed plaintiff's Eighth Amendment claim against the Negotiation Program's excise tax for lack of jurisdiction. Pre-enforcement challenges to the constitutionality of a tax are barred by the Anti-Injunction Act, which prohibits any "suit for the purpose of restraining the assessment or collection of any tax," 26 U.S.C. § 7421(a), and by the tax exception to the Declaratory Judgment Act, which prohibits issuance of declaratory judgments "with respect to Federal taxes," 28 U.S.C. § 2201(a). Because plaintiff's suit seeks to preclude implementation or enforcement of the excise tax, this claim must be dismissed for lack of subject matter jurisdiction.

Plaintiff's excise-tax claim also fails for lack of standing. A plaintiff lacks Article III standing to seek declaratory or injunctive relief if it fails to sue the entities responsible for its purported injuries. *Haaland v. Brackeen*, 599 U.S. 255, 292-93 (2023). Plaintiff's alleged injury arises from a tax assessed and collected by the IRS. But HHS and CMS are the only defendants in this action, and no judgment issued against these agencies could redress plaintiff's excise-tax injury. Although plaintiff argues that it is injured by CMS's "use of the specter" of the excise tax to negotiate for lower drug prices, Br. 24, plaintiff has not identified any actions undertaken by CMS in this respect. Any pressure related to the potential for tax liability comes from the operation of the excise tax itself, independent of any action or inaction from CMS. Only a judgment against Treasury or the IRS—neither of which is a party to this suit—could redress any injury arising from these alleged effects of the tax.

II. The Negotiation Program does not effect a physical taking of plaintiff's drugs, which is the only type of taking plaintiff alleges. To establish a physical takings claim, a plaintiff must show that the government has physically appropriated or otherwise legally compelled the transfer of private property. Although plaintiff asserts that the Negotiation Program "force[s]" it to sell drugs at below-market prices, Br. 35, it acknowledges that as a legal matter it retains the option not to sell its drug to Medicare under the terms established by the IRA.

Plaintiff contends instead that the opportunity to participate in Medicare is so profitable as to leave it with no practical choice but to accept the terms of participation. For decades, however, the courts of appeals have uniformly rejected the argument that the economic pressures to participate in Medicare and Medicaid can support a takings claim. This consistent precedent reflects a straightforward principle: When a company is not legally compelled to sell products or services on the offered terms—but chooses to do so anyway because the alternative is less profitable—no "taking" has occurred.

III. The Negotiation Program does not compel any speech. Participation in the Negotiation Program, like participation in Medicare generally, is voluntary, and plaintiff is thus not "compelled" to do or say anything. Moreover, contrary to plaintiff's assertions, the challenged agreements to negotiate and to honor any agreed upon prices do not require a manufacturer to adopt any government message or to express any views at all. They are purely commercial arrangements that pertain solely to the negotiation of prices, and they use statutorily defined language to ensure a consistent and precise understanding of the agreements' terms. Plaintiff's unsubstantiated fears about how some members of the public might perceive those agreements do not justify abrogating decades of First Amendment case law in favor of a new—and limitless—presumption of First Amendment expression in every commercial act.

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 Court lacks jurisdiction over plaintiff's Eighth Amendment challenge to the excise tax, which is in any event meritless.

A. Plaintiff's challenge to the IRA's excise-tax provision is barred by the Anti-Injunction Act and the tax exception to the Declaratory Judgment Act.

1. The Anti-Injunction Act provides that, with certain enumerated exceptions, "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person." 26 U.S.C. § 7421(a). Courts have long held that pre-enforcement challenges to the constitutionality of a tax fall squarely within the scope of this statutory bar. *See Alexander v. "Americans United" Inc.*, 416 U.S. 752, 759-60 (1974) (collecting cases).

This blanket prohibition against pre-enforcement challenges "also extends to declaratory judgments." *Bob Jones Univ. v. Simon*, 416 U.S. 725, 732 n.7 (1974). As "there is 'little practical difference' between an injunction and anticipatory relief in the form of a declaratory judgment" against a taxing provision, *Jefferson County v. Acker*, 527 U.S. 423, 433 (1999), the Declaratory Judgment Act excludes cases "with respect to Federal taxes," 28 U.S.C. 2201(a). *See also* S. Rep. No. 74-1240, at 11 (1935) (explaining that this tax exception prevents requests for declaratory relief from circumventing the "long-continued policy of Congress" against anticipatory tax suits). There is "no dispute . . . that the federal tax exception to the Declaratory Judgment Act is at least as broad as the Anti-Injunction Act." *Bob Jones*, 416 U.S. at 732 n.7.

2. A claim is barred by the Anti-Injunction Act—and therefore by the tax exception to the Declaratory Judgment Act—if (a) the exaction at issue is a "tax" within the meaning of these statutes, and (b) the purpose of the claim is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a). Because both conditions are met, the district court correctly dismissed plaintiff's excise-tax claim for lack of jurisdiction.

a. In determining whether a payment qualifies as a "tax" for these purposes, courts place particular weight on the language Congress used to describe the exaction at issue. That is because the challenged statute and the "Anti-Injunction Act . . . are creatures of Congress's own creation"—thus, "[h]ow they relate to each other is up to Congress." *National Fed'n of Indep. Bus. v. Sebelius* (*NFIB*), 567 U.S. 519, 544 (2012). As "the best evidence of Congress's intent is the statutory text," *id.*, Congress's decision to call something a tax—or not—is all but conclusive.

The Supreme Court's decision in *NFIB* illustrates this reasoning. In reviewing the constitutionality of the Affordable Care Act's individual mandate, the Court considered whether the Anti-Injunction Act barred a suit that challenged the payment levied on those without health insurance. The Court concluded that it did not: The Affordable Care Act "describe[d] the payment as a 'penalty,' not a 'tax,'" and "that label [was] fatal to the application of the Anti-Injunction Act." *NFIB*, 567 U.S. at 564.

The *NFIB* Court explained that this dispositive reliance on "Congress's choice of label on th[e] question" was grounded in longstanding precedent. 567 U.S. at 564. For over a century, the Court has consistently deferred to congressional labels in determining whether the Anti-Injunction Act applies—even when it ultimately disagreed with the label. For instance, in *Bailey v. George*, 259 U.S. 16, 20 (1922), the Court held that the Act barred a claim challenging a "tax" intended to discourage the use of child labor. But on the same day, the Court also held that this "so-called" child labor tax was, constitutionally speaking, not a tax. *Child Labor Tax Case*, 259 U.S. 20, 38 (1922). The Court has "thus applied the Anti–Injunction Act to statutorily described 'taxes' even where that label was inaccurate." *NFIB*, 567 U.S. at 544. This result follows from the Court's committed deference to the congressional label in this context: "Congress knew that suits to obstruct taxes had to await payment under the Anti–Injunction Act; Congress called the child labor tax a tax; Congress therefore intended the Anti–Injunction Act to apply." *Id.* at 564.

The Court's reasoning is controlling here, for the statutory text and structure leave no doubt that Congress considered the excise tax to be a "tax" and thus subject to the Anti-Injunction Act. The IRA provision concerning the excise tax is codified in the Tax Code (Title 26 of the U.S. Code), *see* 26 U.S.C. § 5000D; the tax is enforced by the IRS; and—most importantly—Congress describes the exaction as a "tax." *Id.* § 5000D(a) ("There is hereby imposed on the sale by the manufacturer . . . of any designated drug . . . a tax . . . ."); *id.* § 5000D(a)(1) (referring to "such tax"); *id.* § 5000D(a)(2) (same); *id.* § 5000D(c) ("Suspension of tax"); *id.* § 5000D(f)(2) (referring to "the tax imposed by this section").

b. Because the excise tax is plainly a "tax" for these purposes, plaintiff's excise-tax claim is barred by the Anti-Injunction Act and thus by the tax exception to the Declaratory Judgment Act as long as the purpose of the claim is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a); *see supra* pp. 21-22. In addressing that question, courts "inquire not into a taxpayer's subjective motive, but into the action's objective aim." *CIC Servs., LLC v. IRS*, 593 U.S. 209, 217 (2021). That aim is "best assessed" by "look[ing] to the face of the taxpayer's complaint" and, "most especially, . . . to the relief requested." *Id.* at 217-18 (quotation marks omitted). If the relief requested runs against the tax itself, the suit is prohibited. *Id.* at 219.

Plaintiff's Eighth Amendment claim is unmistakably directed toward the excise tax itself. The claim, as stated in the complaint, is that the "[Negotiation] Program's excise tax is . . . unconstitutional under the Excessive Fines Clause of the Eighth Amendment." JA84. As relief, plaintiff asks the court to "[d]eclare that the Program's 'excise tax' violates the Excessive Fines Clause," JA86, such that it cannot be enforced. The complaint thus explicitly asks the court to review—and pass judgment upon—the tax's constitutionality so as to block its enforcement. *See CIC Servs.*, 593 U.S. at 219 (explaining that a lawsuit that "target[s]" a tax is subject to the Anti-Injunction Act). For these reasons, plaintiff's Eighth Amendment claim cannot proceed.

3. Plaintiff errs in contending (Br. 23-26) that the Anti-Injunction Act is inapplicable here because, in its view, the excise tax is designed not to generate revenue but to incentivize conduct. This argument is foreclosed by decades of Supreme Court precedent making clear that the Anti-Injunction Act "draws no distinction between regulatory and revenue-raising tax rules." *CIC Servs.*, 593 U.S. at 225. Contrary to plaintiff's suggestion, the Act applies as long as "the dispute is about a tax rule," and "[t]hat is just as true when the tax in question is a so-called regulatory tax—that is, a tax designed mainly to influence private conduct, rather than to raise revenue." *Id.* at 224-25 (citing *Bob Jones*, 416 U.S. 725; *Americans United*, 416 U.S. 752; *Bailey*, 259 U.S. 16).

Plaintiff nonetheless relies on this distinction in asserting that the Anti-Injunction Act does not bar claims challenging the role that a regulatory tax plays in shaping conduct. In particular, plaintiff argues that it has not brought a claim to "restrain[] the assessment or collection of any tax," 26 U.S.C. § 7421(a), but rather a claim to "prevent the government from using the tax to" "coerce" plaintiff's participation in the Negotiation Program. Br. 25. This characterization is squarely at odds with the complaint, which candidly acknowledges that a challenge to the constitutionality of the tax itself is at the very core of the claim. *See supra* p. 25. In any event, "[t]he Supreme Court has consistently ruled . . . that plaintiffs cannot evade the Anti-Injunction Act by purporting to challenge only the regulatory aspect"—that is, the deterrent or incentivizing effect—of a regulatory tax, as plaintiff seeks to do. *Florida Bankers Ass'n v. U.S. Dep't of Treasury*, 799 F.3d 1065, 1070 (D.C. Cir. 2015) (Kavanaugh, J.).

Plaintiff's argument in this respect mirrors one the Supreme Court rejected in *Bob Jones*, which concerned an IRS notice announcing that a university's tax-exempt status would be revoked unless it abandoned its racially discriminatory policies. The university contended that the Anti-Injunction Act did not bar its lawsuit because the challenged actions did "not represent an effort to protect the revenues but an attempt to regulate the admissions policies of private universities." 416 U.S. at 739. In the university's view, the IRS's actions were an "attempt to use the onerous taxing power of the government to force recalcitrant parties in line," and thus "b[ore] no relationship to the federal revenues except to use the threat of the considerable burdens of taxation to cause a relinquishment of basic rights." Brief for the Petitioner, *Bob Jones*, 416 U.S. 725 (No. 72-1470), 1973 WL 172321, at *28, *33. Because the university understood the case to "involve[] not revenue but rather unconstitutional compulsion," *id.* at *28, it urged the Court to hold that the action was not "for the purpose of restraining the assessment or collection of any tax," 26 U.S.C. § 7421(a).

The Supreme Court squarely rejected that argument. *Bob Jones*, 416 U.S. at 738-42; *see also id.* at 741 n.12 (repudiating "such distinctions" "between regulatory and revenue-raising taxes"). In concluding that the Anti-Injunction Act barred the suit, "the Court made clear that the plaintiff['s] reasons for suing did not matter"—it was simply "irrelevant that Bob Jones University objected to the IRS's 'attempt to regulate the admissions policies of private universities.'" *CIC Servs.*, 593 U.S. at 225. "Nor did it matter that the [challenged] tax ruling was in truth an effort to change those [discriminatory] policies." *Id.* What mattered is that the "suit[] sought to prevent the levying of taxes, and so could not go forward." *Id.*

Plaintiff relies on the same argument that the Court rejected in *Bob Jones*. Like the university, plaintiff insists that "the object of [its] lawsuit is to prevent the government from using the tax to unlawfully coerce participation," not to prevent the collection of taxes. Br. 25. And plaintiff similarly argues that the IRA's excise tax is not about revenues at all, but about using the threat of taxation to coerce participation. Br. 24. But *Bob*

Jones makes clear that the Anti-Injunction Act bars such a suit regardless of whether the claim is styled as an attack on the tax or on the "specter" of its imposition, Br. 24.

4. There is likewise no merit to plaintiff's contention that its claim should be allowed to proceed because it is subject to the narrow exception acknowledged in *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1 (1962). A taxpayer's "burden under *Williams Packing* is very substantial." *Flynn v. United States ex rel. Eggers*, 786 F.2d 586, 591 (3d Cir. 1986). Under this limited exception, claims seeking to restrain the assessment of taxes may proceed only if two conditions are satisfied: (1) the plaintiff will suffer irreparable injury, *Bob Jones*, 416 U.S. at 737; and (2) it is "clear that under no circumstances could the Government ultimately prevail," even "under the most liberal view of the law and the facts," *Willams Packing*, 370 U.S. at 7. "Unless both conditions are met, a suit for preventive injunctive relief must be dismissed." *Bob Jones*, 416 U.S. at 758. As the district court explained, plaintiff's argument fails on both counts.

First, because a refund suit is an adequate remedy, plaintiff cannot establish that it will suffer irreparable harm absent preemptive injunctive relief. "This is not a case in which an aggrieved [taxpayer] has no access at all to judicial review." *Bob Jones*, 416 U.S. at 746. A manufacturer that wishes to challenge the excise tax could pay it, seek a refund from the IRS, then sue for a refund in district court or the Court of Federal Claims. *See* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491. And a taxpayer need only pay "the excise tax on a single transaction" before challenging the tax in court. *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991); *see also Flora v. United States*, 362 U.S. 145, 171–75 nn.37-38 (1960). While such a suit is pending, the IRS generally does not collect the remainder of the excise tax that would otherwise be due. IRS, *Internal Revenue Manual* § 1.2.1.6.4(6), 2007 WL 9790655.

Second, plaintiff has fallen well short of establishing a "certainty of success on the merits," *Bob Jones*, 416 U.S. at 737. As the district observed, "Plaintiff has not identified a case that has ever held that a tax—lacking any connection to criminal conduct—was a fine for Excessive Fines Clause purposes." JA9. Plaintiff's claim in this context is thus a "novel" one, and on these grounds alone far from certain to succeed. JA9 (citing *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 23-1103, 2024 WL 3292657, at *23 (D. Conn. July 3, 2024)). *See infra* pp. 34-37 (explaining that plaintiff's Eighth Amendment claim fails on the merits).

B. Plaintiff's Eighth Amendment claim is not redressable.

Plaintiff's Eighth Amendment claim would fail for lack of standing were it not otherwise barred. To show Article III standing, a plaintiff must establish that it has "suffered an injury in fact . . . that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). Redressability must be established "for each claim that [plaintiff] press[es] and for each form of relief that [it] seek[s]." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021).

As the Supreme Court recently reaffirmed in *Haaland v. Brackeen*, 599 U.S. 255, 291-96 (2023), a plaintiff lacks standing to seek declaratory or injunctive relief if it fails to sue the entities responsible for its injuries. *Haaland* concerned a dispute over the constitutionality of a federal law requiring that Native American children in adoption proceedings be preferentially placed with Native families over non-Native families. Certain plaintiffs sought a declaration that these placement preferences were unconstitutional and an injunction preventing their application. The Court held that this claim failed for lack of standing because the entities that implement the statute's placement preferences—state courts and agencies—were not parties to the lawsuit. *Id.* at 292-94. Neither an injunction nor a declaratory judgment would bind the non-party state officials so as to prevent them from applying the placement preferences. *Id.* And a declaratory judgment against the defendants would thus amount to "little more than an advisory opinion." *Id.* at 293.

Plaintiff has similarly failed to sue the entities responsible for the alleged harm. Plaintiff's alleged injury arises from a tax that is assessed and collected by the IRS, which is not a party to the lawsuit. The IRA's tax provisions are codified in the Internal Revenue Code, 26 U.S.C. § 5000D, and the Treasury, of which the IRS is a part, is charged with enforcing section 5000D and interpreting its provisions. *See id.* § 5000D(h) ("The Secretary shall prescribe such regulations and other guidance . . . ."); *see also id.* § 7701(a)(11)(B) ("When used in this title, . . . [unless otherwise stated], [t]he term 'Secretary' means the Secretary of the Treasury or his delegate."). Under this authority, the IRS has published notices and regulations implementing the section 5000D tax: In August 2023, the IRS issued a notice announcing its intent to issue regulations implementing the section 5000D tax and providing taxpayers interim guidance on substantive and procedural issues. JA501-05 (IRS Notice). In July 2024, after notice and comment, the IRS published a final rule establishing relevant procedural requirements. Excise Tax on Designated Drugs; Procedural Requirements, 89 Fed. Reg. 55,507 (July 5, 2024) (codified at 26 C.F.R. pts. 40, 47). Most recently, in January 2025, the IRS published a notice of proposed rulemaking consistent with its substantive interpretations of the tax as described in the 2023 Notice. Excise Tax on Designated Drugs, 90 Fed. Reg. 31.

Treasury and the IRS are thus the only entities responsible for enforcing the excise-tax provisions, but plaintiff has sued neither. The Court cannot enter judgment against these agencies because they are "not parties to the suit," and they would not be "obliged to honor an incidental legal determination the suit produced." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 569 (1992) (plurality opinion); *see also id.* at 570-71 ("The short of the matter is that redress of the only injury in fact respondents complain of requires action . . . *by the individual funding agencies*; and any relief the District Court could have provided in this suit against the Secretary was not likely to produce that action." (emphasis added)).

Any injunctive or declaratory judgments issued against HHS and CMS, the only defendants in this action, would not redress plaintiff's excise-tax injury. In arguing otherwise, plaintiff contends that an injunction would stop CMS from "improperly leveraging" the tax in price negotiations. Pl. Mot. for Summ. J. Reply, Dkt. No. 57, at 53-54; *see* Br. 24 (contesting CMS's alleged "use of the specter" of the excise tax). But any pressure plaintiff faces in this respect comes from the excise tax itself, not from anything CMS does or refrains from doing. If plaintiff chooses to sell the selected drug to Medicare beneficiaries at non-negotiated prices, plaintiff will incur tax liability, and the IRS can collect on that tax regardless of anything CMS does.[1]

C. Even if the Court had jurisdiction, plaintiff's Eighth Amendment claim would fail on the merits.

Plaintiff's excessive fines claim lacks merit because the excise tax is not a "fine" that implicates the Excessive Fines Clause, nor is it "excessive." These deficiencies provide additional grounds for dismissal but would properly be addressed by the district court in the first instance.

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[1] In district court, Plaintiff incorrectly stated that "CMS has explained [that] the excise tax is triggered only when manufacturers are 'referred to IRS' for their failure to sign an agreement" or to reach agreement on a negotiated price. Pl. Mot. for Summ. J. Reply, Dkt. No. 57, at 52. No such referral is necessary for liability to attach, and CMS has never said otherwise.

1. The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII. "Taken together, these Clauses place parallel limitations on the power of those entrusted with the criminal-law function of government." *Timbs v. Indiana*, 586 U.S. 146, 151 (2019) (quotation marks omitted). The Excessive Fines Clause accordingly "limits the government's power to extract payments . . . as punishment for some offense." *Id.* Although the form of proceeding, "civil or criminal," is not entirely dispositive, the question remains whether a particular payment is "punishment for some offense" against the sovereign. *Austin v. United States*, 509 U.S. 602, 610, 622 (1993).

In keeping with the Eighth Amendment's focus on excessive punishment, every Supreme Court case applying the Excessive Fines Clause has involved a forfeiture ordered as a sanction for criminal conduct after an adjudication of guilt in a criminal proceeding, *see United States v. Bajakajian*, 524 U.S. 321, 325-26 (1998); *Alexander v. United States*, 509 U.S. 544, 547-548 (1993), or a civil action brought after the property owner had already been convicted of a crime, seeking forfeiture of property used in the commission of the crime, *see Timbs*, 586 U.S. at 148; *Austin*, 509 U.S. at

605; *see also United States v. Jalaram, Inc.*, 599 F.3d 347, 354 (4th Cir. 2010) ("[T]he [Supreme] Court consistently focused on whether the forfeiture stemmed, at least in part, from the property owner's criminal culpability."); *United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022) (similar), *cert. denied*, 143 S. Ct. 552 (2023).

The excise tax here, by contrast, lacks any connection to criminal conduct. Liability does not depend on the commission of any crime; it is instead triggered by the lawful choices of the taxpayer in connection with drug sales to Medicare. To defendants' knowledge, neither the Supreme Court nor any other court has ever held that a tax—let alone one that lacks any connection to a criminal offense—implicates the Excessive Fines clause. *See* JA9. This Court should reject plaintiff's invitation to break new ground.

2. Plaintiff's claim fails for the independent reason that the excise tax is not "excessive." A fine violates the Excessive Fines Clause only "if it is grossly disproportional to the gravity of a defendant's offense." *Bajakajian*, 524 U.S. at 334, 336. In conducting this inquiry, the Supreme Court has emphasized that "judgments about the appropriate punishment for an offense belong in the first instance to the legislature." *Id.* at 336. Because

"Congress is a representative body, its pronouncements regarding the appropriate range of fines" "represent the collective opinion of the American people as to what is and is not excessive." *United States v. 817 N.E. 29th Drive*, 175 F.3d 1304, 1309 (11th Cir. 1999). There is thus a "strong presumption" that a fine "within the range of fines prescribed by Congress . . . is constitutional." *Id.* That presumption would apply with even greater force in the tax context, as "the appropriate level or rate of taxation is essentially a matter for legislative, and not judicial, resolution." *Commonwealth Edison Co. v. Montana*, 453 U.S. 609, 627 (1981).

The excise tax bears a close and proportional relationship to the burdens on the fisc. The tax is imposed only if the manufacturer continues to sell the selected drug to Medicare at a non-negotiated price and only on sales of the selected drug that are reimbursed by Medicare. 26 U.S.C. § 5000D(b); IRS Notice 3. And the ratio of the tax to the amount charged by the manufacturer falls between 65% and 95%, *see* 26 U.S.C. § 5000D(d); IRS Notice 3-4, which is within the range of constitutional exactions. *See, e.g.*, *United States v. Alt*, 83 F.3d 779, 782-83 (6th Cir. 1996) (81% civil fraud penalty).

II. The Negotiation Program does not effect a physical taking of plaintiff's drugs.

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. Because the IRA's framework for voluntary drug-price negotiations does not physically appropriate a manufacturer's drugs or otherwise compel their sale, plaintiff cannot demonstrate a physical taking.

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

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 U.S.A. Inc.*, 544 U.S. 528, 537 (2005). Plaintiff here alleges only the first type of taking—a physical appropriation of its personal property. *See* Br. 3, 16, 18; *see generally* Br. 34-43.

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 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 restrict the use or limit the value of such property, and which therefore do 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 be a physical taking. *Horne*, 576 U.S. at 362. Similarly, a law prohibiting the sale of eagle feathers would not effect a physical taking because the feather owners "retained the rights to possess, donate, and devise their property." *Id.* at 364 (describing *Andrus v.*

Allard, 444 U.S. 51 (1979)). Although the law sapped the feathers of their commercial value, it 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). The Court has thus carefully superintended the "distinction . . . between appropriation and regulation" for purposes of this analysis. *Id.* at 432.

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.

As these cases confirm, a legal mandate to provide property to the government or third parties is essential to the establishment of a physical takings claim. *See Lingle*, 544 U.S. at 539; *Bowles v. Willingham*, 321 U.S. 503, 517-18 (1944). By contrast, 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 basic 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]

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[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. E. 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").

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

Plaintiff contends that the Negotiation Program effects a taking of physical doses of Entresto. *See* Br. 34-35. This claim fails at the outset because the Negotiation Program does not mandate any physical appropriation or sales of this property.

Plaintiff cannot plausibly allege that the Negotiation Program requires it to physically turn over its drugs to the government or Medicare beneficiaries. Unlike the Department of Agriculture in *Horne*, CMS will not "sen[d] trucks to [plaintiff's] facility at eight o'clock one morning to" haul away pills. 576 U.S. at 356. And as the district court observed, this case is also unlike *Horne* because 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." JA5 (quoting *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-3335, 23-3818, 2024 WL 1855054, at *6 (D.N.J. Apr. 29, 2024)). Here, there is no physical appropriation to speak of.

Plaintiff's takings argument instead rests on a provision directing a participating manufacture to provide Medicare beneficiaries "access to the [negotiated] price" for the selected drug. 42 U.S.C. § 1320f-2(a)(3). But any suggestion that this provision requires manufacturers to make sales against their will, *see* Br. 35, 41, is simply incorrect. First, the Negotiation Program does not require plaintiff to provide Medicare beneficiaries access to any drugs at all because sales to Medicare are voluntary. The provision at issue applies only after a manufacturer (1) voluntarily decides to participate in the Negotiation Program, and (2) subsequently reaches an agreement with CMS on a negotiated price.

Second, even when it does apply, this provision does not require manufacturers to make any sales of the drug. It merely holds the manufacturer to the bargain it struck: The requirement to provide "access to the [negotiated] price," 42 U.S.C. § 1320f-2(a)(3), means only that a manufacturer may not charge Medicare more than the price it agreed to. Under no circumstance is a manufacturer required to provide any party with physical access to its drugs over its objection. *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, § 90.2, at 282 (Oct. 2, 2024), https://perma.cc/GV3J-DRKT ("[T]he Primary

Manufacturer is not obligated to make any sales of the selected drug."); *see also id.* § 40.4, at 195; *id.* § 100.1, at 295. Plaintiff's contrary assertion—that "manufacturers must transfer available units at government-dictated prices to beneficiaries upon request," Br. 41—is wrong.

Plaintiff briefly alludes to a provision requiring *insurance* companies—not drug manufacturers—to include all selected drugs with negotiated prices in the formularies for their Medicare Part D plans. Br. 45 (citing 42 U.S.C. § 1395w-104(b)(3)(I)(i)). This provision does not operate on drug manufacturers at all, and it certainly does not force them to make unwanted sales. It states only that insurance companies that have elected to participate in Medicare Part D shall cover the drugs that manufacturers agree to sell. Neither this formulary provision nor anything else in the IRA requires manufacturers to make sales to Medicare in the first instance.[3]

[3] Plaintiff also indicates that, given its drug distribution operations, it may in practice be unable to withhold the drug from Medicare beneficiaries while continuing to sell it to private buyers. Br. 45. But plaintiff does not and could not argue that these supply-chain constraints are created by the formulary provision it identifies. Such constraints are attributable not to any provision in the IRA, but rather to plaintiff's chosen business model and its own private contractual arrangements in the domestic drug distribution system. Plaintiff conspicuously does not state that its practical options for market segmentation would be different if the formulary requirement did not exist.

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). The Negotiation Program instead alters the terms on which the government is willing to pay for certain drugs, and it leaves companies a choice whether to continue doing business with the government on these terms. If plaintiff is dissatisfied with the terms of the government's offer, it can decline to sell its drugs to Medicare. If it chooses instead to accept the offer, it cannot then complain that the government has effected a physical taking of its personal property.

C. The profitability of Medicare and Medicaid participation does not make participation involuntary.

1. Plaintiff acknowledges that, as a legal matter, it retains the option not to sell its drug to the government under the terms established by the IRA. Br. 36. But it contends that the opportunity to participate in Medicare is so profitable as to leave it with no practical choice but to accept the terms of participation. *See* Br. 39. In other words, plaintiff contends that the government is offering a deal too good for drug companies to refuse. The courts of appeals have uniformly rejected takings claims based on this theory, and this Court should not accept plaintiff's invitation to break new ground.

Although members of the healthcare industry may face significant economic pressure to participate in Medicare and Medicaid, economic incentives 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) ("[T]he 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); *supra* p. 42 n.2 (collecting cases). 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.

Plaintiff observes that the government occupies a significant portion of the prescription drug market, but that does not change the constitutional analysis. 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 no court has ever suggested that the government's market dominance in the defense sector raises coercion concerns of constitutional significance, even though a defense company's very survival depends on government contracts. *Cf. Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127-28 (1940) (observing that "[j]udicial 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).

Just as defense contractors are free to accept or reject the government's contractual terms despite the government's overwhelmingly dominant market position, so too are pharmaceutical companies that participate in Medicare and Medicaid, which occupy a far less significant portion of the prescription drug market. And as the thriving defense industry illustrates, manufacturers of important goods retain significant bargaining power even in markets in which the government is a dominant purchaser. While the government may try to use its purchasing power to negotiate better prices on behalf of taxpayers, defense and drug companies leverage the government's desire for military technologies or critical medicines to negotiate favorable terms. That is particularly true here: The Negotiation Program applies only to drugs without generic or biosimilar competition, *see* 42 U.S.C. § 1320f-1(e), so if the government fails to reach an agreement, Medicare beneficiaries may be left without adequate alternatives for some of the most widely used drugs on the market. The government therefore has a strong interest in reaching a deal to ensure continued access to these essential drugs for Medicare beneficiaries.

This dynamic builds on a well-established relationship between drug manufacturers and federal healthcare programs. For decades, the government has offered to purchase drugs subject to an extensive set of statutory and regulatory requirements that plaintiff has previously accepted. For example, as a condition of its participation in Medicaid, plaintiff has 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, plaintiff has 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). These requirements do not amount to a constitutional taking; they are simply terms that plaintiff has long chosen to accept in exchange for the financial opportunities that these programs confer.

2. Plaintiff contends that its 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). It therefore concludes that, under *Horne*, the ability to withdraw from Medicare and Medicaid is "legally irrelevant." Br. 36. This attempted analogy fails.

The decision in *Horne* was premised on the fact that (1) the farmers were legally compelled to transfer the raisins to the government unless they stopped selling raisins altogether, and (2) the government was not offering anything in exchange for the raisins. 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 365-66; *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 proprietary information 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 plaintiff can take or leave, bears no resemblance to the demand for raisins in *Horne*. Here, the government is not demanding plaintiff's drugs; it is making an offer of payment that plaintiff can reject or accept. The government is thus offering something of value to which plaintiff has 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*, plaintiff here may reject the government's offer without prejudice to any pre-existing property interest, including its ability to sell its drugs to other buyers. Drug companies remain free to sell their products on the vast private market regardless of their participation in Medicare and Medicaid.

Plaintiff also errs in describing the excise tax as a penalty akin to the fine assessed for failure to comply with the raisin requirement in *Horne*. If plaintiff chooses not to sell its drugs to Medicare, it will face no excise tax nor any restriction on its ability to sell drugs to any willing buyer. The plaintiffs in *Horne* were not given a similar choice. While the excise-tax provision gives drug manufacturers 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 would retain its ability to sell its drugs to other buyers. The existence of the excise-tax option does not negate plaintiff's fundamental ability to walk away from any deal with the government (and pay no excise tax) if it is dissatisfied with the terms on which the government is willing to do business. *See* JA5.

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. Plaintiff disagrees that these are satisfactory alternatives. *See* Br. 36-37. But plaintiff's satisfaction with these options has no bearing on its ability to reject the government's offer in the first place.

III. The Negotiation Program does not compel plaintiff's speech.

If a manufacturer of a selected drug chooses to participate in the Negotiation Program, the manufacturer will sign an agreement to negotiate and—if negotiations succeed—an addendum memorializing the negotiated price. These agreements do not compel speech in violation of the First Amendment.

1. Plaintiff's compelled-speech claim fails 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)). Thus, the Supreme Court has found compelled speech violations when the state forced Jehovah's Witnesses to pledge allegiance to the flag, *West Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943), or to display on their cars a slogan repugnant to their faith, *Wooley v. Maynard*, 430 U.S. 705 (1977).

When, by contrast, a drug manufacturer enters into a contractual agreement associated with participation in Medicare or Medicaid, it does so voluntarily in light of the anticipated revenue from sales to these federal programs. For decades, any drug manufacturer that participates in Medicaid has been required to enter into agreements that give certain federal agencies the option to purchase drugs at negotiated prices at or below statutory ceilings. *See* 38 U.S.C. § 8126(a)-(h); *supra* pp. 8, 49-50. The resulting agreements are not compelled speech; they are simply part of the package deal that manufacturers accept when they choose to sell drugs to Medicaid. In making that choice, a manufacturer weighs the financial upside against the cost of the associated obligations. Any resulting compliance is a commercial decision, not a government mandate.

Nothing about this analysis changes when a company's financial success depends on securing or renewing government contracts. Companies choose to seek government contracts, accepting the associated terms in exchange for payment, and those terms are not "compelled" in any relevant sense simply because a contractor finds participation economically desirable. The IRA's negotiation agreements thus do not present any threat of compelled speech, even though plaintiff insists that participation in the program is important for its bottom line. *See C.N.*, 430 F.3d at 189 (rejecting compelled speech claim in the absence of "the compulsion necessary to establish a First Amendment violation").

Although plaintiff's principal argument is that withdrawal from Medicare is financially impractical, plaintiff also asserts that it had no option to withdraw before the deadline for agreeing to negotiate. Br. 53-54. That is incorrect. Manufacturers of selected drugs may withdraw within 30 days of notice to CMS, and plaintiff could thus have opted out of any Negotiation Program proceedings before they began. As the Revised Guidance explains, CMS has statutory authority 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), and CMS determined that a "request for termination to effectuate [a manufacturer's] decision not to participate in the Negotiation Program" would constitute good cause. JA394 (Revised Guidance 131). CMS will "automatically grant such termination requests upon receipt," and the termination would be effective 30 days later, consistent with the statutory requirement for a 30-day exit period. JA384 (Revised Guidance 121). Plaintiff has not availed itself of this opportunity, but it had (and continues to have) that option.[4]

2. Plaintiff's First Amendment claims also fail for the independent reason that the Negotiation Program regulates only non-expressive conduct, not constitutionally protected speech.

Although the constitutionally protected "freedom of expression" extends beyond the "the spoken or written word," *Texas v. Johnson*, 491 U.S. 397, 404, 406 (1989), the Supreme Court has "rejected the view that 'conduct can be labeled "speech" whenever the person engaging in the conduct

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[4] Manufacturers may still withdraw before any negotiated prices first take effect (on January 1, 2026), by notifying CMS at least 30 days in advance.

intends thereby to express an idea,'" *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.* (*FAIR*), 547 U.S. 47, 65-66 (2006) (quoting *United States v. O'Brien*, 391 U.S. 367, 376 (1968)). First Amendment protections for conduct are instead limited to those actions that are "inherently expressive." *Id.* 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).

Consistent with this principle, 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.*; *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 . . . .").

The Negotiation Program contracts regulate only non-expressive, commercial conduct—"the amount that a [manufacturer] c[an] collect" when selling drugs to Medicare, *Expressions Hair Design*, 581 U.S. at 47—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." JA6 (quoting *Bristol Myers*, 2024 WL 1855054, at *11). And plaintiff's signature on the agreement merely memorializes its decision to participate in the Negotiation Program as well as its understanding of the maximum price Medicare will pay for the selected drug. These are among the standard actions often memorialized in commercial contracts. Indeed, 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), (c), 1395w-102(b)(1); *see also* CMS, Form CMS-460, *Medicare Participating Physician or Supplier Agreement*, https://perma.cc/WG64-ZNPL.

The agreements' use of statutory terms of art defined in the IRA is consistent with the goal of ensuring a shared understanding of the program terms and the parties' obligations by reference to the statute. The use of such statutory terms promotes consistency and clarity. For example, the IRA defines the term "maximum fair price" as "the price negotiated pursuant to section 1320f–3 of this title, and updated pursuant to section 1320f–4(b) of this title, as applicable, for such drug and year." 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." *Bristol Myers*, 2024 WL 1855054, at *11; *see Meese v. Keene*, 481 U.S. 465, 485 (1987) (construing statutory terms as defined by Congress, "not as it might be read by a layman"). These terms of art accurately describe the operation of the program and do not convey or require plaintiff to endorse any view regarding the value of its drugs. *Cf. Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 251 (2010) (holding that use of the term "debt relief agency" was necessarily accurate because it was a statutory term of art that defined the scope of a statutory requirement).[5]

There is no merit to plaintiff's contention that the agreements operate as a means of compelling manufacturers to express a view about the value of their drugs. Signing an agreement to negotiate "is simply not the same as forcing a student to pledge allegiance, or forcing a Jehovah's Witness to display [a motto on his license plate], and it trivializes the freedom protected in *Barnette* and *Wooley* to suggest that it is." *FAIR*, 547 U.S. at 61-62.

[5] Congress's use of the term "maximum fair price," moreover, is in keeping with longstanding regulatory requirements that contracting prices be determined to be "fair," and these requirements have never been thought to raise First Amendment concerns. *See United States v. General Dynamics Corp.*, 19 F.3d 770, 771 (2d Cir. 1994); *Air Borealis Ltd. P'ship v. United States*, 167 Fed. Cl. 370, 389 (2023); *Harvey Radio Labs., Inc. v. United States*, 115 F. Supp. 444, 445 (Ct. Cl. 1953).

Were there any doubt on this score, it would be resolved by the text of the agreement itself. The agreement states explicitly that, "[i]n signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug." JA261. And it explains 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." JA261. The agreement cannot reasonably be read to convey plaintiff's endorsement of a particular message or its view about the value of its drugs.

3. As a final recourse, plaintiff briefly invokes the unconstitutional conditions doctrine, Br. 43, 52-53, 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, 196-98 (1991). But even assuming the doctrine applies here, plaintiff's argument fails on its own terms.

As the Supreme Court explained in *Rust*, the government may condition a beneficiary's 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 provisions that set the terms of and define the scope of government *program*s, on the other. *See id.* at 197.

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

Agency for International Development v. Alliance for Open Society International, Inc., 570 U.S. 205 (2013), 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.

The IRA does not set an *external* "condition" on eligibility to sell drugs through Medicare; it permissibly sets the commercial terms of the government's offer to pay for 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. *See Lyng v. International Union, United Auto., Aerospace & Agric. Implement Workers of Am.*, 485 U.S. 360, 373 (1988) (describing the government's legitimate interest in "protecting the fiscal integrity of Government programs, and of the Government as a whole"). The terms that plaintiff challenges—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 plaintiff to surrender any rights beyond the scope of the government's spending on prescription drugs.

CONCLUSION

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

Respectfully submitted,

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* The Acting Assistant Attorney General is recused from this case.

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)(i) because it contains 12,951 words. This brief also complies with the typeface and type-style requirements of Rule 32(a)(5)-(6) because it uses Book Antiqua 14-point font, a proportionally spaced typeface.

3. On February 19, 2025, 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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