UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*, Defendants.	No. 3:23-cv-1103-RNC

DEFENDANTS' OPPOSITION TO PLAINTIFF'S
MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION

Defendants oppose Plaintiff's motion for summary judgment and cross-move for summary judgment on all claims pursuant to Rule 56 of the Federal Rules of Civil Procedure. In support, Defendants rely on the attached memorandum of law.

Dated: December 20, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Alexander V. Sverdlov
ALEXANDER V. SVERDLOV
MICHAEL J. GAFFNEY
CASSANDRA M. SNYDER
CHRISTINE L. COOGLE
Trial Attorneys
STEPHEN M. PEZZI
Senior Trial Counsel
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005
Tel: (202) 305-8550
Email: alexander.v.sverdlov@usdoj.gov

Counsel for Defendants

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MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION

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Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005
Tel: (202) 305-8550
Email: alexander.v.sverdlov@usdoj.gov

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Counsel for Defendants

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INTRODUCTION

For more than 30 years, Congress has imposed limits on how much federal agencies pay for prescription drugs. Manufacturers that wish to sell their drugs to the Department of Defense and the Department of Veterans Affairs (VA) do so at statutorily defined ceiling prices, and both agencies have authority to negotiate prices further below those ceilings. *See* 38 U.S.C. § 8126(a)-(h). Building on this model in last year's Inflation Reduction Act (IRA), Pub. L. No. 117-169, Congress granted the Secretary of Health and Human Services similar authority to negotiate how much Medicare will pay for pharmaceutical products that lack generic (or biosimilar) competition and account for a disproportionate share of Medicare's expense. *See* 42 U.S.C. § 1320f(a) (establishing the "Negotiation Program"); *id.* § 1320f-1(b), (d), (e) (specifying which drugs are eligible for negotiation). For the first time, Medicare will be able to decide how much it is willing to pay for certain prescription drugs it covers—just as it has long determined how much it will reimburse doctors, hospitals, and other providers for medical services provided to Medicare beneficiaries.

Unsurprisingly, drug manufacturers—which have long profited from unrestricted growth in Medicare's prescription drug payments—lobbied hard against legislative efforts to introduce market discipline by giving the Secretary a seat at the negotiating table. And now that their lobbying failed, pharmaceutical companies and interest groups have repacked their policy disagreements into lawsuits, filing complaints around the country challenging the statute on its face. This lawsuit, brought by Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. (BI), largely rehashes the same legal theories proffered by the other manufacturers. And it fails for the same reasons.

As another district court recently recognized when considering an analogous Fifth Amendment challenge to the IRA, Congress's authorization for the Secretary to negotiate how much Medicare will pay for drugs "cannot be considered a constitutional violation" because drug manufacturers "are not legally compelled to participate in the [Negotiation] Program—or in Medicare generally." *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, --- F. Supp. 3d ---, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (*Chamber*). "[P]harmaceutical manufacturers who do not wish to" make their drugs available at negotiated prices can "opt out" by, for example, withdrawing from the

Medicare and Medicaid markets or by divesting their interests in the drugs subject to negotiation before 2026, when any negotiated prices would first take effect. *Id.* The Negotiation Program—like Medicare more broadly—is thus "a completely voluntary" undertaking. *Id.* This basic fact defeats BI's First and Fifth Amendment challenges. Although it may be dissatisfied with the conditions Congress imposed on future Medicare spending, BI is neither deprived of a protected property interest in violation of the Takings or Due Process Clauses, nor required to speak.

BI's constitutional arguments fail in other respects, too. The company's theory that the Negotiation Program effects a "*physical*" taking of its property is untenable under the very Supreme Court cases that BI invokes. Pl.'s Mot. for Summ. J. Br, ECF No. 28-1 at 20 (BI Br.) (emphasis added). Those cases emphasize "the settled difference in [] takings jurisprudence between" the government taking physical control of property and merely regulating its sale. *Horne v. Dep't of Agric.*, 576 U.S. 350, 362 (2015). But the IRA does not authorize the government to requisition a manufacturer's drugs or other property—and therefore cannot constitute a physical taking. Likewise, BI's assertion that the Negotiation Program violates due process fails to identify a protected property interest that Congress ostensibly impaired. As courts have made clear, parties have no protected property interest in their Medicare reimbursement rates—so Congress's alteration of the manner in which such rates are established cannot contravene the Fifth Amendment.

Similar errors infect BI's First Amendment arguments. Contrary to BI's assertions, neither the agreements that manufacturers have now signed with the Centers for Medicare & Medicaid Services (CMS) nor any other component of the Negotiation Program requires a manufacturer to adopt the government's message. Indeed, those agreements do not require manufacturers to express any views at all. Those instruments are purely commercial arrangements that pertain solely to the manufacturers' conduct. BI's unfounded fears about how those agreements might be perceived by the public do not justify abrogating decades of First Amendment case law in favor of a new—and limitless—presumption of First Amendment expression in every commercial act. And BI's alternative Administrative Procedure Act (APA) challenge to the procedures CMS used to develop those agreements fails because CMS followed Congress's express instructions to implement the Negotiation

Program for 2026, 2027, and 2028 "by program instruction or other forms of program guidance" in section 11001(c) of the IRA, 136 Stat. 1818, 1854—thereby exempting the agency from the notice-and-comment requirements that BI claims CMS did not observe.

Disposing of those claims leaves solely BI's Eighth Amendment challenge to the IRA's excise tax provisions. But this Court lacks jurisdiction to entertain that challenge. As a constitutional matter, this claim is not redressable because no defendant in this lawsuit is empowered to enforce the tax that BI seeks to enjoin and have declared unconstitutional. And, as a statutory matter, BI's claim is barred by the Anti-Injunction Act (AIA), 26 U.S.C. § 7421(a), which prohibits any "suit for the purpose of restraining the assessment or collection of any tax," and the tax exception to the Declaratory Judgment Act (DJA), 28 U.S.C. § 2201(a), which prohibits issuance of declaratory judgments "with respect to Federal taxes." For both AIA and DJA purposes, a "tax" is an exaction that Congress has labeled as such, and Congress has unambiguously described the § 5000D excise tax as a "tax." Because BI's Eighth Amendment challenge asks this Court to preemptively enjoin, and declare the constitutionality of, that tax, *see* Compl. ¶ 216, that challenge must be dismissed for lack of subject-matter jurisdiction.

In any event, even if the Court had jurisdiction to consider it, BI's excise-tax claim would also fail on the merits. The tax does not violate the Eighth Amendment because it is neither a fine nor excessive. Neither the Supreme Court nor, to Defendants' knowledge, any other court has ever held that a tax—let alone one that, like the one here, lacks any connection to a criminal offense—was a fine for Excessive Fines Clause purposes. And even if the excise tax were deemed a fine, it would not be a grossly disproportionate one, as the excise tax is proportional to the harm to the fisc and within the range of other constitutionally permissible exactions.

In creating the Negotiation Program, Congress exercised its constitutional prerogative to ensure that federal funds are spent according to its view of the "general Welfare." U.S. Const., art. I, § 8, cl. 1. BI's objections to that program are nothing more than "a dispute with the policy choices" made by Congress masquerading as constitutional theory. *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009). Rather than arguing against established precedent, the "better course of action is to seek redress through the . . . political process." *Id.* BI is not entitled to relief in court.

BACKGROUND

I. MEDICARE AND THE IRA'S DRUG NEGOTIATION PROGRAM

A. Medicare is a federal program that pays for covered health-care services of qualified beneficiaries as well as for prescription drugs. *See generally* 42 U.S.C. §§ 1395 *et seq.* The Medicare statute is divided into five "Parts," which set forth the terms by which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011).

"Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and laboratory services," as well as the cost of drugs administered as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019) (citation omitted). In 2003, Congress added Medicare Part D, which provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *U.S. ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. §§ 1395w-101 *et seq.* Prior to the Inflation Reduction Act (IRA), Congress had not granted the Secretary of Health and Human Services (HHS) authority to negotiate directly with drug manufacturers for the costs of covered medications under Medicare. To the contrary, Congress barred the Secretary from negotiating drug prices under Part D or otherwise interfering in the commercial arrangements between manufacturers and the private insurance plans that, in turn, enter into agreements with Medicare to provide benefits. *See* 42 U.S.C. § 1395w-111(i).

Although this model was relatively economical at first, it has led to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [which] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. II, at 37 (2019). Generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm. on Oversight and Reform, *Drug Pricing Investigation: AbbVie – Humira and Imbruvica* 36 (May 2021), https://perma.cc/9L42-VRBK. And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (June 2020), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to the Medicare program, which undermines the program's premise of using market competition to reduce prices for beneficiaries and taxpayers. *Id.* at 120. Because of how cost-sharing and premiums function under the Part D program, high drug costs also increase out-of-pocket payments by Medicare beneficiaries.

B. The IRA seeks to address these concerns. Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001-11003, 136 Stat. 1818 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). As relevant here, the IRA requires the Secretary, acting through CMS, to establish the Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those that have the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors, and that have been marketable for at least 7 years (*i.e.*, drugs that have long enjoyed little market competition). *See* 42 U.S.C. §§ 1320f *et seq.* The Negotiation Program applies only to the prices Medicare pays for drugs that it covers; the statute regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that do not participate in Medicare or Medicaid. *See, e.g.*, *id.* § 1320f-1(b), (d).

To carry out the Negotiation Program, the statute requires CMS to first identify a set of negotiation-eligible drugs; the agency is then to select up to 10 such drugs for negotiation for price applicability year 2026, up to 15 drugs for price applicability years 2027 and 2028, and up to 20 drugs for price applicability year 2029 and for subsequent years. *Id.* § 1320f-1(a)-(b). After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug in an effort to reach agreement on a "maximum fair price" for that drug. *Id.* § 1320f-3. Congress required CMS to consider numerous categories of information when formulating offers during the course of those negotiations, including (1) "[r]esearch and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs, (2) current "costs of production and distribution," (3) prior "Federal financial support for . . . discovery and development with respect to the drug," and (4) evidence about alternative treatments. *Id.* § 1320f-3(e). In hopes of achieving meaningful savings to the American people, Congress imposed a "ceiling for [the] maximum fair price," which it tied to specified pricing data for the subject drugs. *Id.* § 1320f-3(c). But Congress also directed CMS to "aim[] to achieve the lowest maximum fair price" that manufacturers will accept. *Id.* § 1320f-3(b)(1).

CMS will sign agreements to negotiate prices for selected drugs with willing manufacturers. *Id.* § 1320f-2. If those negotiations prove successful, a manufacturer will then sign an addendum agreement to provide Medicare beneficiaries access to the negotiated price for the drug. *Id.* A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling its drugs to be dispensed or furnished to Medicare beneficiaries at non-negotiated prices and pay an excise tax on those sales. 26 U.S.C. § 5000D. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its own choices about negotiations. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* at 131-32 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). Or it can withdraw from the Medicare and Medicaid programs—in which case it will incur no excise tax and no other liability. *See id.* at 33-34, 120-21, 129-31; *see also* Pub. L. No. 117-169, § 11003 (enacting 26 U.S.C. § 5000D(c)(1)).

These conditions parallel those that Congress has long attached to other government health care programs. For example, Congress has long required that any drug manufacturer wishing to participate in Medicaid enter into agreements with the Secretary of Veterans Affairs—agreements that give the VA, the Department of Defense, the Public Health Service, and the Coast Guard the option to purchase drugs at negotiated prices at or below statutory ceilings. *See* 38 U.S.C. § 8126(a)-(h). Like those statutory provisions, the Negotiation Program thus gives manufacturers a choice: they can sell their products at prices the government is willing to pay, or they can take their business elsewhere.

II. IMPLEMENTATION OF THE NEGOTIATION PROGRAM

Although the IRA provides a wealth of criteria and detail regarding the selection of drugs, the negotiation process, and the requirements of any agreement, Congress also recognized that implementing a new program of such complexity would require numerous operational decisions. Accordingly, Congress directed CMS to implement the Negotiation Program through "program instruction or other forms of program guidance" through 2028. Pub. L. No. 117-169, § 11001(c). Following that statutory mandate, CMS issued initial guidance on March 15, 2023, explaining how it intended to implement certain aspects of the statute and soliciting public input. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum* (Mar. 15, 2023), https://perma.cc/8X4K-CVD8. After considering more than 7,500 public comments "representing a wide range of views," CMS published its Revised Guidance on June 30, 2023. Revised Guidance at 1-2.

The Revised Guidance describes several aspects of the Negotiation Program for initial price applicability year 2026, including information about (1) the methodologies by which CMS selected drugs for negotiation; (2) the negotiation process, including the types of data that CMS will consider, the procedures for exchanges of offers and counteroffers, and the public explanations CMS will provide for negotiated prices; and (3) the procedures for manufacturers to follow if they decide at any point not to participate. *Id.* at 2-8. On that last point, the Revised Guidance expressly provides that if a manufacturer "decides not to participate in the Negotiation Program," CMS will "facilitate an expeditious termination of" the manufacturer's Medicare agreements before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue. *Id.* at 33-34. The Revised Guidance also notes that manufacturers that wish to remain in the Medicare and Medicaid programs but that do not wish to negotiate can divest their interest in the selected drug(s). *Id.* at 131-32.

The Treasury Department and the Internal Revenue Service (IRS) have issued a separate notice outlining how they interpret the IRA's excise-tax provision. *See* IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P (IRS Notice). As that notice explains, Treasury intends to propose regulations specifying that the tax provided for in 26 U.S.C. § 5000D would be imposed on the manufacturer's "sales of designated drugs dispensed, furnished, or administered to individuals *under the terms of Medicare*"—*i.e.*, only those drugs dispensed, furnished, or administered to Medicare beneficiaries. *Id.* at 3 (emphasis added). Further, the notice provides that, consistent with Treasury's pre-existing regulations applicable to certain other excise taxes, "[w]hen no separate charge is made as to the § 5000D tax on the invoice or records pertaining to the sale of a designated drug, it will be presumed that the amount charged for the designated drug includes the proper amount of § 5000D tax and the price of the designated drug." *Id.*

The Treasury Department's notice confirms that, "if a manufacturer charges a purchaser $100 for a designated drug during the first 90 days in a statutory period and does not make a separate charge for the § 5000D tax, $65 is allocated to the § 5000D tax and $35 is allocated to the price of the designated drug." *Id.* at 4. Under this same rule, after 271 days, $95 is allocated to the § 5000D tax and $5 is allocated to the price of the designated drug. Thus, the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95% (not 1900%).[1] This interpretation is effective immediately; as the notice explains, "[u]ntil the Treasury Department and the IRS issue further guidance, taxpayers may rely on" the interpretation the agency has articulated. *Id.* at 5.

The primary manufacturers of all selected drugs for the first negotiation cycle, including BI, have now executed agreements to negotiate. *See Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), https://perma.cc/7R6M-ENEP (Manufacturer Agreements). Under the schedule set by Congress, negotiations are to conclude by August 1, 2024. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b); *see generally* Revised Guidance at 91-92 (statutory timetable). Any agreed-upon prices for the selected drugs will take effect on January 1, 2026, about two years from now. 42 U.S.C. §§ 1320f(b), 1320f-2(a); Revised Guidance at 92.

III. RELATED LITIGATION

Prior to the deadline to execute negotiation agreements with CMS, drug manufacturers and interest groups filed multiple suits across the country challenging the constitutionality of the

[1] This result flows from the statutory formula for the tax amount specified in 26 U.S.C. § 5000D(a), (d).

Negotiation Program. *See Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J. filed June 16, 2023); *Janssen Pharms, Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. filed July 18, 2023); *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-931 (D. Del. Aug. 25, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. June 21, 2023); *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C. June 6, 2023); *Novartis Pharms. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J. Sept. 1, 2023); *Novo Nordisk Inc., et al. v. Becerra*, No. 3:23-cv-20814 (D.N.J. Sept. 29, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio June 9, 2023).[2] Plaintiffs in one such case—brought by the U.S. Chamber of Commerce and its local affiliates—sought a preliminary injunction "to prevent the implementation of [the] Program." *Chamber,* 2023 WL 6378423, at * 1. In doing so, those plaintiffs argued that the Program was akin to utility regulations and would "yield confiscatory rates" in violation of the Fifth Amendment's Due Process Clause. *Id.* at *11.

The court disagreed. Those claims failed "as a matter of law," the court explained, because manufacturers were "not legally compelled to participate in the [Negotiation] Program." *Id.* at *11. As a result, the Negotiation "Program's eventual 'maximum fair price' cannot be considered confiscatory because pharmaceutical manufacturers who do not wish to participate in the Program have the ability—practical or not—to opt out[.]" *Id.* (citation omitted). The *Chamber* court thus denied the plaintiffs' motion. *Id.* at *14. The plaintiffs in that case did not appeal.

ARGUMENT

I. THE COURT LACKS SUBJECT-MATTER JURISDICTION OVER BI'S CLAIM CHALLENGING THE IRA'S EXCISE TAX

As a threshold matter, BI's claim challenging the constitutionality of the excise tax (Count 4) should be dismissed because it runs afoul of two independent jurisdictional barriers. First, this claim is not redressable because BI has not sued the Department of the Treasury or the IRS—the only agencies empowered to enforce the tax that BI seeks to enjoin and have declared unconstitutional. Second, this claim is barred by the AIA, 26 U.S.C. § 7421(a), and the tax exception to the DJA, 28

[2] Another case was filed, but voluntarily dismissed: *Astellas Pharma US, Inc. v. HHS*, No. 1:23-cv-4578 (N.D. Ill. July 14, 2023).

U.S.C. § 2201(a). The Court may dismiss the claim on either of those grounds. Dismissal on the basis of the AIA would be more efficient, however, because BI cannot overcome the AIA by filing a new or revised complaint against the proper defendants. *See Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007).

A. BI's Excise-Tax Claim is not Redressable in this Suit

BI lacks Article III standing to press its constitutional challenge to the excise tax. To show Article III standing, a plaintiff "bears the burden of establishing" that it has "suffered an injury in fact . . . that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "To determine whether an injury is redressable, a court will consider the relationship between 'the judicial relief requested' and the 'injury' suffered." *California v. Texas*, 141 S. Ct. 2104, 2115 (2021). "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998). Redressability must be established "for each claim that [plaintiff] press[es] and for each form of relief that [it] seek[s]." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021); *see also id.* ("[S]tanding is not dispensed in gross.").

BI's excise-tax claim cannot be redressed in this suit against HHS and CMS. *See Haaland v. Brackeen*, 599 U.S. 255, 292 (2023). BI seeks two remedies with respect to the § 5000D tax: injunctive and declaratory relief. *See* Compl. ¶ 216 ("The court should declare that the Program's 'excise tax' penalty violates the requirements of the Excessive Fines Clause, and should enjoin Defendants from enforcing that penalty against BI."). Even if such relief were available, *see infra* Part I.B, neither remedy would provide BI with any redress, and BI therefore lacks standing.

Take the requested injunctive relief first. BI requests that the Court "enjoin Defendants [HHS and CMS] from enforcing [the excise tax] against BI." Compl. ¶ 216. But HHS and CMS do not administer the tax provisions of the IRA, which are codified in the Internal Revenue Code. *See* 26 U.S.C. § 5000D. Rather, the Department of the Treasury, of which the IRS is a part, is charged with enforcing § 5000D and interpreting its provisions. *Compare id.* § 5000D(h) ("The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section."), *with id.*

§ 5000D(b)(1)(B) (referring separately to "the Secretary of Health and Human Services"), *and id.* § 5000D(c)(1)(A)(i) (same); *see also* 26 U.S.C. § 7701(a)(11)(B) ("When used in this title, where not otherwise distinctly expressed or manifestly incompatible with the intent thereof . . . [t]he term 'Secretary' means the Secretary of the Treasury or his delegate."). Under this authority, Treasury has issued a notice explaining how it interprets § 5000D. *See* IRS Notice. The notice explains that the "Treasury Department and the IRS"—not HHS or CMS—"intend" to issue "forthcoming proposed regulations" regarding the scope of taxable sales, *see* IRS Notice § 3.01, and the applicable tax percentage, *see id.* § 3.02 (consistent with Treasury's pre-existing regulations applicable to certain other excise taxes, "[w]hen no separate charge is made as to the § 5000D tax . . . , it will be presumed that the amount charged for the designated drug includes the proper amount of § 5000D tax and the price of the designated drug").

Accordingly, the injunction BI requests cannot redress any tax-based injuries in this suit. Defendants are not the agencies that would assess or collect any tax and, even though Treasury and IRS are of course federal agencies, the Court cannot enter judgment against them because they are "not parties to the suit" and they would not be "obliged to honor an incidental legal determination the suit produced." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 569 (1992) (plurality opinion); *see also id.* at 570-71 ("The short of the matter is that redress of the only injury in fact respondents complain of requires action . . . by the individual funding agencies; and any relief the District Court could have provided in this suit against the Secretary was not likely to produce that action.").

The Supreme Court recently reaffirmed that a plaintiff lacks Article III standing to secure an injunction if it fails to sue the entities allegedly responsible for the plaintiff's purported injuries. *See Brackeen*, 599 U.S. at 292. Specifically, in *Brackeen* the Court found that petitioners could not seek "an injunction preventing the federal parties from enforcing" the challenged provisions of a law dealing with child placement when "state courts apply" those provisions "and state agencies carry out the court-ordered placements." *Id.* So too here. Whatever injury BI might one day suffer "at the hands" of Treasury and the IRS "is insufficient by itself to establish a case or controversy in the context of this suit, for [neither Treasury nor the IRS] is a defendant." *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41 (1976).

BI's "request for a declaratory judgment suffers from the same flaw." *Brackeen*, 599 U.S. at 293. "[J]ust like suits for every other type of remedy, declaratory-judgment actions must satisfy Article III's case-or-controversy requirement." *California*, 141 S. Ct. at 2115. Declaratory relief "conclusively resolves 'the legal rights o*f the parties*.'" *Brackeen*, 599 U.S. at 293 (quoting *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 200 (2014)); *see also Md. Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) ("[T]he question in each case is whether the facts alleged . . . show that there is a substantial controversy, *between parties having adverse legal interests* . . . to warrant the issuance of a declaratory judgment.") (emphasis added). "But again, [Treasury and IRS] are nonparties who would not be bound by the judgment." *Brackeen*, 599 U.S. at 293. Thus, BI's excise-tax challenge "would not be settled between [plaintiff] and the officials who matter—which would leave the declaratory judgment powerless to remedy the alleged harm." *Id.* And "[w]ithout preclusive effect, a declaratory judgment is little more than an advisory opinion." *Id.*; *see also California*, 141 S. Ct. at 2115 ("Remedies . . . operate with respect to specific parties. In the absence of any specific party, they do not simply operate on legal rules in the abstract.") (cleaned up).

The mere possibility that a court's "legal reasoning may inspire or shame others into acting differently" is immaterial; rather, courts "measure redressability by asking whether a court's judgment will remedy the plaintiff's harms." *United States v. Texas*, 143 S. Ct. 1964, 1979 (2023) (Gorsuch, J., concurring). After all, "[i]t is a federal court's judgment, not its opinion, that remedies an injury; thus it is the judgment, not the opinion, that demonstrates redressability." *Brackeen*, 599 U.S. at 294. Because BI "can hope for nothing more than an opinion" in this suit against HHS and CMS, it "cannot satisfy Article III" as to Count 4. *See id.*

B. <u>The Anti-Injunction Act and the Tax Exception to the Declaratory Judgment Act Prohibit this Court from Adjudicating BI's Excise-Tax Claim</u>

BI's excise-tax claim is also independently barred by the AIA and the tax exception to the DJA. Under the AIA, "no court has jurisdiction over a suit" like this one "to preemptively challenge a tax." *RYO Mach., LLC v. Dep't of Treasury*, 696 F.3d 467, 470 (6th Cir. 2012). And, for AIA purposes, a "tax" is any exaction—like the excise tax—that Congress has "label[ed]" as such. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 544, 564 (2012) (*NFIB*); *see also* 26 U.S.C. § 5000D (labeling excise tax as a "tax"). This Court is similarly prohibited from granting the declaratory relief that BI seeks because the tax exception to the DJA bars courts from issuing declaratory judgments "with respect to Federal taxes." 28 U.S.C. § 2201(a). Because Count 4 asks the Court to preemptively enjoin, and declare the constitutionality of, the § 5000D tax, this count must be dismissed.

1. *The AIA Deprives This Court Of Jurisdiction Over The Excise-Tax Claim*

As BI acknowledges, no court may "restrain[] the assessment or collection of any tax." BI Br. at 34 (quoting 26 U.S.C. § 7421(a)). "The [AIA] apparently has no recorded legislative history, but its language could scarcely be more explicit—'no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court . . . .'" *Bob Jones Univ. v. Simon*, 416 U.S. 725, 736 (1974). Accordingly, the "AIA has been interpreted broadly to encompass almost all premature interference with the assessment or collection of any federal tax." *RYO Mach.*, 696 F.3d at 471. "Because of the [AIA], taxes can ordinarily be challenged only after they are paid, by suing for a refund." *NFIB*, 567 U.S. at 543.

The AIA's jurisdictional bar applies with equal force to constitutional challenges to a tax. *See, e.g.*, *Larson v. United States*, 888 F.3d 578, 589 (2d Cir. 2018) (holding district court lacked subject-matter jurisdiction to consider Eighth Amendment claim). The Supreme Court has made "it unmistakably clear that the constitutional nature of a taxpayer's claim . . . is of no consequence under the [AIA]." *Alexander v. Ams. United Inc.*, 416 U.S. 752, 759 (1974). "[N]otwithstanding that [BI] [has] couched [its] tax collection claim in constitutional terms," BI "seek[s] to restrain the Government's collection of taxes, which is precisely what the [AIA] prohibits." *We the People Found., Inc. v. United States*, 485 F.3d 140, 143 (D.C. Cir. 2007); *see also Franklin v. United States*, No. 3:20-cv-1303, 2021 WL 4458377, at *7 (N.D. Tex. Sept. 29, 2021) ("Merely couching an argument against the validity of a tax assessment in constitutional terms will not allow a court to entertain the claim in contravention of the AIA."), *aff'd*, 49 F.4th 429 (5th Cir. 2022).

a. To determine whether the AIA applies, courts ask (1) whether the exaction at issue is a "tax," and (2) whether the purpose of the claim is to "restrain[] the assessment or collection" of that tax. 26 U.S.C. § 7421(a). Because both are true here, Count 4 is barred by the AIA.

First, the § 5000D excise tax is a "tax" for AIA purposes because Congress "label[ed]" it as such. *See NFIB*, 567 U.S. at 564. The AIA and the IRA's excise tax are "creatures of Congress's own creation" and, therefore, "[h]ow they relate to each other is up to Congress, and the best evidence of Congress's intent is the statutory text." *Id.* at 544. Accordingly, "even where [a] label was inaccurate" for constitutional purposes, the Supreme Court has "applied the [AIA]" to bar preemptive challenges "to statutorily described 'taxes.'" *Id.* (citation omitted); *id.* at 564 ("It is up to Congress whether to apply the [AIA] to any particular statute, so it makes sense to be guided by Congress's choice of label on that question."). Simply put, "the [AIA's] reach depends on statutory labels." *In re Juntoff*, 76 F.4th 480, 485 (6th Cir. 2023); *see also Optimal Wireless LLC v. IRS*, 77 F.4th 1069, 1074 (D.C. Cir. 2023) (looking to statutory references to determine whether an exaction is a tax for the purposes of the AIA); *Matter of Westmoreland Coal Co.*, 968 F.3d 526, 534 (5th Cir. 2020) ("With the AIA, form—specifically, the label Congress uses—does matter over substance."). That is, the AIA "draws no distinction between regulatory and revenue-raising tax rules"; rather, if the exaction is labeled a tax by Congress, it is a tax for AIA purposes. *See CIC Servs., LLC v. IRS*, 593 U.S. 209, 225 (2021).

Notably, BI does not contest that Congress labeled the excise tax a "tax." BI Br. at 34. Nor could it. Section 5000D refers to a "tax" nearly a half dozen times. *See* 26 U.S.C. § 5000D(a) ("There is hereby imposed on the sale by the manufacturer . . . of any designated drug . . . a tax . . . ."); *id.* § 5000D(a)(1) (referring to "such tax"); *id.* § 5000D(a)(2) (same); *id.* § 5000D(c) ("Suspension of Tax"). The final of these references makes plain that Congress meant to label the exaction described in § 5000D as a tax: "[i]n the case of a sale which was timed for the purpose *of avoiding the tax imposed by this section*, the Secretary may treat such sale as occurring during a day described in [the subsection defining periods to which the tax applies]." *Id.* § 5000D(f)(2) (emphasis added). Further, Congress codified § 5000D in Title 26—*i.e.*, the Internal Revenue Code—separate from the rest of the drug-negotiation provisions of the IRA. *See* Pub. L. No. 117-169, § 11003 ("Subtitle D of the Internal

Revenue Code of 1986 is amended by adding at the end the following . . ."). For AIA purposes, the statutory text is clear: Section 5000D imposes a "tax."

Second, the purpose of Count 4 is to "restrain[]" the "assessment or collection" of the § 5000D tax. 26 U.S.C. § 7421(a). BI does not contest this point either. *See* BI Br. at 34. In considering a claim's purpose, courts must "inquire not into a taxpayer's subjective motive, but into the action's objective aim—essentially, the relief the suit requests." *CIC Servs.*, 593 U.S. at 217. The relief requested here is to restrain the assessment or collection of the excise tax. *See* Compl. ¶ 216 ("The court should . . . enjoin Defendants from enforcing [the excise tax] against BI."). And BI's legal claim squarely targets the tax. *See id.* ¶¶ 135-45. *Compare CIC Servs.*, 593 U.S. at 219 ("The complaint contests the legality of Notice 2016-66, not of the statutory tax penalty that serves as one way to enforce it. CIC alleges that the Notice is procedurally and substantively flawed; it brings no legal claim against the separate statutory tax."). "These allegations leave little doubt that a primary purpose of" Count 4 "is to prevent the [IRS] from assessing and collecting" the excise tax. *Bob Jones Univ.*, 416 U.S. at 738; *Jacobson v. Organized Crime & Racketeering Section of U.S. Dep't of Just.*, 544 F.2d 637, 639 (2d Cir. 1976) ("it is too clear for reasonable debate that" the acts "sought to be enjoined constitute" the assessment and collection of a tax).

b. "Recognizing the force of this statutory bar to the maintenance of their suit," BI "seek[s] to bring their cause within the judicially created exception[s] to the Anti-Injunction Act." *Laino v. United States*, 633 F.2d 626, 629 (2d Cir. 1980); *see* BI Br. at 34 (asserting exceptions apply). Neither the *Williams Packing* nor the *South Carolina* exception applies.

The "stringent" *Williams Packing* exception requires "proof of the presence of two factors" to avoid "the literal terms of" the AIA: "first, irreparable injury, the essential prerequisite for injunctive relief in any case; and second, certainty of success on the merits." *Bob Jones Univ.*, 416 U.S. at 737 (discussing *Enochs v. Williams Packing & Navig. Co.*, 370 U.S. 1, 6 (1962)). "Unless both conditions are met, a suit for preventive injunctive relief must be dismissed." *Am. United*, 416 U.S. at 758. BI's "attempt to invoke *Williams Packing* must be rejected because [BI has] failed to satisfy either of its prerequisites." *Laino*, 633 F.2d at 629.

First, because a refund suit provides an adequate remedy here, BI cannot establish that it would suffer irreparable harm absent preemptive injunctive relief. *See Gaetano v. United States*, 942 F.3d 727, 734 (6th Cir. 2019) ("The tripping point" for plaintiffs "is that they have not shown an inadequate remedy at law."). Like *Bob Jones University*, "[t]his is not a case in which an aggrieved [taxpayer] has no access at all to judicial review." 416 U.S. at 746. A manufacturer that wished to challenge the excise tax could pay it, seek a refund from the IRS, then sue for a refund in district court or the Court of Federal Claims. *See* 26 U.S.C. § 7422; 28 U.S.C. §§ 1346(a)(1), 1491. Nor would following the procedure Congress required pose the outrageous burden BI asserts. The excise tax is imposed on each "sale" of a designated drug. *See* 26 U.S.C. § 5000D(a). It is therefore a "divisible tax," meaning "one that represents the aggregate of taxes due on multiple transactions (*e.g.*, sales of items subject to excise taxes)." *Rocovich v. United States*, 933 F.2d 991, 995 (Fed. Cir. 1991). A taxpayer who wishes to challenge a divisible tax need only pay "the excise tax on a single transaction [to] satisfy" the rule that it must fully pay the tax before seeking a refund. *Id.*; *see also Flora v. United States*, 362 U.S. 145, 171-75 n. 37, 38 (1960). And while a refund suit is pending, the IRS typically does not collect the balance of any divisible tax that would otherwise be due, except when unusual circumstances warrant. IRS Policy Statement 5-16, IRM § 1.2.1.6.4(6) ("When a refund suit is pending on a divisible assessment, the Service will exercise forbearance with respect to collection provided that the interests of the government are adequately protected and the revenue is not in jeopardy."). Thus, BI cannot show irreparable harm exists from following the path that Congress created.

BI nonetheless maintains—without any factual support—that it would suffer "ruinous" harm if it had to first pay the tax and then sue for a refund. BI Br. at 34; *see also id.* ("the enormity of the [excise tax] would make it impractical for BI to pay it for any meaningful period of time"). BI's assertion ignores the Supreme Court's observation that "the degree of harm is not a factor" in determining whether the AIA applies. *Bob Jones Univ.*, 416 U.S. at 745. It also disregards the divisible nature of the tax and relies on misunderstandings of how the tax operates. *See* BI Br. at 31 (incorrectly asserting, despite the IRS Notice to the contrary, that the excise tax applies to "*all* domestic sales of the selected drug," and that the tax reaches "1,900 percent" "of gross sales revenues"); *see also* IRS

Notice at 3 (stating that "tax would be imposed on taxpayer sales of designated drugs dispensed, furnished, or administered to individuals *under the terms of Medicare*" and that the ratio of the tax to the amount charged by the manufacturer, where the tax is not separately invoiced, would be between 65 and 95%—not "1,900 percent," as BI claims (emphasis added)). Here, as in *Larson*—where the Second Circuit held that the plaintiff was required to pay $61 million penalty and then seek refund before pressing Eighth Amendment Excessive Fines Clause claim—BI "has an adequate remedy; [it] simply doesn't like it." 888 F.3d at 589.

Second, in any event, even a showing of irreparable harm would be insufficient to set the AIA aside. *See Williams Packing*, 370 U.S. at 6 ("a suit may not be entertained merely because collection would cause an irreparable injury"); *see also Gallo v. Dep't of Treasury*, 950 F. Supp. 1246, 1249 (S.D.N.Y. 1997) ("Economic injury alone, even to the point of financial 'ruination of the taxpayer's enterprise' will not allow a party to escape application of the Anti–Injunction Act." (quoting *Williams Packing*, 370 U.S. at 6)). BI also would have to show that, "under the most liberal view of the law and the facts," "it is clear that under no circumstances could the Government ultimately prevail" on its defense of the merits. *Williams Packing*, 370 U.S. at 7. A plaintiff can satisfy this second prong only if it establishes "certainty of success on the merits." *Bob Jones Univ.*, 416 U.S. at 737. That is, the government need only show, taking "'the view of the facts that is most liberal to the Commissioner, not to the taxpayer seeking injunctive relief,'" that it *might* prevail. *Laino*, 633 F.2d at 632. This high bar is rarely met. *See, e.g.*, *Williams Packing*, 370 U.S. at 8 (burden not met because government's defense of tax "was not without foundation"); *RYO Mach.*, 696 F.3d at 473 (government's "interpretation of the Code is plausible on its face"); *Laino*, 633 F.2d at 632 ("[C]annot say that the Government has 'no chance of success on the merits'" (citation omitted)); *Greenhouse v. United States*, 738 F. Supp. 709, 712 (S.D.N.Y. 1990) ("[G]overnment has provided enough support for its position to show that it might prevail"). And, for the reasons set forth below, *see infra* at 43-52, it is plainly not met here either. No court, to Defendants' knowledge, has ever held that a tax—let alone one, like the excise tax, lacking any connection to criminal conduct or a criminal proceeding—was a fine for Excessive Fines Clause purposes.

The *South Carolina* exception similarly offers no safe harbor. *See South Carolina v. Regan*, 465 U.S. 367 (1984). That exception is a "very narrow" one that applies only when "Congress has not 'provided an alternative avenue for an aggrieved party to litigate its claims,'" necessitating the party harmed by the tax to find a third party to assert the legal issues. *RYO Mach.*, 696 F.3d at 472. This case is a far cry from "the unique factual pattern" in *South Carolina*. *Id.* at 472 (quoting *Am. Soc. of Ass'n Execs. v. Bentsen*, 848 F. Supp. 245, 250 (D.D.C. 1994)). In *South Carolina*, the state challenged a change in the tax code that stripped certain state-issued bonds of their tax-exempt status. "Because bondholders, not the issuing state or municipality, pay taxes on taxable debt securities, South Carolina could not bring a refund action itself." *Franklin*, 2021 WL 4458377, at *7. Not so here, where BI may raise the same constitutional challenges by "paying the excise tax" and "then suing for a refund." *RYO Mach.*, 696 F.3d at 472. BI nonetheless objects that a "multiplicity of suits" would be required to fully recover any refund due. BI Br. at 34 (citing *Hill v. Wallace*, 259 U.S. 44 (1922)). Again, this assertion ignores the divisible nature of the excise tax and the IRS's policy statement as to the further collection of such taxes during the pendency of a refund suit. It also rests on an approach to the AIA that the Supreme Court abandoned long ago. *See Bob Jones*, 416 U.S. at 742-43 (characterizing the Court's 1922 decision in *Hill* as "the Court's first departure from a literal reading of the" AIA which, "[s]hortly thereafter," "produced a prompt correction in course"). Because a refund suit is available to BI here, the *South Carolina* exception does not apply.

Count 4 seeks to enjoin the assessment and collection of the excise tax. Because neither of the two narrow exceptions to the AIA applies, the Court "lack[s] subject matter jurisdiction over [BI's] Eighth Amendment claim." *Larson*, 888 F.3d at 589.

2. *<u>The DJA Tax Exception Bars Declaratory Relief Regarding The Excise Tax.</u>*

BI's attempt to obtain declaratory relief also fails. "[T]he federal tax exception to the [DJA] is at least as broad as the [AIA]." *Bob Jones Univ.*, 416 U.S. at 733 n.7; *see also Ams. United Inc.*, 416 U.S. at 759 n.10 (same). Accordingly, courts regularly hold that they lack jurisdiction to issue declaratory relief regarding challenged tax provisions. *See, e.g.*, *Larson*, 888 F.3d at 589 (Eighth Amendment claim for equitable relief barred by AIA and DJA tax exception); *Rivero v. Fid. Invs., Inc.*, 1 F.4th 340, 344

(5th Cir. 2021) ("the DJA's federal-tax exception imposes a jurisdictional condition that was not met [and therefore] the district court properly dismissed Rivero's complaint"). Accordingly, declaratory relief is barred for the same reasons that the AIA bars enjoining assessment or collection of the tax.

* * *

In short, multiple independent jurisdictional bars preclude this Court from evaluating the merits of BI's Eighth Amendment claim. That claim should therefore be dismissed.

II. BI'S FIFTH AMENDMENT CLAIMS FAIL ON THE MERITS BECAUSE THE NEGOTIATION PROGRAM IS VOLUNTARY

BI's Fifth Amendment due process and takings challenges follow a familiar playbook. Hospitals, nursing homes, and other providers have, for decades, raised similar arguments against other limits on Medicare reimbursements—and courts of appeals including the Second Circuit have, for decades, rejected such claims. *See, e.g.*, *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) ("All court decisions of which we are aware that have considered [Fifth Amendment] challenges by physicians to Medicare price regulations have rejected them in the recognition that participation in Medicare is voluntary." (collecting cases)); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276, 1279-80 (11th Cir. 2014) (same). The "law established" in those cases "is clear:" because "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice," "the consequences of that participation cannot be considered a constitutional violation." *Chamber*, 2023 WL 6378423, at *11 (citations omitted). And this principle, the *Chamber* court correctly held, applies equally to the Negotiation Program. *Id.*

Contrary to BI's contentions, neither the IRA nor any other part of Medicare "legally compel[s]" manufacturers to negotiate with CMS or to sell their drugs to Medicare beneficiaries. *Id.* "[P]harmaceutical manufacturers who do not wish to participate in the [Negotiation] Program have the ability . . . to opt out" in several different ways. *Id.* Like other Medicare reimbursement limits, the Negotiation Program reflects a valid exercise of Congress's constitutional authority to control the government's spending as a market participant—and raises no Fifth Amendment concerns.

A. <u>The Negotiation Program Does Not Compel Participation</u>

The Due Process and the Takings Clauses of the Fifth Amendment both protect against improper government infringement of "property." U.S. Const. amend. V. But it is well established that a "property owner must be *legally compelled* to engage in price-regulated activity for [those] regulations to" impugn a property interest that the Fifth Amendment protects. *Garelick*, 987 F.2d at 916 (emphasis added); *see, e.g., Bowles v. Willingham*, 321 U.S. 503, 517-18 (1944) (rent controls do not constitute prohibited taking because statute did not require landlords to offer their apartments for rent). When an entity "voluntarily participates in a price-regulated program or activity, there is no legal compulsion to provide service and thus there can be no" deprivation of property. *Garelick*, 987 F.2d at 916 (citing cases); *Franklin Mem'l Hosp.*, 575 F.3d at 129 ("Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking."). And that is the case with limits on Medicare spending, like the kind Congress sought to achieve with the Negotiation Program. *See Chamber*, 2023 WL 6378423, at *11.

As courts have repeatedly explained, "participation in Medicare is voluntary." *Garelick*, 987 F.2d at 917; *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991) ("[P]articipation in the Medicare program is a voluntary undertaking."); *Baptist Hosp. E. v. Sec'y of Health & Hum. Servs.*, 802 F.2d 860, 869-70 (6th Cir. 1986) (same); *see also Baker Cnty.*, 763 F.3d at 1279-80 (surveying cases); *see generally Chamber*, 2023 WL 6378423, at *11 (discussing this precedent). Unlike public utilities, which "generally are compelled" by statute "to employ their property to provide services to the public," no statutory provision *requires* entities to participate in Medicare or to sell their property. *Garelick*, 987 F.2d at 916. So, whether confronting regulations limiting physician fees, nursing-home payments, or hospital reimbursements, courts have been unequivocal: entities are not required to serve Medicare beneficiaries, and thus the government deprives them of no property interest for purposes of the Fifth Amendment when it imposes caps on the amount the government will reimburse. *Baptist Hosp.*, 802 F.2d at 869-70; *see also Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (no taking because plaintiff "voluntarily chose to participate in the Medicare hospice program"); *Baker Cnty.*, 763 F.3d at 1279-80 (rejecting hospital's "challenge [to] its rate of compensation in a regulated industry for an obligation it voluntarily undertook . . . when it opted into Medicare"); *Franklin Mem'l Hosp.*, 575 F.3d at 129-30; *Garelick*, 987 F.2d at 916-19; *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) ("[A]ppellants are not required to treat Medicare patients, and the temporary freeze is therefore not a taking within the meaning of the Fifth Amendment."). If a provider dislikes the conditions offered by the government, it can simply withdraw from the program. *Baptist Hosp.*, 802 F.2d at 869-70. There is no legal compulsion to participate.

The Negotiation Program is no different. *See Chamber*, 2023 WL 6378423, at *11. The IRA regulates neither the prices manufacturers may charge for drugs generally nor the conduct of manufacturers that elect not to participate in Medicare and Medicaid. *See, e.g.*, 42 U.S.C. § 1320f-1(b), (d). Rather, Congress established the Negotiation Program in an effort to reduce how much Medicare pays for selected drugs provided to Medicare beneficiaries. *See id.* § 1320f-2(a)(2). As CMS noted, "the IRA expressly connects a . . . [m]anufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation" in Medicare and Medicaid. Revised Guidance at 120; *see also* 26 U.S.C. § 5000D(c)(1) (providing that tax consequences are only applicable if the manufacturer continues to participate in Medicare and Medicaid). Drug manufacturers that do not wish to make their drugs available to Medicare beneficiaries at negotiated prices can avoid doing so by withdrawing from the Medicare and Medicaid programs. *See Chamber*, 2023 WL 6378423, at *11; *see also* Revised Guidance at 33-34, 120-21, 129-31. Alternatively, a manufacturer can divest its interest in the selected drug to a separate entity—or otherwise stop selling it to Medicare beneficiaries, permanently or temporarily. Revised Guidance at 131-32.

Thus, contrary to BI's claims, manufacturers "are not legally compelled to participate in the Program" or forced to make any sales they don't want to make. *Chamber*, 2023 WL 6378423, at *11. Unlike laws requiring utilities to serve the public, the IRA does not "compel[] [manufacturers] to employ their property to provide [drugs] to" Medicare beneficiaries—at any price. *Garelick*, 987 F.2d at 916. Rather, a manufacturer of a selected drug is *only* required to provide "access" to negotiated prices if it *chooses* to participate in Medicare and make its drugs available for Medicare coverage. As courts have explained in rejecting Fifth Amendment challenges to other Medicare conditions, "[i]f any provider fears that its participation [in the program] will drive it to insolvency, it may withdraw from participation." *Baptist Hosp.*, 802 F.2d at 869-70. That choice is the manufacturer's to make.

B. Manufacturers Have Adequate Opportunity to Withdraw from the Program

Attempting to evade this well-settled (and binding) precedent, BI asserts that the IRA makes it "legally impossible" for manufacturers to withdraw from the Negotiation Program without incurring a sizeable tax or a penalty. BI Br. at 38. This argument rings hollow. BI has not indicated that it wishes to withdraw from the Negotiation Program or from Medicare and Medicaid; to the contrary, BI has signed an agreement to negotiate. *See Manufacturer Agreements* at 1. So the company's complaints about the process for withdrawal are purely academic. *See* BI Br. at 38. But regardless, these arguments fail because BI misunderstands the IRA's terms.

Section 11003 of the IRA provides that manufacturers will incur no tax if they cease participating in Medicare and Medicaid prior to the statutory deadline to enter into an agreement to negotiate—or, if they have initially agreed to negotiate (as manufacturers of all the selected drugs now have), prior to the statutory deadline to enter into a final pricing agreement with CMS. *See* 26 U.S.C. § 5000D(b)(1)-(2) (defining periods when tax would take effect); *id.* § 5000D(c)(1)(A)(i)-(ii) (providing that the excise tax will be suspended "beginning on the first date on which" "none of the drugs of the manufacturer" are covered by Medicare).[3] The Social Security Act (SSA) provides that the relevant Medicare-participation agreements can be terminated by CMS in 30 days for "good cause." *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i). Relying on these provisions, CMS's Revised Guidance explains that if a "[m]anufacturer determines . . . that it is unwilling to continue its participation in the Negotiation Program and provides a termination notice," CMS will treat that determination as providing "good cause to terminate the . . . Manufacturer's agreement(s) . . . and thus facilitate an expedited" termination in 30 days. Revised Guidance at 130. As a result, "any manufacturer that declines to enter an Agreement for the Negotiation Program may avoid incurring excise tax

[3] Section 5000D(c) also conditions suspension of the tax on a manufacturer giving notice of termination of its drug rebate agreement under Medicaid. 26 U.S.C. § 5000D(c)(2).

liability by submitting the notice and termination requests . . . 30 days in advance of the date that excise tax liability otherwise may begin to accrue." *Id.* at 33-34.

That timeline provides manufacturers flexibility to "opt out" of the Negotiation Program. *Chamber*, 2023 WL 6378423, at *11. Manufacturers of the first 10 selected drugs had 34 days to decide whether they wanted to negotiate with CMS before any tax liability (for selling the drug to Medicare without signing an agreement to negotiate) could be triggered. *See* 42 U.S.C. § 1320f(d)(1) (requiring first list of drugs for negotiation to be published by September 1, 2023);[4] 26 U.S.C. § 5000D(b)(1) (tax triggered on October 2, 2023, absent manufacturer signing agreement to negotiate). BI, along with the manufacturers of all the other selected drugs, signed agreements to negotiate. *See Manufacturer Agreements* at 1. Manufacturers will know how those negotiations are going far in advance of August 2, 2024, when they could first be exposed to tax liability if they have not signed a final price agreement. *See* 26 U.S.C. § 5000D(b)(2). And if a manufacturer signs a final price agreement before the statutory deadline, there is still *at least 17 months* before January 1, 2026, when any negotiated prices would first take effect—and any civil penalty (but no tax) could even possibly be triggered. 42 U.S.C. § 1320f-6(a) (providing for civil monetary penalties for failing to honor agreement). During this period, the manufacturer can (with 30 days' notice) withdraw from Medicare and Medicaid or can divest its interest in the selected drug. Revised Guidance at 129-32. In this way, a "manufacturer that has entered into an Agreement [] retain[s] the ability to promptly withdraw from the program prior to the imposition of civil monetary penalties or excise tax liability." *Id.* at 34.

BI fails to grapple with these various options. Instead, BI merely makes passing claims that CMS's use of its own "good cause" authority to provide for the 30-day withdrawal option is "foreclose[d]" by the statutory language. BI Br. at 38. But BI itself argues that the absence of an adequate opportunity to withdraw from the Negotiation Program would be unconstitutional—so it can hardly claim that CMS lacks "good cause" to facilitate manufacturers' withdrawal. *See, e.g.*, *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 143 S. Ct. 1720, 1730 n.2 (2023) ("good cause" is "a uniquely flexible

[4] In fact, the list was published early, on August 29, 2023.

and capacious concept, meaning simply a legally sufficient reason"); *see generally* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i) (providing for "good cause" termination). That may explain why BI has not actually challenged CMS's interpretation, which operates to the manufacturers' benefit, and which BI would therefore lack standing to contest.

Further, even putting aside CMS's Revised Guidance, BI overlooks the 28-month period between a manufacturer's drug(s) being selected for negotiation and the January 2026 effective date for any negotiated prices. Even by BI's logic, this delay gives a manufacturer ample time to notice its termination of the relevant Medicare agreements (something it could do even while otherwise engaged in negotiations) and have that termination take effect. *See* BI Br. at 38 (claiming that notice must be given at least 11 months in advance); 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (providing that a "manufacturer may terminate an agreement under this section for any reason" and that "if the termination occurs before January 30 of a plan year" it shall become effective "as of the day after the end of the plan year").

In short, BI is wrong to claim that the option to withdraw from the Negotiation Program is "legally impossible" or that Congress did not give manufacturers a genuine choice about whether to sell their drugs at negotiated prices. BI Br. at 38. The choice "to opt out" of the Negotiation Program is real. *Chamber*, 2023 WL 6378423, at *11.

C. <u>The Negotiation Program Does Not "Coerce" Manufacturers</u>

Unable to show that any manufacturer is *legally* compelled to participate in the Negotiation Program, BI tries a workaround. Noting that business realities make it difficult to forego Medicare and Medicaid, BI argues that the Negotiation Program is not voluntary in a practical sense and amounts to "severe economic coercion." BI Br. at 34-37. But this line of argument fares no better.

1. Courts—including the Second Circuit—have clearly held that economic or other practical "hardship is not equivalent to legal compulsion for purposes of" a Fifth Amendment analysis, including in the Medicare context. *Garelick*, 987 F.2d at 917; *see also St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (the "fact that practicalities may in some cases dictate participation does not make participation involuntary"). Even where "business realities" create "strong financial inducement to participate"—such as, for example, when Medicaid provides the vast majority of a nursing home's revenue—courts have emphasized that the decision to participate in the program "is nonetheless voluntary." *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). So the amount of BI's "net sales" to Medicare is completely irrelevant to the voluntariness analysis. BI Br. at 35. As Judge Newman correctly recognized in *Chamber*, this precedent makes clear that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice." *Chamber*, 2023 WL 6378423, at *11 (discussing cases); *see also Baker Cnty.*, 763 F.3d at 1280.

Notably, BI fails to identify *a single* case agreeing with the premise that "manufacturers are *effectively* 'compelled'" to participate in Medicare due to the program's lucrative nature. BI Br. at 39 (emphasis altered). For good reason. Congress enacted Medicare, and imposed conditions on participation, pursuant to its Spending Clause powers. "Unlike ordinary legislation, which imposes congressional policy on regulated parties involuntarily, Spending Clause legislation operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions." *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022) (internal quotes and citation omitted). A party cannot be coerced by such an offer because there is no "right (or requirement)" to conduct business with the government in the first instance. *Chamber*, 2023 WL 6378423, at *11; *see, e.g.*, *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("[P]articipation in the federal Medicare reimbursement program is not a property interest."). "[N]o one has a 'right' to sell to the government that which the government does not wish to buy." *Coyne-Delany Co. v. Cap. Dev. Bd. Of Ill.*, 616 F.2d 341, 342 (7th Cir. 1980); *see also Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940) (government has authority to "determine those with whom it will deal"); *J.H. Rutter Rex Mfg. Co. v. United States*, 706 F.2d 702, 712 (5th Cir. 1983) (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"). Just as defense contractors that derive a substantial portion of their revenues from the Department of Defense are free to refuse contracts they find unprofitable, so too drug manufacturers can walk away from the Negotiation Program—even if doing so comes at a cost.

This fact distinguishes Medicare from *regulatory* cases like the ones BI cites in its brief and on which it builds its coercion theory. BI Br. at 36-39; *Horne*, 576 U.S. at 366; *Valancourt Books, LLC v. Garland,* 82 F.4th 1222 (D.C. Cir. 2023); *Thompson v. Deal*, 92 F.2d 478 (D.C. Cir. 1937); *Union Pacific R.R. Co. v. Public Service Comm'n of Mo.*, 248 U.S. 67 (1918). Plaintiffs in each of those cases were subject to regulatory regimes they could not readily exit—and had to comply with the government's conditions if they wished to sell their products to *anyone*. *See Horne*, 576 U.S. at 365-66 (raisin growers could not avoid government property demand if they wished to continue selling raisins); *Valancourt*, 82 F.4th at 1239 (holder of copyright was subject to "a demand letter indicating no option other than surrendering the property at issue"); *Thompson*, 92 F.2d at 480 (statute fixed the quota of cotton production); *Union Pacific*, 248 U.S. at 67 (plaintiff was subject to statutory prohibitions against issue of a bond unless the prohibition was waived by a state commission). By contrast, the IRA does not prevent manufacturers who are unwilling to participate in the Negotiation Program from selling their drugs to anyone but the government—and those manufacturers would then not need to comply with any of the Negotiation Program's requirements. *See Chamber*, 2023 WL 6378423, at *11. That makes the Program voluntary, and valid.[5]

2. Trying a different tack, BI seeks to analogize the Negotiation Program to the Medicaid expansion in the Affordable Care Act, which the Supreme Court found to be impermissibly "coercive" in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*). BI Br. at 35-36. But this line of argument reflects a basic misunderstanding of *NFIB*, on several levels.

***First*,** the *NFIB* "coercion" framework addresses—and is derived exclusively from cases analyzing—how *federalism* principles inform what conditions Congress may attach to money it grants *to States*. *See NFIB*, 567 U.S. at 579-81 (discussing, *inter alia*, *South Dakota v. Dole*, 483 U.S. 203 (1987)). As the lead opinion in *NFIB* emphasizes, those principles protect "the status of the States as

[5] This same fact defeats BI's suggestion that *Garelick* is "inconsistent" with *Horne*. BI Br. at 39. *Garelick* established the principle that a party lacks a property interest in participation in the Medicare program, and *Horne* casts no doubt on that analysis. In any event, this Court remains bound by Second Circuit precedent. *See Monsanto v. United States*, 348 F.3d 345, 351 (2d Cir. 2003). Nor is there any merit to BI's attempt to cabin *Garelick*'s analysis only to takings claims, BI Br. at 39; the absence of any property interest is fatal to all of BI's Fifth Amendment arguments.

independent sovereigns in our federal system." *Id.* at 577. These federalism-based principles are inapposite in evaluating whether Congress has overstepped its enumerated powers in dealing with private corporations like BI. *See, e.g.*, *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 869 n.5 (8th Cir. 2021) (explaining that *NFIB* "coercion" inquiry "describe[s] the federal government's limited constitutional authority under the Spending Clause to regulate the states, . . . not a federal agency's ability to regulate [private] facilities' use of federal funding"), *cert. denied*, 143 S. Ct. 294 (2022); *see also Northport Health Servs. of Ark., LLC v. HHS*, 438 F. Supp. 3d 956, 970-71 (W.D. Ark. 2020) ("No part of the Court's decision in *NFIB* touched on the government's power to place conditions on private entities.").

Second, inquiring whether Congress has improperly used federal spending to regulate—which is what the *NFIB* "coercion" inquiry analyzes—does not make sense when, rather than using grant conditions to "encourag[e]" States to modify their benefit programs to satisfy federal criteria, Congress has merely set terms for how the federal government will pay for goods in the market. 567 U.S. at 580-81 (quoting *New York v. United States*, 505 U.S. 144, 175 (1992)). Such terms do not seek to end-run limits on Congress's regulatory powers—and any "pressure" Congress may exert through such terms is no different than the leverage of any well-funded market participant, which is of no constitutional import. *Id.* (discussing "coercion" as a limit on Congress's ability to achieve through spending what it cannot achieve directly through regulation). Indeed, the Supreme Court has "long held the view 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) (quoting *Cafeteria & Restaurant Workers v. McElroy,* 367 U.S. 886, 896 (1961)). "Where the government is acting as a proprietor, managing its internal operations, rather than acting as lawmaker with the power to regulate or license, its action will *not* be subjected to the heightened review to which its actions as a lawmaker may be subject." *Int'l Soc. for Krishna Consciousness, Inc. v. Lee*, 505 U.S. 672, 678 (1992) (emphasis added); *Ridley v. Mass. Bay Transp. Auth.*, 390 F.3d 65, 79 (1st Cir. 2004) ("[A] lower level of scrutiny usually applies when the government acts as proprietor."). And because "the Government unquestionably is the proprietor of its own funds, [] when it acts to ensure the most effective use of those funds," such as by setting conditions on their disbursement, "it is acting in a proprietary capacity." *Bldg. & Const. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 35 (D.C. Cir. 2002).

Economical and equitable procurement in the market is exactly what Congress sought with the Negotiation Program. Recognizing that American taxpayers spend far too much on high-cost prescription drugs—more than people in any comparable country, for the same drugs—Congress has taken steps to limit how much the government will pay for selected drugs going forward. These steps to limit government spending on selected drugs reflect a valid exercise of Congress's power to "control" federal "spen[ding] according to its view [that] the 'general Welfare'" is best served by reducing taxpayer expenditure on high-cost pharmaceuticals. *NFIB*, 567 U.S. at 579-80; *cf. Sabri v. United States*, 541 U.S. 600, 608 (2004) ("The power to keep a watchful eye on expenditures . . . is bound up with congressional authority to spend in the first place."). Such spending conditions are "justified on that basis"—and give rise to no *NFIB*-style "coercion" concerns. *NFIB*, 567 U.S. at 579-80.

Third, and finally, the Negotiation Program would not be "coercive" under *NFIB*'s test even if that test were applicable. As the lead opinion in *NFIB* explained, the Spending Clause permits Congress to place "restrictions on the use of [] funds, because that is the means by which Congress ensures that the funds are spent according to its view of the 'general Welfare.'" *Id.* at 580. Such direct restrictions are not subject to *NFIB*'s coercion inquiry. *Id.* at 580-81, 584; *see also Miss. Comm'n on Env't Quality v. EPA*, 790 F.3d 138, 179 (D.C. Cir. 2015) (discussing this framework). And here, the Negotiation Program directly "govern[s] the use of" Medicare funds for the selected drugs. As noted above, the conditions Congress established in the Negotiation Program merely constitute limits on how much the government will spend for the drugs CMS selects for negotiation. If a manufacturer does not wish to comply with those limits, it can avoid them by, for example, divesting its interest in the drug. *See* Revised Guidance at 131-32.

Notably, manufacturers *also* have the option of leaving Medicare and Medicaid entirely. For some manufacturers—particularly those that own only one drug—that may be a more straightforward option. But contrary to BI's characterization, the availability of this second choice does not mean that

Congress has offered manufacturers anything improper. BI Br. at 35-36. Congress routinely conditions Medicare and Medicaid funding on parties observing terms that reach beyond the specific products or services that Medicare reimburses. *See, e.g.*, *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113-16 (2011) (describing the 340B program under 42 U.S.C. § 1396r-8(a)(1), which requires participating drug manufacturers to give steep discounts to various categories of private purchasers); *see also Baker Cnty.*, 763 F.3d at 1277-78 (noting that, "[a]s a condition of participating in and receiving payments from Medicare, a hospital must also opt into EMTALA," which generally "requires participating hospitals to provide care to anyone who visits an emergency room"). Similarly, Congress has long required drug manufacturers wishing to participate in Medicaid to enter into agreements with the VA Secretary, which make those manufacturers' covered drugs available for procurement by the VA and other agencies at or below statutory ceiling prices. *See* 38 U.S.C. § 8126(a)-(h). These arrangements have never been found to trigger coercion concerns, and rightly so: suggesting that Medicaid and Medicare conditions can coerce private parties would be contrary to decades of precedent holding that acceptance of such conditions is fully voluntary. *See, e.g.*, *Baker Cnty.*, 763 F.3d at 1278-79. BI provides no basis to believe that *NFIB* upset that settled law.

Indeed, both before and after *NFIB*, courts have uniformly rejected the idea that the lucrative nature of Medicare and Medicaid coerces private parties to accept any conditions. *See, e.g.*, *id.* at 1280 ("Although the Hospital contends that opting out of Medicare would amount to a grave financial setback, 'economic hardship is not equivalent to legal compulsion . . . .'" (quoting *Garelick*, 987 F.2d at 917)); *Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 209-10 (D.N.J. 2021), *rev'd in part on other grounds*, 58 F.4th 696 (3d Cir. 2023); *see also Minn. Ass'n*, 742 F.2d at 446 (holding that a "strong financial inducement to participate" in a regulated program does not render such participation involuntary); *St. Francis Hosp.*, 714 F.2d at 875. Notably, the Supreme Court itself recently rejected such an argument when it upheld a COVID-19 vaccination requirement for workers in facilities funded by Medicare or Medicaid, emphasizing that "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions"—despite the challengers arguing that those conditions were coercive under *NFIB*. *Biden v. Missouri*, 142 S. Ct. 647, 652 (2022); *see Becerra* *v. Louisiana*, Nos. 21A240, 21A241, Resp. to Stay App. at 27, 2021 WL 8939385 (Dec. 30, 2021) (arguing that the vaccination "condition was impermissibly coercive because the consequence of opting out would be the loss of *all* Medicare and Medicaid funds" (emphasis in original) (citing *NFIB*, 567 U.S. at 580-81)).

* * *

By telling manufacturers that Medicare might not continue paying manufacturers at current levels for their products, Congress has left them free to choose whether they wish to continue selling the drug to Medicare on new terms. That is not coercion: it is simply an offer made by a buyer to a seller who can then either agree or forgo the sale.

D. The Negotiation Program Is a Proper Condition on Medicare and Medicaid Participation

In a final attempt to avoid the conclusion that the Negotiation Program is "completely voluntary" and thus raises no Fifth Amendment concerns, *Chamber*, 2023 WL 6378423, at *11, BI asserts that making the program a condition of Medicare and Medicaid participation violates the unconstitutional-conditions doctrine. BI Br. at 39-40. BI bases this claim on its assertion that Congress has improperly required BI to surrender due process and takings protections to receive a government benefit. *Id.* But, like BI's other claims, this one collapses upon examination.

1. The unconstitutional-conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). At a minimum, then, the "predicate for any unconstitutional conditions claim" is the existence of a protected constitutional right that the government's offer would infringe. *Id.* at 612; *see also Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.* (*FAIR*), 547 U.S. 47, 59-60 (2006) ("It is clear that a funding condition cannot be unconstitutional if it could be constitutionally imposed directly."); *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005) (explaining that while the unconstitutional conditions "doctrine should equally apply to prohibit the government from conditioning benefits on a citizen's agreement to surrender due process rights," the plaintiff must first establish the existence of such a right). And when it comes to an assertion that the government has improperly conditioned a benefit on an entity's surrender of its due process rights, the cases BI itself cites make clear that plaintiffs must first establish the existence of a "liberty or property interest" that the Due Process Clause would protect. *Keego Harbor*, 397 F.3d at 434; *see also Vance v. Barrett*, 345 F.3d 1083, 1090 (9th Cir. 2003) (same). That is, a Plaintiff must demonstrate that the government is seeking to leverage a discretionary benefit against a *separate* vested property interest. *See, e.g.*, *Keego Harbor*, 397 F.3d at 434 (finding that plaintiffs had stated a plausible unconstitutional conditions claim when they alleged that "Defendants withheld certain administrative approvals from it unless it agreed to close" earlier than the regulations governing its liquor license permitted).

Here, however, BI can identify no distinction between the benefit and the right that is supposedly being leveraged. As BI itself explains, the valuable "government benefit" it seeks is continued "Medicare and Medicaid participation" and making sales of its drugs to Medicare beneficiaries. BI Br. at 41. BI appears to recognize that this is not a benefit the government is required to provide—and rightly so. *Id.* As detailed further in the next section, *see infra* at 36-38, BI has no vested right to conduct business with the government at all, and no vested property right to continue participating in Medicare. *Chamber*, 2023 WL 6378423, at *11; *see, e.g.*, *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("[P]articipation in the federal Medicare reimbursement program is not a property interest."). What then is the vested property interest that BI claims Congress is leveraging in exchange for that benefit? In BI's telling, it is the *procedural* right to ensure that the government fairly sets the price for *those very sales to Medicare*, to ensure that they are not unfairly low. *See* BI Br. at 13–17. This argument is completely circular. BI is not claiming that there are free-standing commercial sales that the government is seeking to regulate in exchange for some benefit. *See id.* at 41. Rather, the lack of process they claim as a violation of their rights concerns the *very same Medicare sales* that BI is seeking as a benefit.

Not surprisingly, BI identifies no case that bootstrapped an unconstitutional conditions theory in this manner. The company's argument amounts to nothing more than the idea that the government denies manufacturers a constitutional right by not structuring a benefit in the way that manufacturers like. To state this theory is to refute it. The Supreme Court has "never held that the [government] must grant a benefit . . . to a person who wishes to exercise a constitutional right." *Regan v. Tax'n with*

Representation of Wash., 461 U.S. 540, 545 (1983); *see also J.H. Rutter*, 706 F.2d at 712 (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"). Just as a government contractor cannot claim that the denial of a contract improperly infringed on his procedural rights to negotiate that contract, so too the government cannot be said to violate the unconstitutional conditions doctrine by offering allegedly inadequate procedures for negotiating the price that the government will pay for manufacturers' drugs.

2. BI's attempt to invoke the unconstitutional conditions doctrine in a Fifth Amendment takings framework are similarly unavailing. BI's central claim on this ground is that there is "no rough proportionality" between the Negotiation Program and the benefit of participating in Medicare generally. BI Br. at 41. But this effort to apply a "proportionality" test is irreconcilable with Supreme Court precedent.

The Supreme Court has explicitly rejected extending the "rough proportionality" test BI advocates—which comes from a pair of land-use cases, *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 834-37 (1987) and *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994)—beyond "the special context of [] 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). Indeed, the *Koontz* case BI itself cites makes clear that the *Nollan* and *Dolan* test is reserved for the "'special application' of . . . land-use permits." *Koontz,* 570 U.S. at 604 (discussing the doctrine); *Lingle v. Chevron USA Inc.*, 544 U.S. 528, 538 (2005) (noting the "special context of land-use exactions"). That is for good reason. The "realities of the permitting process" render applicants "especially vulnerable" to the government's demands "because the government often has broad discretion to deny a permit that is worth far more than property it would like to take." *Koontz,* 570 U.S. at 604-05. Evaluating whether a land-use exaction is "proportional[]" to the governmental benefit thus ensures that the condition is part of a voluntary exchange. *Id.*; *see also Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) (explaining this framework).

By contrast, no such proxy tests are necessary or appropriate when Congress merely sets the terms on which the government will do business—business to which the party has no free-standing entitlement and that it can freely decline. Courts do not, for example, superintend government contracts to ensure that they are voluntary and provide contractors sufficient compensation or benefit to avoid a Fifth Amendment taking. *See, e.g.*, *St. Christopher Assocs., L.P. v. United States*, 511 F.3d 1376, 1385 (Fed. Cir. 2008) ("In general, takings claims do not arise under a government contract because . . . the government is acting in its proprietary rather than its sovereign capacity" and any right to compensation has "been voluntarily created" (citations omitted)). BI may be unhappy that Congress created the Negotiation Program as a condition of future Medicare and Medicaid participation. But BI's dissatisfaction does not mean that the condition is improper in a constitutional sense.

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Simply put, BI cannot establish that the Negotiation Program is anything other than "completely voluntary." *Chamber*, 2023 WL 6378423, at *11. And because "there is no legal compulsion to" participate, "there can be no" Fifth Amendment violation. *Garelick*, 987 F.2d at 916.

III. <u>BI's Fifth Amendment Challenges Fail Because the Negotiation Program Does Not Deprive BI of a Vested Property Interest</u>

Even setting aside the voluntary nature of the Negotiation Program—and the settled precedent rejecting Fifth Amendment challenges to Medicare reimbursement caps—BI's takings and due process claims still fail even as articulated. Contrary to BI's claims, the IRA does not require manufacturers to surrender their drugs—and manufacturers have no property interest in their current level of Medicare reimbursement that could form the basis of a due process challenge.

A. <u>The Negotiation Program Is Not a Physical Taking of BI's Drugs</u>

The Supreme Court has established that "a plaintiff seeking to challenge a government regulation as an uncompensated taking of private property may proceed under one of [several] [] theories[:] . . . by alleging a 'physical' taking . . . [a] 'regulatory taking' . . . or a land-use exaction." *Lingle*, 544 U.S. at 548. BI does not—and cannot—allege a regulatory taking: such takings are evaluated on an "ad hoc" basis, and thus are not suitable for the kind of facial challenge that BI has brought. *E. Enters. v. Apfel*, 524 U.S. 498, 523 (1998); *see also Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467, 525 (2002) (noting that takings questions are raised by actual rates, not rate-setting methods). Attempting to evade this bar, BI asserts that the Negotiation Program "effect[s] a *physical* taking of [its] property." BI Br. at 20 (emphasis added). But the Negotiation Program in no way forces manufacturers to surrender their drugs—to the government or to anyone else—and thus bears no resemblance to a "classic" or "physical" taking.

As the Supreme Court has explained, a "classic taking [is one] in which government directly appropriates private property or ousts the owner from his domain." *Lingle*, 544 U.S. at 539. With such takings, the owners "lose the entire 'bundle' of property rights" in a way they do not through regulations. *Horne*, 576 U.S. at 361-62; *see also Cedar Point*, 141 S. Ct. at 2074 (noting the distinction); *Lingle*, 544 U.S. at 539 ("[P]ermanent physical invasion, however minimal the economic cost it entails, eviscerates the owner's right to exclude others . . . perhaps the most fundamental of all property interests."). So even where a "physical taking" and a "regulatory limit . . . may have the same economic impact," a "distinction flows naturally from the settled difference in our takings jurisprudence between appropriation and regulation" that does not allow a court to equate the two. *Horne*, 576 U.S. at 362; *see also Cedar Point*, 141 S. Ct. at 2072 ("The essential question is . . . whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's ability to use his own property.").

Here, there is no "physical appropriation" at all. *Cedar Point*, 141 S. Ct. at 2074. Unlike the Department of Agriculture in *Horne*, CMS will not "sen[d] trucks to [BI's] facility at eight o'clock one morning to" haul away drugs. *Horne*, 576 U.S. at 356. And, contrary to BI's insistent claims, the IRA does not require manufacturers to provide "access" to their drugs against their will. BI. Br. at 21-22. Neither the formulary provision BI cites—which defines circumstances when insurance plans contracting with Medicare are to provide coverage for the selected Part D drugs, 42 U.S.C. § 1395w-104(b)(3)(I)[6]—nor anything else in the IRA requires manufacturers to *make sales* in the first instance. *Contra* BI Br. at 22.

[6] This provision actually offers a *benefit* to manufacturers: that is, a selected drug is guaranteed inclusion in the formulary of all Medicare Part D plans, but only if the manufacturer reaches an agreement with CMS as to the maximum fair price of the drug. 42 U.S.C. § 1395w–104(b)(3)(I)(i). Contrary

What the IRA provides, instead, is that a manufacturer who signs an agreement for a negotiated price will be expected "to provide access *to such price*" for any sales to Medicare beneficiaries. 42 U.S.C. § 1320f-2(a)(1), (a)(3) (emphasis added). Rather than requiring manufacturers to give Medicare beneficiaries *physical* "access" to drugs, this provision merely establishes the prices at which any such sales *may* be made. *Cedar Point*, 141 S. Ct. at 2072. The "penalty" provisions about which BI complains, BI Br. at 23, thus only attach if a manufacturer provides drugs to Medicare beneficiaries at prices *above* those negotiated with CMS. *See* 42 U.S.C. § 1320f-6(a) (penalties apply for failure to "provide access to a *price*" (emphasis added)). There is no penalty (or tax liability) for not *selling* the drugs in the first place. *Id.* BI's physical taking arguments therefore run aground on the "settled difference in [] takings jurisprudence between appropriation and regulation"—a distinction that the Supreme Court has relied upon even when the two may "have the same economic impact." *Horne*, 576 U.S. at 362. And BI's efforts to conflate "access" to *prices* with "access" to *drugs*—which they do by omitting critical parts of the statutory language—betrays the conceptual problem with their physical takings theory writ large. BI Br. at 22.

In any event, even if Congress *had* forced manufacturers to sell their drugs or otherwise "compelled [manufacturers] to employ their property to provide [drugs] to the public," that would (at worst) place those companies in a position similar to public "utilities." *Garelick*, 987 F.2d at 916. Yet the Supreme Court has not treated utility rate-setting as *physical* takings. *See, e.g.*, *Verizon*, 535 U.S. at 524-27; *see also Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307-15 (1989) (discussing evolution of takings jurisprudence with respect to public utilities). That makes sense: imposing limits on rates that utilities may charge customers does not deprive those utilities of the whole "bundle" of rights that are lost when the government physically seizes or invades property. *See, e.g.*, *Horne*, 576 U.S. at 361. And when it comes to utility ratemaking, the Supreme Court has rejected facial challenges to statutory rate-setting methodologies, explaining that "the general rule is that any question about the constitutionality of ratesetting is raised by rates, not methods." *Verizon*, 535 U.S. at 525. BI, of course, is not challenging

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to BI's claims, that statutory provision does not require manufacturers to *make* sales—it merely states that insurance providers shall cover the drugs that manufacturers do, in fact, agree to sell. *See id.*

any "particular, actual . . . rate" yet—nor can it do so. *Id.* at 523-24. The negotiation schedule has barely started; the results of those negotiations are as yet unknown.

This uncertainty would have foreclosed any attempt BI might have made to proceed under a regulatory taking theory. As the Supreme Court has explained, "Government regulation often 'curtails some potential for the use or economic exploitation of private property' . . . and 'not every destruction or injury to property by governmental action has been held to be a taking in the constitutional sense.'" *E. Enters.*, 524 U.S. at 523 (citations omitted). "In light of that understanding, the process for evaluating a regulation's constitutionality . . . is essentially ad hoc and fact intensive," and does not lend itself to broad categorical rules. *Id.*; *see also Lingle,* 544 U.S. at 548. It is thus not surprising that BI expressly eschews a regulatory taking theory. *See* BI Br. at 20 n.14 (explaining that because "BI brings *only* a physical takings claim, the Court need not consider the factors involved in the . . . regulatory takings" analysis (emphasis added)). But BI fares no better with the theory it brought.

B. <u>BI's Due Process Theory Fails Because Manufacturers Have No Property Interest in Future Medicare Sales</u>

Similarly meritless is BI's claim that it is being deprived "of life, liberty, or property, without due process of law," U.S. Const. amend. V. *See* BI Br. at 11.

The threshold "inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest." *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). A protected property interest arises where an individual has "a legitimate claim of entitlement" to a particular benefit, not merely a "unilateral expectation" or "abstract need or desire" for it. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). These property interests are "not created by the Constitution, 'they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law.'" *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 538 (1985) (quoting *Roth*, 408 U.S. at 577). As a result, "a party cannot possess a property interest in the receipt of a benefit when the state's decision to award or withhold the benefit is wholly discretionary." *Med Corp. v. City of Lima,* 296 F.3d 404, 409 (6th Cir. 2002). Rather, "to establish a constitutionally protected property interest," plaintiff "'must point to some policy, law, or mutually explicit understanding that both confers the benefits and limits the discretion of the [government] to rescind'" it. *Keego Harbor*, 397 F.3d at 435 (quoting *Med Corp.*, 296 F.3d at 410).

As explained above, the Negotiation Program does not deprive manufacturers of any interest in their physical drugs. And, contrary to BI's claims, manufacturers do not have an inherent entitlement—and therefore do not have a property interest—in selling their drugs to Medicare at any particular price. *Contra* BI Br. at 12 (claiming that BI has a "right . . . to fix the price at which [it] will sell" its products (quoting *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936)). "The Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases." *Nebbia v. People of State of New York*, 291 U.S. 502, 527-28 (1934); *see also Chamber*, 2023 WL 6378423, at *11. And that is even more obviously true when the business in question operates in a heavily regulated space or requires an outlay of taxpayer funds. *See, e.g.*, *Monsanto*, 467 U.S. at 1006-07; *see also Minn. Ass'n*, 742 F.2d at 446-47 (hospitals that "serve medical assistance recipients have no constitutional right to be free from [government] controls on the rates they charge [patients] who do not receive medical assistance"). Thus, as the *Chamber* court correctly recognized, no one is entitled to conduct business with the government in the first instance. *Chamber*, 2023 WL 6378423, at *11; *see also Coyne-Delany*, 616 F.2d at 342 ("[N]o one has a 'right' to sell to the government that which the government does not wish to buy."); *Perkins*, 310 U.S. at 127 (government has authority to "determine those with whom it will deal"); *J.H. Rutter*, 706 F.2d at 712 (rejecting government contractor's claim for "Fifth Amendment property entitlement to participate in the awarding of government contracts"). By extension, as courts have repeatedly emphasized, no one has a property interest in future Medicare sales. *See, e.g.*, *Shah*, 920 F.3d at 998 ("[P]articipation in the federal Medicare reimbursement program is not a property interest."); *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013) ("[P]roviders do not have a property interest in a particular reimbursement rate."); *Painter v. Shalala*, 97 F.3d 1351, 1358 (10th Cir. 1996) (physician has no property interest in "having his [Medicare] reimbursement payments calculated in a specific manner").

Indeed, crediting BI's claim that manufacturers have a protected property interest in Medicare sales would mean that the manufacturers have a *constitutional* right to dictate the government's expenditures. But it is well established that "Congress may attach appropriate conditions to federal taxing and spending programs to preserve its control over the use of federal funds." *NFIB*, 567 U.S. at 579; *see also Sabri*, 541 U.S. at 608. Not surprisingly, then, courts have explicitly rejected the core premise of BI's theory, noting that "those who opt to participate in Medicare are not assured of revenues." *Livingston Care Ctr.*, 934 F.2d at 721. Just as a defense contractor could not build an aircraft carrier and force an unwilling Pentagon to buy it (at any price), so too manufacturers cannot force their drugs onto the government at unilaterally dictated rates.

Trying to evade this principle, BI asserts that the Negotiation Program implicates its property interest in "confidential data" that it is required to submit to CMS. BI Br. at 13. But, contrary to BI's assertion, the mere submission of data does *not* deprive manufacturers of property rights in that data. BI has not alleged, for example, the agency intends to disseminate the data without observing confidentiality or otherwise compromise BI's interests in that data. *See, e.g.*, *Monsanto*, 467 U.S. at 1000-01 (company's proprietary rights in data implicated by the agency's "disclosure of the data to [] members of the public"). To the contrary, the Revised Guidance makes clear that CMS will observe the proprietary nature of the data it receives and afford that data appropriate protections. *See, e.g.*, Revised Guidance at 33 ("CMS will protect the confidentiality of any proprietary information from Primary Manufacturers or Secondary Manufacturers . . . as required under section 1193(c) of the Act and other applicable law."); *id.* at 123 ("CMS will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information[.]"). So the submission of data, by itself, does not deprive BI of the bundle of rights in that data. *See, e.g.*, *Monsanto*, 467 U.S. at 1011 (because "the right to exclude others is central to the very definition of the property interest," the holder "of the trade secret has lost his property interest in the data" when "the data that constitute a trade secret are disclosed to others, or others are allowed to use those data"). Indeed, although entities participating in Medicare routinely provide data to the government, BI cites no case holding that the submission of such data to CMS presents Fifth Amendment concerns. *See, e.g.*, 42 U.S.C. § 1396r-8(b)(3) (requiring participating manufacturers to report drug pricing data).

More to the point, none of the procedures that BI challenges as supposedly inadequate concern the proprietary data it submits—rather, those procedures *all* relate to the "prices" the IRA authorizes CMS to negotiate for BI's drugs. *See* BI Br. at 14-18; *see also id.* at 17 (alleging that the IRA "will deprive BI of valuable property interests" by allowing "CMS[] [to] dictat[e] *prices* for selected drugs" (emphasis added)). Indeed, BI does not identify a single procedure related to *data* protection. *Id.* at 14-19. This confirms that the only "deprivation" BI alleges concerns Medicare reimbursement rates—something in which it lacks a property interest at all.

In the absence of a protected property interest, BI's due process claim collapses. *See, e.g.*, *Keego Harbor*, 397 F.3d at 434 ("In order to assert a valid due process claim . . . a plaintiff must establish that the interest asserted is a liberty or property interest."). For that reason, there is no need for the Court to address the due-process balancing test set forth in *Mathews v. Eldridge*, 424 U.S. 319 (1976). BI Br. at 17. Simply put, the IRA cannot deprive BI of due process of law in setting the price for Medicare sales when BI has no protected property interest in those sales to begin with. *See, e.g.*, *Roth,* 408 U.S. at 578 (untenured professor, whose appointment was for only one year, did not possess a protected property interest in his continued employment, and university was therefore not required "to give him a hearing when they declined to renew his contract of employment").

IV. BI'S FIRST AMENDMENT CHALLENGE FAILS BECAUSE THE NEGOTIATION PROGRAM DOES NOT COMPEL MANUFACTURERS TO SPEAK

BI's First Amendment claim similarly lacks merit. That challenge rests entirely on BI's unsupported assertions that the agreements manufacturers sign with CMS constitute improperly "compelled" "speech," and thus violate the First Amendment. BI Br. at 25. But this is not true.

1. As an initial matter, reaching an agreement with CMS is not speech, nor is it expressive conduct. Any "speech" that may ordinarily be implicated in the execution of a commercial contract "is plainly incidental to the . . . regulation of conduct" that the contract governs. *FAIR*, 547 U.S. at 62. And the regulation of conduct "has never been deemed an abridgment of freedom of speech . . . merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Id.* (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502

(1949)). Medicare routinely uses agreements that health care providers and other entities may sign to memorialize their voluntary acceptance of the terms for participation in the program; those agreements do not signify providers' endorsement of, for example, the general fairness of the Medicare rate-setting process. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b), (c). The agreements memorializing manufacturers' acceptance of the terms for participation in the Negotiation Program are no different.

A manufacturer that chooses to sign an agreement with CMS undertakes a voluntary obligation to negotiate prices and, ultimately, to provide Medicare beneficiaries with access to the negotiated prices for the selected drugs that the manufacturer sells. *See* Revised Guidance at 118-20; *see also* CMS, Medicare Drug Price Negotiation Program Agreement, https://perma.cc/6VG4-KKF6 (Template Agreement). This does not implicate the First Amendment any more than "typical price regulation," which "would simply regulate the amount [of money] that a [manufacturer] could collect." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). Indeed, courts have confirmed again and again that "ordinary price regulation does not implicate constitutionally protected speech," *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019) (citing *Expressions Hair Design*, 581 U.S. at 47); *see also Campbell v. Robb*, 162 F. App'x 460, 468 (6th Cir. 2006) (recognizing "the general principle that government retains its full power to regulate commercial transactions directly, despite elements of speech and association inherent in such transactions" (citation omitted)). In the same way, because the requirement that a participating manufacturer sign an agreement "is imposed 'for reasons unrelated to the communication of ideas,'" that requirement does "not implicate the First Amendment." *Nicopure*, 944 F.3d at 291 (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001)); *see also Expressions Hair Design*, 581 U.S. at 47 (where a "law's effect on speech would be only incidental to its primary effect on conduct," the law is not a regulation of speech subject to First Amendment scrutiny).

The fact that the negotiation agreement "is not inherently expressive," *FAIR*, 547 U.S. at 64, is "underscored by [the agreement's] bearing only on product price," *Nicopure*, 944 F.3d at 292. The terms of the agreement explicitly state what is already apparent: a manufacturer's signature constitutes neither an "endorsement of CMS' views" nor a representation of the manufacturers' views concerning the fairness of prices. *See* Template Agreement at 4 (explaining that, by "signing this Agreement, the

Manufacturer does not make any statement regarding or endorsement of CMS' views"). Lest there be any doubt, the agreement affirms that the use "of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." *Id.*[7] In other words, the agreement uses statutory terms merely as a way of clarifying the parties' respective obligations.

This commercial arrangement is nothing like regulations requiring expressive conduct, which is what was at issue in the cases BI cites. *See, e.g.*, *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps., Council 31*, 138 S. Ct. 2448, 2464 (2018) (holding that requiring public employees to pay union fees violated their free speech rights); *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 559 (1995) (analyzing whether state "may require private citizens who organize a parade to include among the marchers a group imparting a message the organizers do not wish to convey"); *see generally* BI Br. at 26. The agreement to negotiate does not require manufacturers "to utter or distribute speech bearing a particular message," *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642 (1994), or to say anything about any agreed-upon prices. Nor does the agreement restrict manufacturers' ability to say whatever they wish about the Negotiation Program or to criticize CMS or the IRA.

A manufacturer may, of course, have numerous reasons for signing or not signing an agreement with CMS, and some of those reasons may pertain to views that it holds or wants to communicate to others. But a manufacturer's views regarding the IRA or negotiated prices "do[] not convert all regulation that affects access to [selected drugs] into speech restrictions subject to First Amendment scrutiny." *Nicopure*, 944 F.3d at 291. *Cf. 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

[7] There is no merit to BI's claim that the "disclaimer exacerbates" the constitutional problem by "compel[ling] *more* speech." BI Br. at 29-30 (emphasis in original). The government, no less than a commercial party, is free to emphasize an already obvious point. Contracts do this routinely. BI cites no canon of construction supporting its view that doing so underscores a contract's expressive nature. *See id.*

bring the activity within the protection of the First Amendment."). Signing an agreement to negotiate "is simply not the same as forcing a student to pledge allegiance to the flag . . . or forcing a Jehovah's Witness to display a particular motto on his license plate . . . and it trivializes the freedom protected in [those circumstances] to suggest that it is." *FAIR*, 547 U.S. at 48 (citing *W. Va. Bd. of Educ. v. Barnette,* 319 U.S. 624 (1943), and *Wooley v. Maynard,* 430 U.S. 705 (1977)).

2. BI's First Amendment arguments are all the more inapt given that the Negotiation Program is voluntary, and thus does not compel any manufacturer to sign an agreement—or to do anything at all. *See supra* Section II at 19-24; *see also Chamber*, 2023 WL 6378423, at *11. The First Amendment does not prohibit the government from giving a company the option to sign an agreement governing the terms of a program in which the company chooses to participate. *See, e.g.*, *FAIR*, 547 U.S. at 59 (noting that "Congress is free to attach reasonable and unambiguous conditions to federal" funds without triggering First Amendment scrutiny (quoting *Grove City College v. Bell*, 465 U.S. 555, 575-76 (1984))). Just as manufacturers are not forced to sell drugs to Medicare, manufacturers are not forced to sign agreements to negotiate the prices of those drugs.

Contrary to BI's claims, viewing the Negotiation Program in this way does not raise the specter of it violating the unconstitutional conditions doctrine. BI Br. at 42-43. Even if the agreements were expressive—which, again, they are not—the Supreme Court has long upheld conditions on speech that pertain to the nature of a government program. As the Court has explained, if a program arises under the Spending Clause, Congress is free to attach "conditions that define the limits of the government spending program—those that specify the activities Congress wants to subsidize." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013) (*AID*); *see, e.g.*, *United States v. Am. Lib. Ass'n*, 539 U.S. 194, 212 (2003) (plurality opinion) (rejecting a claim by public libraries that conditioning funds for Internet access on the libraries' installing filtering software violated their First Amendment rights, explaining that "[t]o the extent that libraries wish to offer unfiltered access, they are free to do so without federal assistance"); *Regan*, 461 U.S. at 546 (dismissing "the notion that First Amendment rights are somehow not fully realized unless they are subsidized by the State" (citation omitted)).

Conditions implicating speech may be suspect only where those conditions "seek to leverage funding to regulate speech outside the contours of the program itself." *AID*, 570 U.S. at 214-15.

Here, the supposed condition about which BI complains is the signing of an agreement to negotiate and, ultimately, a pricing agreement. But those voluntary agreements are the core mechanisms by which negotiations will proceed, and the source of the enforceable obligation for manufacturers to provide selected drugs at negotiated prices. *See* Revised Guidance at 118-20. In this way, these agreements "define the [Negotiation] program and" do not "reach outside it." *AID*, 570 U.S. at 217. And because these agreements are simply "designed to ensure that the limits of the federal program are observed"—and that Medicare funds are "spent for the purposes for which they were authorized"—the invitation to sign an agreement to participate in the Negotiation Program does not impose unconstitutional conditions on the use of federal funds. *Rust v. Sullivan*, 500 U.S. 173, 193, 196 (1991).

V. EVEN IF THE COURT HAD JURISDICTION OVER BI'S EIGHTH AMENDMENT CLAIM, THAT CLAIM WOULD FAIL

The IRA's excise tax is likewise constitutional. The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII. "Taken together, these Clauses place 'parallel limitations' on 'the power of those entrusted with the criminal-law function of government.'" *Timbs v. Indiana*, 139 S. Ct. 682, 687 (2019) (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 263 (1989)). "The purpose of the Eighth Amendment"—both the Excessive Fines Clause and the Cruel and Unusual Punishments Clause—"was to limit the government's power to punish." *Austin v. United States*, 509 U.S. 602, 609 (1993); *see also Moser v. United States*, No. 97-6302, 1998 WL 833714, *1 (6th Cir. Nov. 20, 1998) (same). The threshold question in any Excessive Fines Clause case then is whether the challenged exaction constitutes "punishment for an offense"—*i.e.*, whether the exaction is a "fine" covered by the Eighth Amendment. *United States v. Alt*, 83 F.3d 779, 784 (6th Cir. 1996); *see also United States v. Bajakajian*, 524 U.S. 321, 328 (1998) ("Forfeitures—payments in kind—are thus 'fines' if they constitute punishment for an offense."). Only if the exaction is deemed punishment does a court consider whether the fine "is unconstitutionally excessive." *Dewees v. United States*, 272 F. Supp. 3d 96, 100 (D.D.C. 2017), *aff'd*, 767 F. App'x 4 (D.C. Cir. 2019).

The excise tax does not violate the Eighth Amendment's Excessive Fines Clause because it is neither a "fine" nor "excessive." The excise tax is not a "fine" covered by the Eighth Amendment because it is not "punishment for some offense." *Bajakajian*, 524 U.S. at 327 (citation omitted). The excise tax has no connection to a criminal offense or criminal proceedings—unlike the exactions at issue in the Excessive Fines Clause precedents that BI cites. The excise tax also lacks the "unusual features" of the drug tax in *Kurth Ranch* that led the Supreme Court to conclude that the tax there constituted punishment for purposes of the Double Jeopardy Clause. Even if the excise tax were a fine, the proportionality test—which itself looks to the "gravity of the offense," a factor that has no bearing here given the lack of any offense—demonstrates that the excise tax is not grossly disproportionate to the harm to the fisc and is within the range of other constitutional exactions.

1. "[A]t the time the Constitution was adopted, 'the word "fine" was understood to mean a payment to a sovereign as punishment for some offense.'" *Id.* (quoting *Browning-Ferris*, 492 U.S. at 265). "Then, as now," fines were typically imposed as punishments in criminal prosecutions. *Browning-Ferris*, 492 U.S. at 265. While the Supreme Court has found certain civil penalties and forfeitures to constitute "punishment" within the scope of the Excessive Fines Clause, it has only done so in cases where the penalty or forfeiture either constituted a post-conviction sanction, *see Bajakajian*, 524 U.S. at 325 (federal statute that provides that a person convicted of willfully violating reporting requirement shall forfeit any property "involved in such offense"), or was assessed against property used in the commission of a crime for which the owner had already been convicted, *see Austin*, 509 U.S. at 622 (federal statute that makes property used to facilitate drug crimes subject to civil *in rem* forfeiture). The Court has never characterized an exaction with no connection to either criminal activity or a criminal proceeding as "punishment for some offense," let alone punishment that violates the Excessive Fines Clause.

BI does not cite any such case—from the Second Circuit or elsewhere. *See* BI Br. at 31-34. Instead, the two excessive fines cases cited by BI in which the forfeiture or penalty was held to be "punishment" involved criminal conduct or criminal proceedings. Neither case involves taxes or otherwise bears any resemblance to this case.

Take *Austin* first. After Austin pleaded guilty to possession of cocaine with intent to distribute, the government filed an *in rem* action, seeking forfeiture of his mobile home and auto shop pursuant to provisions that made property used in furtherance of certain crimes subject to civil forfeiture. 509 U.S. at 604-05 (citing 21 U.S.C. § 881(a)(4), (7)). Both history and modern practice demonstrated that these provisions constituted punishment. The Court concluded that, "at the time the Eighth Amendment was ratified," forfeiture was understood "as imposing punishment." *Id.* at 611-18. And three features of these provisions demonstrated that they remained "punishment today": (1) the "inclusion of innocent-owner defenses," which reveals a "congressional intent to punish only those involved in drug trafficking"; (2) "Congress [having] chosen to tie forfeiture directly to the commission of drug offenses"; and (3) a legislative history that indicates "Congress recognized 'that the traditional criminal sanctions of fine and imprisonment are inadequate to deter or punish the enormously profitable trade in dangerous drugs.'" *Id.* at 619-20 (citation omitted). Taken together, these forfeiture provisions constituted "punishment for some offense" "subject to the limitations of the Eighth Amendment's Excessive Fines Clause." *Id.* at 622 (citation omitted).

Bajakajian is equally unhelpful to BI. That case involved a criminal forfeiture. After Bajakajian tried to leave the country without reporting that he was transporting over $350,000 in cash, he was charged with three counts. *Bajakajian*, 524 U.S. at 325. The third sought forfeiture of the unreported funds pursuant to 18 U.S.C. § 982(a)(1), which provides that, "in imposing sentence on a person convicted of [failing to report that he was transporting more than $10,000 outside the United States]," the court "shall order that the person forfeit to the United States any property . . . involved in such offense, or any property traceable to such property." *Id.* The Court held that this forfeiture was "punishment" under the Excessive Fines Clause. *Id.* at 328-34. Again, the Court looked to history, concluding that such forfeitures "have historically been treated as punitive, being part of the punishment imposed for felonies and treason in the Middle Ages and at common law." *Id.* at 332. The modern version remained "punishment": the forfeiture is "imposed at the culmination of a criminal proceeding and requires conviction of an underlying felony, and it cannot be imposed upon an innocent owner of unreported currency, but only upon a person who has himself been convicted of a [criminal] reporting violation." *Id.* at 328.

None of the features of the *in rem* civil forfeiture in *Austin* or the criminal forfeiture in *Bajakajian* is present here. *See United States v. Toth*, 33 F.4th 1, 16 (1st Cir. 2022) ("[U]nlike the [] forfeitures held to constitute 'punishment' in both *Austin* and *Bajakajian*, this civil penalty"—"imposed following an administrative tax audit"—"is not tied to any criminal sanction."), *cert. denied*, 143 S. Ct. 552 (2023). Unlike civil or criminal forfeiture, "taxes historically have not been viewed as punishment." *United States v. Beaty*, 147 F.3d 522, 525 (6th Cir. 1998). The other three *Austin* factors are similarly absent. First, § 5000D does not contain an innocent-taxpayer exception and imposition of the tax does not depend on any particular level of culpability. *See generally* 26 U.S.C. § 5000D. Second, the excise tax is not tied to the commission of any crime; rather, tax liability is triggered by the lawful choices of the taxpayer in connection with the Negotiation Program. *See id.* § 5000D(a), (b), (e)(1). Third, Congress did not indicate that the tax is meant to supplement "traditional criminal sanctions of fine and imprisonment" to adequately "deter or punish" illegal activity. *See Austin*, 509 U.S. at 620. And, unlike the criminal forfeiture in *Bajakajian*, the excise tax is not "imposed at the culmination of a criminal proceeding," does not "require[] [a] conviction of an underlying felony," and does not distinguish in its rate or scope between different levels of culpability. *See Bajakajian*, 524 U.S. at 328.

2. Having identified no case in which an exaction untethered from criminal conduct or criminal proceedings was deemed "punishment for some offense" under the Excessive Fines Clause, BI turns to a Double Jeopardy Clause case. *See* BI Br. at 31 (citing *Dep't of Revenue of Mont. v. Kurth Ranch*, 511 U.S. 767 (1994)). That is the *only* case Plaintiff identifies in which a tax was held to be "punishment for some offense" under any provision of the Bill of Rights.[8] BI does not cite *any* case

[8] BI also cites a 1935 case involving a challenge to the validity of a liquor excise tax after the repeal of the Eighteenth Amendment. *See* BI Br. at 31 (citing *United States v. Constantine*, 296 U.S. 287, 294-95 (1935)). The question presented there was whether Congress would have had the authority, absent the Eighteenth Amendment, to enact the tax provision. The legal analysis there has little bearing on the issues presented here. In any event, the excise tax at issue there was deemed a penalty primarily because the "condition of the imposition [of the tax] is the commission of a crime"—namely,

(and Defendants are not aware of one) in which a tax was deemed to be "punishment for some offense" (*i.e.*, a "fine") under the Excessive Fines Clause. In any event, *Kurth Ranch*—which involved a drug tax related to criminal conduct—reinforces why the tax here is *not* punishment.

As a preliminary matter, the analytical framework used by the Supreme Court in *Kurth Ranch* undermines a core premise of BI's argument: that the excise tax is a "fine" if it "serv[es] in part to punish." BI Br. at 31 (quoting *Austin*, 509 U.S. at 610). The Court first adopted that test in *United States v. Halper*, 490 U.S. 435 (1989), a case involving a $130,000 civil penalty on the heels of a 65-count criminal conviction that also resulted in a two-year prison sentence and a $5,000 fine. *Id.* at 437-38. Because that post-conviction civil fine could not "fairly be said *solely* to serve a remedial purpose, but rather can only be explained as *also* serving either retributive or deterrent purposes," the Court held it was "punishment" for Double Jeopardy purposes. *Id.* at 448 (emphasis added).[9]

The Supreme Court has never applied this deterrent-in-part test in the tax context, and, in *Kurth Ranch*, the Court rejected its application to a state drug tax. 511 U.S. at 776. *Kurth Ranch* involved a Double Jeopardy Clause challenge to a Montana tax on possession of illegal drugs. The Court concluded that the *Halper* test was inapplicable. *Id.* While *Halper* held that certain civil *penalties* could constitute punishment under the Double Jeopardy Clause, "*Halper* did not . . . consider whether a *tax* may similarly be characterized as punitive." *Id.* at 778 (emphasis added). The Court then held that evidence of a deterrent purpose does not determine whether a tax is punishment: as the "Chief Justice points out, tax statutes serve a purpose quite different from civil penalties, and *Halper*'s method of determining whether the exaction was remedial or punitive 'simply does not work in the case of a tax statute.' Subjecting Montana's drug tax to *Halper*'s test for civil penalties is therefore inappropriate." *Id.* at 784 (citation omitted). Accordingly, unlike in the penalty and forfeiture context, "neither a high

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"violation of state liquor laws." *Constantine*, 296 U.S. at 295. Accordingly, like the drug tax in *Kurth Ranch*—and unlike the excise tax at issue here—the liquor tax in *Constantine* was assessed only on those engaging in criminal activity.

[9] The Court later abrogated *Halper* in *Hudson v. United States*, 522 U.S. 93, 102 (1997) (noting that "all civil penalties have some deterrent effect" and rejecting "*Halper*'s test for determining whether a particular sanction is 'punitive'" under the Double Jeopardy Clause).

rate of taxation nor an obvious deterrent purpose automatically marks [a] tax as a form of punishment." *Id.* at 780. "Whereas fines, penalties, and forfeitures are readily characterized as sanctions," absent "[o]ther unusual features," "an exaction labeled as a tax" is not deemed punishment, even if it is accompanied by a "deterrent purpose." *Id.* at 779-81; *id.* at 780-81 ("[M]any taxes that are presumed valid, such as taxes on cigarettes and alcohol, are also both high and motivated to some extent by an interest in deterrence . . . ."); *contra* BI Br. at 31-32.

The facts of *Kurth Ranch* are equally unhelpful to BI. The marijuana tax there was deemed "punishment" only because of a host of "unusual features" and "anomalies" absent here. Concluding that the tax's high rate and admittedly deterrent purpose did "not necessarily render the tax punitive," the Court identified three additional, "unusual features" that led the Court to label the "exceptional" Montana tax as punishment. *Kurth Ranch*, 511 U.S. at 781, 783. First, Montana's "so-called tax"[10] was "conditioned on the commission of a crime." *Id.* at 781. Second, it was "exacted only after the taxpayer has been arrested for the precise conduct that gives rise to the tax obligation in the first place" such that "[p]ersons who have been arrested for possessing marijuana constitute[d] the entire class of taxpayers subject to the Montana tax." *Id.* at 781-82. Third, the tax was "levied . . . on previously confiscated goods" that the "taxpayer neither own[ed] nor possess[ed] when the tax [was] imposed." *Id.* at 783. Because of this "concoction of anomalies," the Court held that the tax was "too far-removed in crucial respects from a standard tax assessment to escape characterization as punishment." *Id.*; *see also Beaty*, 147 F.3d at 525 (describing anomalous features of tax in *Kurth Ranch*); *Alt*, 83 F.3d at 781-82 (same).

None of the "unusual features" that made the Montana tax "exceptional" is present here: the excise tax is not conditioned on the commission of a crime, it is not exacted after an arrest, and it is not levied on previously confiscated goods. *See Kurth Ranch*, 511 U.S. at 781-83. Indeed, the excise

[10] BI similarly refers to the § 5000D tax as a "so-called 'tax.'" BI Br. at 32. That characterization, as the Court's own description of the Montana marijuana tax demonstrates, does not alter the punishment analysis. What mattered for purposes of the Court's decision in *Kurth Ranch* was that the Montana tax was "labeled as a tax." 511 U.S. at 780. Given that label, the Court refused, unlike in *Halper* and *Austin*, to hold that the tax constituted punishment on the sole basis that the tax partly had a deterrent purpose.

tax does not follow any determination that the taxpayer has engaged in any unlawful activity. *See generally* 26 U.S.C. § 5000D. Further, unlike the Montana tax assessment in *Kurth Ranch*, which required the taxpayer to pay a *multiple* of gross revenue (approximately 4x), 511 U.S. at 780 n.17, a manufacturer's excise tax obligations may be satisfied by paying a *fraction* of gross revenue because the tax, when not separately invoiced, ranges from 65 to 95% of the amount charged for a designated drug, IRS Notice at 3; *see also* 26 U.S.C.§ 5000D(d).[11]

Further, the excise tax serves a remedial purpose in compensating the public fisc for losses incurred from a manufacturer failing to agree to a maximum fair price and continuing to sell its drugs to Medicare beneficiaries, potentially at much higher prices. Indeed, courts regularly recognize that tax *penalties*—which would appear to have a greater deterrent purpose than taxes themselves—have a remedial purpose. *See Helvering v. Mitchell*, 303 U.S. 391, 401 (1938) (describing "[t]he remedial character of sanctions imposing additions to a tax"); *Dewees*, 272 F. Supp. 3d at 100-01 (courts "have erected 'an insurmountable wall of tax cases' to support" proposition that "tax penalties are remedial"). BI nonetheless asserts that the tax here cannot be deemed to have a remedial purpose because BI believes, based on Congressional Budget Office (CBO) projections, that the tax "is not expected to raise any revenue at all." BI Br. at 32 (citing CBO, No. 58850, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act* at 10 (Feb. 2023), https://perma.cc/K789-T667). But "a CBO cost estimate is not persuasive evidence of congressional intent." *Laumann v. NHL*, 56 F. Supp. 3d 280, 296 (S.D.N.Y. 2014); *see also Sharp v. United States*, 580 F.3d 1234, 1239 (Fed. Cir. 2009) ("the CBO is not Congress, and its reading of the statute is not tantamount to congressional intent"). Regardless, BI's argument confuses purposes and effects. The excise tax can and does have

[11] BI maintains that the tax reaches "nineteen times gross sales revenue." BI Br. at 33 (emphasis omitted). But the IRS has made clear, in a notice that "taxpayers may rely on" now, that—assuming a manufacturer does not separately invoice the tax and assuming 271 days have passed—a covered taxpayer would owe a $95 tax out of $100 charged for a drug by a manufacturer. *See* IRS Notice at 3, 5. In any event, because BI brings a facial challenge—before any tax has been assessed or collected, in violation of the AIA—it must establish that the tax is unconstitutional in all applications. *City of Los Angeles v. Patel*, 576 U.S. 409, 418 (2015). Therefore, to the extent the parties have a dispute about the applicable rate of tax that would apply, BI is entitled to relief only if the excise tax is unconstitutional applying IRS's interpretation of its scope and rate.

a remedial purpose even if, by BI's telling, a manufacturer would not engage in the conduct that would cause the harm the excise tax is designed to remedy. *Cf. United States v. Sanchez*, 340 U.S. 42, 44 (1950) (tax is valid "even [if it] definitely deters the activity taxed").[12]

3. The test used to determine whether a "fine" is "excessive" under the Excessive Fines Clause only reinforces the conclusion that the excise tax here is not "punishment." A fine will not be deemed excessive if the "amount of the [fine] bear[s] *some* relationship to the gravity of the offense that it is designed to punish," an inquiry that requires a court to "compare the amount of the [fine] . . . to the gravity of the defendant's offense." *Bajakajian*, 524 U.S. at 334, 336-37 (emphasis added); *see also United States v. George*, 779 F.3d 113, 122-23 (2d Cir. 2015) (listing the four *Bajakajian* factors typically used in the Second Circuit, including "the essence of the crime of the defendant and its relation to other criminal activity" and "whether the defendant fits into the class of persons for whom the statute was principally designed"). That question has no bearing here given the lack of any "offense" or any "design[] to punish." *Bajakajian*, 524 U.S. at 334.

BI nonetheless argues that "proportionality is not a close question" because "'reprehensibility or culpability' is nonexistent" here. BI Br. at 32. That is precisely the point: Because the tax is not triggered by the commission of *any* offense—reprehensible or otherwise—it is not "punishment for some offense" and therefore is not a "fine" under the Excessive Fines Clause. Embracing BI's argument would lead to absurd results: *most* taxes would be unconstitutionally disproportionate because they are assessed following innocuous conduct like working or shopping. That would stretch the Eighth Amendment, which merely "limit[s] the government's power to punish," beyond recognition. *Austin*, 509 U.S. at 609.

[12] BI's description of these legislative projections are also overstated. For example, the cited statistic from the Joint Committee on Taxation includes no analysis or explanation, and was prepared in connection with different legislation back in 2021. *See* BI Br. at 32 (citing Jt. Comm. on Tax'n, No. JCX-46-21, *Estimated Budget Effects of the Revenue Provisions of Title XIII - Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act," as Passed by the House of Representatives*, at 8 (Nov. 19, 2021)). These projections also do not account for the Treasury Department's reading of the enacted version of the statute, which clarifies both the calculation of the excise tax and the application of that tax only to Medicare sales, rather than to all U.S. sales of selected drugs.

4. If the Court were to reach the excessiveness inquiry, the excise tax would not be a "grossly disproportionate" fine. First, "strict proportionality" is not required; a fine is constitutional unless it is grossly disproportional to the offense. *Bajakajian*, 524 U.S. at 336 (adopting "the standard of gross disproportionality articulated in [the Court's] Cruel and Unusual Punishments Clause precedents"). Second, that inquiry requires "substantial deference" to Congress. *Solem v. Helm*, 463 U.S. 277, 290 (1983); *Bajakajian*, 524 U.S. at 336 ("judgments about the appropriate punishment for an offense belong in the first instance to the legislature"). Because "Congress is a representative body, its pronouncements regarding the appropriate range of fines for a crime represent the collective opinion of the American people as to what is and is not excessive." *United States v. 817 N.E. 29th Dr.*, 175 F.3d 1304, 1309 (11th Cir. 1999). "Given that excessiveness is a highly subjective judgment, the courts should be hesitant to substitute their opinion for that of the people." *Id.* There is accordingly a "strong presumption" that a fine "within the range of fines prescribed by Congress" "is constitutional." *Id.* That is especially true in the tax context, where "the appropriate level or rate of taxation is essentially a matter for legislative, and not judicial, resolution." *Commonwealth Edison Co. v. Montana*, 453 U.S. 609, 627 (1981).

BI fails to overcome the "strong presumption" of constitutionality here, as the *Bajakajian* factors make clear. First, unlike in *Bajakajian*, where the defendant who failed to report the cash in his possession did "not fit into the class of persons for whom the statute was principally designed" because he was not a "money launderer, a drug trafficker, or a tax evader," 524 U.S. at 338, any "manufacturer" "of any designated drug" against whom the excise tax is assessed is an entity for which that statute was designed—a point BI does not contest. 26 U.S.C. § 5000D(a). Second, while the "[f]ailure to report" currency "caused no loss to the public fisc" in *Bajakajian*, 524 U.S. at 339 (government "deprived only of [] information"), here the fisc will likely incur significant losses, and seniors will likely face substantially higher costs, if a manufacturer that chooses to continue participating in Medicare declines to agree to a maximum fair price and sells that drug to Medicare at a higher price than the statutory ceiling. Third, unlike in *Bajakajian*, where there was "no inherent proportionality" in requiring forfeiture of the full amount of the undisclosed cash, *see id.*, the excise tax is proportional to the harm to the fisc: where a manufacturer of a designated drug has refused to fully participate in the Negotiation Program, the more it sells its drug to Medicare (presumably at a price higher than that which the manufacturer could have agreed to as a "maximum fair price"), the greater the loss to the public and the higher the tax liability. *See* 26 U.S.C.§ 5000D(b); IRS Notice at 3. Indeed, because the tax attaches only to sales of the drug that are reimbursed by Medicare, the tax necessarily only recoups a portion of the outlays that the Medicare program or Medicare beneficiaries have paid out for the drug. And, where the tax is not separately invoiced, the ratio of the tax to the amount charged by the manufacturer—between 65 and 95%—is within the range of constitutionally permissible exactions. *See, e.g.*, *Alt*, 83 F.3d at 784 (civil fraud penalty of 81%).[13]

Accordingly, even if BI had sued the proper defendant and even if the AIA and DJA did not preclude jurisdiction, BI's Eighth Amendment claim would fail on the merits because the excise tax is neither a fine nor a grossly disproportionate one.

VI. BI'S APA CHALLENGE FAILS

In a final effort to upend the Negotiation Program, BI brings an APA challenge arguing that CMS improperly issued the manufacturer agreement form "without providing an opportunity for comment on its terms." BI Br. at 43. But this argument ignores the plain text of the IRA.

1. The Medicare Act generally requires notice and comment for any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard." 42 U.S.C. § 1395hh(a)(2). That provision largely tracks the APA's requirement for agencies to engage in notice-

[13] Selected drugs, by definition, have been on the market without competition for a minimum of seven years. 42 U.S.C. §1320f-1(e). Outside experts project that each of the manufacturers of the selected drugs have recouped their fixed-cost investments in those drugs during this time period, long in advance of the drug's selection for negotiation. *See* Richard G. Frank and Caitlin Rowley, *Medicare Negotiations Won't Keep Big Pharma from Making a Fortune*, Bloomberg Law (Sept. 5, 2023); *see also* Kiu Tay-Teo et al., *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, 2019 JAMA Network Open 186875 (2019). And, once a manufacturer has recouped its fixed costs, its marginal cost of producing small-molecule drugs is generally "just pennies per pill." CBO, *Prescription Drugs: Spending, Uses, and Prices* 20 (Jan. 19, 2022). Some manufacturers may thus find it to be in their business interest to continue to make Medicare-reimbursable sales of their selected drugs and to pay a portion of that Medicare reimbursement back in the form of the excise tax. *Contra* BI Br. at 32 (arguing that no manufacturer expected to pay excise tax).

and-comment rulemaking when issuing legislative rules. *See* 5 U.S.C. § 553(b). Even so, both the Medicare Act and the APA explicitly contemplate situations in which Congress "expressly" authorizes agencies to depart from these procedures. *Id.* § 559; *see also* 42 U.S.C. § 1395hh(b)(2)(A) (similar). The Supreme Court has emphasized that "the word 'expressly' does not require Congress to use any 'magical passwords' to exempt a later statute from the provision." *Dorsey v. United States*, 567 U.S. 260, 274 (2012) (quoting *Marcello v. Bonds*, 349 U.S. 302, 310 (1955)). Rather, "the Court has described the necessary indicia of congressional intent by the terms 'necessary implication,' 'clear implication,' and 'fair implication.'" *Id.* (citing *Great Northern R. Co. v. United States*, 208 U.S. 452, 465, 466 (2012); *Hertz v. Woodman,* 218 U.S. 205, 218 (1910); *Warden v. Marrero,* 417 U.S. 653, 660 n.10 (1974)). The requisite intent can be found when, for example, Congress "specifie[s] procedures . . . that cannot be reconciled with the notice and comment requirements of [5 U.S.C.] § 533," *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998), or of the Medicare Act, *see* 42 U.S.C. § 1395hh(a)(2).

That is the case here. Although BI ignores it in its brief, the plain text of the IRA—later-enacted and more specific—is clear. That text directs CMS to implement the Negotiation Program for 2026, 2027, and 2028 "by program instruction or other forms of program guidance." § 11001(c), 136 Stat. at 1854. Congress thus "specifie[d] procedures which differ from those of the APA" and the Medicare Act by directing CMS "to issue not a proposed rule" but rather program instruction or guidance. *Asiana Airlines*, 134 F.3d at 398. It is doubtful that the agreement form—which merely tracks the Revised Guidance and therefore does not purport to "establish[] . . . a substantive legal standard"—would ever be subject to notice and comment in the first instance. 42 U.S.C. § 1395hh(a)(2). But regardless, Congress's express direction in the IRA clearly relieved CMS of any such requirement for at least the first three negotiation cycles.

Indeed, finding a notice-and-comment violation here would render § 11001(c) a nullity, contrary to the canon against surplusage. *See, e.g.*, *Pharaohs GC, Inc. v. U.S. Small Bus. Admin.*, 990 F.3d 217, 227 (2d Cir. 2021) ("[A] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009))). Congress expressly directed CMS to implement the Negotiation Program through program instruction or guidance—but only through 2028. BI's interpretation would not give effect to Congress's explicit distinction between the first three years and all future years of the Negotiation Program. Yet that distinction was deliberate. The IRA was enacted on August 16, 2022, yet directed CMS to publish the list of selected drugs for price applicability year 2026 by September 1, 2023, *see* 42 U.S.C. §§ 1320f(b)(3), (d)(1), and to enter into the first agreements with manufacturers of selected drugs by October 1, 2023, *see id.* §§ 1320f(a)(2), (d)(4). Full notice-and-comment rulemaking might have jeopardized the implementation of the Negotiation Program in its early years. Much as BI might dislike Congress's policy choices, it cannot seek to undo them through an APA claim.

2. Even absent the IRA's plain language, BI's notice-and-comment claim would still fail. The APA provides that "due account shall be taken of the rule of prejudicial error," 5 U.S.C. § 706, which is like "an administrative law harmless error rule," *Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020) (alteration and citation omitted); *see also, e.g.*, *Magellan Tech., Inc. v. FDA*, 70 F.4th 622, 630 (2d Cir. 2023) ("Even assuming that the FDA's decision not to evaluate Magellan's marketing plan as part of its PMTA review was error, any such error was harmless because it did not affect the outcome of the FDA's review."). "The party claiming injury bears the burden of demonstrating harm; the agency need not prove its absence." *Combat Veterans for Cong. Political Action Comm. v. FEC*, 795 F.3d 151, 157 (D.C. Cir. 2015); *see also Shinseki v. Sanders*, 556 U.S. 396, 409-11 (2009) (the "burden of showing that an error is harmful normally falls upon the party attacking the agency's determination").

BI has not made (and cannot make) any showing of prejudice. Contrary to BI's suggestion, CMS *did* solicit, accept, and consider comments on all material requirements that appear in the Agreement. The Initial Guidance stated that "CMS is voluntarily soliciting comments" on all relevant sections, including on "the "[t]erms and conditions contained in the manufacturer agreement." Initial Guidance at 5; *see also* Revised Guidance at 30 ("In section 40 of the [Initial Guidance], CMS included descriptions of and solicited comments on the Agreement requirements to provide interested parties an opportunity to comment on these requirements.").

CMS received extensive comments on the Agreement requirements during the comment period. *See* Revised Guidance at 30; *see also id.* at 28-46 (considering and responding to comments on section 40).[14] And CMS exhaustively responded to these comments and made certain changes to the Agreement requirements in section 40. *See id.* at 28-46; *see, e.g.*, *id.* at 31, 120 (revising policy regarding providing points of contact); *id.* at 33, 120-21 (revising policy to clarify voluntary termination procedures); *id.* at 125 (adding new section on opportunity for corrective action); *id.* at 128 (clarifying compliance and monitoring requirements); *id.* at 129 (clarifying termination requirements). Additionally, CMS decided to include all Agreement requirements in the Revised Guidance and to "not separately repeat the program requirements in the Agreement." *Id.* at 30. Instead, CMS provided only "certain general provisions and term and termination provisions" directly in the Agreement. *Id.* As a result, the Agreement requirements "are preserved and presented in th[e] revised guidance for which there has been public notice and comment." *Id.*

Not surprisingly then, BI does not identify any aspect of the Agreement that it did not have an opportunity to comment on, as part of the creation of the Revised Guidance. Given the absence of any demonstratable "prejudice," it "would be senseless to vacate and remand." *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004).

CONCLUSION

For these reasons, Plaintiff's pre-enforcement challenge to the excise tax should be dismissed for lack of subject-matter jurisdiction, and the Court should deny Plaintiff's motion for summary judgment and grant Defendants' cross-motion on all other claims.

[14] Notably, BI submitted a comment expressing its views with regard to various aspects of the Initial Guidance, but declined to respond to CMS's request for comments on the terms and conditions of the Agreement. *See* Letter from Bridget Walsh, Vice President, Boehringer Ingelheim Pharmaceuticals, Inc., to Meena Seshamani, Deputy Administrator, CMS (Apr. 14, 2023) (available at https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation).

Dated: December 20, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Alexander V. Sverdlov
ALEXANDER V. SVERDLOV
MICHAEL J. GAFFNEY
CASSANDRA M. SNYDER
CHRISTINE L. COOGLE
Trial Attorneys
STEPHEN M. PEZZI
Senior Trial Counsel
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005
Tel: (202) 305-8550
Email: alexander.v.sverdlov@usdoj.gov

Counsel for Defendants

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*, Defendants.	No. 3:23-cv-1103-RNC

[PROPOSED] ORDER

Upon consideration of Defendants' opposition to Plaintiff's motion for summary judgment, Defendants' cross-motion for summary judgment, and the entire record herein, it is hereby

ORDERED that Plaintiff's motion for summary judgment is **DENIED**; and it is further

ORDERED that Defendants' cross-motion for summary judgment is **GRANTED**.

SO ORDERED.

Date:

JUDGE ROBERT N. CHATIGNY
United States District Judge