APPENDIX

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APPENDIX A

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*.

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* 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.

MAXWELL A. BALDI, Attorney, Appellate Staff Civil Division, U.S. Department of Justice (Michael S. Raab, Lindsey Powell, Cathrine Padhi, Attorneys, Appellate Staff Civil Division, U.S. Department of Justice, Rachel H. Park, Acting General Counsel, Joel McElvain, Acting Deputy General Counsel, Janice L. Hoffman, Associate General Counsel, U.S. Department of Health and Human Services, *on the brief*), *for* Brian M. Boynton, Principal Deputy Assistant Attorney General, U.S. Department of Justice, Washington, DC, *for Defendants-Appellees*.

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Society, and the American Society of Hematology, *in support of Defendants-Appellees*.

Kelly Bagby, Rebecca Rodgers, William Alvarado Rivera, AARP Foundation, Washington, DC, *for Amici Curiae* AARP, AARP Foundation, Justice in Aging, the Center for Medicare Advocacy, and the Medicare Rights Center, *in support of Defendants-Appellees*.

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William B. Schultz, Margaret M. Dotzel, Alyssa Howard Card, Zuckerman Spaeder LLP, Washington, DC, *for Amici Curiae* Nationally Recognized Healthcare and Medicare Experts, *in support of Defendants-Appellees*.

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 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

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

[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).

whether they intend to participate in the program. CMS must "enter into agreements," by specified deadlines, with the 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"). Addition-

ally, 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.

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

Id.

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. § 1320f-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-114c(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. §§ 1395w114a(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.

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-CV01103 (MPS), 2024 WL 3292657, at *16 (D. Conn. July 3, 2024). The court also dismissed Boehringer's unconstitutional conditions claim, largely for the

[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.

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.

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

[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.

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]

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[6] "A regulatory taking . . . occurs where even absent a direct physical appropriation, governmental regulation of private (cont.)

We affirmed the dismissal of the anesthesiologists' takings claim on the ground that their participation in Medicare was in fact 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] any other physicians, to provide serv-

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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.

[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 (cont.)

ices 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 govern-

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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).

[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.*

ment." *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.*

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,

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[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 volun-

(cont.)

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 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*

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tary because no law requires the company to participate in Medicare generally or in the Negotiation Program specifically.

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, 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

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[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").

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 that, "[l]ike private individuals and

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[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 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 (cont.)

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 *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

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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.

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 dismissed due

[12] Boehringer cites the Fifth Circuit's opinion in *National Infusion Center Association v. Becerra* ("*NICA*"), 116 F.4th 488 (5th Cir. (cont.)

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

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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 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*.

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.

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. § 1395w114a(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 protected conduct outside the scope of

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[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.

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

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[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.

Regan v. 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,

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[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.

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

[Filed: 07/03/24]

No. 3:23-cv-01103 (MPS)

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

RULING ON MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

The plaintiff, Boehringer Ingelheim Pharmaceuticals, Inc. ("BI"), challenges the Inflation Reduction Act's Drug Price Negotiation Program (the "Program"), alleging that the Program violates its rights under the Due Process Clause, the Takings Clause, the First Amendment, and the Excessive Fines Clause. BI also claims that the Center for Medicare and Medicaid Services issued a legislative rule implementing the Program without complying with the Administrative Procedure Act's and Medicare Act's notice and comment requirements. The parties filed cross-motions for summary judgment, and I heard oral argument on June 20, 2024. For the reasons

explained herein, I grant the defendants' motion and deny BI's motion as to all claims.

II. FACTS AND PROCEDURAL HISTORY

A. Medicare's Prescription Drug Coverage

Medicare is a federally funded health insurance program for individuals 65 or older and for some younger individuals with disabilities. It covers prescription drugs through two programs: Medicare Part B and Part D. Medicare Part B covers certain medically necessary services or preventative services, including prescription drugs that are administered by medical providers. *See* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2). Medicare Part D is an optional program that provides outpatient prescription drug coverage to individuals who enroll in plans administered by private insurance companies. *See Brew v. Burwell*, 263 F. Supp. 3d 431, 433 (W.D.N.Y. 2017) (describing Part D coverage); 42 U.S.C. § 1395w-102 *et seq*. The government covers a portion of the cost of covered drugs through Medicare Part D.

B. The Drug Price Negotiation Program

In 2022, Congress passed the Inflation Reduction Act (the "IRA"). Pub. L. No. 117-169 §§ 11001-11003, 136 Stat. 1818 (codified in pertinent part at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). The IRA authorizes the Secretary of Health and Human Services to establish a Drug Price Negotiation Program (the "Program"), which aims to limit the cost of certain drugs under Medicare Parts B and D. 42 U.S.C. § 1320f *et seq*. The Secretary has delegated this

authority to the Centers for Medicare and Medicaid Services ("CMS").[1]

"The Program operates in cycles," which I will refer to as Negotiation Periods. *AstraZeneca Pharms. LP v. Becerra*, No. 23-CV-00931, 2024 WL 895036, at *2 (D. Del. Mar. 1, 2024). For each Negotiation Period, CMS must (1) publish a list of drugs selected for the Program, 42 U.S.C. §§ 1320f(a)(1), 1320f-1, (2) "enter into agreements with manufacturers of [the] selected drugs," *id.* §§ 1320f(a)(2), 1320f-2, and (3) "negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs," *id.* §§ 1320f(a)(3), 1320f-3. I will refer to the negotiation period that began in 2023 as the "Initial Negotiation Period."

(i) Drug Selection

To be eligible for the Program, among other requirements, a drug must be (1) on the market for at least 7 years, *id.* § 1320f-1(e)(1)(ii), (2) "single source," i.e., there is no FDA-approved generic version of the drug on the market, *id.* § 1320f-1(e)(1)(A)(iii), and (3) "among the 50 qualifying . . . drugs with the highest total expenditures" for either Medicare Part B or Part D,[2] *id.* § 1320f-1(b). From the eligible drugs, CMS then ranks the drugs according to total Medicare expenditures. *Id.* § 1320f-1(b)(A). CMS must select a specified number of drugs with the highest total

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[1] Because the Secretary of Health and Human Service's authority under the IRA and other related statutes has been delegated to CMS, I will refer to CMS when describing the statutory requirements, although the statutes refer to the Secretary.

[2] For the Initial Negotiation Period, only the 50 drugs with the highest expenditures under Medicare Part D are negotiation eligible. *Id.* § 1320f-1(d)(1); ECF No. 28-5 at 105 (CMS guidance describing the process for identifying negotiation-eligible drugs).

expenditures (the "Selected Drugs") for the Program—10 drugs for the Initial Negotiation Period, 15 drugs for each of the next two Negotiation Periods, and 20 drugs for every subsequent Negotiation Period. *Id.* § 1320f-1(a).

On September 1, 2023, CMS published a list of ten Selected Drugs for the Initial Negotiation Period. *See* 42 U.S.C. §§ 1320f(d)(1), 1320f-1(a)(1) (setting September 1 deadline to select drugs). Jardiance, one of BI's drugs, was one of the Selected Drugs. *See* ECF No. 28-4; U.S. Dep't of Health & Hum. Servs., *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (August 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

(ii) Manufacturer Agreement

Once drugs are selected for the Program, the IRA sets a deadline for CMS to "enter into agreements" with manufacturers that will govern the drug negotiation process. 42 U.S.C. § 1320f-2(a). For the Initial Negotiation Period, that deadline was October 1, 2023. *Id.* § 1320f(d)(4), 1320f-2(a).

On July 3, 2023, CMS issued a Medicare Drug Price Negotiation Program Agreement (the "Manufacturer Agreement"). ECF No. 28-3 ¶ 4; ECF No. 28-6. CMS did not go through a formal notice and comment process before issuing the Manufacturer Agreement. *See* ECF No. 28-7. On March 15, 2023, however, CMS issued guidance describing the possible contents of the Manufacturer Agreement and "voluntarily solicit[ed] comments" on "[t]erms and conditions contained in the manufacturer agreement." CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum* (Mar. 15, 2023).

The Manufacturer Agreement provides that "CMS and the Manufacturer shall negotiate to determine . . . a maximum fair price for the Selected Drug." ECF No. 28-6 at 3. The manufacturer agrees to make that price available to "maximum fair price eligible" individuals, health care providers, pharmacies, or other entities described in the IRA. *Id.*; *see also* 42 U.S.C. § 1320f(c)(2) (defining "maximum fair price eligible individual"). And the Manufacturer must provide certain information to CMS about the drug, including the average price the drug is sold for on the "non-federal market" (i.e., the wholesaler price in non-governmental sales), and any other information that CMS requires to carry out its duties during the negotiation process. ECF No. 28-6 at 4; *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). Any information the manufacturer submits that CMS determines is "proprietary information" can be used only for the purposes of carrying out the Program. 42 U.S.C. § 1320f-2(c). The Agreement contains the following disclaimer:

> In 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. 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.

ECF No. 28-6 at 5.

If a manufacturer does not sign the Manufacturer Agreement by the statutory deadline, i.e., October 1, 2023, it "could be exposed to potential excise tax liability" starting the day after the deadline and continuing until the manufacturer signs the agreement. ECF No. 28-5 at 121 (CMS guidance); 26 U.S.C. § 5000D(b)(1). The excise tax provisions of the IRA are described in more detail below.

On October 3, 2023, CMS released a statement indicating that the manufacturers of all Selected Drugs, including BI, had "chosen to participate in the [Program]" and had signed the Manufacturer Agreement. CMS, *Medicare Drug Price Negotiation Program: Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (October 3, 2023).

(iii) Negotiation Process

For the Initial Negotiation Period, negotiations opened October 2, 2023, unless the manufacturer signed the Manufacturer Agreement on an earlier date.

Negotiations proceed in several steps. 42 U.S.C. § 1320f-3(b)(2). First, the manufacturer must provide CMS with data about the selected drug. *Id.* §§ 1320f-3(b)(2)(A), 1320f(d)(5)(A) (setting October 2, 2023 deadline for data to be submitted).

Second, CMS makes an initial offer as to the "maximum fair price" Medicare will pay for the drug. For the Initial Negotiation Period, the deadline for CMS to make its initial offer was February 1, 2024. *Id.*

§ 1320f(d)(5)(B), 1320f-3(b)(2)(B). To determine the maximum fair price, CMS must consider specified factors, such as (1) data about the costs of researching, developing, manufacturing, and distributing the drug, and (2) evidence about whether alternative treatments are available and about the comparative effectiveness of those treatments. *Id.* § 1320f-3(e). The IRA also sets a ceiling on the maximum fair price. *Id.* § 1320f-3(c). For the Initial Negotiation Period, the price ceiling is the lower of (1) the price Medicare paid for the drug in the prior year, *id.* § 1320f-3(c)(1)(B), or (2) a percentage, ranging from 40 percent to 75 percent, of the average price that wholesalers other than the federal government paid for the drug (adjusted for inflation), *id.* § 1320f-3(c)(1)(C)(i), (c)(3). For most drugs, including Jardiance, there is no floor on the price CMS can offer. *Id.* § 1320f-3(d).

Next, within 30 days after receipt of CMS's initial offer, the manufacturer must either accept the initial 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). CMS is then required to "respond in writing" to the counteroffer. *Id.* § 1320f-3(b)(2)(D). CMS guidance says that CMS will "act on [the] manufacturer['s] counteroffer" by April 1, 2024. ECF No. 28-5 at 92. "CMS may accept or decline [the] counteroffer." *Id.* If CMS declines the counteroffer, CMS and the manufacturer can schedule "[u]p to three possible negotiation meetings" to "negotiate [the maximum fair price] for the selected drug." *Id.* at 93. By July 15, 2024, CMS must make its final maximum fair price offer to the manufacturer, which the manufacturer must respond to by July 31, 2024. *Id.*

For the Initial Negotiation Period, negotiations end on August 1, 2024. *Id.*; 42 U.S.C. § 1320f(b)(4)(B), (d)(2)(B). If the manufacturer agrees to the maximum fair price, that price is incorporated into the Manufacturer Agreement via an addendum the manufacturer signs. *See* ECF No. 28-6 at 8 (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 a Manufacturer does not agree to the maximum fair price by August 1, it may incur "potential excise tax liability." ECF No. 28-5 at 156-57; 26 U.S.C. § 5000D(b)(2).

By September 1, 2024, CMS must "publish the maximum fair price" it has selected for the drug. And CMS must publish an "explanation for the maximum fair price with respect to the [factors specified in the statute]" by March 1, 2025. 42 U.S.C. §§ 1320f-4(a)(1)-(2), 1320f(d)(6). The final selected price will take effect on January 1, 2026. *Id.* § 1320f(b)(1)-(2). The maximum fair price may be renegotiated in subsequent years.

The IRA 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 Drug Price Negotiation Program, or (3) the final selected maximum fair price. *Id.* § 1320f-7(2)-(3).

(iv) Civil Monetary Penalties

The IRA imposes civil monetary penalties on manufacturers that violate certain statutory requirements after they sign the Manufacturer Agreement. *Id.* § 1320f-6. A manufacturer that does not "provide access to a price that is equal to or less than the

maximum fair price for such drug" to eligible individuals and entities is "subject to a civil monetary penalty." *Id.* § 1320f-6(a). For every unit of the drug the manufacturer sells for more than the maximum fair price, the manufacturer must pay a civil monetary penalty equal to ten times the difference between the higher price and the maximum fair price. *Id.* In addition, any manufacturer that has signed the Manufacturer Agreement but fails to submit information CMS needs to administer the program or otherwise comply with Program requirements is subject to a civil monetary penalty of $1,000,000 for each day of the violation. *Id.* §§ 1320f-6(c), 1320f-2(a)(4)-(5).

(v) The Excise Tax

Manufacturers that do not sign the Manufacturer Agreement or agree to the maximum fair price may be subject to an excise tax on sales of Selected Drugs for each day of the "noncompliance periods." 26 U.S.C. § 5000D(a)-(b). Noncompliance periods begin when the deadline to sign the Manufacturer Agreement or agree to the maximum fair price has passed—for the Initial Negotiation Period, on October 2, 2023 and August 2, 2024, respectively. *Id.* § 5000D(b)(1)-(2). These noncompliance periods 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 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). The parties disagree as to whether the tax applies to

all domestic sales of the drug, ECF No. 28-1 at 17 (plaintiff's position), or only sales made "under the terms of Medicare," ECF No. 96 at 46 (defendants' position). For its part, the IRS posted a Notice indicating that it will promulgate regulations establishing that "the § 5000D tax would be imposed on taxpayer sales of designated drugs dispensed, furnished, or administered to individuals *under the terms of Medicare*." ECF No. 28-14 at 4 (emphasis added). The Notice states that taxpayers "may rely on" its contents. *Id.* at 6.

The parties also disagree as to the excise tax rates the statutory formula requires. *See* ECF No. 28-1 at 17 (plaintiff arguing that the tax rate "begin[s] at 186 percent and escalate[s] to 1,900 percent"); ECF No. 96 at 46 (defendant arguing that the tax rate begins at 65 percent and escalates to 95 percent).[3]

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[3] While the parties disagree as to whether the tax is correctly described as a 186 to 1900 percent tax or a 65 to 95 percent tax, they seem to agree as to the actual amount of the tax for any given transaction. As discussed, the amount of the tax is set by a statutory formula: the ratio of the tax to the "sum of the tax and the price for which [the drug is] sold" must equal an "applicable percentage," which ranges from 65 percent to 95 percent. 42 U.S.C. § 5000D(a), (d). For instance, if the applicable percentage is 95 percent and the "price for which [the drug is] sold" is $1000, the tax would be $19,000 under the formula. However, an IRS Notice indicates that, under forthcoming IRS regulations, the manufacturer can pass the cost of the tax to the consumer. ECF No. 28-14 at 4-5. In our example, then, the manufacturer could invoice the consumer for a total of $20,000—$1,000 for the price of the drug and $19,000 for the tax. The government would then take $19,000 in tax revenue. The parties apparently do not disagree as to these amounts, but they do disagree as to how to characterize the resultant tax rate. The plaintiff argues that this example represents a 1900 percent tax rate, because the $19,000 (cont.)

(vi) Alternatives to Excise Tax Liability

A manufacturer that does not wish to participate in the Program can avoid the excise tax by transferring ownership of the Selected Drug to another entity, ECF No. 28-5 at 132-33, or withdrawing all its products from Medicare and Medicaid, 26 U.S.C. § 5000D(c).

If a manufacturer decides to transfer ownership of a drug to another entity, under CMS guidance, it must notify CMS at least 30 days before the transfer becomes effective. ECF No. 28-5 at 132. Once the transfer becomes effective, any excise tax liability could be imposed on the new owner. *Id.*

Alternatively, the manufacturer can maintain ownership of the drug and instead notify CMS of its withdrawal from Medicare and Medicaid. The excise tax is "suspend[ed]" if (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). In other

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the government receives is 1900 percent of the $1000 pretax cost of the drug. ECF No. 28-1 at 17; *see also* ECF No. 28-15 at 32 (Congressional Research Service report on the IRA's tax provisions stating that "[t]he excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance"). The defendants argue that this example represents a 95 percent tax rate, because the government takes 95 percent of the total post-tax amount the consumer pays. ECF No. 96 at 46 (noting that "the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95%").

words, the manufacturer must withdraw all of its products from Medicare and Medicaid to avoid the excise tax.

After the IRA was enacted, some manufacturers raised the possibility that they would be subject to excise tax liability while they were waiting to terminate their relationship with Medicare and Medicaid. *See* ECF No. 28-5 at 34 (CMS's revised guidance addressing this concern); Complaint ¶¶ 6, 82, *Merck v. Becerra*, No. 23-cv-01615 (D.D.C June 6, 2023) (ECF No. 1); Complaint ¶¶ 96, 98–100, *Dayton Area Chamber of Com. v. Becerra*, No. 23-cv-00156 (S.D. Ohio June 9, 2023) (ECF No. 1). A manufacturer can terminate its agreements under the Medicare Coverage Gap Discount Program and Manufacturer Discount Program "for any reason." 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). By statute, however, the termination will not become effective until between 11 and 23 months later. *Id.*

Through guidance, CMS has established a process for a manufacturer "that is unwilling to enter into [a Manufacturer Agreement] to expedite its termination from the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program." ECF No. 28-5 at 4. 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 send CMS a notice that states its intent not to participate in the Program and requests termination of its agreements under Medicare and

Medicaid. ECF No. 28-5 at 121-22. Upon receipt of that 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)]." *Id.* at 122; *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 termination so that it occurs thirty days after the manufacturer gives notice]."). Under this expedited process, the manufacture could withdraw from Medicare and Medicaid in as few as 30 days. *Id.*

BI claims that withdrawing from Medicare and Medicaid is "not a real option" for it. ECF No. 28-1 at 45. As of 2021, Medicare accounted for 21 percent of national health expenditures, and Medicaid accounted for an additional 17 percent. ECF No. 28-11 at 3 (CMS National Health Expenditure Fact Sheet). According to BI, it sells more than 20 drugs through Medicare and Medicaid, and its income from participating in those programs "accounts for more than half of the company's net sales in the United States in many years." ECF No. 28-2 ¶ 7.

C. Procedural History

On August 18, 2023, BI filed a complaint alleging that the Program (1) violates its Fifth Amendment right to procedural due process, (2) constitutes a physical taking under the Fifth Amendment, (3) compels speech in violation of the First Amendment, (3) violates the Excessive Fines Clause of the Eighth Amendment, and (5) unconstitutionally conditions BI's participation in federal programs on relinquish-

ment of constitutional rights.[4] ECF No. 1 ¶¶ 90-158. BI also alleges that CMS violated the Administrative Procedure Act ("APA") and Medicare Statute by issuing legislative rules without notice and comment. *Id.* ¶¶ 159-231. The parties filed a joint motion indicating that this matter "can properly be resolved through dispositive motions without the need for discovery" and requesting that the Court set a briefing schedule, ECF No. 16, and the Court granted that motion, ECF No. 17. In accordance with the briefing schedule set by the Court, ECF No. 17, the parties cross-moved for summary judgment, ECF Nos. 28, 48.[5]

This case is one of multiple constitutional and APA challenges to the Program filed in federal district courts. *See Dayton Area Chamber of Com. v. Becerra*, No. 23-CV-00156, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023) (denying plaintiffs' motion for a preliminary injunction because plaintiffs had not demonstrated a strong likelihood of success or irreparable harm); *AstraZeneca Pharms. LP v. Becerra*, No. 23-CV-00931, 2024 WL 895036 (D. Del. Mar. 1, 2024) (dismissing APA claims for lack of standing and granting summary judgment for government on due process claim); *Bristol Myers Squibb Co. v. Becerra*, No. 23-CV-03335, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) (granting summary judgment for government on Fifth Amendment Takings Clause claim, First Amendment claim, and unconstitutional conditions claim); *Nat'l*

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[4] The complaint also briefly suggests that the Program constitutes an unconstitutional delegation of Congress's authority, ECF No. 1 ¶¶ 90-92, but the complaint does not allege this as a distinct claim and none of the parties raise this issue in their summary judgment briefing. As such, I do not address it.

[5] The Court also exempted the parties from Local Rule 56(a)'s requirement that they file statements of undisputed fact.

Infusion Ctr. Ass'n v. Becerra, No. 23-CV-00707, 2024 WL 561860, at *5 (W.D. Tex. Feb. 12, 2024) (granting motion to dismiss claims for lack of jurisdiction and improper venue); *Novo Nordisk Inc. v. Becerra*, No. 3:23-CV-20814 (D.N.J.) (motion for summary judgment pending); *Novartis Pharmaceuticals Corp.*, No. 3:23-CV-14221 (D.N.J) (motion for summary judgment pending); *Merck & Co. v. Becerra*, No. 1:23-CV-01615 (D.D.C.) (motion for summary judgment pending).

III. LEGAL STANDARD

"Summary judgment is appropriate only if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." *Tolan v. Cotton*, 572 U.S. 650, 656-57 (2014) (internal quotation marks and citations omitted). In reviewing the summary judgment record, a court must "construe the facts in the light most favorable to the non-moving party and must resolve all ambiguities and draw all reasonable inferences against the movant." *Caronia v. Philip Morris USA, Inc.*, 715 F.3d 417, 427 (2d Cir. 2013). "A genuine dispute of material fact exists for summary judgment purposes where the evidence, viewed in the light most favorable to the nonmoving party, is such that a reasonable jury could decide in that party's favor." *Zann Kwan v. Andalex Grp. LLC*, 737 F.3d 834, 843 (2d Cir. 2013). The moving party bears the burden of demonstrating that no genuine issue exists as to any material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986). "Claims turning entirely on the constitutional validity or invalidity of a statute are particularly conducive to disposition by summary judgment as they involve purely legal questions."

Connecticut ex Rel. Blumenthal v. Crotty, 346 F.3d 84, 93 (2d Cir. 2003).

IV. DISCUSSION

A. Fifth Amendment Claims

BI argues that the Program violates the Fifth Amendment because (1) it deprives BI of its property interest in both "physical doses of Jardiance" and BI's confidential data without due process of law,[6] ECF No. 28-1 at 21-30, and (2) it effects a physical taking of BI's doses of Jardiance without just compensation, *id.* at 30-35.

Both the Due Process Clause and the Takings Clause require BI to establish that the government has "deprived [it] of a protected property interest." *Story v. Green*, 978 F.2d 60, 62 (2d. Cir. 1992). To raise a procedural due process claim, BI 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. New York State United Tchrs.*, 80 F.4th 386, 392 (2d Cir. 2023).

The Takings Clause provides that "private property [shall not] be taken for public use, 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

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[6] I note that BI does not argue that it has a property interest in charging Medicare a certain rate for its drugs. Nor could it: "procedural due process protections" attach when "state or federal law confers an entitlement to benefits." *Kapps v. Wing*, 404 F.3d 105, 113 (2d Cir. 2005). BI points to no law that entitles it to any particular rate of Medicare reimbursement.

taking has occurred." *74 Pinehurst LLC v. New York*, 59 F.4th 557, 563 (2d Cir. 2023). The Takings Clause protects "personal property . . . against physical appropriation" by the government, just as it protects real property. *Horne v. Dep't of Agriculture*, 576 U.S. 350, 359 (2015). BI contends that the Program constitutes a physical taking of its property. But it disavows any claim of a regulatory taking, ECF No. 28-1 at 30 n.14, which "occurs when a regulation goes 'too far' in restricting a landowner's ability to use his own property." *74 Pinehurst LLC*, 59 F.4th at 564 (quoting *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)).

The defendants argue that the Program does not deprive BI of its property under the Due Process Clause or Takings Clause, because participation in the Program is voluntary: BI can "withdraw[] from the Medicare and Medicaid programs," it can "divest its interest in the [Selected Drug] to a separate entity," or it can "stop selling [the Selected Drug] to Medicare beneficiaries, permanently or temporarily." ECF No. 48-1 at 37.

BI disputes whether it can evade the Program's requirements through the mechanisms the government proposes. And it argues that withdrawing from Medicare and Medicaid is not a realistic option, because of the large economic cost. I disagree and hold that because BI can opt out of Medicare and Medicaid, it has not been deprived of property for the purposes of its Due Process Clause and Takings Clause claims.

(i) Alternatives to Participating in the Program

The parties disagree as to whether the IRA allows manufacturers to avoid participating in the Program.

I begin, then, by assessing whether manufacturers seeking to escape the Program can opt out of Medicare and Medicaid, divest their interest in the Selected Drug, or decline to sell the Selected Drug to Medicare.

Withdrawing from Medicare and Medicaid

BI argues that there is no expeditious way for manufacturers to terminate their Medicare agreements. ECF No. 28-1 at 48. By statute, a manufacturer's notice of withdrawal from the Medicare Coverage Gap Discount Program Agreement or the Manufacturer Discount Program Agreement will not become effective until at least 11 months and up to 23 months after the notice is submitted. 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). If a manufacturer learned its drug was selected for the Program on September 1, 2023, and sought to withdraw from those agreements immediately, its withdrawal would not be effective until January 1, 2025. *Id.* §§ 1395w-114a(b)(4)(B)(ii)(II), 1395w-114c(b)(4)(B)(ii)(II). In the meantime, if it refused to sign the Manufacturer Agreement on October 1, 2023 or did not agree to the maximum fair price on August 1, 2024, it could be subject to excise tax liability. *Id.* § 5000D(c)(1)(A)(ii) (providing that the excise tax is suspended only if "none of the drugs of the manufacturer of the designated drug are covered by a [Medicare Coverage Gap Discount Program Agreement or Manufacturer Discount Program Agreement.]").

Even when this delay is factored in, however, BI can still withdraw from Medicare without penalty before the maximum fair price takes effect. A manufacturer seeking to escape the Program can sign the Manufacturer Agreement and agree to a maximum fair price for its Selected Drug by August 1,

2024, and then, before January 30, 2025, give notice of its withdrawal from the Medicare and Medicaid Programs. *See* ECF No. 121 (BI's counsel conceding that this is an option). Such a manufacturer would never have to sell the Selected Drug at the maximum fair price and would face no excise taxes or civil penalties.

In addition, CMS has created an accelerated path for manufacturers to terminate their Medicare agreements. CMS guidance states that, upon notice from the manufacturer that it does not wish to participate in the Program and that it requests termination, CMS will find "good cause" to terminate any Medicare Coverage Gap Discount Program Agreement or Manufacturer Discount Program Agreement. ECF No. 28-5 at 121-22; *see id.* at 122 (CMS "will automatically grant such termination requests upon receipt"). Existing statutes permit (and in some cases, require) CMS to "provide for termination of" Medicare agreements after 30 days for "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). CMS notified BI that Jardiance was a Selected Drug on September 1, 2023. This means that BI had an opportunity to withdraw from Medicare and Medicaid even before the October 2 deadline for committing to negotiations with and submitting data to CMS.[7]

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[7] It is true that, if BI did not wish to submit data, the 30-day notice period would have meant that it had to act within a day of learning that Jardiance had been selected if it wanted to avoid the excise tax. But BI was on notice that Jardiance might be selected from the date of the enactment of the IRA, i.e., August 16, 2022. And the selection of Jardiance on September 1, 2023 (cont.)

BI argues that CMS's accelerated termination option is "foreclose[d]" by "the text and structure of the relevant statutory provisions." ECF No. 28-1 at 48. It accuses CMS of "ignor[ing]" the statutory language by "treating termination requests *by manufacturers* as termination requests *by the Government*." *Id.* And it claims that the IRA "limits 'good cause' to 'knowing and willful violations of the requirements of the agreements' and related malfeasance." ECF No. 92 at 19.

The statutory text does not support BI's interpretation. Nothing 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. 42 U.S.C. § 1395w-114a(b)(4)(B)(i) (providing for 30-day "good cause" terminations by CMS under the subheading "Termination – By the Secretary"), (ii) (providing for 11 to 23 month termination for any reason by the manufacturer under the subheading "Termination – By a manufacturer"); *id.* § 1395w-114c(b)(4)(B)(i), (ii) (same). Further, the statute states that CMS "may *provide for* termination of an agreement . . . for a knowing and willful violation of the . . . agreement or other *good cause* shown.'" *Id.* § 1395w-114a(b)(4)(B)(i) (termination by the Secretary of Medicare Coverage Gap Discount Program agreements; emphases added); *id.* § 1395w-114c(b)(4)(B)(i) (same language for

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could hardly have been a surprise given the statutory selection criteria, which focus on drugs that account for the highest total expenditures by Medicare. *See* 42 U.S.C. § 1320f-1(d)(1). Further, BI was alerted to the 30-day withdrawal option no later than June 30, 2023, when CMS published its revised guidance.

termination of Manufacturer discount program agreements, except that CMS "*shall* provide for termination" of such agreements in such circumstances (emphasis added)). Congress's use of the phrase "provide for" suggests that it expected CMS to identify specific instances of "good cause" in the future as experience under the statute developed. *See* Provides For, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/provide%20for (defining "provides for" as "to cause (something) to be available or to happen in the future"); Provide For, Oxford Learner's Dictionaries, https://www.oxfordlearnersdictionaries.com/definition/english/provide-for (defining "provide for" as "to make preparations to deal with something that might happen in the future" and "to make it possible for something to be done," among other definitions). Such a direction to an agency to adapt to future scenarios would be superfluous if Congress intended to restrict "good cause" to "other related malfeasance."

In addition, 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) (citation and internal quotation marks omitted).[8] A manufacturer's desire to withdraw from

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[8] To the extent BI relies on the *ejusdem generis* canon to support its argument that "good cause" is restricted to "related malfeasance" because it follows "knowing and willful violation of . . . the agreement," *see* ECF No. 92 at 19-20 (citing *Owen of Georgia, Inc. v. Shelby County*, 547 F.2d 1084 (6th Cir. 1981)), its reliance is misplaced. *Ejusdem generis* holds that "words grouped in a *list* should be given should be given related meaning." *Shelby County*, 648 F.2d at 109 (emphasis added); *see also id.* ("[W]here general words follow specific words in an *enumeration* describing (cont.)

the Program before its teeth clamp down is good cause, particularly where "the absence of a speedy exit option would raise serious constitutional questions." ECF No. 96 at 17; *see Field Day, LLC v. Cnty. of Suffolk*, 463 F.3d 167, 182 (2d Cir. 2006) ("Court[s] must construe statutes, where necessary and possible, to avoid serious constitutional issues."). So CMS's creation of the accelerated termination option was well within its statutory authority to "provide for termination of" Medicare agreements for good cause.

BI also argues that, even if it has the option to withdraw from Medicare and Medicaid after a 30-day delay, it is still required to "participate in the Program for a period of time." ECF No. 92 at 13. But mere participation in the Program, i.e., signing the Manufacturer Agreement and responding to CMS' offer of a "maximum fair price," does not constitute a deprivation of property under the Takings Clause or the Due Process Clause. Any deprivation of BI's alleged interest in Jardiance would occur, if at all, after the maximum fair price goes into effect in 2026.[9]

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the legal subject, the general words are construed to embrace only objects similar to those objects enumerated by the preceding specific words." (emphasis added)); Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 199 (2012) (explaining that "[t]he *ejusdem generis* canon applies" where "general words follow an enumeration of *two or more* things" (emphasis added and internal alterations omitted)). Here, by contrast, "other good cause" follows a single term, "knowing and willful violation" of the agreement. There is no cluster of related, specific terms to confine the meaning of "other good cause."

[9] BI's counsel stated during oral argument that, in his view, the physical taking of BI's property occurs at the moment BI is "required to give that access [to Jardiance], that's when [its] right (cont.)

As to BI's claim that it has been deprived of its "property interest in its confidential data regarding Jardiance," ECF No. 28-1 at 23, BI was not required to turn over any data until October 2, 2023, *id.* §1320f-3(b)(2)(A), 1320f(d)(2)(A) (setting October 2, 2023 deadline for data to be submitted). As I have explained, it had an option to withdraw from Medicare and Medicaid before that point. *See* note 7, *supra*.

For all these reasons, I conclude that BI had the option to withdraw from Medicare and Medicaid before any taking or deprivation of its property interests.

Divesting Interest in Jardiance

The defendants also claim—and BI does not contest—that BI can avoid participating in the Program by divesting its interest in Jardiance. ECF No. 48-1 at 36. But the existence of this option is not relevant to the Fifth Amendment analysis. The government cannot evade a Fifth Amendment challenge by requiring manufacturers to choose between losing any property rights they have through government appropriation and losing them through divestment. Nor do the defendants cite any caselaw to support the notion that the option to divest property prior to deprivation can prevent a Fifth Amendment violation, and the Supreme Court has rejected this notion. *See Horne*, 576 U.S. at 363 (noting that, in

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to exclude . . . is appropriated for the benefit of third parties." ECF No. 121 at 15. That moment, he agreed, does not occur until the first date BI has to sell the product at the maximum fair price: January 1, 2026. *Id.* at 17 ("The Court: So [Medicare beneficiaries] don't have access to the price till January 1, 2026; is that true? Mr. King: Yes, that's correct, [they] don't have access to the price until January 1, 2026.").

Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 430, 436 (1983), the Court "held that the installation of a cable box on a small corner of Loretto's rooftop was a *per se* taking, even though she could of course still sell and economically benefit from the property").

Stopping Sales of Jardiance to Medicare

Finally, the defendants suggest that the IRA permits BI to avoid any statutory penalties if it "stop[s] selling [Jardiance] to Medicare beneficiaries, permanently or temporarily." ECF No. 48-1 at 36. They point out that while the statute and agency guidance require manufacturers to provide Medicare beneficiaries with access to a certain *price*, nothing requires manufacturers to provide access to the drug itself. ECF No. 96 at 30-31; *see* 42 U.S.C. § 1320f-2(a)(3) ("[CMS] shall enter into agreements with manufacturers . . . under which . . . access to the maximum fair *price* . . . shall be provided by the manufacturer" to Medicare beneficiaries and their medical providers (emphasis added)); ECF No. 28-6 at 2 (Manufacturer Agreement: "[T]he Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined *price* to [maximum fair price]-eligible individuals . . . ." (emphasis added)); ECF No. 28-5 at 126-27 (CMS Guidance: "After entering into an Agreement with CMS . . . the manufacturer of a selected drug must provide access to the [maximum fair *price*]" to Medicare beneficiaries and their medical providers (emphasis added)). The defendants also claim the statutory penalties (the excise tax and civil monetary penalties) are imposed only on sales that BI makes to Medicare. ECF No. 48-1 at 23. Thus, the defendants argue, "if, after signing the agreement with CMS, BI were to refuse to sell

Jardiance to Medicare beneficiaries, that would not be prohibited by the IRA—and would subject BI to no 'penalty.'" ECF No. 96 at 31.[10]

BI responds that the defendants "do[] not say how a third party supposedly could access an abstract price without also receiving the underlying product." ECF No. 92 at 38. It argues the defendants' "cramped reading would defeat the Program's core purpose of providing access to drugs at lower prices." *Id.* It also maintains that the excise tax applies not only to sales to Medicare beneficiaries and their providers but also to all domestic sales of each Selected Drug. ECF No. 28-1 at 41.

But I need not decide whether manufacturers can evade the Program (or its penalties) by refusing to sell the Selected Drug to Medicare beneficiaries. Even if they cannot, as I explain in the next section, that does not deprive manufacturers of their property, because they have the option to withdraw from Medicare and Medicaid. So for the purposes of my analysis, I assume without deciding that withdrawing from Medicare and Medicaid is the only alternative to participating in the Program.

(ii) Voluntariness of the Program

BI argues that the option to withdraw from Medicare and Medicaid does not render the Program voluntary, because "forcing [it] to abandon [Medicare

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[10] During oral argument, however, defense counsel acknowledged that "it might be logistically difficult for companies to start parsing where the sale is going and try to restrict the Medicare beneficiaries from receiving a drug," because manufacturers use intermediaries to distribute drugs. ECF No. 121 at 50. So while this option may exist in theory, it is unclear whether any manufacturer can realistically make use of it.

and Medicaid]," which occupy "nearly half the U.S. health care market" and account for over half BI's sales, is "'economic dragooning that leaves [it] with no choice but to acquiesce' to the Program." ECF No. 28-1 at 45 (citation omitted). The question, then, is whether the government can use its power as a dominant buyer to demand lower prices from drug manufacturers. The caselaw makes clear that it can.

The leading case is *Garelick v. Sullivan*, in which the Second Circuit considered a challenge by anesthesiologists to a law that limited the amount they could charge Medicare beneficiaries under Medicare Part B. 987 F.2d 913, 915 (2d Cir. 1993). The anesthesiologists claimed that "the limiting charge regime g[ave] rise to a taking of property without just compensation." *Id.* The Second Circuit concluded that there "[could] be no taking," because the anesthesiologists had "voluntarily participate[d]" in Medicare. *Id.* at 916. The court noted that the law did not require the anesthesiologists to treat Medicare patients, and they "retain[ed] the right to provide medical services to non-Medicare patients free of price regulations." *Id.* at 916-17 ("Because they voluntarily [chose] to provide services in the price-regulated Part B Program, the plaintiff anesthesiologists do not have a viable takings claim."). And it rejected an argument that participation in Medicare was not voluntary because refusing to treat Medicare beneficiaries was "not an economically viable option" for the anesthesiologists. *Id.* at 917. The court observed that "economic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Id.*

Other circuits have reached similar conclusions in evaluating other governmental limits on reimbursements to healthcare providers. *See, e.g.*, *Baker Cnty.*

Med. Servs., Inc. v. Atty. Gen., 763 F.3d 1274, 1276, 1279-80 (11th Cir. 2014) (noting that a "long line of cases instructs that no taking occurs where a person or entity voluntarily participates in a regulated Program or activity," rejecting Takings Clause challenge to federal statute requiring hospitals that opted into Medicare to treat federal detainees in emergency rooms at Medicare reimbursement rates, and finding participation in Medicare voluntary, even though "opting out of Medicare would amount to a grave financial setback"); *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009) (rejecting Takings Clause challenge to state law requiring hospitals that participate in MaineCare to provide care to low-income patients at capped reimbursement rates, and observing that "where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking"); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 445 (8th Cir. 1984) (rejecting Takings Clause challenge to state statute conditioning participation in Medicaid on agreement by nursing home that it would not charge residents rates that were more than a specified amount: "it is . . . only through voluntary participation in the state's Medicaid program that a nursing home falls within the purview of [the state law]," and "[d]espite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary"); *see also Nat'l Lifeline Ass'n v. Fed. Commc'ns Comm'n*, 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" (citation and internal quotation marks omitted)). BI cites no case to the contrary

involving the government as a market participant, let alone a case involving a government health insurance program.

Courts in other circuits have also rejected Takings Clause challenges to the 340B Drug Price Program, which conditions drug manufacturers' participation in Medicaid and Medicare Part B on their agreement to sell drugs at a discounted price to the Veterans Health Administration and certain non-profit hospitals, among other entities. *Eli Lilly & Co. v. United States Dep't of Health & Hum. Servs.*, No. 1:21-CV-00081, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021) ("[Drug manufacturers] have voluntarily chosen to participate in the 340B program and are thus free to terminate their participation if and when they may choose to do so . . . . We concede that in withdrawing from the 340B program Lilly would no longer receive coverage or reimbursement for its products under Medicaid and Medicare Part B, which would result in a significant financial impact for Lilly, but 'economic hardship is not equivalent to legal compulsion for purposes of takings analysis.'" (quoting *Garelick*, 987 F.2d at 917)); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 210 (D.N.J. 2021) ("[F]inancial inducement generally does not rise to the level of a taking, 'as long as' a private party is 'aware of the conditions' and the conditions are 'rationally related to a legitimate Government interest.'" (quoting *Ruckelhaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984)), *rev'd on other grounds*, 58 F.4th 696 (3d Cir. 2023).

BI nonetheless argues that the reasoning in *Garelick* and other similar cases "is inconsistent with the Supreme Court's later decision in [*Horne v. Dep't of Agriculture*, 576 U.S. 350 (2015)]." ECF No. 28-1 at

49. In *Horne*, the Supreme Court weighed a Takings Clause challenge to a Department of Agriculture market order requiring raisin growers to reserve a portion of their crop for the government's use. 576 U.S. 350. The government argued that "the reserve requirement [was] not a taking because raisin growers voluntarily choose to participate in the raisin market," and had the option to "sell their raisin-variety grapes as table grapes or for use in juice or wine." *Id.* at 365. The Court disagreed, holding that "a governmental mandate to relinquish specific, identifiable property as a 'condition' on permission to engage in commerce effects a per se taking." *Id.* at 364-65.

The marketing order in *Horne* is readily distinguishable from the statutory provision at issue in *Garelick*—and the statute at issue in this case. First, the plaintiffs in *Garelick* and this case may continue to sell their medical services or products on the private market if they withdraw from Medicare. By contrast, the raisin growers in *Horne* were barred from the entire market for raisins if they did not comply with the reserve requirement. *Bristol Myers Squibb Co.*, 2024 WL 1855054, at *6 (discussing this distinction). Not surprisingly, then, even after *Horne*, the Second Circuit has continued to rely on the same general principle articulated in *Garelick*, i.e., that voluntary participation in a regulated market precludes a takings claim. *74 Pinehurst LLC v. New York*, 59 F.4th at 564 (citing *Horne*, but rejecting physical takings challenge brought by associations of landlords against amendments to New York rent stabilization law: "[N]o plaintiff alleges that the [rent stabilization law] forces [landlords] to place their properties into the regulated housing market.").

Second, the statutes in *Garelick* and this case seek to regulate prices only in a portion of the drug market created and funded by the federal government: the purchasing of drugs on behalf of Medicare beneficiaries. In a variety of contexts, the Supreme Court and the Second Circuit have recognized 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.'" *Engquist v. Oregon Dep't of Agric.*, 553 U.S. 591, 598 (2008) (collecting cases applying this distinction to government regulation of its employees in the First and Fourth Amendment contexts); *Selevan v. New York Thruway Auth.,* 584 F.3d 82, 93 (2d Cir. 2009) (discussing the market participant doctrine, which "differentiates between a State's acting in its distinctive governmental capacity, and a State's acting in the more general capacity of a market participant" in the Dormant Commerce Clause context (citations and internal quotation marks omitted)). Likewise, other circuit courts have found that "[t]aking claims rarely arise under government contracts because the Government acts in its commercial or proprietary capacity in entering contracts, rather than in its sovereign capacity." *Hughes Commc'ns Galaxy, Inc. v. United States*, 271 F.3d 1060, 1070 (Fed. Cir. 2001) (finding that government breach of contract does not "give rise to compensation under the Fifth Amendment"); *see also Preston Hollow Cap., L.L.C. v. Cottonwood Dev. Corp.*, 23 F.4th 550, 554 (5th Cir. 2022) (same); *Masso-Torrellas v. Municipality of Toa Alta*, 845 F.3d 461, 467-68 (1st Cir. 2017) (same). The government has broad leeway to impose conditions on its own purchases of goods and services. *See Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) ("Like 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.").

Third, in *Horne*, the government enforced its raisin regulation by physically appropriating the Hornes' raisins. *Horne v. Dep't of Agric.*, 576 U.S. 350, 356 (2015) ("The Government sent trucks to the Hornes' facility at eight o'clock one morning to pick up the raisins."). In *Garelick* and in this case, the statutes do not permit the government to seize the plaintiffs' property (or to provide access to it by others) if they refuse to turn it over. Moreover, unlike a price regulation, which is ordinarily applied at the point of sale, the reserve requirement meant the Hornes needed to give up their raisins before any sale occurred. *Horne*, 576 U.S. at 356. By contrast, the government in *Garelick* and in this case is regulating the price of drugs or services only at the moment the service provider or supplier chooses to sell, i.e., to engage in a voluntary transfer with a third party. *See* note 9, *supra*. As the Government notes, nothing in the IRA requires BI to sell or otherwise give up a single dose of Jardiance. ECF No. 48-1 at 3-5.[11]

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[11] To be sure, this may appear to be a narrow distinction from *Horne*, because the reserve requirement apparently applied only to raisin growers that wanted to sell their crop in the market. But a physical taking is a narrow species of claim. It occurs only "[w]hen the government effects a physical appropriation of private property for itself or another," including when the government "grant[s] a third party the right to invade property closed to the public." *74 Pinehurst LLC*, 54 F.4th at 557, 563. When a property owner offers her property for sale, however, the property is no longer "closed to the public" and there is "no (cont.)

For these reasons, the statute at issue in *Garelick*— and the statute at issue in this case— are "markedly different" from the reserve requirement in *Horne*. *Bristol Myers Squibb Co. v. Becerra*, 2024 WL 1855054, at *6. And I am "required to follow Second Circuit precedent 'unless and until it is overruled in a precedential opinion by the Second Circuit itself or unless a subsequent decision of the Supreme Court so undermines it that it will almost inevitably be overruled by the Second Circuit.'" *Boone v. United States*, No. 02-CR-01185 (JMF), 2017 WL 398386, at *1 (S.D.N.Y. Jan. 30, 2017) (citation omitted); *Monsanto v. United States*, 348 F.3d 345, 351 (2d Cir. 2003) (despite "tension" between Supreme Court decision and governing Circuit precedent, "[w]e are bound by [circuit precedent] . . . unless and until [that precedent] is reconsidered by our court sitting in banc . . . or is rejected by a later Supreme Court decision"). Given the significant distinctions between *Horne* and *Garelick*, I cannot say that the Supreme Court's decision in *Horne* "so undermines [*Garelick*] that it will almost inevitably be overruled by the Second Circuit." *Boone*, 2017 WL 398386, at *1.

BI argues that *Garelick* is not binding as to all Fifth Amendment claims here for several reasons, including

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inva[sion]." There is, instead, a voluntary decision by the property owner to transfer her property, and any price regulation of the sale is just that—regulation. *See Horne*, 576 U.S. at 362 (noting that although "[a] physical taking of raisins and a regulatory limit on production may have the same economic impact on a grower," the Constitution prohibits only the former— a "distinction [that] flows naturally from the settled difference in our takings jurisprudence between appropriation and regulation").

that did not involve a procedural due process claim.[12] ECF No. 28-1 at 49. Yet while it may not be binding, *Garelick*'s reasoning remains persuasive in the due process context. Due Process Clause claims and Takings Clause claims both involve the question of whether BI has been deprived of a property interest. *Story v. Green*, 978 F.2d at 62. Although there are differences in how courts approach this issue in the two contexts, *Burns v. Pa. Dep't of Correction*, 544 F.3d 279, 285 n.3 (3d Cir. 2008) (discussing distinctions), I see no reason that voluntary participation in a government program should amount to a deprivation of property any more than it amounts to a taking of property. The few courts that have considered the application of *Garelick* to procedural due process claims have agreed: no deprivation of property occurs when the government places conditions on participation in a voluntary government program. *See,*

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[12] Beyond the due process issue, BI raises two other distinctions between *Garelick* and this case, namely that: (1) the plaintiffs in *Garelick* raised a regulatory takings claim, not a per se physical takings claim, ECF No. 92 at 31, and (2) the government in *Garelick* did not "select[] some, but all, providers for participation," *id.* at 30. Despite these differences, *Garelick* stands for a broader principle that participation in Medicare is voluntary and conditions placed on such participation therefore cannot constitute a taking. *Garelick*, 987 F.2d at 916 ("A property owner must be legally compelled to engage in price-regulated activity for regulations to give rise to a taking."). The Court did not base its decision on the narrower ground that the cap on the anesthesiologists' reimbursement did not satisfy the regulatory taking factors in the Supreme Court's regulatory takings jurisprudence. And many of the cases it relied on were not regulatory takings cases. *Id.* Finally, the fact that the IRA singles out certain manufacturers for the Program by focusing on the drugs that are the biggest drains on Medicare has no bearing on whether participation in Medicare is voluntary.

e.g., *Kaiser Found. Health Plan, Inc. v. Burwell*, 147 F. Supp. 3d 897, 911 (N.D. Cal. 2015) (regulation of Medicare Advantage organization's (MAO's) expenditure of Medicare funds did not violate MAO's procedural due process rights, because "[p]articipation in the Medicare program is a voluntary undertaking" and MAO "ha[d] no property interest in Medicaid or Medicare payments"); *cf. Hinesburg Sand & Gravel Co. v. Chittenden Solid Waste Dist.*, 959 F. Supp. 652, 659 (D. Vt. 1997) (citing *Garelick* and finding no deprivation of property interests for the purposes of Due Process or Takings Clause claims where plaintiff decided to expend resources in response to government action, because plaintiff's "decision to expend its own funds to challenge [the government action] was entirely voluntary").[13]

Finally, BI cites *National Federation of Independent Businesses v. Sebelius*, 567 U.S. 519, 582 (2012) ("NFIB") for the premise that "actions taken under threat of severe economic coercion are not

[13] To be sure, voluntary participation in a government program does not bar a due process claim where the plaintiff has a property interest in the government program *itself*. If an individual has a "legitimate claim of entitlement" to a government benefit under "statutory and administrative standards defining eligibility for them," the government cannot deprive the individual of that government benefit without due process. *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 576 (1972). But BI does not claim it has a property interest in selling its products through Medicare or Medicaid or to any particular rate of reimbursement. Nor could it, because no statute or regulation entitles it to sell its products to the government at all, let alone to do so at a particular rate of reimbursement.

voluntary."[14] ECF No. 28-1 at 46-47. In *NFIB*, the Court held unconstitutional a provision of the Affordable Care Act that withdrew all Medicaid funding from states that "opt[ed] out of the Affordable Care Act's [Medicaid] expansion." 567 U.S. at 581. The Court

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[14] BI also cites several *Lochner*-era Supreme Court cases to support its argument that participation in the Program is coerced. *See* ECF No. 28-1 at 46-47 (citing *Union Pacific Rail Road Co. v. Public Service Commission*, 248 U.S. 67, 69-70 (1918) (challenge to state law as "interference with interstate commerce and as bad under the Fourteenth Amendment"); *United States v. Butler*, 297 U.S. 1, 70 (1936) (challenge to Congress's authority to use its taxing and spending power to regulate matters it could not regulate under the Commerce Clause); *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (same)). None of those cases resembles this one. In *Union Pacific Rail Road Co.*, a railroad company could not obtain a certificate necessary to issue bonds secured by its entire 3500-mile line unless it paid a large fee to the state of Missouri, where it had less than a mile of trackage. 248 U.S. at 68-69. The Court found that Missouri's interference with interstate commerce was not diminished by the railroad's option not to apply for the certificate, because this would not "adequately . . . have avoided evils that made it practically impossible not to comply with the terms of the law." *Id.* at 70. In the other two cases, *Butler* and *Carter*, where the plaintiffs were subject to a tax if they refused to comply with a government regulation, *Butler*, 297 U.S. at 70-71; *Carter*, 298 U.S. at 289, they could not avoid the tax by declining to participate in a voluntary government program. I also note that it is questionable whether *Butler* and *Carter* remain good law—both cases relied on a narrow view of the federal government's powers that has since largely been rejected by the Supreme Court. *See Kansas v. United States*, 214 F.3d 1196, 1200 n.6 (10th Cir. 2000) ("The analysis in *Butler* has been discredited as flawed and unworkable, and has not been followed."); *see also NFIB*, 567 U.S. at 572-73 (noting that some early cases, including *Butler*, had "policed [Congress's taxing power] aggressively," but more recent cases "have declined to closely examine the regulatory motive or effect of revenue-raising measures").

found that "[t]he threatened loss of over 10 percent of a State's overall budget . . . is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion." *Id.* at 582. But *NFIB* involved the anti-commandeering doctrine, which bars "federal legislation that commandeers a State's legislative or administrative apparatus for federal purposes." *Id.* at 577. The Anti-Commandeering Doctrine rests on the notion that "the Constitution has never been understood to confer upon Congress the ability to require the States to govern according to Congress' instructions." *Id.* (internal quotation marks omitted). It is designed to preserve "our system of federalism" by preventing Congress from interfering with state governments by placing overly controlling conditions on federal dollars. *Id.* at 577-78 ("[W]hen pressure turns into compulsion, the legislation runs contrary to our system of federalism." (internal quotation marks and citations omitted)). No similar limit on Congress' spending powers applies here, where the government is dealing with private parties instead of state agencies. The federal government is free to use its economic power as a bulk purchaser of certain goods to negotiate better deals for those goods.

For all these reasons, I find that BI's participation in Medicare and Medicaid is voluntary, even if BI has a considerable economic incentive to participate. With all the resources at the federal government's disposal, private corporations will often have an incentive to participate in federal programs. The Fifth Amendment does not prevent the federal government from placing conditions on participation in those programs.

B. First Amendment Claim

BI next argues that the Program "violates BI's First Amendment rights by compelling BI to echo the Government's preferred narrative regarding the Program." ECF No. 28-1 at 35. BI objects to the requirement that it sign the Manufacturer Agreement, because that agreement uses terms like "negotiation" and "maximum fair price." *Id.* at 35-36. In BI's view, the text of the Manufacturer Agreement conveys messages with which it "strongly disagrees": that BI "has voluntarily agreed to participate in the Program," that the Program "involves an actual 'negotiation,'" and that the resulting price is the "maximum fair" one. *Id.* at 36-37.

The First Amendment prohibits the government from "telling people what they must say." *Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 61 (2006) [hereinafter "*FAIR*"]. But "[t]he government . . . does not necessarily run afoul of the First Amendment when it regulates conduct in a manner that incidentally burdens one's speech." *Moore v. Hadestown Broadway Ltd. Liab. Co.*, No. 23-CV-04837, 2024 WL 989843, at *17 (S.D.N.Y. Mar. 7, 2024); *see FAIR*, 547 U.S. at 62 (holding that compelling speech that "is plainly incidental to [a statute's] regulation of conduct" does not violate the First Amendment); *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017) (observing that a typical price regulation's "effect on speech would be only incidental to its primary effect on conduct, and it has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either

spoken, written, or printed'" (citation and internal quotation marks omitted)).

To begin with, as previously discussed, BI's participation in the Program is voluntary, and BI was free to withdraw from Medicare and Medicaid before the deadline for signing the Manufacturer Agreement. So the Agreement did not "compel" BI to do anything.

Beyond that, however, the Manufacturer Agreement regulates BI's conduct, and any effects it may have on speech are "plainly incidental." *FAIR*, 547 U.S. at 62. The language that BI objects to appears in provisions requiring that BI participate in the Program and provide access to the "maximum fair price," among other regulations of BI's conduct. ECF No. 28-6. Certainly, regulations are frequently "initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *FAIR*, 547 U.S. at 62. Indeed, the IRA requires BI to communicate in various ways, including, arguably, by signing the Manufacturer Agreement and by making a written counteroffer that must "be justified based on [the statutory factors]." 42 U.S.C. § 1320f-3(b)(2)(C). But as with "typical price regulations," the words CMS requires manufacturers to use are just an incidental means to CMS' goal of regulating drug prices. *Expressions Hair Design*, 581 U.S. at 47.

Though not required to do so by the Constitution, CMS took steps to minimize the communicative content of the Manufacturer Agreement. The Manufacturer Agreement makes clear that its "[u]se 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." ECF

No. 28-6 at 5; *see also id.* at 2 (noting that the price of drugs is "referred to as 'maximum fair price' in the act"). Another provision specifies that "[i]n signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views . . . ." *Id.*

BI nonetheless argues that the use of statutory terms in the Manufacturer Agreement constitutes compelled speech because an uninformed observer might read those terms out of context—and in conflict with the express terms of the contract—and draw inferences about BI's views.[15] This argument finds no support in precedent.[16] The First Amendment is not

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[15] Adopting this argument could have broad implications for government contracting. Many statutes have names or use terms that some observer might read to suggest an ideological message (e.g., the Patient Protection and Affordable Care Act and Medicare Modernization and Prescription Drug Act, among many others). The logical extension of BI's reasoning is that government contracts that referenced these statutes must face First Amendment scrutiny as potential compelled speech or unconstitutional conditions on government funds. To avoid burdening speech, BI would require the government to substitute terms that some observer might find more neutral for an endless list of statutory words. ECF No. 92 at 43-44 ("The IRA could mandate that BI *do* everything set forth in the Agreement without compelling it to [use the statutory terms].").

[16] This is not to say that government contracts never infringe on First Amendment rights. During oral argument, BI pointed to *Agency for International Development v. Alliance for Open Society International, Inc.*, 570 U.S. 205 (2013) [hereinafter *USAID*] as an example of a case standing "for the proposition that signing an agreement amounts to speech as opposed to conduct." ECF No. 121 at 68. In that case, a federal statute required recipients of HIV/AIDs relief funding to "agree in their award documents that they oppose prostitution." *Id.* at 205; *see also* Joint App'x at 303, *Agency for International Development v. Alliance for Open* (cont.)

implicated when, in the course of regulating conduct, the government burdens speech in such a speculative and incidental manner. *See Arkansas Times LP v. Waldrip*, 37 F.4th 1386, 1390, 1394 (8th Cir. 2022) (holding that statutory requirement that state contracts include a certification that a company "is not currently engaged in, and agrees for the duration of the contract not to engage in, a boycott of Israel" does not violate the First Amendment because "[t]he 'speech' aspect—signing the certification—is incidental to the regulation of conduct"—boycotts of Israel).

BI also suggests that signing the Manufacturer Agreement might constitute expressive conduct. *See* ECF No. 28-1 at 39-40 (citing a number of expressive conduct cases). The First Amendment "affords protection to symbolic or expressive conduct as well as to actual speech." *Virginia v. Black*, 538 U.S. 343, 358 (2003). So where the government regulates or compels

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Society, Int'l, Inc., 591 U.S. 430 (2020) (contractual language: "[B]y accepting this award . . . a non-governmental organization . . . agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose . . . .") *USAID* suggests that requiring an entity to sign a government contract can have First Amendment implications. But it does not say that government contracts are compelled speech (or unconstitutional conditions on speech) merely because they contain words that, in some contexts, may be understood to convey a political message. The contractual provision in *USAID* went far beyond "incidental" regulation of speech: it was plainly designed to compel recipients to endorse a government-sanctioned message. By contrast, the provisions BI points to in the Manufacturer Agreement primarily serve to regulate the price BI may charge. The Manufacturer Agreement expressly states that BI is not endorsing any government-sanctioned message.

expressive conduct, the First Amendment is implicated.

However, the Supreme Court has "rejected the view that an apparently limitless variety of conduct can be labeled 'speech' whenever the person engaging in the conduct intends thereby to express an idea." *Texas v. Johnson*, 491 U.S. 397, 404 (1989) (citation and internal quotation marks omitted); *see also City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989) ("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."). "[T]o fall within the scope of the [First Amendment]," the conduct must be "sufficiently imbued with elements of communication." *Johnson*, 491 U.S. at 404. To determine whether it is, "courts consider 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." *Slattery v. Hochul*, 61 F.4th 278, 291 (2d Cir. 2023) (citation and internal quotation marks omitted). Given the text of the Manufacturer Agreement, including the disclaimers added by CMS, BI 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 BI to be espousing the views with which it "strongly disagrees." ECF No. 28-1 at 36.

C. Unconstitutional Conditions Claims

Next, BI argues that even if participation in the Program is voluntary, the Program places an unconstitutional condition on BI's "ability to participate in Medicare and Medicaid." ECF No. 28-1

at 50. BI claims that CMS requires it to sacrifice its rights under the First Amendment, Due Process Clause, and Takings Clause in order to continue selling its products to Medicare and Medicaid. *Id.*

The unconstitutional conditions doctrine bars the government from "deny[ing] a benefit to a person because he exercises a constitutional right." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (citation and internal quotation marks omitted). The fact that BI's participation in the Program is voluntary is not dispositive: "[T]he government may not, as a general rule, grant even a gratuitous benefit on condition that the beneficiary relinquish a constitutional right." *O'Connor v. Pierson*, 426 F.3d 187, 201 (2d Cir. 2005).

The doctrine is most frequently applied in the First Amendment context, *see Koontz*, 570 U.S. at 604 (collecting cases), but the Supreme Court has also applied it in Takings Clause cases involving zoning regulations, *see id.*; *Dolan v. City of Tigard*, 512 U.S. 374 (1994); *Nollan v. California Coastal Comm'n*, 483 U.S. 825 (1987). Because the application of the doctrine varies depending on the constitutional right at stake, I summarize the applicable rules for BI's First Amendment, Due Process, and Takings Clause claims separately.

(i) First Amendment

"[T]he Government may not deny a benefit to a person on a basis that infringes his constitutionally protected freedom of speech even if he has no entitlement to that benefit." *USAID*, 570 U.S. at 214 (citations, alterations, and internal quotation marks omitted). In such cases, "the relevant distinction that has emerged" 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." *Id.* at 214-215. But the unconstitutional conditions doctrine is only implicated where the plaintiff is asked to sacrifice a constitutional right. So BI must first establish, at minimum, that it had a First Amendment right to refuse to sign the Manufacturer Agreement, i.e., that "the government could not have constitutionally ordered [BI] . . . to do what it attempted to pressure [BI] into doing," *Koontz*, 570 U.S. at 612. BI cannot make that showing. As I have explained, the Manufacturer Agreement primarily regulates BI's conduct, and any effects on speech are incidental. So the First Amendment does not bar CMS from ordering BI to do what the Manufacturer Agreement requires it to do. And CMS is free to condition BI's participation in Medicare and Medicaid on its signing the Agreement.

(ii) Takings Clause

In the Takings Clause context, courts have applied the unconstitutional conditions doctrine to certain land-use decisions. In *Nollan* and *Dolan*, the Supreme Court considered whether local governments could condition building permits on a landowner's agreeing to sacrifice a portion of her property for public use. *Nollan*, 483 U.S. 825 (building permit conditioned on landowner's granting the public an easement in the form of a path to the beach); *Dolan*, 512 U.S. 374 (building permit conditioned on landowner's dedicating a portion of her property for improvement of storm drainage system and bicycle path). The Court has held that "[t]he government [may] condition approval of a permit on the dedication of property to

the public" only if there "is a 'nexus' and 'rough proportionality' between the property that the government demands and the social costs of the applicant's proposal." *Koontz*, 570 U.S. at 605-06. BI urges me to consider whether a nexus and rough proportionality exist here. ECF No. 28-1 at 51-52.

As the defendants point out, however, the Supreme Court has declined to "extend[] the rough-proportionality test of *Dolan* beyond the special context of exactions—land-use decisions conditioning approval of development on the dedication of property to public use." *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702 (1999). The test is tailored to the land-use permit context, and it does not work well in other areas.[17] Indeed, the Supreme Court has suggested that the unconstitutional conditions doctrine does not ordinarily bar the government from requiring corporations to sacrifice certain property rights to receive a voluntary government benefit. *See Monsanto Co.*, 467 U.S. at 1007 (dismissing unconstitutional conditions claim, and observing that

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[17] The challenges of applying the test from *Nollan* and *Dolan* outside of the land use context are evident here. The test requires a "nexus" and "rough proportionality" between "the property that the government demands" and "the social costs of the [government benefit the property owner wants, i.e., the building permit]." *Koontz*, 570 U.S. at 605-06. The test is tailor-made for balancing an owner's right to use his or her land against the "negative externalities" such use entails. *Koontz*, 570 U.S. at 605. But it is a poor fit for a seller's participation in a government program: it is unclear whether there are any "social costs" to the benefit BI wants, i.e., the right to participate in Medicare and Medicaid (beyond the possibility that BI might overcharge the government). So the test provides little guidance when determining what conditions the government can place on Medicare and Medicaid participation.

"a voluntary submission of data by an applicant in exchange for the economic advantages of a [pesticide] registration can hardly be called a taking").

(iii) Due Process Clause

Courts rarely apply the unconstitutional conditions doctrine to due process claims. Indeed, BI cites only one case in which a court done so. *See* ECF No. 28-1 at 51 (citing *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427 (6th Cir. 2005)). And the court in *R.S.W.W.* did not reach the merits of the due process claim, finding only that the district court had jurisdiction over that claim. *R.S.W.W.*, 397 F.3d at 433-34, 436.[18]

Ultimately, BI advocates for a broad rule that the government cannot "require BI to give up its due

[18] In any event, BI's analogy to *R.S.W.W.* falls apart upon inspection. *R.S.W.W.* involved a municipality's conditioning zoning approvals on a liquor license holder's agreement to close its premises during late night hours in which state law permitted it to remain open. The liquor license holder may have had a property right in remaining open as late as state law allowed; but BI has no property right in refraining from participating in the Program, which is the analogue BI identifies for the liquor license holder's right. ECF No. 28-1 at 41 ("By making Medicare and Medicaid participation contingent on Program participation, the Government would unconstitutionally require BI to give up its due process rights to obtain a government benefit."). For BI's analogy to work, refraining from participating in the Program must mean continuing to sell Jardiance to Medicare beneficiaries at whatever price BI sets—something BI has no entitlement to do—just as the liquor license holder sought to continue remaining open during late-night hours. If BI instead is equating refraining from participating in the Program with continuing to sell Jardiance at all, then its claim fails because the Government has imposed no condition on that activity; BI is free to continue selling Jardiance at its preferred price to private buyers, regardless of whether it participates in the Program.

process rights to obtain a government benefit." ECF No. 28-1 at 51. Applied to facts like those in this case, however, BI's rule would subject nearly every government purchase from a private sector firm to Fifth Amendment scrutiny. Any private firm that wants to sell to the government (or through a government funded program) must—if it wishes to continue receiving the benefit of participating in the government spending financing the purchase—surrender its product, sometimes at a price or under terms it does not like. To subject every such transaction to scrutiny about the adequacy of procedures afforded the seller would inundate the courts and reverse longstanding principles allowing the government the same leeway as private firms when it participates in the market in its proprietary capacity. *See Perkins*, 310 U.S. at 127-28 ("Like private individuals and businesses, the Government enjoys the unrestricted power . . . to determine those with which it will deal, and to fix the terms and conditions upon which it will make needed purchases . . . . Judicial restraint of those who administer the Government's purchasing would constitute a break with settled judicial practice and a departure into fields hitherto wisely and happily apportioned . . . to the administration of another branch of Government."); *United States v. Bostwick*, 94 U.S. 53, 66 (1876) ("The United States, when they contract with their citizens, are controlled by the same laws that govern the citizen . . . ."); *cf. S&D Maintenance Co., Inc. v. Golding*, 844 F.2d 962, 967 (2d Cir. 1988) (noting that courts of appeals have been "reluctant to surround the entire body of public contract rights with due process protections").

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Regardless of the constitutional right at issue, the core feature of the unconstitutional conditions 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. If any applicable principle emerges from the unconstitutional conditions caselaw, it is that courts are skeptical of conditions on government benefits that bear little relationship to the goals of the government program. *See, e.g.*, *Nollan*, 483 U.S. at 836, 838 (noting weak ties between the condition the government imposed and the supposed harms of issuing a building permit, i.e., that it would limit "the public's view of the beach"); *see also USAID*, 570 U.S. at 214-15 (describing test for permissible government conditions on federal spending in First Amendment context: "[T]he relevant distinction that has emerged from our 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"). But here, the condition the government has imposed—that BI sell the drug for the maximum fair price—is closely related to the government's goal of controlling spending in the Medicare program. And the benefit BI seeks is the ability to continue participating in that spending program by selling its products to Medicare beneficiaries. So the condition and the benefit are closely intertwined.

Accordingly, to the extent the unconstitutional condition doctrine applies at all to claims such as these, the IRA does not impose an unconstitutional condition.

D. APA and Medicare Act Claims

Next, BI argues that CMS violated the APA and Medicare Act when it "issued the form Manufacturer Agreement summarily, without providing an opportunity for comment on its terms." ECF No. 28-1 at 53. I conclude that CMS need not follow the APA and Medicare Act's notice and comment rulemaking procedures, because the IRA exempts the Manufacturing Agreement from those requirements through 2028.

As a general rule, "contract provisions that are legislative are subject to [the APA's] notice and comment requirements." *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1054 (D.C. Cir. 1987).[19] The Medicare Act likewise "places notice and comment requirements on the Secretary's substantive rulemaking similar to those created by the APA." *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001) (citing 42 U.S.C. § 1395hh(b)); *see also Post Acute Med. at Hammond, LLC v. Azar*, 311 F. Supp. 3d 176, 183 n.3 (D.D.C. 2018).

Still, Congress can supersede the APA's and Medicare Act's notice and comment requirements by statute. 5 U.S.C. § 559 (the APA's rulemaking

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[19] While the APA exempts "matter[s] relating to . . . contracts" from notice and comment rulemaking, 5 U.S.C. § 553(a)(2), the Department of Health and Human Services (by its predecessor) has waived that exemption. 36 Fed. Reg. 2532 (Feb. 5, 1971); *see also Humana of S.C., Inc. v. Califano*, 590 F.2d 1070, 1084 (D.C. Cir. 1978) ("Cognizant of the prudence . . . of allowing public input in the wide variety of rulemaking covered by Section 553(a)(2), the Secretary [of Health, Education, and Welfare] in 1971 elected to waive the exemption and to submit to the normal requirements of the Administrative Procedure Act, and regulations promulgated since that time are subject to mandatory rulemaking procedures.").

requirements may be superseded, but only if the subsequent statute "does so expressly"); 42 U.S.C. § 1395hh(b)(2)(A) ("[The Medicare Act's notice and comment requirement] shall not apply where . . . a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment."). Exemptions from notice and comment 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)); *see also* 42 U.S.C. § 1395hh(b)(2)(A) (Medicare Act provision requiring that exemption from notice and comment be "specific"). Courts consider an exemption to be express where Congress "has established procedures so clearly different from those required by the APA that it must have intended to displace the norm." *Asiana Airlines*, 134 F.3d at 397.

The IRA states that CMS "shall implement [the Program] . . . for 2026, 2027, and 2028 by program instruction or other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854. This language is a departure from other implementation provisions in the IRA that call for the promulgation of regulations, suggesting that Congress's omission of any reference to "regulations" or "rules" here was a deliberate choice. *See id.* § 10101(a)(1), 136 Stat. at 1821 (in section making change to alternative minimum tax, stating that "[t]he Secretary shall provide regulations or other guidance for the purpose of carrying out this subsection . . . ."); *id.* § 10101(b)(1), 136 Stat. at 1823-24 (same language in section regulating corporations' adjusted financial statements); *id.* § 11003, 136 Stat. at 1864 (in section imposing excise tax on manu-

facturers of Selected Drugs who do not sign Manufacturer Agreements, stating "[t]he Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section"). Further, the statute suggests that Congress departed from the ordinary "regulations and other guidance" formulation only when it wanted the relevant agencies to expedite implementation of specific changes, including the Program, and then only as a temporary measure to jump start those changes. *See id.* § 11102(a), 136 Stat. at 1876 (providing for implementation of changes to manufacturer rebate provisions under Part D "for 2022, 2023, and 2024 by program instruction or other forms of program guidance"); *id.* § 11201, 136 Stat. at 1892 (providing for implementation of selected drug subsidy program "for 2024, 2025, and 2026 by program instruction or other forms of program guidance").

Section 11001(c) plainly contemplates a different procedure than the APA and Medicare Act, because it provides for the IRA to be implemented—for the first three years the Maximum Fair Prices will be operative—only through guidance, rather than notice and comment rulemaking.[20] Any other interpretation

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[20] BI points to *NRDC v. EPA*, 22 F.3d 1125, 1147 (D.C. Cir.) to support its claim that the language in 11001(c) does not waive the APA's notice and comment requirements. In that case, the statute directed the EPA to "review, revise, update, and republish in the Federal Register . . . guidance." *Id.* at 1146. One of the petitioners, the National Automobile Dealers Association ("NADA"), argued that CMS did not have the authority under the statute to issue such guidance "in the form of a final rule promulgated pursuant to the APA's notice and comment procedures." *Id.* The court ultimately held that NADA lacked standing to challenge the issuance of the guidance in the form of a final rule, because it was not prejudiced by the agency's (cont.)

of this provision would fail to account for Congress' deliberate choice to eschew regulations in the first three years of the Program.

During oral argument, BI offered an alternative theory: that Congress intentionally "clipped [CMS's] wings" for the first three years by requiring it to implement the Program without altering substantive rights. ECF No. 121 at 86-87. But this interpretation is squarely at odds with the text of the statute, which

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decision to use notice and comment rulemaking procedures. *Id.* at 1147. But it commented about the meaning of the statute in dicta, observing that "Congress unambiguously intended [the aspects of the regulations the agency was directed to implement through guidance] . . . to be binding on the states." *Id.* at 1146. And since those rules "set[] forth the mandatory parameters of the states' obligations . . . [and were therefore] legislative in character," the court found "the EPA probably was *required* to promulgate such rules only through APA rulemaking procedures." *Id.* at 1147. Of course, the D.C. Circuit's opinion is not binding here, since it is dicta and from a different circuit. Nor do I find the court's brief analysis of this issue persuasive, since the court did not clearly explain the basis for concluding that the EPA could only promulgate binding rules through rulemakings.

BI has suggested that the promulgation of regulations that alter substantive rights without notice and comment might violate its right to procedural due process. ECF No. 121 at 83-84. Of course, to establish such a claim, it would first need to demonstrate that it has been deprived of a property right. But even if it could, "courts have generally held that the Due Process Clause does not require [the government] to engage in notice-and-comment rulemaking." *Wheeler v. Cohen*, No. 2:15-CV-00170, 2015 WL 6872338, at *5 (D. Vt. Nov. 9, 2015) (collecting cases) (citations and internal quotation marks omitted). Indeed, the APA itself includes numerous exceptions to its notice and comment requirements, including a broad exception for "matter[s] relating to agency management or personnel or to public property, loans, grants, benefits, or contracts." 5 U.S.C. § 553(a)(2).

repeatedly directs CMS, from the outset of the program, to formulate standards of a kind that undoubtedly affect substantive rights. *See, e.g.*, 42 U.S.C. § 1320f-3(b)(1) ("The Secretary shall develop and use a consistent methodology and process . . . that aims to achieve the lowest maximum fair price for each selected drug."); *id.* § 1320f-2(a)(5) ("[T]he Secretary shall enter into agreements with manufacturers of selected drugs . . . under which . . . the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program."); *id.* § 1320f-2(a)(4)(B) ("[T]he Secretary shall enter into agreements with manufacturers of selected drugs . . . under which . . . the manufacturer submits to the Secretary, in a form or manner specified by the Secretary . . . information that the Secretary requires to carry out the negotiation (or renegotiation process).") BI fails to explain how CMS could have accomplished these tasks without using its authority to implement the Program through "program instructions and other forms of program guidance" to issue pronouncements that affected substantive rights.

BI also argues that Section 11001(c) exempts CMS guidance, but not the Manufacturer Agreement, from notice and comment. ECF No. 92 at 55. I disagree. The statute instructs CMS to implement "this Section, including the amendments made by this Section" through "program instruction and other forms of program guidance." IRA § 11001(c), 136 Stat. at 1854. The "Section" referred to is Section 11001, 136 Stat. at 1833-54, which contains most provisions related to the Program, including the provisions governing CMS's implementation of the Manufacturer Agreement, Section 1193, 136 Stat. at 1841-42 (included as a

subsection of Section 11001 and later codified at 42 U.S.C. § 1320f-2). So Congress' instruction about implementation plainly applies to the Program as a whole, including the Manufacturer Agreement. And as with other elements of the Program, Congress directed CMS to establish substantive standards when implementing the Manufacturer Agreement. *See* 42 U.S.C. § 1320f-2(a)(5) (directing CMS to include in the Manufacturer Agreement "requirements . . . necessary for purposes of administering the program"); *id.* § 1320f-2(a)(4)(C) (directing CMS to include in the Manufacture Agreement a requirement that manufacturers submit "information that the Secretary requires to carry out the negotiation (or renegotiation) process").

Finally, if I adopted BI's view, the statute would leave arbitrary gaps in CMS's ability to implement the Program promptly. CMS's lengthy, detailed guidance would not be subject to notice and comment procedures, but the Manufacturer Agreement, which largely tracks the statutory text and CMS guidance, would be. "It is a well-established canon of statutory construction that statutes should not be interpreted to reach an absurd result." *Guglietta v. Meredith Corp.*, 301 F. Supp. 2d 209, 213 (D. Conn. 2004).

Because CMS is expressly permitted to implement the Program through guidance for the first three negotiation cycles, its release of the Manufacturer Agreement does not violate the Medicare Act or the APA.

E. Excessive Fines Claim

Finally, BI challenges the IRA's excise tax provisions under the Excessive Fines Clause of the Eighth Amendment. ECF No. 28-1 at 41. The

defendants contend that the Court lacks jurisdiction over BI's Excessive Fines Clause claim, because (1) the claim is barred by the Anti-Injunction Act ("AIA"), 26 U.S.C. § 7421, and (2) the claim "is not redressable because BI has not sued the Department of Treasury or the IRS—the only agencies empowered to enforce the tax that BI seeks to enjoin and have declared unconstitutional." ECF No. 48-1 at 24. Because I find that the Court lacks jurisdiction over this challenge under the AIA, I do not address the defendants' redressability argument.

The AIA provides that, subject to certain exceptions, "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person, whether or not such person is the person against whom such tax was assessed." 26 U.S.C. § 7421. "The manifest purpose of [the AIA] is to permit the United States to assess and collect taxes alleged to be due without judicial intervention, and to require that the legal right to the disputed sums be determined in a suit for refund." *Enochs v. Williams Packing & Nav. Co.*, 370 U.S. 1, 7 (1962).

BI does not contest that the excise tax in this case is subject to the AIA, but it argues that the *Williams Packing* exception to the AIA applies. Under that exception, BI must show "[1] irreparable injury," and "[2] certainty of success on the merits." *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974) (citation omitted). BI cannot meet either of these requirements.

(i) Irreparable Injury

BI claims that it would be "irreversibly damaged by having to pay the tax for any meaningful period of time" because of "the extraordinary magnitude of the tax." ECF No. 92 at 52; *See* ECF No. 28-2 ¶ 16

(estimating that if BI refused to sign the Manufacturer Agreement and continued to sell Jardiance at its current volumes, "the statutory penalties [would] amount to more than $500 million per week initially, later increasing to more than $5.5 billion per week").[21]

But BI can bring a refund suit after incurring the tax on a single transaction. *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991). And it need not pay the entire tax upfront while it waits for courts to adjudicate its Eighth Amendment claim. Under an IRS Policy Statement, "[w]hen a refund suit is pending on a divisible [tax] assessment, the [IRS] will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy . . . ." IRS Policy Statement 5-16, IRM § 1.2.1.6.4(6). "Divisible tax cases are those in which the tax assessment may be divided into separate portions or transactions." *Id.* § 1.2.1.6.4(7); *Rocovich*, 933 F.2d at 995 ("A divisible tax . . . is one that represents the aggregate of taxes due on multiple transactions (e.g., sales of items

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[21] BI's estimates rely on the assumption that the excise tax will be imposed on all sales of Jardiance in the United States, rather than only those sales made through Medicare. ECF No. 28-1 at 43. As BI acknowledges, this assumption disregards an IRS Notice, which interprets the statute to apply only to sales made through Medicare. *Id.* at 44; ECF No. 28-14 at 4. The statute says that the excise tax is "imposed on the sale by the manufacturer, producer, or importer of any designated drug," 26 U.S.C. § 5000D(a), which is defined as "any negotiation-eligible drug . . . included on the list [of drugs selected under 42 U.S.C. § 1320f-1(a) for the 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). BI argues that the IRS Notice is non-binding and runs contrary to the text of the statute. ECF No. 28-1 at 43.

subject to excise taxes))." The IRA's excise tax is imposed on each "sale . . . of any designated drug," 26 U.S.C. § 5000D, and it is therefore divisible. So the IRS would likely exercise forbearance during the period when BI's refund suit was pending.

Of course, if BI continues to sell Jardiance—at least through Medicare, *see* discussion *supra*—it may accrue tax liability during the pendency of any refund suit. But when determining whether harm is irreparable, courts consider only the harm that arises "during the interim between the request for an injunction and final disposition of the case on the merits." *Jayaraj v. Scappini*, 66 F.3d 36, 40 (2d Cir. 1995). Due to the IRS's forbearance policy, the harm during this interim period is minimal: BI would need to pay the excise tax on only one transaction in order to bring the refund suit. If BI ultimately prevailed, the IRS could not require it to pay the tax at all and would have to refund any amount BI had already paid. If it did not prevail, the IRS could constitutionally require it to pay the tax, which would mean the tax inflicted no actionable harm.

(ii) Certainty of Success

Even if BI could show an irreparable harm, it cannot show "certainty of success on the merits." *Bob Jones Univ.*, 416 U.S. at 737. "Certainty of success" means "it is clear" that "under no circumstances could the Government ultimately prevail." *Id.* (internal quotation marks omitted). BI cannot meet this demanding standard because its Eighth Amendment claim is novel and, so, far from certain. BI has identified no case in which a court has applied the Excessive Fines Clause to a monetary amount that was not connected to criminal conduct or a criminal proceeding. Further, the defendants' position that the

Excessive Fines Clause applies only to fines imposed on criminal conduct finds support in the text and structure of the Constitution. The Excessive Fines Clause appears in the Eighth Amendment, which addresses only punishment for criminal conduct. Specifically, the Excessive Fines Clause sits alongside the Excessive Bail Clause and the Cruel and Unusual Punishment Clause. *See Austin v. United* States, 509 U.S. 602 (1993) (finding that civil forfeiture action seeking forfeiture of convicted drug dealer's home and business was subject to Excessive Fines Clause and noting that the Clause "limits the government's power to extract payments . . . as *punishment* for some *offense*." (second emphasis added and internal quotation marks omitted)).

BI points out that two concurring justices in *Tyler v. Hennepin County* would have applied the Excessive Fines Clause in the context of a foreclosure proceeding. 598 U.S. 631, 658-660 (Gorsuch, J., concurring). But the view of a minority of justices, expressed in dicta in a concurrence, does not demonstrate a certainty of success. And each of the other Excessive Fines Clause cases BI cites involves a criminal violation of some type: either a criminal defendant's forfeiture of property,[22] or civil penalties imposed on criminal conduct.[23] None of the cases it cites involves a tax.

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[22] *United States v. Bajakajian*, 524 U.S. 321, 328 (1998); *Austin v. United States*, 509 U.S. 602, 619-620 (1993).

[23] *Pimentel v. City of Los Angeles*, 974 F.3d 917, 923 (9th Cir. 2020) (civil penalty imposed for parking violations); *WCI, Inc. v. Ohio Dep't of Pub. Safety*, 774 F. App'x 959, 961 (6th Cir. 2019) (civil penalty imposed on strip club for performer's illegal conduct).

Because BI has not met either prong of the *Williams Packing* exception to the AIA, this Court lacks jurisdiction to consider a pre-enforcement challenge to the excise tax provisions of the IRA.

V. CONCLUSION

For the reasons explained above, I grant the defendants' motion for summary judgment as to all claims and deny the plaintiff's motion for summary judgment. The Clerk is directed to close this case.

IT IS SO ORDERED.

/s/
Michael P. Shea, U.S.D.J.

Dated: Hartford, Connecticut
July 3, 2024

APPENDIX C

42 U.S.C. §§ 1320f–1320f-6

§ 1320f. Establishment of program

(a) In general

The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the "program"). Under the program, with respect to each price applicability period, the Secretary shall—

(1) publish a list of selected drugs in accordance with section 1320f-1 of this title;

(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1320f-2 of this title;

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1320f-3 of this title;[1]

(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1320f-4 and 1320f-5 of this title.

(b) Definitions relating to timing

For purposes of this part:

(1) Initial price applicability year

The term "initial price applicability year" means a year (beginning with 2026).

(2) Price applicability period

The term "price applicability period" means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability

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[1] So in original. Probably should be followed by "and".

year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

(3) Selected drug publication date

The term "selected drug publication date" means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year.

(4) Negotiation period

The term "negotiation period" means, with respect to an initial price applicability year with respect to a selected drug, the period—

(A) beginning on the sooner of—

(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1320f-2 of this title with respect to such drug; or

(ii) February 28 following the selected drug publication date with respect to such selected drug; and

(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

(c) Other definitions

For purposes of this part:

(1) Manufacturer

The term "manufacturer" has the meaning given that term in section 1395w-3a(c)(6)(A) of this title.

(2) Maximum fair price eligible individual

The term "maximum fair price eligible individual" means, with respect to a selected drug—

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of subchapter XVIII or an MA–PD plan under part C of such subchapter if coverage is provided under such plan for such selected drug; and

(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of subchapter XVIII, including an individual who is enrolled in an MA plan under part C of such subchapter, if payment may be made under part B for such selected drug.

(3) Maximum fair price

The term "maximum fair price" means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1320f-1(c) of this title) with respect to such period, the price negotiated pursuant to section 1320f-3 of this title, and updated pursuant to section 1320f-4(b) of this title, as applicable, for such drug and year.

(4) Reference product

The term "reference product" has the meaning given such term in section 262(i) of this title.

(5) Total expenditures

The term "total expenditures" includes, in the case of expenditures with respect to part D of subchapter XVIII, the total gross covered prescription drug costs (as defined in section 1395w-115(b)(3) of this title). The term "total expenditures" excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

(6) Unit

The term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

d) Timing for initial price applicability year 2026

Notwithstanding the provisions of this part, in he case of initial price applicability year 2026, he following rules shall apply for purposes of implementing the program:

(1) Subsection (b)(3) shall be applied by substituting "September 1, 2023" for ", with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year".

(2) Subsection (b)(4) shall be applied—

(A) in subparagraph (A)(ii), by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug"; and

(B) in subparagraph (B), by substituting "August 1, 2024" for "November 1 of the year that

begins 2 years prior to the initial price applicability year".

(3) Section 1320f-1 of this title shall be applied—

(A) in subsection (b)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available"; and

(B) in subsection (d)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year".[2]

(4) Section 1320f-2(a) of this title shall be applied by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug".

(5) Section 1320f-3(b)(2) of this title shall be applied—

(A) in subparagraph (A), by substituting "October 2, 2023" for "March 1 of the year of the

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[2] So in original. Probably should read as follows: "during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date)".

selected drug publication date, with respect to the selected drug";

(B) in subparagraph (B), by substituting "February 1, 2024" for "the June 1 following the selected drug publication date"; and

(C) in subparagraph (E), by substituting "August 1, 2024" for "the first day of November following the selected drug publication date, with respect to the initial price applicability year".

(6) Section 1320f-4(a)(1) of this title shall be applied by substituting "September 1, 2024" for "November 30 of the year that is 2 years prior to such initial price applicability year".

§ 1320f-1. Selection of negotiation-eligible drugs as selected drugs

(a) In general

Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15)

such negotiation-eligible drugs with respect to such year);

(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1320f-3(f)(5) of this title, each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1320f-3 of this title for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

(b) Selection of drugs

(1) In general

In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of subchapter XVIII, as determined by the Secretary, during the most recent period of 12

months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

(2) High spend part D drugs for 2026 and 2027

With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to "negotiation-eligible drugs described in subsection (d)(1)" were a reference to "negotiation-eligible drugs described in subsection (d)(1)(A)" and as if the reference to "total expenditures for such drugs under parts B and D of subchapter XVIII" were a reference to "total expenditures for such drugs under part D of subchapter XVIII".

(3) Inclusion of delayed biological products

Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a)

the biological products described in such subparagraphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).

(c) Selected drug

(1) In general

For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a "selected drug" with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product—

(A) is approved or licensed (as applicable)—

(i) under section 355(j) of title 21 using such drug as the listed drug; or

(ii) under section 262(k) of this title using such drug as the reference product; and

(B) is marketed pursuant to such approval or licensure.

(2) Clarification

A negotiation-eligible drug—

(A) that is included on the list published under subsection (a) with respect to an initial price applicability year; and

(B) for which the Secretary makes a determination described in paragraph (1) before

or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1320f-3 of this title with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

(d) Negotiation-eligible drug

(1) In general

For purposes of this part, subject to paragraph (2), the term "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

(A) Part D high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

(B) Part B high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

(2) Exception for small biotech drugs

(A) In general

Subject to subparagraph (C), the term "negotiation-eligible drug" shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

(i) Part D drugs

The total expenditures for the qualifying single source drug under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021

(I) are equal to or less than 1 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as defined in section 1395w-102(e) of this title) during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part D, as so determined, for all covered part D drugs for which the manufacturer of the drug has an agreement in effect under section 1395w-114a of this title during such year.

(ii) Part B drugs

The total expenditures for the qualifying single source drug under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

(I) are equal to or less than 1 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs for which payment may be made under such part B during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs of the manufacturer for which payment may be made under such part B during such year.

(B) Clarifications relating to manufacturers

(i) Aggregation rule

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this paragraph.

(ii) Limitation

A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified Manufacturer under section 1395w-114c(g)(4)(B)(ii) of this

title, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(C) Drugs not included as small biotech drugs

A new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a qualifying single source drug described in subparagraph (A).

(3) Clarifications and determinations

(A) Previously selected drugs and small biotech drugs excluded

In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count—

(i) drugs that are already selected drugs; and

(ii) for initial price applicability years 2026, 2027, and 2028, qualifying single source drugs described in paragraph (2)(A).

(B) Use of data

In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

(e) Qualifying single source drug

(1) In general

For purposes of this part, the term "qualifying single source drug" means, with respect to an initial price applicability year, subject to paragraphs (2) and (3), a covered part D drug (as defined in section 1395w-102(e) of this title) that is described in any of the following or a drug or biological product for which payment may be made under part B of subchapter XVIII that is described in any of the following:

(A) Drug products

A drug—

(i) that is approved under section 355(c) of title 21 and is marketed pursuant to such approval;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

(iii) that is not the listed drug for any drug that is approved and marketed under section 355(j) of such title.

(B) Biological products

A biological product—

(i) that is licensed under section 262(a) of this title and is marketed under section 262 of this title;

(ii) for which, as of the selected drug publication date with respect to such initial

price applicability year, at least 11 years will have elapsed since the date of such licensure; and that is not the reference product for any biological product that is licensed and marketed under section 262(k) of this title.

(2) Treatment of authorized generic drugs

(A) In general

In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 355(j) of title 21) or a product described in clause (ii) of subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

(B) Authorized generic drug defined

For purposes of this paragraph, the term "authorized generic drug" means

(i) in the case of a drug, an authorized generic drug (as such term is defined in section 355(t)(3) of title 21); and

(ii) in the case of a biological product, a product that—

(I) has been licensed under section 262(a) of this title;[3] and

(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in

[3] See References in Text note below.

blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

(3) Exclusions

In this part, the term "qualifying single source drug" does not include any of the following:

(A) Certain orphan drugs

A drug that is designated as a drug for only one rare disease or condition under section 360bb of title 21 and for which the only approved indication (or indications) is for such disease or condition.

(B) Low spend medicare drugs

A drug or biological product with respect to which the total expenditures under parts B and D of subchapter XVIII, as determined by the Secretary in accordance with subsection (d)(3)(B)—

(i) with respect to initial price applicability year 2026, is less than, during the period beginning on June 1, 2022, and ending on May 31, 2023, $200,000,000;

(ii) with respect to initial price applicability year 2027, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in clause (i) increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the period beginning on June 1, 2023, and ending on September 30, 2024; or

(iii) with respect to a subsequent initial price applicability year, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in this subparagraph for the previous initial price applicability year increased by the annual percentage increase in such consumer price index for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to such subsequent initial price applicability year.

(C) Plasma-derived products

A biological product that is derived from human whole blood or plasma.

(f) Special rule to delay selection and negotiation of biologics for biosimilar market entry

(1) Application

(A) In general

Subject to subparagraph (B), in the case of a biological product that would (but for this subsection) be an extended-monopoly drug (as defined in section 1320f-3(c)(4) of this title) included as a selected drug on the list published under subsection (a) with respect to an initial price applicability year, the rules described in paragraph (2) shall apply if the Secretary determines that there is a high likelihood (as described in paragraph (3)) that a biosimilar biological product (for which such biological product will be the reference product) will be licensed and marketed under section 262(k) of this title before the date that is 2 years after the

selected drug publication date with respect to such initial price applicability year.

(B) Request required

(i) In general

The Secretary shall not provide for a delay under—

(I) paragraph (2)(A) unless a request is made for such a delay by a manufacturer of a biosimilar biological product prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year for which the biological product may have been included as a selected drug on such list but for subparagraph (2)(A); or

(II) paragraph (2)(B)(iii) unless a request is made for such a delay by such a manufacturer prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product described in sub-section (a) would have been included as a selected drug on such list but for paragraph (2)(A).

(ii) Information and documents

(I) In general

A request made under clause (i) shall be submitted to the Secretary by such manufacturer at a time and in a form and manner specified by the Secretary, and contain—

(aa) information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary and including, to the extent available, items described in subclause (III); and

(bb) all agreements related to the biosimilar biological product filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(II) Additional information and documents

After the Secretary has reviewed the request and materials submitted under subclause (I), the manufacturer shall submit any additional information and documents requested by the Secretary necessary to make determinations under this subsection.

(III) Items described

The items described in this clause are the following:

(aa) The manufacturing schedule for such biosimilar biological product submitted to the Food and Drug Administration during its review of the application under such section 262(k) of this title.

(bb) Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 78*l*(b),

78*l*(g), 78m(a), or 78*o*(d) of title 15 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of such biosimilar biological product, or comparable documentation that is distributed to the shareholders of privately held companies.

(C) Aggregation rule

(i) In general

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer for purposes of paragraph (2)(D)(iv).

(ii) Partnership defined

In clause (i), the term "partnership" means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer of the biological product and the manufacturer of the biosimilar biological product.

(2) Rules described

The rules described in this paragraph are the following:

(A) Delayed selection and negotiation for 1 year

If a determination of high likelihood is made under paragraph (3), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until such list is published with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product would have been included as a selected drug on such list.

(B) If not licensed and marketed during the initial delay

(i) In general

If, during the time period between the selected drug publication date on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A) and the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(i)(II) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under section 262(k) of this title, the Secretary shall, at the request of such manufacturer—

(I) reevaluate whether there is a high likelihood (as described in paragraph (3)) that such biosimilar biological product will be

licensed and marketed under such section 262(k) before the date that is 2 years after the selected drug publication date for which such biological product would have been included as a selected drug on such list published but for subparagraph (A); and

(II) evaluate whether, on the basis of clear and convincing evidence, the manufacturer of such biosimilar biological product has made a significant amount of progress (as determined by the Secretary) towards both such licensure and the marketing of such biosimilar biological product (based on information from items described in subclauses (I)(bb) and (II) of paragraph (1)(B)(ii)) since the receipt by the Secretary of the request made by such manufacturer under paragraph (1)(B)(i)(I).

(ii) Selection and negotiation

If the Secretary determines that there is not a high likelihood that such biosimilar biological product will be licensed and marketed as described in clause (i)(I) or there has not been a significant amount of progress as described in clause (i)(II)—

(I) the Secretary shall include the biological product as a selected drug on the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for subparagraph (A); and

(II) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the year for which such manufacturer would have provided access to a maximum fair price for such biological product but for subparagraph (A).

(iii) Second 1-year delay

If the Secretary determines that there is a high likelihood that such biosimilar biological product will be licensed and marketed (as described in clause (i)(I)) and a significant amount of progress has been made by the manufacturer of such biosimilar biological product towards such licensure and marketing (as described in clause (i)(II)), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until the selected drug publication date of such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection.

(C) If not licensed and marketed during the year two delay

If, during the time period between the selected drug publication date of the list for which the biological product would have been included as a selected drug but for subparagraph (B)(iii) and the selected drug publication date with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a

selected drug on such list but for this subsection, the Secretary determines that such biosimilar biological product has not been licensed and marketed—

(i) the Secretary shall include such biological product as a selected drug on such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list; and

(ii) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the years for which such manufacturer would have provided access to a maximum fair price for such biological product but for this subsection.

(D) Limitations on delays

(i) Limited to 2 years

In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) for more than 2 years.

(ii) Exclusion of biological products that transitioned to a long-monopoly drug during the delay

In the case of a biological product for which the inclusion on the list published pursuant to subsection (a) was delayed by 1 year under subparagraph (A) and for which there would have been a change in status to a long-monopoly drug (as defined in section 1320f-3(c)(5) of this title) if such biological product had been a

selected drug, in no case may the Secretary provide for a second 1-year delay under subparagraph (B)(iii).

(iii) Exclusion of biological products if more than 1 year since licensure

In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) if more than 1 year has elapsed since the biosimilar biological product has been licensed under section 262(k) of this title and marketing has not commenced for such biosimilar biological product.

(iv) Certain manufacturers of biosimilar biological products excluded

In no case shall the Secretary delay the inclusion of a biological product as a selected drug on the list published under subsection (a) if Secretary determined that the manufacturer of the biosimilar biological product described in paragraph (1)(A)—

(I) is the same as the manufacturer of the reference product described in such paragraph or is treated as being the same pursuant to paragraph (1)(C); or

(II) has, based on information from items described in paragraph (1)(B)(ii)(I)(bb), entered into any agreement described in such paragraph with the manufacturer of the reference product described in paragraph (1)(A) that—

(aa) requires or incentivizes the manufacturer of the biosimilar biological

product to submit a request described in paragraph (1)(B); or

(bb) restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time.

(3) High likelihood

For purposes of this subsection, there is a high likelihood described in paragraph (1) or paragraph (2), as applicable, if the Secretary finds that—

(A) an application for licensure under section 262(k) of this title for the biosimilar biological product has been accepted for review or approved by the Food and Drug Administration; and

(B) information from items described in sub clauses [4] (I)(bb) and (III) of paragraph (1)(B)(ii) submitted to the Secretary by the manufacturer requesting a delay under such paragraph provides clear and convincing evidence that such biosimilar biological product will, within the time period specified under paragraph (1)(A) or (2)(B)(i)(I), be marketed.

(4) Rebate

(A) In general

For purposes of subparagraphs (B)(ii)(II) and (C)(ii) of paragraph (2), in the case of a biological product for which the inclusion on the list under subsection (a) was delayed under this subsection and for which the Secretary has negotiated and

[4] So in original

entered into an agreement under section 1320f-2 of this title with respect to such biological product, the manufacturer shall be required to pay a rebate to the Secretary at such time and in such manner as determined by the Secretary.

(B) Amount

Subject to subparagraph (C), the amount of the rebate under subparagraph (A) with respect to a biological product shall be equal to the estimated amount—

(i) in the case of a biological product that is a covered part D drug (as defined in section 1395w-102(e) of this title), that is the sum of the products of—

(I) 75 percent of the amount by which—

(aa) the average manufacturer price, as reported by the manufacturer of such covered part D drug under section 1396r-8 of this title (or, if not reported by such manufacturer under section 1396r-8 of this title, as reported by such manufacturer to the Secretary pursuant to the agreement under section 1320f-2(a) of this title) for such biological product, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1320f-3 of this title for such

biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1320f-4(b)(1)(A) of this title; and

(II) the number of units dispensed under part D of subchapter XVIII for such covered part D drug during each such calendar quarter of such price applicability period; and

(ii) in the case of a biological product for which payment may be made under part B of subchapter XVIII, that is the sum of the products of—

(I) 80 percent of the amount by which—

(aa) the payment amount for such biological product under section 1395w-3a(b) of this title, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1320f-3 of this title for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as

described in section 1320f-4(b)(1)(A) of this title; and

(II) the number of units (excluding units that are packaged into the payment amount for an item or service and are not separately payable under such part B) of the billing and payment code of such biological product administered or furnished under such part B during each such calendar quarter of such price applicability period.

(C) Special rule for delayed biological products that are long-monopoly drugs

(i) In general

In the case of a biological product with respect to which a rebate is required to be paid under this paragraph, if such biological product qualifies as a long-monopoly drug (as defined in section 1320f-3(c)(5) of this title) at the time of its inclusion on the list published under subsection (a), in determining the amount of the rebate for such biological product under subparagraph (B), the amount described in clause shall be substituted for the maximum fair price described in clause (i)(I) or (ii)(I) of such subparagraph (B), as applicable.

(ii) Amount described

The amount described in this clause is an amount equal to 65 percent of the average non-Federal average manufacturer price for the biological product for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such biological product for 2021, for the first full year following

the market entry for such biological product), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year that would have applied but for this subsection.

(D) Rebate deposits

Amounts paid as rebates under this paragraph shall be deposited into—

(i) in the case payment is made for such biological product under part B of subchapter XVIII, the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title; and

(ii) in the case such biological product is a covered part D drug (as defined in section 1395w-102(e) of this title), the Medicare Prescription Drug Account under section 1395w-116 of this title in such Trust Fund.

(5) Definitions of biosimilar biological product

In this subsection, the term "biosimilar biological product" has the meaning given such term in section 1395w-3a(c)(6) of this title.

§ 1320f-2. Manufacturer agreements

(a) In general

For purposes of section 1320f(a)(2) of this title, the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price

applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

(1) during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1320f-3 of this title, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

(2) the Secretary and the manufacturer shall, in accordance with section 1320f-3 of this title, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for such drug, in order for the

manufacturer to provide access to such maximum fair price (as so renegotiated)—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title, at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as

described in paragraph (1)(A) or (2)(A), as applicable; and

(B) hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1320f-3(f) of this title), and for section 1320f-1(f) of this title, with respect to such drug—

(A) information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38) for the drug for the applicable year or period;

(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

(C) information that the Secretary requires to carry out section 1320f-1(f) of this title, including rebates under paragraph (4) of such section; and

(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

(b) Agreement in effect until drug is no longer a selected drug

An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1320f-1(c) of this title.

(c) Confidentiality of information

Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

(d) Nonduplication with 340B ceiling price

Under an agreement entered into under this section, the manufacturer of a selected drug—

(1) shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act [42 U.S.C. 256b(a)(4)], to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)] and the ceiling price (defined in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)]) is lower than the maximum fair price for such selected drug; and

(2) shall be required to provide access to the maximum fair price to such covered entity with

respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a non-duplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

§ 1320f-3. Negotiation and renegotiation process

(a) In general

For purposes of this part, under an agreement under section 1320f-2 of this title between the Secretary and a manufacturer of a selected drug (or selected drugs), with respect to the period for which such agreement is in effect and in accordance with subsections (b), (c), and (d), the Secretary and the manufacturer—

(1) shall during the negotiation period with respect to such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1320f-2(a)(1) of this title; and

(2) renegotiate, in accordance with the process specified pursuant to subsection (f), such maximum fair price for such drug for the purpose described in section 1320f-2(a)(2) of this title if such drug is a renegotiation-eligible drug under such subsection.

(b) Negotiation process requirements

(1) Methodology and process

The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

(2) Specific elements of negotiation process

As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

(A) Submission of information

Not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the manufacturer of the drug shall submit to the Secretary, in accordance with section 1320f-2(a)(4) of this title, the information described in such section.

(B) Initial offer by Secretary

Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of the selected drug with a written initial offer that contains the Secretary's proposal for the maximum fair price of the drug and a concise justification based on the factors described in subsection (e) that were used in developing such offer.

(C) Response to initial offer

(i) In general

Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

(ii) Counteroffer requirements

If a manufacturer proposes a counteroffer, such counteroffer—

(I) shall be in writing; and

(II) shall be justified based on the factors described in subsection (e).

(D) Response to counteroffer

After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

(E) Deadline

All negotiations between the Secretary and the manufacturer of the selected drug shall end prior to the first day of November following the selected drug publication date, with respect to the initial price applicability year.

(F) Limitations on offer amount

In negotiating the maximum fair price of a selected drug, with respect to the initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, the Secretary shall not offer (or agree to a counteroffer for) a maximum fair price for the selected drug that—

(i) exceeds the ceiling determined under subsection (c) for the selected drug and year; or

(ii) as applicable, is less than the floor determined under subsection (d) for the selected drug and year.

(c) Ceiling for maximum fair price

(1) General ceiling

(A) In general

The maximum fair price negotiated under this section for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

(B) Subparagraph (B) amount

An amount equal to the following:

(i) Covered part D drug

In the case of a covered part D drug (as defined in section 1395w-102(e) of this title), the sum of the plan specific enrollment weighted amounts for each prescription drug plan or MA–PD plan (as determined under paragraph (2)).

(ii) Part B drug or biological

In the case of a drug or biological product for which payment may be made under part B of subchapter XVIII, the payment amount under section 1395w-3a(b)(4) of this title for the drug or biological product for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug or biological product.

(C) Subparagraph (C) amount

An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

(i) Initial price applicability year 2026

In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average

manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

(ii) Initial price applicability year 2027 and subsequent years

In the case of a selected drug with respect to which such initial price applicability year is 2027 or a subsequent year, the lower of—

(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

(II) the average non-Federal average manufacturer price for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year.

(2) Plan specific enrollment weighted amount

For purposes of paragraph (1)(B)(i), the plan specific enrollment weighted amount for a prescription drug plan or an MA–PD plan with respect to a covered Part D drug is an amount equal to the product of—

(A) the negotiated price of the drug under such plan under part D of subchapter XVIII, net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan, for the most recent year for which data is available; and

(B) a fraction—

(i) the numerator of which is the total number of individuals enrolled in such plan in such year; and

(ii) the denominator of which is the total number of individuals enrolled in a prescription drug plan or an MA–PD plan in such year.

(3) Applicable percent described

For purposes of this subsection, the applicable percent described in this paragraph is the following:

(A) Short-monopoly drugs and vaccines

With respect to a selected drug (other than an extended-monopoly drug and a long-monopoly drug), 75 percent.

(B) Extended-monopoly drugs

With respect to an extended-monopoly drug, 65 percent.

(C) Long-monopoly drugs

With respect to a long-monopoly drug, 40 percent.

(4) Extended-monopoly drug defined

(A) In general

In this part, subject to subparagraph (B), the term "extended-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusions

The term "extended-monopoly drug" shall not include any of the following:

(i) A vaccine that is licensed under section 262 of this title and marketed pursuant to such section.

(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

(C) Clarification

Nothing in subparagraph (B)(ii) shall limit the transition of a selected drug described in paragraph (3)(A) to a long-monopoly drug if the

selected drug meets the definition of a long-monopoly drug.

(5) Long-monopoly drug defined

(A) In general

In this part, subject to subparagraph (B), the term "long-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusion

The term "long-monopoly drug" shall not include a vaccine that is licensed under section 262 of this title and marketed pursuant to such section.

(6) Average non-Federal average manufacturer price

In this part, the term "average non-Federal average manufacturer price" means the average of the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38) for the 4 calendar quarters of the year involved.

(d) Temporary floor for small biotech drugs

In the case of a selected drug that is a qualifying single source drug described in section 1320f-1(d)(2) of this title and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, the maximum fair price negotiated under this section for such drug for such initial price applicability year may

not be less than 66 percent of the average non-Federal average manufacturer price for such drug (as defined in subsection (c)(6)) for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year.

(e) Factors

For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

(1) Manufacturer-specific data

The following data, with respect to such selected drug, as submitted by the manufacturer:

(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

(B) Current unit costs of production and distribution of the drug.

(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 355(c) of title 21 or section 262(a) of this title for the drug.

(E) Market data and revenue and sales volume data for the drug in the United States.

(2) Evidence about alternative treatments

The following evidence, as available, with respect to such selected drug and therapeutic alternatives to such drug:

(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.

(B) Prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to such drug.

(C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

(D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

In using evidence described in subparagraph (C), the Secretary shall not use evidence from

comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(f) Renegotiation process

(1) In general

In the case of a renegotiation-eligible drug (as defined in paragraph (2)) that is selected under paragraph (3), the Secretary shall provide for a process of renegotiation (for years (beginning with 2028) during the price applicability period, with respect to such drug) of the maximum fair price for such drug consistent with paragraph (4).

(2) Renegotiation-eligible drug defined

In this section, the term "renegotiation-eligible drug" means a selected drug that is any of the following:

(A) Addition of new indication

A selected drug for which a new indication is added to the drug.

(B) Change of status to an extended-monopoly drug

A selected drug that—

(i) is not an extended-monopoly or a long-monopoly drug; and

(ii) for which there is a change in status to that of an extended-monopoly drug.

(C) Change of status to a long-monopoly drug

A selected drug that—

(i) is not a long-monopoly drug; and

(ii) for which there is a change in status to that of a long-monopoly drug.

(D) Material changes

A selected drug for which the Secretary determines there has been a material change of any of the factors described in paragraph (1) or (2) of subsection (e).

(3) Selection of drugs for renegotiation

For each year (beginning with 2028), the Secretary shall select among renegotiation-eligible drugs for renegotiation as follows:

(A) All extended-monopoly negotiation-eligible drugs

The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(B).

(B) All long-monopoly negotiation-eligible drugs

The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(C).

(C) Remaining drugs

Among the remaining renegotiation-eligible drugs described in subparagraphs (A) and (D) of paragraph (2), the Secretary shall select renegotiation-eligible drugs for which the Secretary expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.

(4) Renegotiation process

(A) In general

The Secretary shall specify the process for renegotiation of maximum fair prices with the manufacturer of a renegotiation-eligible drug selected for renegotiation under this subsection.

(B) Consistent with negotiation process

The process specified under subparagraph (A) shall, to the extent practicable, be consistent with the methodology and process established under subsection (b) and in accordance with subsections (c), (d), and (e), and for purposes of applying subsections (c)(1)(A) and (d), the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to such renegotiation applies, including for applying subsection (c)(3)(B) in the case of renegotiation-eligible drugs described in paragraph (3)(A) of this subsection and subsection (c)(3)(C) in the case of renegotiation-eligible drugs described in paragraph (3)(B) of this subsection.

(5) Clarification

A renegotiation-eligible drug for which the Secretary makes a determination described in section 1320f-1(c)(1)[5] of this title before or during the period of renegotiation shall not be subject to the renegotiation process under this section.

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[5] So in original. Probably means subparagraph (A) or (B) of paragraph (1) of section 1320f-1(e) of this title.

(g) Clarification

The maximum fair price for a selected drug described in subparagraph (A) or (B) of paragraph (1) shall take effect no later than the first day of the first calendar quarter that begins after the date described in subparagraph [6] (A) or (B), as applicable.

§ 1320f-4. Publication of maximum fair prices

(a) In general

With respect to an initial price applicability year and a selected drug with respect to such year—(1) not later than November 30 of the year that is 2 years prior to such initial price applicability year, the Secretary shall publish the maximum fair price for such drug negotiated with the manufacturer of such drug under this part; and

(2) not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1320f-2(c) of this title, the explanation for the maximum fair price with respect to the factors as applied under section 1320f-3(e) of this title for such drug described in paragraph (1).

(b) Updates

(1) Subsequent year maximum fair prices

For a selected drug, for each year subsequent to the first initial price applicability year of the price applicability period with respect to such drug, with respect to which an agreement for such drug is in effect under section 1320f-2 of this title, not later than November 30 of the year that is 2 years

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[6] So in original. Probably should be preceded by "such".

prior to such subsequent year, the Secretary shall publish the maximum fair price applicable to such drug and year, which shall be—(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with the July immediately preceding such November 30; or

(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

(2) Prices negotiated after deadline

In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price by not later than 30 days after the date such maximum price is so determined.

§ 1320f-5. Administrative duties and compliance monitoring

(a) Administrative duties

For purposes of section 1320f(a)(4) of this title, the administrative duties described in this section are the following:

(1) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

(A) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals; and

(B) any other discounts.

(2) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.

(3) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

(A) maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of subchapter XVIII or an MA–PD plan under part C of such subchapter; and

(B) maximum fair price eligible individuals who are enrolled under part B of such subchapter, including who are enrolled in an MA plan under part C of such subchapter.

(4) The establishment of a negotiation process and renegotiation process in accordance with section 1320f-3 of this title.

(5) The establishment of a process for manufacturers to submit information described in section 1320f-3(b)(2)(A) of this title.

(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 5000D of the

Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—(A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1395w-114a of this title and the date on which any subsequent agreement under such program is entered into;

(B) the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1395w-114c of this title and the date on which any subsequent agreement under such program is entered into; and

(C) the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1396r-8(b) of this title and the date on which any subsequent rebate agreement described in such section is entered into.

(7) The establishment of procedures for purposes of applying subsections (d)(2)(B) and (f)(1)(C) of section 1320f-1 of this title.

(b) Compliance monitoring

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1320f-2 of this title and establish a mechanism through which violations of such terms shall be reported.

§ 1320f-6. Civil monetary penalties

(a) Violations relating to offering of maximum fair price

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that does not provide access to a price that is equal to or less than the maximum fair price for such drug for such year—

(1) to a maximum fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1320f(c)(2) of this title and who is dispensed such drug during such year (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs); or

(2) to a hospital, physician, or other provider of services or supplier with respect to maximum fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

(b) Violations relating to providing rebates

Any manufacturer that fails to comply with the rebate requirements under section 1320f-1(f)(4) of this title shall be subject to a civil monetary penalty equal to 10 times the amount of the rebate the manufacturer failed to pay under such section.

(c) Violations of certain terms of agreement

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, with respect to a year during the price applicability period with respect to such drug, that is in violation of a requirement imposed pursuant to section 1320f-2(a)(5) of this title, including the requirement to submit information pursuant to section 1320f-2(a)(4) of this title, shall be subject to a civil monetary penalty equal to $1,000,000 for each day of such violation.

(d) False information

Any manufacturer that knowingly provides false information pursuant to section 1320f-5(a)(7) of this title shall be subject to a civil monetary penalty equal to $100,000,000 for each item of such false information.

(e) Application

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1320-7a(a) of this title.

§ 1320f-7. Limitation on Administrative and Judicial Review.

There shall be no administrative or judicial review of any of the following:

(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1320f(c)(6) of this title.

(2) The selection of drugs under section 1320f–1(b) of this title, the determination of negotiation-eligible drugs under section 1320f–1(d) of this title, and the determination of qualifying single source drugs under section 1320f–1(e) of this title the application of section 1320f–1(f) of this title.

(3) The determination of a maximum fair price under subsection (b) or (f) of section 1320f–3 of this title.

(4) The determination of renegotiation-eligible drugs under section 1320f–3(f)(2) of this title and the selection of renegotiation-eligible drugs under section 1320f–3(f)(3) of this title.

APPENDIX D

26 U.S.C. § 5000D

§ 5000D. Designated drugs during noncompliance periods

(a) In general

(1) There is hereby imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—such tax, divided by

(2) the sum of such tax and the price for which so sold.

(b) Noncompliance periods

A day is described in this subsection with respect to a designated drug if it is a day during one of the following periods:

(1) The period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of—(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price under an agreement described in section 1193(a) of the Social Security Act, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(3) In the case of any designated drug which is a selected drug (as defined in section 1192(c) of the Social Security Act) that the Secretary of Health and Human Services has selected for renegotiation under section 1194(f) of such Act, the period beginning on the November 2nd of the year that begins 2 years prior to the first initial price applicability year of the price applicability period for which the maximum fair price established pursuant to such renegotiation applies and ending on the earlier of—

(A) the first date on which the manufacturer of such designated drug has agreed to a renegotiated maximum fair price under such agreement, or

(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under an agreement described in section 1193(a) of the Social Security Act, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

(c) Suspension of tax

(1) In general

A day shall not be taken into account as a day during a period described in subsection (b) if such day is also a day during the period—

(A) beginning on the first date on which—

(i) the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services, and

(ii) none of the drugs of the manufacturer of the designated drug are covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act, and

(B) ending on the last day of February following the earlier of—

(i) the first day after the date described in subparagraph (A) on which the manufacturer enters into any subsequent applicable agreement, or

(ii) the first date any drug of the manufacturer of the designated drug is covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act.

(2) Applicable agreement

For purposes of this subsection, the term "applicable agreement" means the following:

(A) An agreement under—

(i) the Medicare coverage gap discount program under section 1860D-14A of the Social Security Act, or

(ii) the manufacturer discount program under section 1860D-14C of such Act.

(B) A rebate agreement described in section 1927(b) of such Act.

(d) Applicable percentage

For purposes of this section, the term "applicable percentage" means—

(1) in the case of sales of a designated drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

(2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

(3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

(4) in the case of sales of such drug during any subsequent day, 95 percent.

(e) Definitions

For purposes of this section—

(1) Designated drug

The term "designated drug" means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act) included on the list published under section 1192(a) of such Act which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

(2) United States

The term "United States" has the meaning given such term by section 4612(a)(4).

(3) Other terms

The terms "initial price applicability year", "price applicability period", and "maximum fair price" have the meaning given such terms in section 1191 of the Social Security Act.

(f) Special rules

(1) Coordination with rules for possessions of the United States

Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

(2) Anti-abuse rule

In the case of a sale which was timed for the purpose of avoiding the tax imposed by this section, the Secretary may treat such sale as occurring during a day described in subsection (b).

(g) Exports

Rules similar to the rules of section 4662(e) (other than section 4662(e)(2)(A)(ii)(II)) shall apply for purposes of this chapter.

(h) Regulations

The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section.

APPENDIX E

MEDICARE DRUG PRICE
NEGOTIATION PROGRAM AGREEMENT
(hereinafter referred to as the "Agreement")

Between

the Centers for Medicare & Medicaid Services (CMS),
pursuant to delegated authority of the Secretary of
Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act ("the Act"), as set forth in the Inflation Reduction Act (IRA), Pub. L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the "Negotiation Program"), which sets forth a framework under which manufacturers and CMS may negotiate to determine a price (referred to as "maximum fair price" in the Act) for selected drugs in order for manufacturers to provide access to such price to maximum fair price eligible individuals; and

WHEREAS, CMS has designated the Manufacturer as the Primary Manufacturer, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act, of the Selected Drug, and CMS has included the Selected Drug on the list of selected drugs published on [Date]; and

WHEREAS, the Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined price pursuant to section 1193 of the Act and in accordance with how the price is computed and applied across different strengths and dosage forms of the Selected Drug as identified by CMS and updated, as applicable, in accordance with sections 1194(f), 1195(b), and 1196(a)(2) of the Act and applicable guidance and regulations, including where the Selected Drug is sold or marketed by any Secondary Manufacturers as defined in applicable guidance or regulations;

NOW THEREFORE, CMS, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. Definitions

All terms included in this Agreement shall have the meaning given to them under the provisions of sections 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions, except where such terms are expressly defined in this Agreement.

II. CMS and Manufacturer Responsibilities

CMS shall administer the Negotiation Program and the Manufacturer agrees to comply with all applicable requirements and conditions for the Negotiation Program set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations implementing those provisions and any changes to the Act that affect the Negotiation Program.

Without limiting the foregoing, CMS and the Manufacturer agree:

a) During the negotiation period for the initial price applicability year for the Selected Drug, in accordance with section 1194 of the Act and applicable guidance and regulations CMS and the Manufacturer shall negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for the Selected Drug of the Manufacturer in order for the Manufacturer to provide access to such price—

   i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during, subject to paragraph (b) of this section, the price applicability period; and

   ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during, subject to paragraph (b) of this section, the price applicability period.

b) As applicable, CMS and the Manufacturer shall, in accordance with section 1194 of the Act and applicable guidance and regulations, renegotiate (and, by not later than the last date of the period

of renegotiation, agree to) the maximum fair price for the Selected Drug, in order for the Manufacturer to provide access to such maximum fair price (as so renegotiated)—

i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug; and

ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug.

c) Subject to paragraph (f) of this section and in accordance with applicable guidance and regulations, access to the maximum fair price (including as renegotiated pursuant to paragraph (b) of this section), with respect to such a Selected Drug, shall be provided by the Manufacturer to—

i. maximum fair price eligible individuals, who with respect to the Selected Drug are described

in subparagraph (A) of section 1191(c)(2) of the Act, at the pharmacy, mail order service, or other dispenser at the point-of-sale of the Selected Drug (and shall be provided by the Manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug), as described in paragraph (a)(i) or (b)(i) of this section, as applicable; and

ii. hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug, as described in paragraph (a)(ii) or (b)(ii) of this section, as applicable.

d) The Manufacturer shall submit to CMS, in a form and manner specified by CMS and in accordance with applicable guidance and regulations, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f) of the Act), and for section 1192(f) of the Act, with respect to the Selected Drug—

i. information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the Selected Drug for the applicable year or period;

ii. information that CMS requires to carry out the negotiation (or renegotiation) process under sections 1191 through 1198 of the Act; and

iii. information that CMS requires to carry out section 1192(f) of the Act, including rebates under section 1192(f)(4) of the Act.

e) The Manufacturer shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations.

f) Under this Agreement and in accordance with applicable guidance and regulations, the Manufacturer—

i. Shall not be required to provide access to the maximum fair price under paragraph (c), with respect to the Selected Drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if the Selected Drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

ii. Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for the Selected Drug.

g) In accordance with section 1193(c) of the Act and applicable guidance and regulations, information submitted to CMS under the Negotiation Program by the Manufacturer that is proprietary information of such Manufacturer, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States to carry out such Negotiation Program, unless otherwise required by law.

III. Effective Date, Term and Termination

a) This Agreement shall have an effective date of the date this Agreement is signed by both parties.

b) The term of this Agreement shall be from the effective date until the termination date, which shall be the earlier of the first day that the Selected Drug is no longer a selected drug pursuant to CMS' determination in accordance with section 1192(c) of the Act and applicable guidance and regulations, or the date that the Agreement is terminated by either party in accordance with applicable guidance and regulations.

c) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations.

IV. General Provisions

a) This Agreement contains the entire agreement of the parties with respect to the subject matter of this Agreement and supersedes all prior oral and written representations, agreements, and understandings of the parties. If CMS and the

Manufacturer reach agreement on a price for the Selected Drug pursuant to section II(a) or II(b) of this Agreement, CMS and the Manufacturer shall execute an addendum setting forth the price for the Selected Drug that will apply for purposes of this Agreement.

b) CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement.

c) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement shall be sent by email. CMS shall provide the appropriate email address for notice in guidance, rulemaking, or other publications. The Manufacturer shall provide the appropriate email address(es) for notice to CMS in a form and manner specified by CMS.

d) Nothing in this Agreement shall prohibit the Manufacturer from transferring the Selected Drug and obligations of this Agreement to another entity in accordance with applicable guidance and regulations.

e) Nothing in this Agreement shall limit the Manufacturer from providing access under the Medicare program to a price lower than the price determined pursuant to this Agreement.

f) 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.

g) Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

h) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.

i) This Agreement shall be construed in accordance with Federal law and any ambiguities shall be interpreted in the manner that best effectuates the statute. Any litigation relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court. Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations, or guidance.

j) CMS and the Manufacturer acknowledge and agree that in accordance with section 1197 of the Act and 26 U.S.C. § 5000D, the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the

requirements of the Negotiation Program, including violations of this Agreement.

k) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, includeing, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

V. Signatures

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or

she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

_____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By: _____

Print Name: _____

Signature: _____

Title: _____

Date: _____

Addendum 1: Negotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT NEGOTIATED MAXIMUM FAIR PRICE ADDENDUM
(hereinafter referred to as the "Addendum")

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the "Manufacturer")

For

[Name of Selected Drug]
(hereinafter referred to as the "Selected Drug")

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the "Agreement"), which the Manufacturer entered into with CMS on [Date], to negotiate to determine a price (referred to as "maximum fair price" in the Social Security Act ("the Act")) for the Selected Drug under the Negotiation Program; and

WHEREAS, the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug in accordance with the negotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a price for the Selected Drug, as published by CMS in accordance with section 1195(a) of the Act and updated in accordance with sections 1195(b) and 1196(a)(2) of the Act and applicable guidance and

regulations, which will apply for purposes of the Agreement;

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

a) The parties agree to a price of [$] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.
b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.
c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing below, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Name: _____

Signature: _____

Title: _____

Date: _____

APPENDIX F

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

Civil Action No. 3:23-cv-01103

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiff,

v.

XAVIER BECERRA, Secretary of
Health and Human Services, *et al.*,

Defendants.

DECLARATION OF CHRISTINE MARSH
IN SUPPORT OF PLAINTIFF'S MOTION
FOR SUMMARY JUDGMENT

I, Christine Marsh, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am Senior Vice President, Value and Access for Boehringer Ingelheim Pharmaceuticals, Inc. ("BI"), and have held that position since July 2019. I submit this declaration in support of BI's Motion for Summary Judgment.

2. As Senior Vice President, Value and Access, I am responsible for, among other things, collaborating with a broad range of BI departments to ensure that BI's medicines are accessible to patients, including Medicare Part D enrollees. Prior to my current position, I served as Senior Vice President, Market Access and Vice President, Managed Markets Sales at

BI, and in senior strategic leadership roles at BI (where I have worked in various capacities since 1999), and Roxane Laboratories. In these roles I have gained significant experience in pricing and government contracting for pharmaceutical products.

3. This declaration is based on my personal knowledge, including knowledge I have gained from others at BI and company documents.

BI's Jardiance® Products

4. BI has a long history of research and development of novel pharmaceutical products. In 2020 alone, the BI family of companies (consisting of Boehringer Ingelheim Pharmaceuticals, Inc. and related entities globally) invested $4.2 billion in pharmaceutical research and development, covering work on approximately 100 projects across all phases of the research process, many of which addressed unmet medical needs. Those investments increased to $5.3 billion in 2022, a year in which more than 30 million people globally benefitted from therapies developed by the BI family of companies.

5. One of the medications that has resulted from BI's investments is empagliflozin—a medication used to lower blood sugar in adults with type 2 diabetes and to reduce the risk of cardiovascular death in those adults and adults with heart failure—which BI manufactures and sells under the trade name Jardiance®. BI is continuing to pursue innovative new indications for Jardiance®. For example, the FDA recently (on September 21, 2023) approved Jardiance® for treatment of chronic kidney disease, which affects more than one in seven U.S. adults (an estimated 37 million Americans).

6. BI markets Jardiance® in the United States under a license for the patents claiming empagliflozin and its uses. BI owns title to its Jardiance® products (i.e., the physical, retail-packaged tablets) and exercises its rights to possess, sell, and otherwise dispose of those products, including by determining when and on what terms to make them available to others.

BI's Broader Participation in Medicare and Medicaid

7. BI makes Jardiance® and all of its other drugs—numbering more than 20—available through Medicare and Medicaid. BI's participation in the Medicare and Medicaid programs accounts for more than half of the company's net sales in the United States in many years. For example, in 2022 Medicare and Medicaid sales accounted for more than 55% of BI's net sales in the United States.

8. According to a study published by the U.S. Department of Health and Human Services, more than 1.3 million patients received Jardiance® products through Medicare alone in 2022.[1] If BI were forced to withdraw from Medicare and Medicaid, those patients would lose insurance coverage for Jardiance® products and the life-saving benefits they provide.

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[1] *See* U.S. Dept. of Health & Human Services, Assistant Sec'y for Planning and Evaluation, *Fact Sheet: Inflation Reduction Act Research Series—Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program*, HP-2021-21, at 2, 5 & tbl. 1 (Aug. 29, 2023) ("HHS Fact Sheet"), https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPEIRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf (showing that 1,321,000 Medicare Part D enrollees were prescribed Jardiance® in 2022).

9. Given the major role played by Medicare and Medicaid in the U.S. healthcare market, participation in those programs is critical to BI's business and continuing ability to develop innovative treatments and pursue new indications for and formulations of previously approved medicines.

The Program's Effects on BI

10. On August 29, 2023, the Centers for Medicare and Medicaid Services ("CMS") ordered that Jardiance® be included in the Inflation Reduction Act's ("IRA") Drug Price Negotiation Program (the "Program"). *See* HHS Fact Sheet, *supra*, at 1.

11. BI faces a deadline of October 1, 2023 to sign a "Manufacturer Agreement" stating that it will participate in a "negotiation" with CMS with respect to a "maximum fair price" for Jardiance®. 42 U.S.C. §§ 1320f(d)(2)(A), 1320f-2.

12. CMS has not provided BI with an opportunity to negotiate the terms of the "Agreement," and instead has presented the document to manufacturers on a take-it-or-leave-it basis. If BI had received an opportunity to negotiate the terms of the "Agreement," BI would have proposed substantive changes to the document.

13. Contrary to the terms of the "Agreement" dictated by CMS, BI does not believe that the Program involves a genuine "negotiation" or that the prices imposed under the Program are "fair." Were it not for the IRA's compulsion, BI would not convey the message that it "agrees" to participate in the Program, that the Program involves a genuine "negotiation," or that the prices imposed under the Program are "fair."

14. Because the Program employs coercive, misleading, and one-sided terms, BI does not wish to

participate in the Program and BI's participation is not voluntary. BI is compelled to sign the "Agreement" because a failure to sign it would subject BI to a daily penalty on every domestic sale of its Jardiance® products—not just on sales for use by Medicare beneficiaries. *See* 26 U.S.C. § 5000D. The penalty begins at 186 percent of the drug's daily U.S. revenues and rapidly escalates to 1900 percent.

15. In practice, the excessive penalties are even more severe because they are based on the drug's gross revenues—an approach that causes the maximum penalty to be much higher than 1900 percent of the net revenues BI earns on its Jardiance® products after subtracting rebates and discounts.

16. If BI does not sign the "Agreement" and continues to sell its Jardiance® products at volumes similar to today, the statutory penalties will amount to more than $500 million per week initially, later increasing to more than $5.5 billion per week.

17. Aside from submitting to the Program, the only way BI can avoid these penalties is to withdraw all of its products from both Medicare and Medicaid. *See* 26 U.S.C. § 5000D(c). BI cannot pull out of a market that accounts for almost half the annual nationwide spending on prescription drugs and more than half of BI's net sales in the United States. That drastic step would deprive BI of the resources needed to continue developing innovative treatments in the future. Because of the high costs and failure rates associated with drug development, BI relies on revenues from the small fraction of its drugs that are approved by FDA and find success in the marketplace in order to continue investing in innovation.

18. Wholesale withdrawal of BI's products also would leave Medicare and Medicaid patients without access to medications they rely on to treat serious, life-threatening conditions. Millions of Medicare and Medicaid patients depend on BI medications—a relationship that implicates BI's core values, including improving human health and responsibility to the community. Forcing BI to withdraw all of its drugs from Medicare and Medicaid would contravene those values and risk unnecessary harm to patients.

19. For example, many patients would have to switch from their current medication to other treatments that may be less effective or cause adverse reactions. In some instances, where BI's drug is the only one approved by FDA for a particular condition or patient population (as is the case with Spevigo®, a BI product that treats a rare, lifelong skin disease), forced withdrawal from Medicare and Medicaid would leave patients in those programs without insurance for any FDA-approved treatment.

20. The Program grants third parties "access" to BI's Jardiance® products over BI's objection, thus appropriating BI's ability to determine whether, and on what terms, to make its Jardiance® products available to third parties.

21. The Program implicates BI's property interests in its Jardiance® products in several ways, including by interfering with BI's rights to possess, dispose of, and exclude others from possessing physical doses of Jardiance®, and by undermining the value and utility of the patents that cover the Jardiance® products as well as licensing rights with respect to those patents. In addition, the Program requires BI to disclose a substantial amount of confidential and proprietary data regarding its Jardiance® products to CMS no

later than October 2, 2023. BI would not provide that confidential and proprietary data to CMS but for the Program's requirements.

22. BI has incurred substantial costs to collect the information that the Program requires it to disclose to CMS, including the opportunity cost of employees being diverted from other tasks.

23. BI will be harmed further if it is forced to participate in the "negotiation" process, including because employees will need to be diverted from other tasks in order to participate in that process.

24. In participating—involuntarily—in the Program, BI will be subjected not just to the IRA hut also to the Guidance that CMS has issued under the IRA. A key portion of the Guidance is Section 30, which CMS designated as final immediately upon. issuance, and as to which CMS did not accept public comments. Section 30 imposes substantive obligations different than those set forth in the IRA, and BI would have provided detailed comments on Section 30 had CMS accepted comments on that section. BI did not file comments on Section 30 in light of CMS's announcement that the section. was final and not subject to comment, and in order 10 use the limited comment period available to focus on the issues on which CMS stated that it would consider public comments.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 26th day of September, 2023.

/s/ Christine Marsh

Christine Marsh
Senior Vice President, Value and Access
Boehringer Ingelheim Pharmaceuticals, Inc.