# No. 24-2092

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

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, *in his official capacity as Secretary of Health and Human Services*; CENTERS FOR MEDICARE AND MEDICAID SERVICES; *and* CHIQUITA BROOKS-LASURE, *in her official capacity as Administrator of Centers for Medicare and Medicaid Services*,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Connecticut

**BRIEF FOR APPELLEES U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, CENTERS FOR MEDICARE & MEDICAID SERVICES, AND CHIQUITA BROOKS-LASURE**

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## INTRODUCTION

For more than 30 years, Congress has limited how much 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 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 companies that choose to sell drugs to Medicare and Medicaid.

Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc., challenges the Negotiation Program as effecting a physical taking of its drugs, as fixing a price cap without due process, as compelling its speech in violation of the

First Amendment, and as otherwise coercing 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 goods and that it acted well within this authority in establishing a framework for negotiating the prices that Medicare pays for certain high-expenditure drugs.

Binding precedent establishes that participation in Medicare is voluntary. *See Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993). Pharmaceutical manufacturers like Boehringer choose to accept the terms of the Medicare program and sell drugs to the government because doing so is immensely lucrative. If participating in Medicare stopped being profitable, Boehringer could walk away.

The voluntary nature of Boehringer's participation undermines most of its constitutional claims. Boehringer has the option not to sell its drugs on the terms offered by the government. If it chooses to do so anyway because the alternative is less profitable, Boehringer cannot complain that a taking has occurred. In setting the terms of its offer to pay for drugs for Medicare beneficiaries, the government has neither mandated the transfer of Boehringer's property nor deprived Boehringer of any protected property

interest. Pharmaceutical companies have no constitutionally protected interest in dictating the price that the government will pay for their products. The voluntariness of participation in Medicare—and thus in the Negotiation Program—is also fatal to Boehringer's contention that the contract terms impermissibly compel speech.

Boehringer's attempt to repackage these arguments as unconstitutional conditions claims also fails because the government has substantial leeway to 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 pricing and contracting requirements that Boehringer challenges are integral parts of the Program's operation—not extrinsic conditions preventing Boehringer from exercising its constitutional rights. Because the IRA expressly directs CMS to implement the Negotiation Program through guidance through 2028, Boehringer's challenge to the procedures used by the agency likewise lacks merit.

## STATEMENT OF JURISDICTION

Boehringer invoked the jurisdiction of the district court under 28 U.S.C. §§ 1331 and 1346. JA33. On July 9, 2024, the district court entered final judgment against Boehringer. SPA48. On July 26, 2024, Boehringer timely noticed this appeal. JA412; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.

## STATEMENT OF THE ISSUES

I. Whether the district court correctly rejected Boehringer's claims that Congress violated Fifth Amendment takings and due process principles when it authorized CMS to negotiate the price the government will pay for certain prescription drugs for Medicare beneficiaries.

II. Whether the district court correctly rejected Boehringer's claim that by signing a contract memorializing its decision to participate in drug-price negotiations, as well as the negotiated price, it was compelled to speak in violation of the First Amendment.

III. Whether the district court correctly rejected Boehringer's claim that the Negotiation Program forces it to give up constitutional rights in order to receive unrelated benefits.

IV. Whether the district court correctly rejected Boehringer's claim that, despite express statutory instructions to implement the Negotiation Program through guidance, CMS was actually required to proceed through notice-and-comment rulemaking.

## STATEMENT OF THE CASE

### A. Medicare and the Escalating Cost of Prescription Drug Coverage

Congress created Medicare in 1965. Social Security Amendments of 1965, Pub. L. No. 89-97, tit. I, 79 Stat. 286, 290-353. 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 HHS.

Medicare is divided into "Parts," which establish the terms under which Medicare pays 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). For nearly four decades, Medicare did not cover the cost of prescription drugs unless they were administered by medical professionals. That changed in 2003, when Congress enacted Medicare Part D to provide "a voluntary prescription drug

benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *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); *see also* Michelle Singer, *Under the Influence*, CBS News (Mar. 29. 2007), https://perma.cc/5U9Z-M2YS (documenting extensive industry efforts to lobby for price-negotiation bar in lead-up to enactment of Part D). 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 Report). 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 fisc, 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 Report 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 Report 7. By 2021, the top ten drugs by total spending accounted for 22% of spending under Part D. *See* Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (July 12, 2023), https://perma.cc/2PF2-336Z.

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 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. As a condition on Medicaid participation, manufacturers that wish to sell drugs to the government through these programs have long been required to negotiate with the government and reach agreements subject to statutorily defined ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). 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 Department of Defense, the Department of Veterans Affairs, and the Coast Guard 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 dictate the prices paid by other buyers of those drugs.

By statute, only certain drugs are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years. *See* 42 U.S.C. § 1320f-1(d), (e). For the first negotiation cycle, CMS selects ten 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 a Manufacturer Agreement 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 Manufacturer 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 revised 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," SPA28 (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 Excise Tax on Designated Drugs*, 90 Fed. Reg. 31 (Jan. 2, 2025); Internal Revenue Serv., Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice).

### C. Implementing the Negotiation Program

1. 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 three 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.

The Revised Guidance also sets out procedures for manufacturers that choose not to participate in the Negotiation Program. Revised Guidance 118-21, 129-31. In those circumstances, CMS will "facilitate an expeditious termination of" a manufacturer's Medicare agreement before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies the agency of its desire to withdraw at least 30 days in advance of when the tax would otherwise begin to accrue. Revised Guidance 33-34. The Treasury Department and the Internal Revenue Service issued a notice explaining that, when excise tax liability is triggered, the tax will be imposed only on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare"—*i.e.*, not on drugs dispensed, furnished, or administered outside of Medicare. IRS Notice 3. That interpretation is effective immediately. *See id.* at 5. The Treasury Department and the IRS have reiterated their understanding of the application of the tax in a proposed rule. *See* 90 Fed. Reg. 31.

2. In August 2023, CMS selected drugs 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 ten 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 id.*; CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94. Boehringer's glycemic-control drug Jardiance was among the those selected for negotiation. *Id.* Boehringer executed a Manufacturer Agreement with CMS to negotiate the price of its drug, and negotiations proceeded over the spring and summer of 2024. *See* CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/3222-VPEE.

In accordance with the schedule established by Congress, CMS presented Boehringer 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. Boehringer 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, including Boehringer, by July 15. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the ten selected drugs. *Id.* *See also* CMS, *Maximum Fair Price (MFP) Explanation for Jardiance* 1-4 (Dec. 20, 2024), https://perma.cc/HEP2-NFJU. Assuming that none of the ten manufacturers withdraws from the negotiation agreement 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

1. Boehringer sued, asserting violations of the Due Process and Takings Clauses of the Fifth Amendment, the First Amendment, the unconstitutional conditions doctrine, the Administrative Procedure Act

(APA), and the Excessive Fines Clause of the Eighth Amendment. JA74-83. The parties cross-moved for summary judgment. After oral argument, the district court granted summary judgment to the government on all of Boehringer's claims. SPA48; *see* SPA1.[1]

The district court first rejected Boehringer's claims that the Negotiation Program deprives it of its property interest in its "physical doses of Jardiance," without due process, and that it effects a physical taking of Jardiance. SPA13 (quotation marks omitted). The district court explained that, because Boehringer can "opt out of Medicare and Medicaid" without penalty before the maximum fair price takes effect, participation in the Negotiation Program is voluntary and does not deprive Boehringer of its property. SPA14; *see* SPA15-19. With respect to the takings claim, the court emphasized that the Negotiation Program affects "prices only in a portion of the drug market created and funded by the federal government" and not the market as a whole, SPA24-25, and it "do[es] not permit the government to seize [manufacturers'] property (or to provide access to it by others) if they refuse to turn it over," SPA26 (distinguishing *Horne v. Department of*

[1] Because Boehringer has abandoned its Eighth Amendment claim on appeal, Br. 14 n.5, we do not address it. *See* SPA43-46 (rejecting that claim).

*Agriculture*, 576 U.S. 350 (2015)). The court rejected plaintiff's argument that argument that, because participating in Medicare is lucrative, that financial incentive renders such participation involuntary. SPA21-23.

The district court next rejected the argument that the requirement to sign a Manufacturer Agreement impermissibly forces Boehringer to speak or to engage in expressive conduct because the Agreement uses terms like "negotiation" and "maximum fair price." The court reiterated that the Negotiation Program "d[oes] not 'compel' [Boehringer] to do anything" because manufacturers can opt out of participation and avoid signing the Agreement. SPA31. And it further explained that "the Manufacturer Agreement regulates [Boehringer]'s conduct," rather than speech, and that "any effects it may have on speech are 'plainly incidental'" to the government's goal of negotiating drug prices. SPA31. Noting that the Agreement includes a disclaimer stating, *inter alia*, that "[i]n signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS'[s] views," JA299; *see* SPA32, and finding no "intent to convey a particularized message," the court also rejected Boehringer's argument that signing the Agreement constitutes expressive conduct, SPA33 (quoting *Slattery v. Hochul*, 61 F.4th 278, 291 (2d Cir. 2023)).

The district court likewise found no merit to Boehringer's argument that the Negotiation Program impermissibly requires it to forfeit its rights under the First and Fifth Amendments as a condition on participation in Medicare and Medicaid. The court explained that, "to the extent the unconstitutional condition[s] doctrine applies at all to claims such as these," the "core feature" of the doctrine "is a concern that the government will tie its own goals to unrelated benefits that flow from its regulatory and spending programs—and that feature is missing here" because the conditions imposed are "closely related to the government's goal of controlling spending in the Medicare program." SPA38.

The district court also rejected Boehringer's challenge to the procedures used in implementing the Revised Guidance, concluding that the IRA expressly directed CMS to implement the Negotiation Program—including the Manufacturer Agreement—through guidance and did not require notice and comment. SPA43.

2. Other drug manufacturers and interest groups have filed related suits across the country challenging the constitutionality and implementation of the Negotiation Program. To date, every court to reach the merits of such claims have rejected them. *See AstraZeneca Pharm. LP v. Becerra*,

719 F. Supp. 3d. 377 (D. Del. 2024), *appeal pending*, No. 24-1819 (3d Cir.); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-cv-3335, 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024), *appeals pending*, Nos. 24-1810, 24-1821 (3d Cir.); *Novo Nordisk Inc. v. Becerra*, No. 23-cv-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *appeal pending*, No. 24-2510 (3d Cir.); *Novartis Pharm. Corp. v. Becerra*, No. 23-cv-14221, 2024 WL 4524357 (D.N.J. Oct. 18, 2024), *appeal pending*, No. 24-2968 (3d Cir.).

A district court rejected another challenge on threshold grounds. *Dayton Area Chamber of Commerce v. Becerra*, No. 3:23-cv-156, 2024 WL 3741510 (S.D. Ohio Aug. 8, 2024), *appeal pending*, No. 24-3868 (6th Cir.). And two other cases raising related issues remain pending in district court. *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C. June 6, 2023); *National Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. June 21, 2023); *see also National Infusion Ctr. Ass'n v. Becerra* (*NICA*), 116 F.4th 488 (5th Cir. 2024) (reversing order dismissing action on threshold grounds).

## SUMMARY OF ARGUMENT

I. The district court correctly held that Congress's establishment of the terms on which the government will pay for prescription drugs for

Medicare beneficiaries is consistent with the Takings and Due Process Clauses.

A. 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—which is the only type of taking Boehringer 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. Absent either showing, there is no deprivation that could give rise to such a claim.

In the IRA, Congress established a framework for negotiations over the prices that Medicare will pay for certain drugs. Contrary to Boehringer's contention, the Negotiation Program simply adjusts the terms of the government's offer to pay for drugs for beneficiaries. It does not physically appropriate any manufacturer's drugs or otherwise compel their surrender, and therefore it does not effect a physical taking.

Boehringer errs in asserting that the Negotiation Program "forces" it to sell its drugs to the government at below-market value by compelling participation in the Negotiation Program. Boehringer is not legally required to make any sales to the government or to otherwise provide drugs to

Medicare. Longstanding precedent forecloses the contention that the profitability of Medicare effectively compels participation: The economic incentives for manufacturers to participate in Medicare and Medicaid do not make such participation involuntary. *See Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993). When a company retains the option not to sell products on the offered terms—but chooses to anyway because the alternative is less profitable—no physical "taking" has occurred.

B. The district court also correctly rejected Boehringer's due process claim because Boehringer fails to identify a protected property interest affected by the Negotiation Program. There is no substance to Boehringer's assertion that it has a protected property interest in dictating the price the government pays for drugs.

II. The Negotiation Program does not compel speech in violation of the First Amendment by requiring manufacturers that choose to participate to enter a Manufacturer Agreement to negotiate with the government and to honor any agreed-upon prices. Because participation in the Negotiation Program is voluntary, Boehringer is not compelled to sign the Manufacturer Agreement. In any event, the challenged Agreement implicates only non-expressive commercial conduct and does not regulate Boehringer's speech.

As the district court observed, the Agreement includes a disclaimer stating, *inter alia*, that "[i]n signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS'[s] views." JA299; *see* SPA31. The absence of any "intent to convey a particularized message" is fatal to Boehringer's claim. SPA33 (quoting *Slattery v. Hochul*, 61 F.4th 278, 291 (2d Cir. 2023)).

III. The Negotiation Program also does not contravene the unconstitutional conditions doctrine. 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. Boehringer complains 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 Boehringer's ability to exercise its rights outside the scope of Medicare sales.

IV. Finally, the district court correctly rejected Boehringer's APA claim because the IRA directs CMS to "implement" the Negotiation Program's first three years through "program instruction or other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854. That clear statement displaces the default requirement for CMS to proceed through notice-and-comment rulemaking. And the Manufacturer Agreement is plainly part of the program implementation.

## STANDARD OF REVIEW

This court reviews de novo an order granting summary judgment. *Jabar v. DOJ*, 62 F.4th 44, 48 (2d Cir. 2023) (per curiam).

## ARGUMENT

### I. Congress's authority to set the terms on which the government offers to pay for goods is well established.

Boehringer asserts that Congress violated the Fifth Amendment when it authorized CMS to negotiate the prices it will pay for certain prescription drugs. There is no substance to the contention that these provisions effect a taking or violate Boehringer's right to due process.

#### A. The Negotiation Program does not effect a physical taking of Boehringer'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. In the IRA, 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 pay for drugs for Medicare beneficiaries, but it does not physically appropriate any manufacturer's drugs or otherwise compel their surrender or transfer. If Boehringer prefers not to sell selected drugs to Medicare on the terms established by Congress, it need not sell drugs to Medicare at all.

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

a. 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). Boehringer alleges only the

first type of taking—a physical appropriation of its personal property. *See* Br. 21 n.6 (citing JA75-77).

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. *Id.* at 361, 364.

The Supreme Court has distinguished this sort of 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. The Court has held, for example, that a law prohibiting the sale of eagle feathers did not effect a taking—even though the law sapped the feathers of all commercial value—because the law neither "compel[led] the surrender of the artifacts" nor resulted in any "physical invasion or restraint

upon them," and the feather owners "retained the rights to possess, donate, and devise their property." *Horne*, 576 U.S. at 364 (quotation marks omitted) (describing the holding in *Andrus v. Allard*, 444 U.S. 51 (1979)). Relying on that analysis, the *Horne* Court explained that although a regulation limiting the production of raisins might well have "the same economic impact" on a farmer as a requirement to surrender raisins to the government, the former does not constitute a physical taking because it does not entail an appropriation. *Id.* at 362.

The Supreme Court recently reiterated in *Cedar Point* that a physical appropriation is an essential element of a physical takings claim. 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 regulation 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 occupation was a physical

taking. *Id.* at 152. *See also Lingle*, 544 U.S. at 539; *Bowles v. Willingham*, 321 U.S. 503, 517-18 (1944).

**b.** 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). This Court applied these principles in *Garelick* to reject a takings challenge to other Medicare pricing restrictions. 987 F.2d at 918. In that case, physicians challenged statutory caps on the amount they could charge Medicare beneficiaries for services. *Id.* at 914-15. This Court rejected the challenge because the physicians "voluntarily choose to provide services in the price-regulated Part B program." *Id.* at 916.[2]

Other courts of appeals have uniformly rejected similar takings challenges 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

[2] That this Court reached that conclusion, because participation was voluntary under federal law, even though New York law arguably required the physicians to treat Medicaid patients who presented at New York hospitals only underscores that the key question is whether federal law permits the provider to opt. *Garelick*, 987 F.2d at 917.

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, when 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) ("[The 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))); *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. Secretary of 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); *Baker Cty. Med. Servs., Inc. v. U.S. Attorney Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014).

### 2. The Negotiation Program does not physically appropriate or otherwise compel the transfer of Boehringer's property.

In contending that the Negotiation Program effects a physical taking of property, Boehringer points to physical doses of Jardiance. *See, e.g.*, Br. 21-22. That the Negotiation Program does not mandate any physical appropriation of this property defeats Boehringer's physical takings claim.

Boehringer cannot allege that CMS will "sen[d] trucks to [its] facility" to haul away its products as in *Horne*. 576 U.S. at 356. Nor is there any plausible suggestion that Boehringer must otherwise physically turn over its drugs to the government or Medicare beneficiaries. Instead, Boehringer asserts that the Negotiation Program effects a physical taking by requiring it to "grant Medicare beneficiaries and their providers 'access to the maximum fair price' for" its drug if the company participates in Medicare. Br. 22. But "access to [a] . . . price" is an entirely different thing from physical access to drugs—particularly when the price is determined through

a series of offers and counteroffers made after the manufacturer elects to participate in Medicare and agrees to negotiate.

The requirement to provide "access to [the negotiated] price," 42 U.S.C. § 1320f-2(a)(1), (3), means only that a manufacturer that chooses to participate in Medicare may not charge Medicare beneficiaries who are dispensed, furnished, or administered the drug more than that price. *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*, § 90.1, p. 282 (Oct. 2, 2024), https://perma.cc/GV3J-DRKT ("Although the Primary Manufacturer is obligated to provide access to the [maximum fair price] for all dosage forms, strengths, and package sizes of the selected drug that are dispensed to [ ] eligible individuals, the Primary Manufacturer is not obligated to make any sales of the selected drug."); *see also id.*, § 40.4, p. 195; § 100.1, p. 295

Contrary to Boehringer's suggestion, the statute does not require it to sell its drugs to Medicare in the first instance or to give anyone physical

access to its drugs over its objection.[3] The Negotiation Program altered what Medicare will pay for certain drugs, but it does not require any pharmaceutical company to accept that offer to pay. Instead, the Negotiation Program gives companies a choice whether to continue doing business with the government on the terms the government is presently offering. A manufacturer is subject to the negotiated price only if it chooses to sell its drugs to Medicare beneficiaries. As CMS has explained, "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. If Boehringer 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

[3] Boehringer cites *Cedar Point* for the proposition that an "access" requirement can amount to a physical taking, Br. 23-24, but *Cedar Point* underscores that physical takings arise from "[g]overnment action that physically appropriates property," as by granting physical access to private farmland in that case. 594 U.S. at 149.

offer and provide its drugs on those terms, it cannot then complain that the government has effected a physical taking of its drugs.

### 3. As this Court has long held, participation in Medicare is voluntary, and Boehringer may choose not to accept the terms of the government's offer.

a. Boehringer's takings argument ultimately rests on the erroneous assertion that it is being "coerced" to sell its drugs to the government on the terms established by the Negotiation Program because it cannot afford to forgo the profits it accrues through participation in Medicare and Medicaid. Br. 47-50. 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. As this Court has explained, economic or other practical "hardship is not equivalent to legal compulsion for purposes of [a] takings analysis." *Garelick*, 987 F.2d at 917. Thus, even where "business realities" create "strong financial inducement to participate"—*e.g.*, as where Medicaid provides the vast majority of a nursing home's revenue—the decision to participate in the program "is nonetheless voluntary." *Minnesota Ass'n*, 742 F.2d at 446; *see also St. Francis Hosp. Ctr.*, 714 F.2d at 875 (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"); *Whitney*, 780 F.2d at

972 n.12 (same). That the government spends significant money on drugs for Medicare and Medicaid, and that this money translates into substantial, but highly regulated, commercial opportunities for pharmaceutical companies, does not in any relevant sense mandate participation in those programs.

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" or appropriated 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—nothing has been "taken."

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—and that fact has never been understood to transform the government's bargaining terms into matters of constitutional concern. *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). Accordingly, the government has for decades offered to purchase drugs subject to an extensive set of statutory and regulatory requirements that Boehringer has previously accepted. For example, as a condition on its participation in Medicaid, Boehringer 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, Boehringer has likewise been required to enter into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. *SeeAstra 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 the government is offering. And these choices have long been held to be voluntary even though the financial incentives to participate are great. The Negotiation Program works the same way. And any company that rejects the government's offer can continue to sell its drugs to any other purchaser. Boehringer's view that the

Program is nevertheless mandatory runs counter to longstanding precedent and would have sweeping implications across a wide range of industries and programs.

b. Boehringer cites *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519 (2012), for the idea that these incentives are coercive, but that reliance is misplaced. 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 Government may not compel the States to enact or administer a federal regulatory program.'" *Id.* at 575-76 (lead 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.

*NFIB* thus addressed federalism-based limits on the conditions that Congress may attach to money it grants to States. *See NFIB*, 567 U.S. at 579 (lead 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 or support the contention that such offers to pay for goods can be coercive in any constitutional sense.

Boehringer errs in attempting to analogize the federal assistance to States at issue in *NFIB* to Boehringer's history of profitable sales 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 so as to make their participation involuntary. *See, e.g.*, *Garelick*, 987 F.2d at 917; *Southeast Ark. Hospice, Inc.*, 815 F.3d at 450. 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 (lead opinion) (discussing, *inter alia*, *South Dakota v. Dole*, 483 U.S. 203 (1987)). As the lead opinion in *NFIB* emphasizes, those principles sound in the anticommandeering doctrine and protect "the status of the States as independent sovereigns in our federal system." *Id.* at 577 (citing *Printz v. United States*, 521 U.S. 898, 933 (1997); *New York*, 505 U.S. at 174-75));[4] *see id.* at 579-81 (discussing "coercion" as a limit on Congress's

[4] *Accord NFIB*, 567 U.S. at 677 (Scalia, Kennedy, Thomas, and Alito, JJ., dissenting) ("Congress may not 'simply commandeer the legislative

*Continued on next page.*

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). *See generally New Jersey Thoroughbred Horsemen's Ass'n v. NCAA*, 584 U.S. 453, 473-74 (2018) (describing the federalism-based rationale for the anticommandeering doctrine).

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. *See NFIB*, 567 U.S. at 579-81 (lead 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)

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processes of the States by directly compelling them to enact and enforce a federal regulatory program.'" (quoting *New York*, 505 U.S. at 161)).

(quoting *Perkins*, 310 U.S. at 127). Courts thus distinguish, for constitutional purposes, between the government acting "as a regulator" and the government acting as "a market participant." *Chamber of Commerce of the U.S. 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) (first citing *Chamber of Commerce*, 554 U.S. at 70; then citing *Boston Harbor*, 507 U.S. at 228-30; and then citing *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").

The Supreme Court has reiterated since *NFIB* that "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). And the Court has not accepted the contention that such "condition[s] [are] impermissibly coercive because the consequence of opting out would be the loss of all Medicare and Medicaid funds." Response to Application for a Stay Pending Appeal at 27, *Becerra v. Louisiana*, Nos. 21A240, 21A241, 2021 WL 8939385, at *27 (U.S. Dec. 30, 2021) (emphasis omitted) (citing *NFIB*, 567 U.S. at 580-81 (lead opinion)).

Boehringer finds no more support in its reliance on *Lochner* Era regulatory cases that are of limited continuing vitality. *See* Br. 50. These cases are distinguishable because, in each, the government put sellers to the choice of submitting to government regulation or not doing business in the private market at all. *See Union Pac. R.R. Co. v. Public Serv. Comm'n*, 248 U.S. 67 (1918); *United States v. Butler*, 297 U.S. 1, 54 (1936); *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936). The same analysis does apply where a party can avoid regulation simply by forgoing sales to a government program, rather than exiting the industry altogether. It is well established that, when Congress spends money, it has wide latitude to require recipients to "agree to comply with federally imposed conditions." *Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 219 (2022) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)). *Butler* is further

distinguishable because it rests on a long-since abandoned view that Congress lacks authority to regulate agricultural commodities directly, 297 U.S. at 70; *see, e.g.*, *United States v. Lopez*, 514 U.S. 549, 558 (1995); *NFIB*, 567 U.S. at 572-73 (lead opinion) (noting that *Butler*'s analysis of regulatory taxes has been discarded), and there is no doubt here that Congress has authority to determine how it spends federal funds on prescription drugs, *see Dole*, 483 U.S. at 206.

In paying for drugs for Medicare beneficiaries, the government has legitimate interests in achieving the best prices it can for taxpayers and ensuring the financial integrity of Medicare's prescription drug programs. Boehringer's argument overlooks these interests, and it also elides the fact that, even in markets in which the government is a dominant purchaser, manufacturers often retain significant bargaining power. In the defense context, for example, while the government uses its market position to negotiate lower prices, defense contractors also leverage the government's desire for specific military technologies to negotiate favorable terms. The same is true for prescription drugs. The government may try to use its purchasing power to negotiate better prices on behalf of taxpayers, but drug companies also wield substantial power given the government's significant

interest in providing coverage for critical medicines. That is particularly true here: The Negotiation Program applies only to drugs without generic competition, *see* 42 U.S.C. § 1320f-1(e), so if the government fails to reach a deal, Medicare beneficiaries would likely be left without direct substitutes. The government thus has a strong interest in reaching a deal under which these important drugs will continue to be covered. And the parties here engaged in a genuine back-and-forth, through a series of offers and counteroffers, before arriving at a compromise position.

c. There is no merit to Boehringer's contention that its ability to withdraw from Medicare and Medicaid (and thus avoid the terms of the Negotiation Program) is analogous to the option available to the farmers in *Horne* to withdraw from the broader raisin market (and thus avoid the requirement to turn over raisins to the government). Br. 52-53. The *Horne* 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 the farmers as part of an exchange. 576 U.S. at 366. And the farmers' only options under the challenged provision, besides turning over their raisins, were to sacrifice their preexisting ability to engage in the ordinary commercial activity of selling raisins 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—in exchange for nothing from the government.

The government's offer to pay for drugs for Medicare beneficiaries, which Boehringer 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 to pay for them and thereby offering something of value to which Boehringer has no pre-existing right. That offer to pay stands in contrast to the raisin farmers' ability to "sell produce in interstate commerce," which is not a thing of value provided by the government. Moreover, Boehringer may reject the government's offer without prejudice to any pre-existing property interest, including its ability to sell its drugs to other buyers. This offer to pay for goods or services, which the provider of goods or services may accept or refuse, is also present in other Medicare takings cases and refutes Boehringer's suggestion (Br. 19) that there is tension between *Horne* and *Garelick*.

There is likewise no merit to Boehringer's contention that the excise tax applicable to companies that choose to participate in Medicare and to sell selected drugs to beneficiaries at a non-negotiated price is akin to the fine

assessed for failure to comply with the raisin requirement in *Horne*. *See* Br.21-23. This argument overlooks the fact that a manufacturer may avoid both the excise tax and any restriction on its ability to sell drugs to willing buyers by choosing not to participate in Medicare and Medicaid. The plaintiffs in *Horne* were not given a similar opportunity to decline to engage with the government while continuing to sell their goods to private purchasers.

While the excise tax provision gives pharmaceutical companies that do not wish to participate in the Negotiation Program an alternative to 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—it is only one means for a manufacturer to reject the government's offer. A manufacturer could instead opt out of business with the government by withdrawing from Medicare and Medicaid, in which case it would avoid the excise tax and retain its ability to sell its drugs to other buyers. Or a manufacturer could divest its interest in a selected drug or end sales of a selected drug while continuing to sell its other drugs to Medicare. Thus, the availability of the excise tax option does not undermine Boehringer's ability to walk away from any deal with the government (and

pay no excise tax) if it is dissatisfied with the terms the government is offering.

### B. The Negotiation Program does not deprive Boehringer of a protected property interest so as to implicate principles of due process.

The IRA provisions establishing the Negotiation Program do not implicate Boehringer's due process rights. The Due Process Clause protects against the deprivation "of life, liberty, or property, without due process of law." U.S. Const. amend. V. The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property. *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). Boehringer's argument fails at that first step.

There is no substance to Boehringer's assertion that the Negotiation Program deprives it of a protected property interest in its physical doses of Jardiance or in its proprietary information about that drug. Br. 26-27. Boehringer's argument in this respect is premised on the idea that the Negotiation Program compels it to make its drugs available to beneficiaries and its information available to the government. But, as discussed above, participation in the Negotiation Program is voluntary, and it does not require Boehringer to do anything if the company chooses not to participate. *See*

*supra* pp. 32-43 Thus, contrary to Boehringer's suggestion, the Negotiation Program does not require it to make any sales to Medicare or to provide drugs to any party. Nor does it require Boehringer to provide information to CMS. While Boehringer undoubtedly has a property interest in certain proprietary commercial information, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984)—on which Boehringer relies (Br. 27)—underscores that the "voluntary submission of data by an applicant in exchange for the economic advantages of a registration" does not entail a deprivation of that interest. *Ruckelshaus*, 467 U.S. at 1007.[5]

There is likewise no merit to Boehringer's assertion that it has a protected property interest in selling Jardiance to the government at a particular price. Br. 26-27. "[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). Just like private individuals and businesses, "the Government enjoys the unrestricted

[5] Even if the Negotiation Program did deprive Boehringer of a property interest in its trade secrets, its due process claim would still fail because Boehringer has not advanced—and has therefore forfeited—any argument as to what additional process it would be due before it submits data to the government. *See JP Morgan Chase Bank v. Altos Hornos de Mexico, S.A. de C.V.*, 412 F.3d 418, 428 (2d Cir. 2005).

power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases."[6] *Perkins*, 310 U.S. at 127.

Pursuant to the government's power to determine the prices it will pay for goods and services, other federal agencies have for decades negotiated with drug manufacturers over the price paid for drugs in other government programs. *See, e.g.*, 38 U.S.C. § 8126(a)-(h). Similarly, as a condition of Medicaid participation, drug manufacturers have long entered into agreements to provide drugs to certain healthcare facilities subject to statutory price ceilings. *See Astra USA*, 563 U.S. at 113 (describing requirements under Section 340B of the Public Health Service Act). And the government regularly negotiates the price it will pay for other goods. *See,*

[6] 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 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.

*e.g.*, 48 C.F.R. pts. 15, 215. Just as military contractors have no right to sell their products to the Department of Defense at prices above what the government is willing to pay, pharmaceutical companies have no right to sell drugs to Medicare at a particular price.

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

Contrary to Boehringer's contention, *Old Dearborn Distributing Co. v. Seagram-Distillers Corp.*, 299 U.S. 183 (1936), does not support its asserted

"property interest in deciding 'the price at which [it] will sell' its Jardiance[ ] products." Br. 26 (first alteration in original) (quoting *Old Dearborn*, 299 U.S. at 192). Citing a line of cases that have since been overruled, *Old Dearborn* asserted that legislatures generally may not impair "the right of the owner of property to fix the price at which he will sell" his property in the broader marketplace. 299 U.S. at 192. But the Supreme Court has since held that the Constitution does not substantively constrain a legislature's ability to fix the price of goods. *Olsen v. Nebraska ex rel. Western Reference & Bond Ass'n*, 313 U.S. 236, 247 (1941); *see also Nebbia v. New York*, 291 U.S. 502, 516 (1934) ("So far as the requirement of due process is concerned, and in the absence of other constitutional restriction, a state is free to adopt whatever economic policy may reasonably be deemed to promote public welfare, and to enforce that policy by legislation adapted to its purpose."). And *Old Dearborn* itself expressly affirmed the validity of legislation that allowed parties to fix the price of goods by contract. 299 U.S. at 192. Even on its terms, it did not recognize a freestanding property right to force a price on an unwilling buyer.

Boehringer's reliance (Br. 26-27) on cases concerning market-wide price-control regimes similarly underscores the lack of a protected property

interest in these circumstances. Unlike the provisions challenged in *Bowles*, 321 U.S. at 520-22, and *Yakus v. United States*, 321 U.S. 414, 432-43 (1944), in which Congress sought to regulate the price at which any person could sell or lease his property to *any* buyer, the Negotiation Program does not regulate the price at which Boehringer may sell Jardiance to any buyer other than the government. And Boehringer offers no sound reason to extend the analysis that applies to market-wide price restrictions to a law that governs only the procedures used to determine the price the government itself is willing to pay.

Boehringer's reliance (Br. 26-27) on *NICA*, is also misplaced. In *NICA*, the Fifth Circuit reversed an order dismissing a challenge to the IRA for lack of standing and lack of statutory jurisdiction. *See* 116 F.4th 488, 509 (5th Cir. 2024). By shearing crucial context from a quotation, Boehringer suggests that the Fifth Circuit recognized a "protected property interest[ ]" in avoiding a "revenue decrease." Br. 26 (quotation marks omitted). That language, however, comes from the Fifth Circuit's analysis of whether NICA had pleaded a sufficient injury to establish standing. The Fifth Circuit explained in that context that NICA "has a concrete interest in not seeing its members' revenue decrease as a result of allegedly unconstitutional

government action." 116 F.4th at 503. But whether a party has suffered an economic injury sufficient to establish standing and whether a party has a protected property interest for due process purposes are wholly separate questions. *Compare, e.g.*, *Booker-El v. Superintendent, Ind. State Prison*, 668 F.3d 896, 899 (7th Cir. 2012) (holding that plaintiff had adequately pleaded an injury-in-fact based on "a substantial risk in losing benefits"), *with id.* at 900-01 (holding that plaintiff lacked a property interest in those same benefits).

## II. The Negotiation Program is consistent with the First Amendment.

1. The Negotiation Program does not compel manufacturers' speech by requiring that participants sign a Manufacturer Agreement memorializing their decision to negotiate and—if negotiations succeed—the maximum amount that Medicare will pay for a selected drug. As the district court recognized, SPA31, Boehringer's compelled speech claims fail at the outset because "[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)). Boehringer faces no "actual compulsion" to engage in any speech because its participation in the Negotiation Program,

like its participation in Medicare and Medicaid, is voluntary. *See supra* pp. 32-43.

As discussed, manufacturers are subject to the Negotiation Program's terms—including the requirement to sign a Manufacturer Agreement—only if they choose to do business with the government by selling their drugs to Medicare and Medicaid. Just as nothing compels Boehringer to participate in these programs in the first instance, nothing compels it to engage in any form of protected speech. The voluntariness of the Negotiation Program and any attendant "speech" requirements is fatal to these 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").

2. The First Amendment claims also fail for the independent reason that the Negotiation Program regulates only non-expressive conduct and does not regulate Boehringer's 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) (quotation marks omitted), 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,'" *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 cover only the "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 about the product's price, 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) (noting that 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 *Giboney 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) (emphasizing that "offer and acceptance are communications incidental to the regulable transaction called a contract").

In requiring the parties to sign documents memorializing their intent to negotiate and their agreement upon the maximum price that Medicare will pay for selected drugs, the Negotiation Program regulates only non-expressive, commercial conduct, and any effects on speech are "plainly incidental." *FAIR*, 547 U.S. at 62. As the district court explained, the Manufacturer Agreement implements the Negotiation Program as "an

incidental means to CMS'[s] goal of regulating drug prices." SPA31. Manufacturers that choose to participate in the Program engage in negotiations with the government and agree to make any negotiated prices available when Medicare beneficiaries purchase selected drugs, and the Manufacturer Agreement memorializes those program terms. *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. Such commercial arrangements between the government and private parties to document agreed-upon prices raise no First Amendment concerns. 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, HHS, Form CMS-460, *Medicare Participating Physician or Supplier Agreement* (Nov. 2022), https://perma.cc/WG64-ZNPL.

3. There is no merit to Boehringer's objection (Br. 39-43) to the Manufacturer Agreement's use of statutory terms of art that are defined in

the IRA. The use of statutory terms in the Manufacturer Agreement promotes consistency and clarity. For example, the IRA defines the term "maximum fair price," 42 U.S.C. § 1320f(c)(3), and when that term is used in the Agreement, its meaning reflects its statutorily defined definition. *See Meese v. Keene*, 481 U.S. 465, 484-85 (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 Negotiation Program and do not convey or require Boehringer 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).

Indeed, the Manufacturer Agreement states explicitly that a manufacturer's signature reflects neither an "endorsement of CMS'[s] views" nor a representation of the manufacturers' views concerning the fairness of prices. JA299. 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." JA299. This language confirms that the Manufacturer Agreement uses statutory terms as a way of ensuring a consistent understanding of 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.

Boehringer errs in asserting (Br. 40-41) that language in a government contract describing a price as "fair" is atypical. Government contracting is premised on the government obtaining a "fair and reasonable price." 48 C.F.R. § 15.402(a); *see* 2 Karen L. Manos, *Government Contract Costs & Pricing* § 84:19, Westlaw (database updated Nov. 2024) ("The Government's stated pricing policy is to award contracts at fair and reasonable prices."). Every government contractor entering a fixed-price contract implicitly agrees that the price is fair; were it otherwise, the contractor could never defend its contract award against a bid protest. Nor is the IRA the first scheme to require a contractor to agree *expressly* that a price charged is "fair." *See, e.g.*, *United States v. General Dynamics Corp.*, 19 F.3d 770, 771 (2d Cir. 1994) (statute requires that in order to obtain a federal subsidy "the proposed ship purchaser and the shipyard submit backup cost details and evidence that the negotiated price is fair and reasonable" (quotation marks omitted)); *Air Borealis Ltd. P'ship v. United States*, 167 Fed. Cl. 370, 389

(2023) (contractor allowed to certify that price is "fair and reasonable" in lieu of providing cost data to government purchaser (quotation marks omitted)); *Sea-Land Serv., Inc. v. United States*, 493 F.2d 1357, 1360 (Ct. Cl. 1974) (agreement to sell ships to purchaser at "fair and reasonable values").

4. There is likewise no merit to Boehringer's contention that signing the Manufacturer Agreement constitutes expressive conduct. "In determining whether particular conduct possesses sufficient communicative elements to bring the First Amendment into play," courts ask "whether an intent to convey a particularized message was present, and whether the likelihood was great that the message would be understood by those who viewed it." *Young v. New York City Transit Auth.*, 903 F.2d 146, 153 (2d Cir. 1990) (cleaned up). As the district court correctly held, Boehringer has failed to carry its burden of showing that the First Amendment applies to its signing of the Agreement because it "cannot show it has been forced to 'convey a particularized message,' or that the 'likelihood was great' that anyone who read the Agreement would understand [Boehringer] to be espousing the views with which it 'strongly disagrees.'" SPA33; *see Clark v. Community for Creative Non-Violence*, 468 U.S. 288, 293 n.5 (1984) (the burden to show the First Amendment applies rests with the plaintiff).

Boehringer's signature memorializes its decision to participate in the Negotiation Program as well as the parties' understanding of the maximum price Medicare will pay for the selected drug. Those are among the standard actions often memorialized in commercial contracts. And the text of the Manufacturer Agreement in any event expressly disclaims any "intent to convey a particularized message" through the Agreement. *Young*, 903 F.2d at 153 (quotation marks omitted). The disclaimer provides that, "[i]n signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS'[s] 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." JA299. The Manufacturer Agreement, therefore, cannot reasonably be read to convey Boehringer's endorsement of a particular message. Signing an agreement to negotiate "is simply not the same as forcing a student to pledge allegiance [to the flag] or forcing a Jehovah's Witness to display [a particular motto on his license plate], and it trivializes the freedom protected in [those circumstances] to suggest that it is." *FAIR*, 547 U.S. at 61-62 (first citing *West Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943); and then citing *Wooley v. Maynard*, 430 U.S. 705 (1977)).

Boehringer's reliance on *Pacific Gas & Electric Co. v. Public Utilities Commission*, 475 U.S. 1 (1986) (plurality opinion), for the proposition that "disclaimers cannot negate a compelled-speech injury" is misplaced. Br. 46 (citing 475 U.S. at 15 n.11 (plurality opinion)). *Pacific Gas* involved a challenge to a rule requiring "a privately owned utility company to include in its billing envelopes speech of a third party with which the utility disagree[d]." 475 U.S. at 4 (plurality opinion). The Supreme Court held in that context that, while a disclaimer stating that the third-party speech did not represent the views of the utility was ineffective to avoid certain First Amendment harms, it indeed served "to avoid giving readers the mistaken impression that [the third party's] words are really those of [the utility]." *Id.* at 15 n.11. *Pacific Gas* thus underscores that such disclaimers prevent reader misapprehension of the views being expressed and confirms the absence of any intent in the Manufacturer Agreement to convey a particularized message.

## III. The Negotiation Program does not leverage a discretionary benefit to compel a waiver of Boehringer's constitutional rights.

Congress acted well within any constraints that the unconstitutional conditions doctrine imposes in this context by making the government's offer

to pay for drugs through Medicare and Medicaid contingent on manufacturers' agreement to negotiate the price of certain high-expenditure drugs. The unconstitutional conditions doctrine prevents the government from requiring a person to give up a constitutional right in order to receive an unrelated benefit. *See Rust v. Sullivan*, 500 U.S. 173, 196-98 (1991). Even assuming the doctrine applies here, where Boehringer is neither a beneficiary of discretionary benefits nor a government employee or independent contractor, *see* Br. 57-58 (collecting cases limited to those contexts),[7] the requirements imposed by the Negotiation Program directly relate to the program's goal of controlling costs and do not impede Boehringer's ability to exercise its rights outside the scope of the Program.[8]

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[7] Contrary to Boehringer's suggestion that the unconstitutional conditions doctrine has been held to apply "when the Government contracts for goods," Br. 58, Boehringer cites no case in which the doctrine has been applied in that context. The cases on which it relies for this point all concern the doctrine's application in the context of government employment and hold that, in general, independent contractors are not treated differently from employees for purposes of this analysis. *O'Hare Truck Serv., Inc. v. City of Northlake*, 518 U.S. 712, 720 (1996); *Board of Cty. Comm'rs v. Umbehr*, 518 U.S. 668, 678-79 (1996); *Oscar Renda Contracting, Inc. v. City of Lubbock*, 463 F.3d 378, 385 (5th Cir. 2006). Boehringer plainly is not an independent contractor, and those cases have no bearing on this analysis.

[8] Boehringer's reliance (Br. 59) on the "nexus-and-proportionality test from *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994)," and *Nollan v. California Coastal Commission*, 483 U.S. 825, 834-37 (1987), is misplaced, as

*Continued on next page.*

As the Supreme Court explained in *Rust*, the government may condition the receipt of federal funds on compliance with program-specific requirements without violating the unconstitutional conditions doctrine, so long as the conditions are relevant to the program's purpose and "leave the grantee unfettered in its other activities." 500 U.S. at 196. The "'unconstitutional conditions' cases involve situations in which the Government has placed a condition on the recipient of the subsidy rather than on a particular program or service, thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally funded program." *Id.* at 197 (emphasis omitted). This jurisprudence has thus consistently distinguished between provisions that set the terms of and define the scope of government programs, on the one hand, and provisions that impose external conditions on the recipient of a government benefit, 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

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the Supreme Court has made clear that this 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").

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.* (*AID*), the Court struck down a condition that required non-governmental organizations receiving federal HIV/AIDS funding to adopt a policy announcing their opposition to prostitution and sex trafficking that extended well beyond the scope of the funded program. 570 U.S. 205, 218 (2013).

These cases underscore the permissibility of the Negotiation Program terms. The IRA sets the terms of the government's offer to pay for drugs for Medicare beneficiaries and does not set an external "condition" on manufacturers' ability to sell drugs. The government has a substantial interest in curbing the rising costs of public spending on prescription drugs. *See Lyng v. International Union, United Auto., Aerospace & Agric. Implement Workers of Am.*, 485 U.S. 360, 373 (1988) (acknowledging the government's legitimate interest in "protecting the fiscal integrity of[g]overnment programs, and of the [g]overnment as a whole"). 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 Boehringer 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-payment program, and they do not impede Boehringer's ability to exercise its rights outside of the government's prescription drug spending.

To the extent that Boehringer objects to signing (1) an agreement to negotiate and (2) an addendum stipulating the agreed price after a deal is reached, Br. 62, those requirements are central to the operation of the Negotiation Program as they 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 Manufacturer Agreement "define[s] the federal program" and does not "reach outside it." *AID*, 570 U.S. at 217. Indeed, Boehringer can and has spoken out against the Negotiation Program. *See, e.g.*, Br. 14 (noting that Boehringer signed Agreement "under protest"). Thus, even if the Manufacturer Agreement implicated Boehringer's speech interests—which, for the reasons discussed, it does not, *see supra* pp. 50-59—there is no serious argument that Congress

has impermissibly leveraged its spending "to regulate speech outside the contours of the program itself." *AID*, 570 U.S. at 214-15.

Boehringer's contention that the Negotiation Program impermissibly conditions participation on the relinquishment of Fifth Amendment rights likewise fails because the terms to which Boehringer objects are central to the operation of the program and "leave [Boehringer] unfettered in its other activities." *Rust*, 500 U.S. at 196. The negotiation of prices is the central point of Congress's decision to establish the Program and cannot reasonably be described as an extrinsic condition imposed on manufacturers. And because Boehringer remains free to sell its drugs to other purchasers at any price, this requirement does not infringe on Boehringer's rights "outside the scope of the federally funded program." *Id.* at 197.

## IV. Congress authorized CMS to implement the Negotiation Program without resort to notice-and-comment rulemaking.

The IRA directs CMS to "implement" the Negotiation Program's first three years through "program instruction or other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854. After that initial period, beginning in 2028, CMS is to follow the Medicare Act's default rule and use notice-and-comment procedures before promulgating any "rule,

requirement, or other statement of policy . . . that establishes or changes a substantive legal standard." 42 U.S.C. § 1395hh(a)(2).

CMS followed Congress's directive when it implemented the first year of the Negotiation Program through guidance that includes the terms of the Manufacturer Agreement. Revised Guidance 118-32. There is no merit to Boehringer's argument that CMS needed to promulgate the Agreement through notice-and-comment rulemaking.

Both the Medicare Act and the APA explicitly contemplate situations in which Congress "expressly" authorizes agencies to depart from notice-and-comment procedures. 5 U.S.C. § 559; 42 U.S.C. § 1395hh(b)(2)(A). It is well established that Congress need not employ "'magical passwords'" to exempt a subsequent statutory scheme from notice-and-comment requirements; it simply needs to demonstrate its intent to apply a different procedural framework. *Dorsey v. United States*, 567 U.S. 260, 274 (2012). When Congress "specifie[s] procedures . . . that cannot be reconciled with the notice and comment requirements of [the APA]" or the Medicare Act, it has manifested its intent to waive notice-and-comment requirements. *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998).

Despite the IRA's express text, Boehringer argues that Congress was not clear enough in directing CMS to implement the Negotiation Program through guidance. Br. 33-34. But Congress made its intent perfectly clear when it "specifie[d] procedures which differ from those of the APA" and the Medicare Act by directing CMS "to issue not a proposed rule" but rather program instruction or other guidance. *Asiana Airlines*, 134 F.3d at 398. CMS did not err in following those procedures.[9]

Accepting Boehringer's argument would render section 11001(c) meaningless, as Boehringer fails to suggest what purpose the directive to implement the Negotiation Program through guidance would serve if not to obviate the need for notice-and-comment procedures during the initial years of the Program's implementation. *See Pulsifer v. United States*, 601 U.S. 124, 142-43 (2024) (rejecting interpretation that would give subparagraph of statute "no independent work" to do). Boehringer is thus asking this Court to disregard not just a word but an entire substantive provision of the IRA,

[9] Although not required by the IRA, CMS voluntarily solicited comments on the content of the Manufacturer Agreement. *See* Revised Guidance 30. Boehringer chose not to avail itself of this opportunity. *See* Dkt. No. 48-1, at 55 n.14 ("[Boehringer] submitted a comment expressing its views with regard to various aspects of the Initial Guidance, but declined to respond to CMS's request for comments on the terms and conditions of the Agreement.").

which "is so evidently designed to serve a concrete function." *Id.* at 143. "[T]he canon against surplusage applies with special force" when it would invalidate an entire provision of an Act. *Id.*; *see also National Ass'n of Mfrs. v. DOD*, 583 U.S. 109, 128 (2018).

Boehringer fares no better with its argument that the Manufacturer Agreement "does not fall within the scope of section 11001(c)" because the "IRA distinguishes between the Agreement and 'program instructions or other forms of program guidance.'" Br. 32 (cleaned up). Contrary to Boehringer's suggestion, the material terms of the Agreement are contained in the guidance that CMS issued. *See* Revised Guidance 118-32. And the Agreement plainly is part of CMS's "implement[ation]" of the Negotiation Program, as it is the means through which the parties memorialize the decision to negotiate, as well as any negotiated price. IRA § 11001(c), 136 Stat. at 1854. The idea that Congress generally authorized CMS to implement the Negotiation Program through guidance but required notice-and-comment procedures in connection with the Agreement that provides the central means for effectuating the Program's terms runs counter to the text and purpose of the statute.

## CONCLUSION

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

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## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 13,759 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 Century Expanded BT 14-point font, a proportionally spaced typeface.

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