In the
United States Court of Appeals
For the Second Circuit

August Term, 2024
No. 24-2092

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, CENTERS FOR MEDICARE AND MEDICAID SERVICES, MEHMET OZ, in his official capacity as Administrator of Centers for Medicare and Medicaid Services,
Defendants-Appellees.*

On Appeal from a Judgment of the United States District Court for the District of Connecticut.

ARGUED: APRIL 3, 2025
DECIDED: AUGUST 7, 2025

Before: LEVAL, BIANCO, and NARDINI, *Circuit Judges*.

* The Clerk of Court is respectfully directed to amend the official caption as set forth above.

The Inflation Reduction Act of 2022 (the "IRA") authorized the creation of the Medicare Drug Price Negotiation Program (the "Negotiation Program") to limit the federal government's spending on prescription drugs under Medicare. Under the statute, the Centers for Medicare and Medicaid Services ("CMS") must select a certain number of the highest-expenditure drugs for participation in the program each year. For the initial 2026 pricing period, CMS selected ten drugs, including Jardiance, which is produced by Plaintiff-Appellant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer").

Boehringer signed an agreement with CMS to participate in the Negotiation Program, but it did so "under protest" and at the same time commenced this lawsuit against the government. Boehringer raised five constitutional claims, alleging that the Negotiation Program (1) violates its Fifth Amendment right to procedural due process, (2) effects a *per se* physical taking of its Jardiance product in violation of the Fifth Amendment, (3) compels speech in violation of the First Amendment, (4) violates the Excessive Fines Clause of the Eighth Amendment, and (5) unconstitutionally conditions its participation in Medicare and Medicaid on the relinquishment of its constitutional rights. The company also alleged that CMS violated the Administrative Procedure Act (the "APA") and the Medicare Act by issuing the standard agreement for the Negotiation Program without following notice-and-comment procedures. The district

court (Michael P. Shea, *Chief Judge*) granted summary judgment to the defendants on all claims.

Boehringer appeals the district court's dismissal of its claims under the First and Fifth Amendments and the APA. We agree with the district court's principal conclusions that: (1) Boehringer's direct constitutional claims fail because, under *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), participation in the Negotiation Program is voluntary and thus does not entail an unlawful deprivation of rights; (2) the program does not impose unconstitutional conditions on Boehringer's ability to participate in Medicare and Medicaid because the program is designed to promote the legitimate government purpose of controlling Medicare spending and does not regulate the company's conduct in the private market; and (3) the IRA expressly authorized CMS to implement the program during its first three years without following the APA's notice-and-comment requirement.

Accordingly, the judgment of the district court is AFFIRMED.

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Constitutional Accountability Center, *in support of Defendants-Appellees*.

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WILLIAM J. NARDINI, *Circuit Judge*:

Reversing a nearly twenty-year policy that prevented the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program, from negotiating the prices of drugs purchased for the Medicare program, the Inflation Reduction Act of 2022 (the "IRA") authorized the creation of the Medicare Drug Price Negotiation Program (the "Negotiation Program") to limit the federal government's spending on prescription drugs under Medicare. CMS is required to pick a certain number of the highest-expenditure drugs—subject to other criteria, including a lack of generic competitors—for participation in the program each year, beginning with 2026. The IRA sets price ceilings for the selected drugs—ranging from 40 to 75 percent of the average price paid by wholesalers in the private market—and requires CMS and the drug

manufacturers to agree to a statutorily defined "maximum fair price," which must reflect factors such as the research and development costs of the drug. For the initial 2026 pricing period, CMS chose ten drugs, including Jardiance, which is produced by Plaintiff-Appellant Boehringer Ingelheim Pharmaceuticals, Inc.

Boehringer signed an agreement with CMS to participate in the Negotiation Program, but it did so "under protest" and at the same time brought this lawsuit against CMS; the U.S. Department of Health and Human Services, of which CMS is a constituent agency; and the leaders of both agencies. Boehringer raised five constitutional claims, alleging that the Negotiation Program (1) violates its Fifth Amendment right to procedural due process, (2) effects a *per se* physical taking of its Jardiance product in violation of the Fifth Amendment, (3) compels speech in violation of the First Amendment, (4) violates the Excessive Fines Clause of the Eighth Amendment, and (5) unconstitutionally conditions its participation in Medicare and Medicaid on the relinquishment of its constitutional rights. The company also alleged that CMS violated the Administrative Procedure Act (the "APA") and the Medicare Act by issuing the standard agreement for the Negotiation Program without following notice-and-comment procedures. In a careful and comprehensive opinion, the district court (Michael P. Shea, *Chief Judge*) granted summary judgment to the defendants on all claims.

Boehringer appeals the district court's dismissal of its claims under the First and Fifth Amendments and the APA. We agree with the district court's principal conclusions that: (1) Boehringer's direct

constitutional claims fail because, under *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), participation in the Negotiation Program is voluntary and thus does not entail an unlawful deprivation of rights; (2) the program does not impose unconstitutional conditions on Boehringer's ability to participate in Medicare and Medicaid because the program is designed to promote the legitimate government purpose of controlling Medicare spending and does not regulate the company's conduct in the private market; and (3) the IRA expressly authorized CMS to implement the program during its first three years without following the APA's notice-and-comment requirement. Accordingly, the judgment of the district court is AFFIRMED.

I. Background

A. The Medicare Drug Price Negotiation Program

Medicare is a federal medical insurance program for people aged sixty-five and older and for certain younger people with disabilities. *See* 42 U.S.C. § 1395 *et seq.* The program is administered by CMS, a constituent agency of the U.S. Department of Health and Human Services ("HHS"). The Medicare statute is divided into five "Parts," lettered A through E, which establish the terms of benefits provided under the program. As relevant here, Part B is a voluntary supplemental insurance program that covers outpatient care, including certain prescription drugs that are typically administered by a physician, and Part D is a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums. *See* 42 C.F.R. §§ 410.28,

423.120. Part D "operates as a public-private partnership between [CMS] and . . . private insurance companies called 'Sponsors' that administer prescription drug plans." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017). Under Part D, insurers negotiate drug prices with manufacturers, and then CMS pays the insurers fixed amounts based on their anticipated drug spending.

When Congress enacted Medicare Part D in 2003, it barred CMS from negotiating, or otherwise attempting to influence, the price of drugs covered by the program. Specifically, Congress provided that CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and . . . sponsors," and "may not . . . institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1), (3) (2003). Nearly two decades later, Congress created an exception to that non-interference provision via the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (codified in pertinent part at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D), which authorized the Secretary of Health and Human Services to establish a Negotiation Program to limit the cost of certain drugs under Medicare Parts B and D.[1]

[1] The Secretary delegated authority to administer the Negotiation Program to CMS. We therefore refer to CMS when discussing the program.

1. The Drug Selection Phase

The Negotiation Program operates in annual drug-pricing cycles in which CMS selects participating drugs and negotiates prices for a given calendar year ("pricing period"), beginning with 2026. 42 U.S.C. § 1320f(b). During each cycle, CMS first must identify negotiation-eligible drugs, which must have no generic or biosimilar competitors; must have been approved or licensed for at least seven years; and must rank among the fifty drugs with the highest total expenditures under either Medicare Part B or Part D over a recent twelve-month period. *See* 42 U.S.C. § 1320f-1(d), (e).[2] Next, CMS must select and publish a list of the negotiation-eligible drugs with the highest expenditures that will be subject to negotiation for that drug-pricing cycle. *Id.* § 1320f-1(a), (b)(1)(B). The statute requires the selection of ten drugs for the 2026 pricing period, fifteen drugs for 2027 and 2028, and twenty drugs for 2029 and all subsequent pricing periods. *Id*. § 1320f-1(a).

2. The Manufacturer Agreement

After completing the drug selection phase of a drug-pricing cycle, CMS has to engage with the manufacturers of the selected drugs to determine whether they intend to participate in the program. CMS must "enter into agreements," by specified deadlines, with the

[2] The Negotiation Program applies only to drugs covered by Medicare Part D for the 2026 and 2027 pricing periods. 42 U.S.C. § 1320f-1(a)(1)–(2), (d)(1). Beginning with the 2028 pricing period, the program will also apply to drugs covered by Medicare Part B. *Id.* § 1320f-1(a)(3)–(4), (d)(1).

manufacturers that are willing to participate in negotiations. *Id.* §§ 1320f(a)(2), 1320f-2. Pursuant to this directive, CMS set out to create a standard agreement that could be used for negotiations with the manufacturer of each selected drug. On March 15, 2023, CMS issued initial guidance describing the possible contents of the prospective agreement and "voluntarily solicit[ed] comments" on the "[t]erms and conditions" that the agreement should contain. CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum* (Mar. 15, 2023), https://perma.cc/54JU-BQDP. In response to the comments received on the initial guidance, CMS issued revised guidance on June 30, 2023, which included the material terms of the negotiation agreement. *See* Joint App'x 97–294. Finally, on July 3, 2023, CMS issued a template of the Medicare Drug Price Negotiation Agreement (the "Manufacturer Agreement"). Although CMS solicited comments from the public in its March 15, 2023, guidance memorandum, the agency did not conduct a formal notice-and-comment process before issuing the agreement template.

Several provisions of the Manufacturer Agreement are relevant here. For one, the agreement provides that "CMS and the Manufacturer shall negotiate to determine . . . a maximum fair price for the Selected Drug." Joint App'x 297. The manufacturer agrees to make that price available to "maximum fair price eligible individuals," hospitals, health care providers, pharmacies, and other entities described in the IRA. *Id.*; *see also* 42 U.S.C. § 1320f(c)(2) (defining "maximum fair price eligible individual"). Additionally, the manufacturer must provide certain information to CMS about the

drug, including the average price paid by wholesalers to the manufacturer in the private market (the "private market price") and any other information that CMS requires for the negotiation process. Joint App'x 297–98; *see also* 42 U.S.C. § 1320f-2(a)(4) (statutory provision stating that the Manufacturer Agreement must require the manufacturer to provide this information).[3] Any information submitted by the manufacturer that CMS deems "proprietary information" can be used only for the Negotiation Program. 42 U.S.C. § 1320f-2(c). The agreement also provides that the manufacturer, by entering into the agreement, does not endorse CMS's views or adopt the statutory definitions of terms such as "maximum fair price" for purposes other than carrying out the agreement. *See* Joint App'x 299. Specifically, the disclaimer states:

> In 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. Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.

Id.

[3] The deadline to submit that data during the initial negotiation period was October 2, 2023. 42 U.S.C. § 1320f(d)(5)(A).

3. The Negotiation Phase

Once CMS and the manufacturer of a selected drug execute the Manufacturer Agreement, the negotiation phase begins. The IRA directs CMS to negotiate a statutorily defined "maximum fair price[]" for each selected drug. 42 U.S.C. § 1320f(a)(3). As an initial matter, the manufacturer must provide CMS with the required data about the selected drug. *Id.* §§ 1320f-3(b)(2)(A), 1320f(d)(5)(A). The negotiation then proceeds in a familiar pattern: offer, acceptance or counteroffer, response, and so on. But unlike typical negotiations, these have strict parameters for pricing, and they end with CMS effectively getting the final word.

CMS must make an initial offer as to the "maximum fair price" that it will pay for the drug. The IRA establishes a price ceiling on the maximum fair price based on the private market price of the selected drug. *See id.* § 1320f-3(c). In general, CMS may not offer or agree to a price that exceeds 75 percent of the private market price for any selected drug. *Id.* Lower price ceilings apply to drugs that have been approved or licensed for longer periods: 65 percent for drugs that have been approved or licensed for at least 12 years, and 40 percent for those that have been approved or licensed for at least 16 years. *Id.* To determine the maximum fair price, CMS must consider several factors, including the costs of researching, developing, manufacturing, and distributing the drug; whether alternative treatments are available; and the comparative effectiveness of any such alternatives. *Id.* § 1320f-3(e). Save for an exception not relevant here, there is no floor on the maximum fair price. *Id.* § 1320f-3(d).

Within thirty days of receiving CMS's initial offer, the manufacturer must either accept that offer or make a written counteroffer, which must be "justified based on the factors [specified in the statute]." *Id.* § 1320f-3(b)(2)(C)(i)–(ii). If the manufacturer makes a counteroffer, CMS must respond to it in writing. *Id.* § 1320f-3(b)(2)(D). CMS guidance provides that if CMS declines the counteroffer, the agency and the manufacturer may schedule "[u]p to three possible negotiation meetings" to "negotiate [the maximum fair price] for the selected drug." Joint App'x 187–88. During the initial negotiation period, CMS was required to make its final maximum fair price offer to the manufacturer by July 15, 2024, which the manufacturer was required to respond to by July 31, 2024; negotiations were to conclude by August 1, 2024.

The Manufacturer Agreement provides that if CMS and the manufacturer agree to a maximum fair price, that price is incorporated into the agreement through an addendum signed by the manufacturer. Joint App'x 302 (addendum providing that "the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug," and "the Manufacturer and CMS now agree to a price for the Selected Drug"). If the manufacturer does not agree to a maximum fair price by the deadline, it may incur "potential excise tax liability," as discussed below. *Id.* at 252; 26 U.S.C. § 5000D(b)(2). Once the maximum fair price is set, that price will take effect at the beginning of the first applicable pricing period and will continue to apply during subsequent pricing periods until the selected drug is no

longer eligible for the Negotiation Program or the price is renegotiated. *Id.* §§ 1320f(b)(1)–(2), 1320f-1(c), and 1320f-3(f).

4. Civil Monetary Penalties and the Excise Tax

Under the IRA, manufacturers that sign the Manufacturing Agreement but later violate certain statutory requirements are subject to civil monetary penalties. For every unit of a selected drug that a manufacturer sells at a price exceeding the maximum fair price, the manufacturer must pay a penalty equal to ten times the difference between the higher price and the maximum fair price. 42 U.S.C. § l320f-6(a). Additionally, any manufacturer that fails to submit required information to CMS or otherwise fails to comply with the Negotiation Program's requirements must pay a penalty of $1,000,000 for each day of the violation. *Id.* §§ 1320f-6(c), 1320f-2(a)(4)–(5).

The IRA also authorizes an excise tax on sales of selected drugs by manufacturers that do not sign the Manufacturer Agreement or that fail to agree to a maximum fair price during negotiations with CMS. 26 U.S.C. § 5000D(a)–(b). The tax is assessed for each day of the "noncompliance periods," which begin when the deadline to sign the Manufacturer Agreement or to agree to a maximum fair price has passed and generally end when the manufacturer reaches an agreement with CMS. *Id.* § 5000D(b). The excise tax is imposed "on the sale by the manufacturer . . . of any designated drug," *id.* § 5000D(a), which the statute defines as "any negotiation-eligible drug . . . included on the list [of drugs selected under 42 U.S.C. § 1320f-1(a) for the Negotiation Program] which is manufactured or

produced in the United States or entered into the United States for consumption, use, or warehousing," *id.* § 5000D(e)(1).

5. Alternatives to the Penalties and Excise Tax

A manufacturer that does not wish to participate in the Negotiation Program can avoid the excise tax by transferring ownership of the selected drug to another entity, or withdrawing all its products from Medicare and Medicaid. If, after signing the Manufacturer Agreement, a manufacturer decides to transfer ownership of the drug to another entity, it must notify CMS at least thirty days before the transfer becomes effective, per CMS guidance. Once the transfer becomes effective, any excise tax liability could be imposed on the new owner. If the manufacturer instead chooses to maintain ownership of the selected drug and withdraw all its products from Medicare and Medicaid, the excise tax will be "suspend[ed]" provided that (1) the manufacturer provides CMS with notice of termination of certain Medicare and Medicaid agreements, 26 U.S.C. § 5000D(c)(1)(A)(i), (c)(2)(B); and (2) none of the manufacturer's drugs are covered by the Medicare Coverage Gap Discount Program Agreement or the Medicare Part D Manufacturer Discount Program Agreement, 26 U.S.C. § 5000D(c)(1)(A)(ii).

A manufacturer may terminate its agreements under the Medicare Coverage Gap Discount Program or the Medicare Part D Manufacturer Discount Program "for any reason," but the termination will not become effective for eleven to twenty-three months after CMS receives the termination notice. 42 U.S.C.

§§ 1395w-114a(b)(4)(B)(ii), 1395w-l14c(b)(4)(B)(ii). Following the enactment of the IRA, some manufacturers, citing the long period before termination of those agreements can become effective, petitioned CMS to permit immediate termination of the agreements so that manufacturers could avoid the excise tax that they would otherwise need to pay during the statutory pre-termination period. To address this concern, CMS issued guidance establishing a process for manufacturers "to expedite [their] termination" from the Medicare programs. Joint App'x 99. By statute, CMS "may provide for termination" of Medicare Coverage Gap Discount Program agreements, and "shall provide for termination" of Manufacturer Discount Program agreements, after just 30 days "for a knowing and willful violation of the requirements of the agreement or other good cause shown." 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). The CMS guidance permits the manufacturer to submit a notice to CMS stating its intent not to participate in the Negotiation Program and requesting termination of its agreements under Medicare and Medicaid. Upon receipt of such notice, "CMS will find good cause to terminate the [manufacturer's] agreement(s) under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program . . . pursuant to [42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i)]." Joint App'x 217; *see also id.* ("CMS has determined . . . that it will automatically grant such termination requests upon receipt, and that it will expedite the effective date [of the termination so that it occurs thirty days after the manufacturer gives notice]."). Thus, under this process, a

manufacturer could withdraw from Medicare and Medicaid in as few as thirty days after providing notice to CMS.

6. Preclusion of Judicial and Administrative Review

The IRA precludes HHS and the federal courts from reviewing CMS's decisions regarding the selection and pricing of drugs for the Negotiation Program. Specifically, the statute provides that "[t]here shall be no administrative or judicial review" of (1) the determination of which drugs are negotiation-eligible, (2) the selection of drugs for the Negotiation Program, or (3) the final maximum fair price. 42 U.S.C. § 1320f-7(2)–(3).

B. Selection of Jardiance for the Negotiation Program

Pursuant to the IRA, CMS selected ten drugs for the initial 2026 pricing period, including Boehringer's Jardiance product. 42 U.S.C. § 1320f-1(a)(1); HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The deadlines for CMS and the manufacturers of the selected drugs to enter into Manufacturer Agreements and for the manufacturers to submit the required data for the selected drugs were October 1 and 2, 2023, respectively. *See* 42 U.S.C. § 1320f(d)(4)–(5), 1320f-2(a), and 1320f-3(b)(2)(A). On October 3, 2023, CMS announced that each of the manufacturers, including Boehringer, had "chosen to participate in the Negotiation Program" and had signed the Manufacturer Agreement. 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 August 2024, CMS announced that negotiations with Boehringer resulted in an agreement on a maximum fair price for Jardiance equal to 34 percent of its 2023 private market price. That price is scheduled to take effect on January 1, 2026.

C. District Court Proceedings

On August 18, 2023, Boehringer commenced this suit against HHS; Xavier Becerra, then-Secretary of Health and Human Services; CMS; and Chiquita Brooks-Lasure, then-Administrator of CMS.[4] Boehringer raised five constitutional claims, alleging that the Negotiation Program (1) violates its Fifth Amendment right to procedural due process, (2) effects a *per se* physical taking of its Jardiance product in violation of the Fifth Amendment, (3) compels speech in violation of the First Amendment, (4) violates the Excessive Fines Clause of the Eighth Amendment, and (5) unconstitutionally conditions its participation in Medicare and Medicaid on the relinquishment of its constitutional rights. Boehringer also alleged that CMS violated the Administrative Procedure Act and the Medicare statute by issuing legislative rules without notice and comment. The parties subsequently cross-moved for summary judgment.

[4] Pursuant to Federal Rule of Appellate Procedure 43(c)(2), Secretary of Health and Human Services Robert F. Kennedy, Jr., and CMS Administrator Mehmet Oz are automatically substituted for their predecessors as defendants.

In an order entered on July 3, 2024, the district court granted summary judgment to the defendants. The court first concluded that Boehringer's Fifth Amendment takings and due process claims fail because participation in the Negotiation Program is voluntary, and thus Boehringer has not been illegally deprived of any property interests. Next, the court dismissed Boehringer's First Amendment compelled speech claim, reasoning that because participation in the Negotiation Program is voluntary, the Manufacturer Agreement "did not 'compel' [Boehringer] to do anything." *Boehringer Ingelheim Pharms., Inc. v. United States Dep't of Health & Hum. Servs.*, No. 23-CV-01103 (MPS), 2024 WL 3292657, at *16 (D. Conn. July 3, 2024). The court also dismissed Boehringer's unconstitutional conditions claim, largely for the reasons it set forth with respect to the direct constitutional claims, and for the additional reason that "the condition the government has imposed—that [Boehringer] sell the drug for the maximum fair price—is closely related to the government's goal of controlling spending in the Medicare program." *Id.* at *19. Finally (as relevant here), the court dismissed Boehringer's APA claim, concluding that the IRA expressly permitted CMS "to implement the [Negotiation] Program through guidance for the first three negotiation cycles" and forgo the notice-and-comment requirement that otherwise would have applied.[5] *Id.* at *21.

[5] In the district court, Boehringer also alleged that CMS violated the Medicare Act's notice-and-comment requirement (in addition to the APA's) and that the IRA's excise tax violated the Excessive Fines Clause of the Eighth Amendment. The district court also dismissed those claims, but Boehringer does not raise them on appeal.

II. Discussion

Boehringer raises six principal arguments on appeal. First, the company argues that the Negotiation Program effects a *per se* taking of its Jardiance products (that is, the physical doses of the drug) by giving Medicare beneficiaries access to Jardiance on terms dictated by the government, in violation of the Takings Clause of the Fifth Amendment. Second, the company argues that the program violates the Due Process Clause of the Fifth Amendment because, among other reasons, the IRA bars administrative and judicial review of CMS's price-setting decisions. Third, the company argues that the program violates its First Amendment right to free speech by compelling the company to endorse the government's characterization of the program, including that the CMS-determined price is the "maximum fair price." Fourth, in connection with the foregoing arguments, Boehringer contends that the district court erroneously dismissed the company's three direct constitutional claims based on the incorrect conclusion that participation in the Negotiation Program is voluntary. Fifth, Boehringer argues that even if participation in the program were voluntary, the program would violate the unconstitutional conditions doctrine because Congress conditioned Boehringer's ability to market *any* products through Medicare and Medicaid on the company's participation in the program and relinquishment of its First and Fifth Amendment rights. Finally, Boehringer argues that CMS violated the Administrative Procedure Act by issuing the Manufacturer Agreement without following notice-and-comment procedures.

"We review a district court's grant of summary judgment de novo, construing the evidence in the light most favorable to the nonmoving party and drawing all reasonable inferences in that party's favor." *Kuebel v. Black & Decker Inc.*, 643 F.3d 352, 358 (2d Cir. 2011). "Summary judgment is appropriate only if 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Id.* (quoting Fed. R. Civ. P. 56(a)).

The district court correctly granted summary judgment to the government on all claims. Applying our holding in *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), we conclude that participation in the Negotiation Program is voluntary because there is no legal compulsion to offer products or services through the program. We therefore reject Boehringer's argument that the Negotiation Program directly violates the company's rights under the First and Fifth Amendments. Further, we conclude that the program does not *indirectly* violate Boehringer's constitutional rights under the unconstitutional conditions doctrine because the requirements to which Boehringer objects fall within Congress's broad power to set the terms of federally funded programs and have no bearing on the company's activity outside the contours of Medicare and Medicaid. Lastly, we conclude that Boehringer's APA claim fails because CMS's issuance of the Manufacturer Agreement fell within the IRA's exemption from the APA's notice-and-comment requirement.

A. Whether Participation in the Negotiation Program Is Voluntary

The threshold question underlying Boehringer's direct constitutional claims is whether participation in the Negotiation Program is voluntary. Under *Garelick*, the answer is yes.

In that case, a group of New York hospital-based anesthesiologists challenged a federal law that limited the amount they could charge under Medicare Part B to set percentages of the Medicare-defined "reasonable" charge for their services. The anesthesiologists argued that they were required to treat Medicare patients under New York law and thus had no choice but to submit to the Medicare price regulations. This regulatory scheme, they argued, gave rise to a regulatory taking of their property interests in their licenses and medical practices without just compensation, in violation of the Fifth Amendment.[6]

We affirmed the dismissal of the anesthesiologists' takings claim on the ground that their participation in Medicare was in fact

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[6] "A regulatory taking . . . occurs where even absent a direct physical appropriation, governmental regulation of private property 'goes too far' and is 'tantamount to a direct appropriation or ouster.'" *1256 Hertel Ave. Assocs., LLC v. Calloway*, 761 F.3d 252, 263 (2d Cir. 2014) (quoting *Lingle v. Chevron USA Inc.*, 544 U.S. 528, 537 (2005)). In contrast, "[a] physical taking occurs when there is either a condemnation or a physical appropriation of property." *Id.*

The anesthesiologists in *Garelick* also raised a second takings theory that has no bearing on this case, so we need not address it here. *See Garelick*, 987 F.2d at 916.

voluntary.[7] We explained that "[a] property owner must be legally compelled to engage in price-regulated activity for regulations to give rise to a taking." *Garelick*, 987 F.2d at 916 (citing *Bowles v. Willingham*, 321 U.S. 503, 517–18 (1944)). "By contrast," we continued, "where a service provider voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no taking." *Id.* Applying these principles, we determined that the anesthesiologists had no viable takings claim because the challenged statute "d[id] not require anesthesiologists, or

[7] Other circuits have recognized in various contexts that participation in Medicare and Medicaid is voluntary. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1279–80 (11th Cir. 2014) (explaining that participation in Medicare is voluntary); *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009) (provider participation in Medicaid is voluntary); *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) ("participation in the Medicare program is a voluntary undertaking"); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary."); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) ("provider participation [in Medicare] is voluntary"); *see also Nat'l Lifeline Ass'n v FCC*, 983 F.3d 498, 515 (D.C. Cir. 2020) ("[W]hen an owner of property voluntarily participates in a regulated market, additional regulations that 'may reduce the value of the property regulated' do not result in a taking." (quoting *Bowles*, 321 U.S. at 517)).

Moreover, we recently recognized in the context of a physical takings claim (specifically, a challenge to a New York rent control law) that such a claim cannot succeed when it is premised on a plaintiff's voluntary participation in a price-regulated market. *See 74 Pinehurst LLC v. New York*, 59 F.4th 557, 563 (2d Cir. 2023) ("[W]here . . . property owners *voluntarily* invite third parties to use their properties, regulations of those properties are 'readily distinguishable' from those that compel invasions of properties closed to the public.") (quoting *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 157 (2021)), *cert. denied*, 218 L. Ed. 2d 66 (Feb. 20, 2024).

any other physicians, to provide services to Medicare beneficiaries." *Id.* The statute "simply limit[ed] the amounts" that the anesthesiologists could "charge those Medicare beneficiaries whom they [chose] to serve." *Id.* The anesthesiologists "retain[ed] the right to provide medical services to non-Medicare patients free of price regulations." *Id.*

We rejected the anesthesiologists' argument that other factors, if not the challenged statute itself, created a legal compulsion to participate in Medicare.[8] For one, under their theory, it was New York State, a non-party, that "indirectly compel[led] anesthesiologists to treat Medicare patients and thus submit to price regulations, not the federal government." *Id.* at 917. Moreover, as relevant here, we concluded that "even if the alleged compulsion to serve Medicare patients [in hospitals] were imputed to the federal government," the anesthesiologists' takings claim would fail because they could "avoid treating Medicare beneficiaries by practicing on an outpatient basis." *Id.* Although the anesthesiologists insisted that "limiting themselves to outpatient practices [was] not an economically viable option," we explained that "economic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Id.*

[8] We assumed, without deciding, that New York law required hospitals to treat Medicare patients, but we were not persuaded that the law applied to the anesthesiologists because the statute "does not on its face apply to individual physicians." *Id.* at 917. We went on to conclude that even if the New York law required hospital-based anesthesiologists to treat Medicare patients, their argument failed for the additional reasons discussed here. *See id.*

Participation in the Negotiation Program, like participation in Medicare as a whole, is voluntary. Nothing in the IRA, or in any other statute, compels pharmaceutical companies to offer products or services through Medicare, via the Negotiation Program or otherwise. Boehringer does not argue to the contrary; instead, it advances an economic hardship argument substantially like the one raised by the anesthesiologists, and rejected by this Court, in *Garelick*. Boehringer contends that the government has employed economic pressure to compel the company's participation in the Negotiation Program on CMS's preferred terms. The company submits that its only alternatives to participation, short of divesting its interest in Jardiance, are to decline to sign the Manufacturer Agreement and incur a significant excise tax on any future sales of Jardiance to Medicare beneficiaries, or withdraw all its products from Medicare and Medicaid.[9] Putting aside the excise tax, the fact remains that Boehringer can simply opt out of Medicare and Medicaid. Boehringer estimates that if it took that route, it would lose more than half its U.S. net sales. That possibility, Boehringer argues, would bring economic "devastat[ion]," not mere economic hardship, "making any 'choice' to avoid the Program illusory." Appellant's Br. 48, 51. As we observed in *Garelick*, however, the choice to participate in a voluntary government program does not become involuntary simply because the alternatives to participation appear to entail worse, even

[9] The parties dispute whether the possibility of divestment is relevant for purposes of our Fifth Amendment analysis, but we need not resolve that question given our conclusion that Boehringer's participation in the Negotiation Program is voluntary because no law requires the company to participate in Medicare generally or in the Negotiation Program specifically.

substantially worse, economic outcomes. *See* 987 F.2d at 917; *see also St. Francis Hosp. Ctr.*, 714 F.2d at 875 ("[T]he fact that practicalities may in some cases dictate participation [in Medicare] does not make participation involuntary.").

The Supreme Court's analysis in *National Federation of Independent Businesses v. Sebelius* ("*NFIB*") does not command a different result. 567 U.S. 519 (2012). There, the Court considered a provision of the Affordable Care Act that required states to choose between accepting new Medicaid funding or losing all existing Medicaid funding. The Court held that the provision violated the Spending Clause because it amounted to "economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion." *Id.* at 519.

Boehringer insists that the Negotiation Program is "similarly coercive." Appellant's Br. at 48. But the Supreme Court's holding in *NFIB* very clearly derived from federalism concerns, i.e., the scope of the federal government's authority to regulate the states. *See NFIB*, 567 U.S. at 578 ("Permitting the Federal Government to force the States to implement a federal program would threaten the political accountability key to our federal system."); *id.* ("Spending Clause programs do not [threaten political accountability] when a State has a legitimate choice whether to accept the federal conditions in exchange for federal funds. . . . But when the State has no choice, the Federal Government can achieve its objectives without accountability.") Such concerns are not present where, as here, the federal government program at issue sets the terms for how the federal government will

pay for goods sold by private parties. *See Northport Health Servs. of Arkansas, LLC v. U.S. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (noting Supreme Court in *NFIB* used "economic dragooning" language "to describe the federal government's limited constitutional authority under the Spending Cluase to regulate the states, not a federal agency's ability to regulate [private parties'] use of federal funding") (citation omitted).

Thus, even accepting Boehringer's argument that the Negotiation Program presents the company with a choice between only bad options—opting into a government program with price controls or bowing out of the program entirely—that choice is nonetheless voluntary.

B. Direct Constitutional Claims

Having determined that participation in the Negotiation Program is voluntary, we now consider Boehringer's direct constitutional claims in light of that conclusion.

1. Takings Claim

Boehringer argues that the Negotiation Program effects a *per se* physical taking of physical doses of its Jardiance product, in violation of the Takings Clause of the Fifth Amendment.[10] The Takings Clause provides that "private property [shall not] be taken for public use,

[10] Boehringer expressly disclaims any argument that the program effects a regulatory taking. *See* Appellant's Br. 21 n.6 ("Boehringer has asserted only a *per se* [physical] takings claim."); *see also id.* at 19 (noting that "regulatory takings claims . . . are not at issue here").

without just compensation." U.S. Const. amend. V. "When the government effects a physical appropriation of private property for itself or another—whether by law, regulation, or another means—a *per se* physical taking has occurred." *74 Pinehurst LLC*, 59 F.4th at 563. Here, because Boehringer voluntarily chose to participate in the Negotiation Program, no taking has occurred. *See Garelick*, 987 F.2d at 916–17 ("Because they voluntarily choose to provide services in the price-regulated Part B program, the plaintiff anesthesiologists do not have a viable takings claim.").

Boehringer's arguments that *Garelick* does not apply are unavailing. First, the company asserts that because that case involved a regulatory takings theory, it is "not 'controlling precedent' for Boehringer's *per se* [physical] takings claim." Appellant's Br. 51 (quoting *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 323 (2002)). It is true that "[i]t is inappropriate to treat cases involving physical takings as controlling precedents for the evaluation of a claim that there has been a regulatory taking, and vice versa." *Horne v. Dep't of Agric.*, 576 U.S. 350, 361 (2015) (internal quotation marks omitted). But we agree with the district court that "*Garelick* stands for a broader principle that participation in Medicare is voluntary and conditions placed on such participation therefore cannot constitute a taking." *Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *14 n.12. Indeed, no part of our analysis in *Garelick* regarding the voluntariness of participation in Medicare implicated the differences between regulatory and physical takings, and Boehringer points to none. Boehringer also argues that, unlike the

plaintiffs in *Garelick*, it is subject to "coercive mechanisms" that give it no choice but to keep participating in Medicare. Appellant's Br. 51. As discussed above, however, this argument is merely a variation of the economic hardship theory rejected in *Garelick*. *See* 987 F.3d at 916.

Boehringer also argues that the Supreme Court's decision in *Horne* undermines the reasoning in *Garelick*. In *Horne*, a family of raisin growers challenged a program by the Department of Agriculture requiring them to set aside a percentage of their raisin crop in certain years for the government, without compensation. 576 U.S. at 355-56. The program, which was intended to maintain a stable raisin market, required raisin growers to "physical[ly] surrender" the raisins and transfer title to the government, which in turn would sell, allocate, or otherwise dispose of the reserve raisins as it deemed appropriate. *Id.* at 354–55, 364. Raisin growers retained only an interest in any net proceeds from sales of the raisins by the government, after deductions for certain expenses. *See id.* at 355. The Supreme Court concluded that the program deprived raisin growers of "the entire 'bundle' of property rights in the appropriated raisins . . . with the exception of the speculative hope that some residual proceeds may be left when the Government is done with the raisins and has deducted the expenses of implementing all aspects of the [program]." *Id.* at 361–62. The Court rejected the government's argument that raisin growers voluntarily chose to participate in the raisin market, and dismissed its suggestion that raisin growers could simply "plant different crops, or sell their raisin-variety grapes as table grapes or for use in juice or wine." *Id.* at 365 (internal quotation

marks omitted). The Court explained that "[s]elling produce in interstate commerce, although certainly subject to reasonable government regulation, is . . . not a special governmental benefit that the Government may hold hostage." *Id.* at 366. Boehringer contends that this analysis governs its takings claim because the Negotiation Program appropriates its rights "to possess, use and dispose of" its Jardiance products, and its right to exclude others from possessing those products, by "giv[ing] every Medicare enrollee a right to take possession of Jardiance products on terms set by the Government." Appellant's Br. 22 (internal quotation marks omitted) (citing *Horne*, 576 U.S. at 361–62; *Cedar Point Nursery*, 594 U.S. at 149–52).

But *Horne* is materially different from both *Garelick* and this case. Whereas the *Horne* plaintiffs challenged an actual seizure of their personal property (raisins) without compensation, the *Garelick* plaintiffs challenged regulations that merely limited the price they could charge under Medicare. In other words, while the government in *Horne* was directly appropriating the plaintiffs' property, the government in *Garelick* was setting the price that it would pay for certain services in its commercial capacity.[11] It is well established

[11] Boehringer argues that the government is not acting as a market participant but instead as a market regulator that is "exercis[ing] [its] *sovereign* powers by 'employ[ing] . . . coercive mechanism[s] available to no private party.'" Appellant's Br. 56 (quoting *Am. Trucking Ass'n v. City of Los Angeles*, 569 U.S. 641, 651 (2013)). Thus, Boehringer argues, "a market-participant theory cannot excuse the Program's constitutional violations." *Id.* But in negotiating prices for pharmaceuticals for Medicare beneficiaries, the government acts as a market participant, not a regulator. *Cf. United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 438 F.3d 150, 158 (2d Cir. 2006) ("It is plain that the Authority

that, "[l]ike private individuals and businesses, the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases." *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940); *see also Engquist v. Oregon Dep't of Agric.*, 553 U.S. 591, 598 (2008) (recognizing that "there is a crucial difference, with respect to constitutional analysis, between the government exercising 'the power to regulate or license, as lawmaker,' and the government acting 'as proprietor'") (quoting

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participates in the marketplace as any other economic actor would when, after having employed its regulatory powers to compel delivery of the waste generated within the Counties to its processing facilities, it contracts with private parties to deliver its processed wastes to landfill sites that meet its requirements."), *aff'd*, 550 U.S. 330 (2007). Like any other private party seeking to leverage its purchasing power to get a better bargain, the government through the Negotiation Program forces pharmaceutical manufacturers to decide whether to do business according to its terms. *See Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (noting that in its capacity as a market participant, the government may set the terms under which it will purchase goods and services). Although the government acts as a market regulator when it employs tools "that no private actor could wield," such as civil fines, that activity is "evaluate[d] separately" from its activity as a market participant. *Id.* at 157–58 (internal quotation marks omitted).

Pharmaceutical manufacturers, such as Boehringer, furthermore are not without leverage in these negotiations. While the government has a strong interest in using its purchasing power to drive drug costs down, the Negotiation Program can cover only drugs without generic alternatives, so that the government will be incentivized to reach a deal with drug manufacturers to avoid leaving Medicare beneficiaries without viable substitutes. The ramifications of Boehringer's withdrawal from Medicare and Medicaid would be significant, and potentially harmful to the Medicare program, in that it would result in 20 drugs falling out of those programs and "more than 1.3 million Americans losing insurance coverage for Jardiance alone." Chamber of Commerce Amicus Curiae Br. at 15.

Cafeteria & Restaurant Workers v. McElroy, 367 U.S. 886, 896 (1961)). Moreover, the raisin growers in *Horne* faced a choice between surrendering a portion of their raisin crop to the government without compensation as a condition of being able to sell raisins to any buyer, on the one hand, and exiting the raisin market altogether, on the other; by contrast, the physicians in *Garelick* could still offer their full suite of services (or products) to buyers in the private sector even if they withdrew from Medicare. *See Garelick*, 987 F.2d at 916 (noting that the plaintiffs "retain[ed] the right to provide medical services to non-Medicare patients free of price regulations"). Because the two cases required different constitutional analyses, *see Engquist*, 553 U.S. at 598, Boehringer's argument that *Horne* somehow rejected the reasoning in *Garelick* is not persuasive.

In summary, the district court properly dismissed Boehringer's takings claim on the ground that participation in Medicare, and thus in the Negotiation Program, is voluntary.

2. Due Process Claim

Boehringer also argues that the Negotiation Program deprives it of constitutionally protected property interests without procedural due process, in violation of the Due Process Clause of the Fifth Amendment. To prevail on a procedural due process claim, Boehringer must "(1) identify a liberty or property interest, (2) show that the state has deprived [it] of that interest, and (3) show that the deprivation was [e]ffected without due process." *Wheatley v. N.Y. State United Tchrs.*, 80 F.4th 386, 392 (2d Cir. 2023). The threshold

"inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest" in liberty or property. *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). Boehringer asserts that it has protected property interests in: (1) its "physical doses of Jardiance," (2) the ability to "decid[e] the price at which [it] will sell its Jardiance products," and (3) "its confidential data regarding Jardiance." Appellant's Br. 26–27 (internal quotation marks omitted).

Boehringer's claim fails because the Negotiation Program does not deprive it of any protected property interest. Although *Garelick* involved a takings claim, our analysis in that context is equally applicable in the context of a due process claim: A company suffers no deprivation of its property interests by voluntarily submitting to a price-regulated government program.[12] Indeed, several courts have

[12] Boehringer cites the Fifth Circuit's opinion in *National Infusion Center Association v. Becerra* ("*NICA*"), 116 F.4th 488 (5th Cir. 2024), in support of its due process argument. In *NICA*, the Fifth Circuit reversed an order dismissing a challenge to the IRA for lack of standing and lack of statutory jurisdiction. In doing so, the court recognized that the plaintiff—a trade association whose members provide infusion treatments for cancer and chronic diseases—had standing to challenge the Negotiation Program because it sufficiently alleged that it had been deprived of an opportunity to protect its concrete interest in "not seeing its members' revenue decrease as a result of allegedly unconstitutional government action." *Id.* at 503. But even if the Fifth Circuit correctly decided the standing question, whether a party bringing a due process claim has a "colorable claim" to a protected property interest for purposes of standing is a different question from whether, on consideration of the merits, the party in fact has a protected property interest. *Booker-El v. Superintendent, Ind. State Prison*, 668 F.3d 896, 899–901 (7th Cir. 2012) (holding that for purposes of standing the plaintiff had adequately pleaded an injury-in-fact based on "a substantial risk [of] losing benefits" to which he was allegedly entitled, and then holding that the plaintiff in

dismissed due process claims arising under Medicare and Medicaid on this basis. *See, e.g.*, *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869–70 (6th Cir. 1986) (rejecting due process claim by hospitals seeking reimbursement from Medicare because "participation in the Medicare program is wholly voluntary" and "any obligations are as freely accepted as the benefits"); *Kaiser Found. Health Plan, Inc. v. Burwell*, 147 F. Supp. 3d 897, 911 (N.D. Cal. 2015) (regulation of Medicare Advantage organization's expenditure of Medicare funds did not violate the organization's procedural due process rights because "[p]articipation in the Medicare program is a voluntary undertaking"); *Idaho Health Care Ass'n v. Sullivan*, 716 F. Supp. 464, 472 (D. Idaho 1989) (rejecting due process challenge to Medicaid regulations because the plaintiffs voluntarily participated in the program and thereby agreed to "accept imposition of governmental regulation" under the program). Boehringer had the choice to opt out of the Negotiation Program and withdraw from Medicare and Medicaid before the deadlines to sign the Manufacturer Agreement and submit relevant data to CMS, and long before it would begin selling Jardiance products at the "maximum fair price" established during its negotiations with CMS. The company instead chose to participate in the program. That voluntary decision did not give rise to any protected property interest. Accordingly, the district court committed no error in dismissing Boehringer's due process claim.

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fact lacked a protected property interest in those same benefits). In any event, the Fifth Circuit did not address the fact that participation in the Negotiation Program is voluntary, which is dispositive of Boehringer's claim under *Garelick*.

3. First Amendment Claim

Additionally, Boehringer argues that the Negotiation Program violates its First Amendment right to free speech by compelling it to adopt the government's views as set forth in the Manufacturer Agreement. In particular, Boehringer takes issue with the Manufacturer Agreement's references to "negotiations" and "maximum fair price," and any statement that Boehringer "agree[d]" (that is, voluntarily) to the program's terms. Appellant's Br. 36–38. The company argues that the Negotiation Program does not involve "genuine negotiation" because "the 'severe' consequences for manufacturers that do not reach 'agreement' effectively ensure that manufacturers cannot walk away." *Id.* at 37 (quoting *NICA*, 116 F.4th at 500). The company also "disagrees that the prices set through the Program are 'fair,' much less the 'maximum fair price[s],'" because "the IRA requires prices set through the Program to be at least 25-60% below the market-based rate paid by wholesalers, and CMS must go as far below that ceiling as possible." *Id.* (citing 42 U.S.C. § 1320f-3(b)(1), (c)). Further, Boehringer argues that it did not "agree" to participate in the program, again insisting that it was "coerced into doing so." *Id.* at 38. The company notes that it "signed the Manufacturer Agreement under protest, and only as a means of avoiding even larger penalties." *Id.*

"[T]he First Amendment protects the right to decide what to say and what not to say." *Burns v. Martuscello*, 890 F.3d 77, 84 (2d Cir. 2018) (internal quotation marks omitted). Any "Government action that . . . requires the utterance of a particular message favored by the

Government[] contravenes this essential right." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994); *see also 303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023) ("[T]he government may not compel a person to speak its own preferred messages.") (citations omitted)). Corporations and individuals equally enjoy the protection of this right. *See Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality op.) ("For corporations as for individuals, the choice to speak includes within it the choice of what not to say."); *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 343 (2010) (rejecting "the argument that political speech of corporations or other associations should be treated differently under the First Amendment simply because such associations are not natural persons" (internal quotation marks omitted)). A violation of this right occurs only when "the application of the law at issue *actually compels* [] expressive conduct." *Emilee Carpenter, LLC v. James*, 107 F.4th 92, 96 (2d Cir. 2024) (emphasis added); *see also C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005) ("[A] violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion."). To constitute actual compulsion, "the governmental measure must punish, or threaten to punish, protected speech by governmental action that is regulatory, proscriptive, or compulsory in nature." *Ridgewood Bd. of Educ.*, 430 F.3d at 189 (internal quotation marks omitted).

Boehringer argues that it suffered legal compulsion for purposes of its First Amendment claim because it "could not have withdrawn from the [Negotiation] Program before the deadlines to

sign the Manufacturer Agreement and participate in the negotiation process." Appellant's Br. 55 n.25. The company contends that "[t]he IRA suspends the excise tax only when a *manufacturer* terminates its Medicare and Medicaid agreements," and at the same time delays the effective date of manufacturer withdrawal by eleven to twenty-three months. *Id.* (citing 26 U.S.C. § 5000D(c); 42 U.S.C. § 1395w-114a(b)(4)(B)(ii)). Yet CMS has established a process through which a manufacturer can substantially expedite its withdrawal. Per CMS guidance, when a manufacturer provides notice that it does not intend to participate in the Negotiation Program and wishes to terminate its Medicare and Medicaid agreements, the agency "will automatically grant such termination requests upon receipt," and "will expedite the effective date of the . . . termination" so that termination occurs thirty days after receipt of the notice. Joint App'x 217.

Boehringer contends that CMS's expedited termination guidance conflicts with the text of the IRA and thus did not offer a legitimate alternative to participating in the Negotiation Program. But as the district court explained, "[n]othing in the statute prohibits CMS from commencing the 30-day good cause termination process upon receiving a notice from the manufacturer; it simply precludes the manufacturer from opting for the 30-day termination process unilaterally." *Boehringer*, 2024 WL 3292657, at *9. The statute expressly provides that "[t]he Secretary may provide for termination of an agreement under [the Medicare Coverage Gap Discount Program] for a knowing and willful violation of the requirements of

the agreement or other good cause shown," 42 U.S.C. § 1395w-114a(b)(4)(B)(i), and that "[t]he Secretary shall provide for termination of an agreement" under the Manufacturer Discount Program for the same reasons, *id.* § 1395w-114c(b)(4)(B)(i). The term "good cause" is "a uniquely flexible and capacious concept, meaning simply a legally sufficient reason." *United States, ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 429 n.2 (2023) (internal quotation marks omitted). Boehringer does not contest that a manufacturer's wish to withdraw from the Negotiation Program before it becomes subject to any new obligation or penalty constitutes good cause. Accordingly, Boehringer's argument that it could not, in fact, withdraw from the Negotiation Program within the thirty-day period offered by CMS is not persuasive.

Because Boehringer's assent to the Manufacturer Agreement did not occur in the context of actual compulsion, the company suffered no First Amendment violation. *See Corren v. Condos*, 898 F.3d 209, 220 (2d Cir. 2018) (rejecting First Amendment freedom of speech challenge to a campaign public financing program because the plaintiffs voluntarily chose to participate in the program and "remain[ed] free to reject the [program's] funding . . . if they believe[d] that private financing of their campaigns [would] facilitate greater speech"); c*f. Grove City Coll. v. Bell*, 465 U.S. 555, 575–76 (1984)

(rejecting First Amendment freedom of association claim premised on participation in voluntary government program).[13]

C. Unconstitutional Conditions Claims

In the alternative to its argument that the Negotiation Program directly violates its rights under the First and Fifth Amendments, Boehringer contends that even if the program were voluntary, the program indirectly violates the company's rights by imposing unconstitutional conditions on its ability to participate in Medicare and Medicaid.

The unconstitutional conditions doctrine prevents the government from "burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013). Put differently, the government may not produce indirectly "a result which [it] could not command directly," *Speiser v. Randall*, 357 U.S. 513, 526 (1958), by requiring a regulated party to give up its constitutional rights in exchange for a government benefit. This occurs when, for example, the government places "a condition on the *recipient* of the [benefit] rather than on a particular program or service, thus effectively prohibiting the recipient from engaging in the

[13] Having disposed of Boehringer's First Amendment claim on the grounds explained above, we need not address the government's contention that the Manufacturer Agreement explicitly excludes any interpretation to the effect that it expresses views of Boehringer.

protected conduct outside the scope of the federally funded program." *Rust v. Sullivan*, 500 U.S. 173, 197 (1991).

The Supreme Court has applied this "overarching principle" of constitutional law in "a variety of contexts."[14] *Koontz*, 570 U.S. at 604 (collecting cases). The doctrine applies even when a party has no right to the benefit at issue—that is, even when a party voluntarily participates in a government program. Indeed, the Supreme Court recognized in *Koontz* that "[v]irtually all of [its] unconstitutional conditions cases involve a gratuitous governmental benefit of some kind," and that it has "repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights." 570 U.S. at 608; *see also O'Connor v. Pierson*, 426 F.3d 187, 201 (2d Cir. 2005) ("It is settled law that the government may not, as a general rule, grant even a gratuitous benefit on condition that the beneficiary relinquish a constitutional right.") (internal quotation marks omitted).

Supreme Court precedent makes clear that laws establishing conditions on spending under federally funded programs without implicating recipients' activity in the private market do not run afoul of the unconstitutional conditions doctrine. For example, in *Regan v.*

[14] The government contends that Boehringer offers no support for applying the doctrine when, as here, the government contracts for goods. The cases on which Boehringer relies, the government submits, involved plaintiffs who, unlike Boehringer, were either a beneficiary of discretionary benefits or a government employee or independent contractor. We need not decide whether the doctrine is so limited, however, because we conclude that the Negotiation Program withstands scrutiny under the doctrine in any event.

Taxation With Representation of Washington, the Supreme Court upheld a regulation prohibiting nonprofit organizations seeking tax-exempt status under 26 U.S.C. § 501(c)(3) from engaging in lobbying. 461 U.S. 540, 543–44 (1983). "In rejecting the nonprofit's First Amendment claim, the Court highlighted . . . the fact that the condition did not prohibit that organization from lobbying Congress altogether." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.* ("*USAID*"), 570 U.S. 205, 215 (2013) (discussing *Regan*). The nonprofit had the option to divide its operations between "a § 501(c)(3) organization for non-lobbying activities and a § 501(c)(4) organization for lobbying," the Court explained. *Regan*, 461 U.S. at 544. Put simply, Congress did not completely prevent the nonprofit from lobbying; it "merely refused to pay for the lobbying out of public monies." *Id.* at 545.

Similarly, in *Rust v. Sullivan*, the Supreme Court considered a challenge to HHS regulations implementing Title X of the Public Health Service Act. 500 U.S. at 177–78. Title X authorizes HHS to make grants to nonprofit healthcare organizations "to assist in the establishment and operation of voluntary family planning projects [to] offer a broad range of acceptable and effective family planning methods and services." *Id.* at 178 (internal quotation marks omitted). The statute prohibits the funds from being "used in programs where abortion is a method of family planning." *Id.* (internal quotation marks omitted). The challenged regulations prohibited Title X from "provid[ing] counseling concerning the use of abortion as a method of family planning or provid[ing] referral for abortion," and from "engaging in activities that encourage, promote or advocate abortion

as a method of family planning." *Id.* at 179–80 (internal quotation marks omitted). The regulations also "require[d] that Title X projects be organized so that they are physically and financially separate from prohibited abortion activities." *Id.* at 180 (internal quotation marks omitted). The Supreme Court rejected the challenge to these regulations, explaining that the regulations governed only the scope of a grantee's Title X projects, leaving it "unfettered in its other activities." *Id.* at 196. Because the regulations did not "prohibit[] the recipient from engaging in the protected conduct outside the scope of the federally funded program," the Court reasoned, the regulations did not violate the First Amendment. *Id.* at 197.

In *FCC v. League of Women Voters of California*, on the other hand, the Supreme Court invalidated a statutory provision that forbade noncommercial broadcast television and radio stations to engage in any editorializing, including with private funds, if the stations received any federal grants. 468 U.S. 364, 399–401 (1984). The Court explained that in contrast to the situation faced by the plaintiff charitable organization in *Regan*, which remained free to use private funds without restriction, the broadcasting stations covered by the blanket ban on editorializing were "barred from using even wholly private funds to finance [their] editorial activity." *Id.* at 400.

As the Supreme Court observed in *USAID*, "the relevant distinction that has emerged from [the Court's unconstitutional conditions] cases is between conditions that define the limits of the government spending program—those that specify the activities Congress wants to subsidize—and conditions that seek to leverage

funding to regulate speech outside the contours of the program itself." 570 U.S. at 214–15. Although this distinction emerged in First Amendment cases, the same core logic applies with equal force in other constitutional contexts: Congress has considerable authority to impose reasonable conditions on parties' conduct within the four corners of federally funded programs, but it may not condition parties' ability to participate in such programs on compliance with conditions that burden the parties' constitutionally protected conduct beyond those programs.[15]

The Negotiation Program does not impose unconstitutional conditions on Boehringer's rights under the First and Fifth Amendments. The program simply establishes a price structure to limit CMS's costs for certain high-expenditure drugs. Whatever its merits as a matter of policy, the program is plainly related to the government's legitimate goal of controlling Medicare costs. Moreover, the program applies only to sales of the selected drugs that occur within the four corners of Medicare; it does not regulate Boehringer's sales of Jardiance in the private market. Accordingly,

[15] With respect to the unconstitutional conditions analysis of its takings claim, Boehringer argues that we should apply the nexus-and-proportionality test set forth in *Dolan v. City of Tigard*, 512 U.S. 374 (1994), and *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987). The Supreme Court has applied that test only in "the special context of exactions—land-use decisions conditioning approval of development on the dedication of property to public use," and has explained that the test "was not designed to address, and is not readily applicable to, . . . much different questions arising [in other contexts]." *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702–03 (1999). We see no basis for extending the nexus-and-proportionality test to the wholly different context here. This case has nothing to do with land use permitting, let alone excessive exactions.

the program is a lawful exercise of Congress's spending power under the statute.

D. APA Claim

Lastly, Boehringer argues that CMS violated the APA by issuing the Manufacturer Agreement without providing the public notice and an opportunity to comment. The APA requires "legislative rule[s]" that "impose legally binding obligations . . . on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements"—to undergo a notice-and-comment process. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014); *see also White v. Shalala*, *7* F.3d 296, 303–04 (2d Cir. 1993). This requirement also generally applies to government "contract provisions that are legislative." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1054 (D.C. Cir. 1987). But the APA provides that a subsequent statute may supersede the APA's rulemaking provisions, including the notice-and-comment requirement, provided that the subsequent statute "does so expressly." 5 U.S.C. § 559. Courts have emphasized that exemptions from the APA's rulemaking requirements "are not lightly to be presumed in view of the statement in [the APA] that modifications must be express." *Asiana Airlines v. Fed. Aviation Admin.*, 134 F.3d 393, 397 (D.C. Cir. 1998) (quoting *Marcello v. Bonds*, 349 U.S. 302, 310 (1955)). An exemption is express when Congress "has established procedures so clearly different from those required by the APA that it must have intended to displace the norm." *Id.*

The IRA expressly exempts CMS from the APA's rulemaking requirements, including the notice-and-comment requirement, with respect to the Negotiation Program, including the Manufacturer Agreement, through 2028. Specifically, the IRA states that CMS "shall implement this section . . . for 2026, 2027, and 2028 by program instruction or other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854. This section and others that authorize the use of guidance stand in contrast to the provisions that expressly require the promulgation of rules, which strongly indicates that Congress displaced the APA's requirements for certain provisions of the IRA. *Compare id.* § 11003, 136 Stat. at 1864 (stating that "[t]he Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section," which establishes the excise tax), *with id.* § 11201, 136 Stat. at 1892 (providing for the implementation of a subsidy program "for 2024, 2025, and 2026 by program instruction or other forms of program guidance"). Moreover, the fact that Section 11001 authorizes the use of guidance only for the program's first three pricing periods underscores that Congress made a deliberate decision to authorize an exemption (albeit temporary) from the APA's requirements. And although Boehringer argues that, in any event, Section 11001 does not encompass the Manufacturer Agreement, that argument is unpersuasive because Section 11001 sets forth the provisions governing CMS's implementation of the agreement. *See id.* § 11001(c), 136 Stat. at 1841–42 (codified at 42 U.S.C. § 1320f-2).

III. Conclusion

In summary, we hold:

1. Participation in the Negotiation Program is voluntary because there is no legal compulsion to offer products or services through the program.

2. Because participation in the Negotiation Program is voluntary, the program neither effects an unlawful taking or deprivation of property interests under the Fifth Amendment nor compels speech in violation of the First Amendment.

3. The Negotiation Program does not violate the unconstitutional conditions doctrine because the program is designed to promote the legitimate government purpose of controlling Medicare spending and does not regulate conduct outside the scope of Medicare and Medicaid.

4. CMS's issuance of the Manufacturer Agreement fell within the IRA's exemption from the APA's notice-and-comment requirement.

For the foregoing reasons, we AFFIRM the district court's judgment.