UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., *Plaintiff*, v. UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, *et al.*, *Defendants*.	No. 3:23-cv-01103 (MPS)

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."

[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.

(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 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).

[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).

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]

(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 words, the

[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 the government receives is 1900 percent of the $1000 pre-tax 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%").

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 relinquishment 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

[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.

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 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

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

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

[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.

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 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]

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

[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 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.

'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 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 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

[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 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."

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]

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 *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

[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 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.").

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]

[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.

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 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]

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

[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 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").

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 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

[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.

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, 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 voluntary."[14] ECF No. 28-1 at 46-47. In *NFIB*, the Court held unconstitutional a

[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.

[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.

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 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

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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").

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 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."

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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 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.

Virginia v. Black, 538 U.S. 343, 358 (2003). So where the government regulates or compels 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 "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]

[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.

[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

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

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 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

[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.").

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 manufacturers 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 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 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

[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 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).

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

[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.

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 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.

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.

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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).

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