UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB CO., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 23-cv-03335-ZNQ
JANSSEN PHARMACEUTICALS, INC., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 23-cv-03818-ZNQ

DEFENDANTS' NOTICE OF 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: October 16, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Alexander V. Sverdlov
ALEXANDER V. SVERDLOV
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 NEW JERSEY

BRISTOL MYERS SQUIBB CO., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 23-cv-03335-ZNQ
JANSSEN PHARMACEUTICALS, INC., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 23-cv-03818-ZNQ

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

CONSTIUTIONS

OTHER AUTHORITIES

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. Most of these cases are in their early stages. But a judge presiding over one such case in the Southern District of Ohio recently denied plaintiffs' request for a preliminary injunction. *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, --- F. Supp. 3d ---, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023) (*Chamber*). And the reasoning of that decision—which explains that the Negotiation Program raises no Due Process concerns—also defeats the analogous

claims brought by Plaintiffs Bristol Myers Squibb Co. (BMS) and Janssen Pharmaceuticals, Inc. (Janssen) here.

As the *Chamber* court correctly recognized, Congress's authorization for the Secretary to negotiate Medicare prices "cannot be considered a constitutional violation" because drug manufacturers "are not legally compelled to participate in the [Negotiation] Program . . . or in Medicare generally." *Id.* at *11. "[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 the negotiated prices would first take effect. *Id.* The Negotiation Program—like Medicare more broadly—is thus "a completely voluntary" undertaking. *Id.* So, while Plaintiffs may be dissatisfied with the conditions this program imposes on future Medicare spending, they are neither compelled to surrender their property in violation of the Fifth Amendment nor required to speak in violation of the First.

Plaintiffs' constitutional arguments fail in other respects, too. The companies' primary legal theory—that the Negotiation Program effects a "*physical*" taking of their property—is untenable under the very Supreme Court cases that Plaintiffs invoke. *Janssen Pharms., Inc. v. Becerra*, Mem. of L. in Supp. of Pl.'s Mot. for Summ. J., No. 3:23-cv-3818, ECF No. 30-1 at 3 (emphasis added) (Janssen Br.); *Bristol Myers Squibb Co. v. Becerra*, Mem. of L. in Supp. of Pl.'s Mot. for Summ. J. Br., Case No. 3:23-cv-3335, ECF No. 36-3 (BMS Br.). 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. Nor does the IRA require a manufacturer to relinquish any drug it does not wish to sell. Plaintiffs' physical-taking theory—the only taking theory they posit—therefore fails outright.

Similar errors infect Plaintiffs' First Amendment arguments. Contrary to Plaintiffs' assertions, neither the agreements that manufacturers have now signed with 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. And Plaintiffs' 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.

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. Plaintiffs' 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.* Plaintiffs are 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 items and services, including prescription drugs, for qualified beneficiaries. *See generally* 42 U.S.C. § 1395 *et seq.* The Medicare statute encompasses several "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) (internal quotes 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." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. § 1395w-101 *et seq.* Prior to the IRA, Congress had not granted the Secretary authority to directly negotiate 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 contributed 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 Office, *Prescription Drugs: Spending, Use, and Prices* at 16 (Jan. 2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [that] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. II, at 37 (2019). Congressional reports have found that 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 & Reform, 117th Cong., *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* at 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* at 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, the high drug costs also increase the out-of-pocked payments by Medicare beneficiaries.

B. The IRA seeks to address these concerns. Pub. L. No. 117-169, §§ 11001-11003 (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. In formulating offers during the course of those negotiations, the statute requires CMS to consider numerous categories of information, 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 drug at the negotiated price. *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* 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 Congress has long attached to other government healthcare 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 which 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. CMS'S 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 within the new statutory framework. 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 (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 exchange 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.

Following the issuance of the Revised Guidance, the Treasury Department issued a separate notice outlining how it interprets 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 (addressing interpretation of 26 U.S.C. § 5000D) (IRS Notice). As that notice explains, Treasury intends to propose regulations specifying that the tax provided for in section 11003 of the IRA, and codified 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 [would be] allocated to the § 5000D tax and $35 [would be] allocated to the price of the designated drug." *Id.* at 4. The result is that the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95% (not 1900%, as Plaintiffs claim).[1] *Contra* BMS Br. at 8. This

[1] This result flows from the statutory formula for the tax amount specified in 26 U.S.C. § 5000D(d), which defines the "applicable percentage" of the tax during different periods. Under that provision—assuming a manufacturer does not separately invoice the tax—after 271 days $95 out of a $100 total amount charged for a drug by the manufacturer would go to the tax (leaving the designated price of the drug at $5).

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. IRS Notice at 5.

On August 29, 2023, CMS published the list of drugs selected for negotiation for initial price applicability year 2026. *See HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), available here. The drugs selected accounted for more than $50 billion—or about 20%—of gross Medicare Part D spending between June 2022 and May 2023. *See Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), available here. BMS's drug Eliquis and Janssen's drug Xarelto were each among the 10 drugs selected for negotiation. *Id.*

BMS and Janssen have now executed agreements to negotiate the price of Eliquis and Xarelto, respectively. *See Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026* (Oct. 3, 2023), available here (*Manufacturer Agreements*).[2] So too have the manufacturers of each of the other selected drugs. *Id.* Under the schedule established 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 (outlining statutory timetable). Any agreed-upon prices for the selected drugs will take effect on January 1, 2026—more than 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 Negotiation Program. *See AstraZeneca Pharms. LP v. Becerra*,

[2] A different company, Janssen Biotech, Inc., has also executed an agreement to negotiate the price of another drug, Stelara. *See Manufacturer Agreements* at 1. Janssen Biotech, Inc. is not a party to either of these cases, however. No party in this litigation has requested any relief specific to Stelara, which is not mentioned in either complaint or either summary-judgment motion.

No. 1:23-cv-931 (D. Del. Aug. 25, 2023); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103 (D. Conn. Aug. 18, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707 (W.D. Tex. June 21, 2023); *Merck & Co., Inc. 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).[3] 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, 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.

As Judge Newman detailed, plaintiffs' arguments failed "as a matter of law" because manufacturers were "not legally compelled to participate in the [Negotiation] Program." *Id.* at *11. As a result, the court explained, 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 court thus denied plaintiffs' motion. *Id.* at *14. And plaintiffs decided not to appeal that decision. *Chamber*, No. 3:23-cv-156, ECF No. 56 at 2 (N.D. OH, Oct. 12, 2023) (joint scheduling motion stating plaintiffs do not intend to appeal).

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

ARGUMENT

I. THE NEGOTIATION PROGRAM IS NOT A TAKING BECAUSE PARTICIPATION IS VOLUNTARY

BMS's and Janssen's Takings Clause 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 have, for decades, rejected such claims. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276, 1279-80 (11th Cir. 2014) (collecting cases); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993). As the *Chamber* court observed, 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." 2023 WL 6378423, at *11 (citations omitted). And this principle, the *Chamber* court correctly held, applies equally to the Negotiation Program. *Id.*

Contrary to Plaintiffs' 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.*; *contra* BMS Br. at 1. "[P]harmaceutical manufacturers who do not wish to participate in the [Negotiation] Program have the ability . . . to opt out" in several different ways. *Chamber*, 2023 WL 6378423, at *11. Like other Medicare reimbursement limits, the voluntary Negotiation Program thus reflects a valid exercise of Congress's constitutional authority to control the government's spending as a market participant. Imposing such controls implicates no takings concerns under any standard—much less under the demanding standard of a facial challenge, which requires Plaintiffs to "'establish[] that no set of circumstances exists under which the Act would be valid,' *i.e.*, that the law is unconstitutional in all of its applications." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449 (2008) (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)).

A. The Negotiation Program Does Not Compel Participation

The Takings Clause of the Fifth Amendment prohibits the taking of private property for public use without just compensation. 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 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."). Likewise, a "demand for personal property [is] not [] a taking . . . if it involve[s] a voluntary exchange for a governmental benefit." *Valancourt Books, LLC v. Garland*, No. 21-5203, --- F. 4th ---, 2023 WL 5536195, at *6 (D.C. Cir. Aug. 29, 2023); *see also Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) (a "voluntary submission of data . . . in exchange for the economic advantages of" a program "can hardly be called a 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 the Medicare program is a voluntary undertaking." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991); *see 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); *Garelick*, 987 F.2d at 917 (same); *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.

This uniform recognition that Medicare reimbursement caps do not implicate the Fifth Amendment is unsurprising. 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*, 142 S. Ct. 1562, 1570 (2022) (internal quotes and citation omitted). And, as with any voluntary undertaking, "if a party objects to a condition on the receipt of federal funding, its recourse is to decline the funds." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013).

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 markets. *See Chamber*, 2023 WL 6378423, at *11; *see also* Revised Guidance at 33-34, 120-21, 129-31.[4] Alternatively, a manufacturer can divest its interest in the selected drug to a subsidiary or a separate entity—or otherwise stop selling it to Medicare beneficiaries, either permanently or temporarily, which would expose it to no penalty or tax. *Id.* at 131-32.

Thus, contrary to Plaintiffs' claims, manufacturers "are not legally compelled to participate in the Program" or forced to make 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

[4] Recognizing the viability of this option, some manufacturers previously stated that they might do so. *See* Zachary Brennan, *IRA side effect: Pharma companies will increasingly skip Medicare altogether, Lilly CEO says*, Endpoint News (June 14, 2023), https://perma.cc/ZWJ4-6EXF.

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 manufacturers' to make.

B. Manufacturers Have Adequate Opportunity to Withdraw from the Program

Attempting to evade this well-settled precedent, Plaintiffs assert that the IRA makes it impossible for manufacturers to withdraw from the Negotiation Program without incurring a sizeable tax or a penalty—making the choice to leave the program "illusory." BMS Br. at 32; Janssen Br. at 22. These arguments ring hollow. Neither Janssen nor BMS has indicated that it wishes to withdraw from the Negotiation Program or from Medicare; to the contrary, both companies have signed agreements to negotiate. *See Manufacturer Agreements* at 1. So Plaintiffs' complaints about the process for withdrawal are purely academic. *See* BMS Br. at 32; Janssen Br. at 12 n.13. But regardless, these arguments fail because Plaintiffs misunderstand 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).[5] The Social Security Act (SSA)

[5] 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).

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 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 like Janssen and BMS 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 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);[6] 26 U.S.C. § 5000D(b)(1) (tax triggered on October 2, 2023, absent manufacturer signing agreement to negotiate). Janssen and BMS, along with the manufacturers of all the other selected drugs, signed agreements to negotiate. *See Manufacturer Agreements* at 1. Those 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 16 months* before January 1, 2026, when any negotiated prices would first take effect—and any civil penalty (but no tax) could even

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

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.

Plaintiffs fail to appreciate these various options—just as they fail to appreciate that the tax about which they complain attaches *only* to Medicare sales and does not exceed the total amount a manufacturer charges for the drug. *Compare* BMS Br. at 8 *with* IRS Notice at 3-4 (stating that, absent a manufacturer's choice to the contrary, the tax will be deemed included in the sale price of the drug). Instead, Plaintiffs merely make passing claims that CMS's use of its own "good cause" authority to provide for the 30-day withdrawal option is an impermissible "end-run" around the statutory language. BMS Br. at 32-33; Janssen Br. at 12 n.13. But Plaintiffs themselves contend that the absence of an adequate opportunity to withdraw from the Negotiation Program would be unconstitutional—so they can hardly claim that CMS lacks "good cause" to facilitate their 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 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 Plaintiffs have not actually challenged CMS's interpretation, which operates to their benefit, and which they would therefore lack standing to contest.

Further, even putting aside CMS's Revised Guidance, Plaintiffs overlook the 28-month period between a manufacturer's drug(s) being selected for negotiation and the January 2026 effective date for any negotiated prices. *See* BMS Br. at 42. Even by Plaintiffs' 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* BMS Br. at 32 (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"). Notably, the Supreme Court has found no taking where a property owner could choose to leave a price-capped market with "6 or 12 *months* notice." *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992) (emphasis added). Manufacturers have far more flexibility here.

Plaintiffs separately complain that withdrawing from Medicare is not "practical" because it would prove financially ruinous for them and would leave Medicare beneficiaries without much-needed drug products. Janssen Br. at 21. But, as Judge Newman recognized in *Chamber*, it makes no difference legally whether withdrawing from Medicare is "practical or not." 2023 WL 6378423, at *11. Courts have, for decades, held that economic or other practical "hardship is not equivalent to legal compulsion for purposes of [a] takings analysis." *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). 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. And to the extent that the government has an interest in manufacturers continuing to participate in Medicare and making their drugs available

at negotiated prices, Janssen Br. at 21, that only confirms that manufacturers have leverage in negotiating prices with CMS. 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.

In short, Plaintiffs are wrong to claim that the option to withdraw from the Negotiation Program is "illusory" or that Congress did not "give manufacturers a genuine choice" about whether to sell their drugs at negotiated prices. BMS Br. at 32-33. The choice "to opt out" of the Negotiation Program is real. *Chamber*, 2023 WL 6378423, at *11.

C. The Negotiation Program Does Not "Coerce" Manufacturers

Unable to show that any manufacturer is *legally* compelled to participate in the Negotiation Program, Plaintiffs try one final workaround. Relying on the Supreme Court's decision in *National Federation of Independent Businesses v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*), BMS argues that the Negotiation Program is impermissibly "coercive" because Congress has improperly "leverage[d]" Medicare spending as a means of compelling participation. BMS Br. at 34-36.[7] But this argument reflects a basic misunderstanding of *NFIB*, on several levels.

1. 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.*, *Baker Cnty.*, 763 F.3d 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

[7] Janssen makes only a cursory allusion to this argument in its papers. *See* Janssen Br. at 39.

(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. For good reason. 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 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 Janssen and BMS. *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.").[8] After all, Janssen and BMS are not states and have no equivalent Tenth Amendment interest in being free of direct congressional regulation. *See, e.g.*, *Sabri v. United States*, 541 U.S. 600, 608 (2004) (drawing distinction between congressional "authority to bring federal power to bear directly on individuals who convert public

[8] BMS incorrectly suggests that the Third Circuit has opened the door to applying the "coercion" inquiry to private parties in *Doe v. University of Sciences*, 961 F.3d 203, 213 (3d Cir. 2020). BMS Br. at 36. That case involved a contractual dispute between two private parties, not a challenge to a condition on federal funding. *See Doe*, 961 F.3d at 212. And although the court observed in passing that the loss of federal funds could be "ruinous" for private parties, it never analyzed whether the withdrawal of such funds would be impermissible (which the "coercion" inquiry would demand). *Id.* at 213.

spending into unearned private gain," and Congress "bringing federal economic might to bear on a State's own choices of public policy"); *see generally Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1476 (2018) ("The Constitution . . . 'confers upon Congress the power to regulate individuals, not States.'" (quoting *New York v. United States,* 505 U.S. 144, 166 (1992))).

2. In any event, 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, 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*, 505 U.S. at 175). 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); *cf. Ray Baillie Trash Hauling, Inc. v. Kleppe*, 477 F.2d 696, 709 (5th Cir. 1973) (noting that it "has long been recognized that the government, like private individuals and businesses, has the power 'to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases'" (quoting *Perkins v. Lukens Steel Co., 1939*, 310 U.S. 113, 127 (1940))).

Indeed, courts—including the Supreme Court—have long distinguished, for constitutional purposes, between government acting "as a regulator rather than a market participant" vindicating a "legitimate proprietary interest." *Chamber of Com. of U.S. v. Brown*, 554 U.S. 60, 70-71 (2008); *see also Bldg. & Const. Trades Council of Metro. Dist. v. Associated Builders & Contractors of Mass./R.I., Inc.*, 507 U.S. 218, 229 (1993) (discussing the "conceptual distinction between regulator and purchaser") (*Bos. Harbor*); *Reeves, Inc. v. Stake*, 447 U.S. 429, 436 (1980) (noting the difference "between States as market participants and States as market regulators"). This distinction reflects the

"principle that a government, just like any other party participating in an economic market, is free to engage in the efficient procurement and sale of goods and services." *Associated Builders & Contractors Inc. N.J. Chapter v. City of Jersey City*, 836 F.3d 412, 417-18 (3d Cir. 2016) (citing *Chamber of Com.*, 554 U.S. at 70; *Bos. Harbor*, 507 U.S. at 228-30; *Reeves*, 447 U.S. at 437-40); *see also Brooks v. Vassar*, 462 F.3d 341, 356 (4th Cir. 2006) (government can be a market participant even when it regulates "the specific market in which it participates"). Observing this distinction, last year the Supreme Court 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).

Efficient 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*, 541 U.S. at 608 ("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.

3. For similar reasons, the Negotiation Program would not be "coercive" under *NFIB*'s test even if that test were applicable. BMS Br. at 34-35. 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. But "[c]onditions that do not . . . govern the use of the funds . . . cannot be justified on that basis." *Id.* Particularly when "such conditions take the form of threats to terminate other significant independent grants," their coerciveness must be evaluated—a test Congress failed in *NFIB* because it threatened to revoke *all* of a state's traditional federal Medicaid funding unless the state agreed to create a "new health care program." *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).

Unlike the challenged statutory provisions in *NFIB*, however, the Negotiation Program directly "govern[s] the use of" Medicare funds for the selected drugs. *See generally Miss. Comm'n*, 790 F.3d at 179 ("[A]s described in *NFIB*, the [coerciveness] inquiry . . . was triggered by the fact that the Congress had imposed a condition that did not restrict how the . . . funds at issue were to be used."). 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 not selling the selected drug to Medicare beneficiaries during the relevant period (including by 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 BMS's characterization, the availability of this second choice does not mean that Congress has offered manufacturers anything improper. BMS Br. at 35. Congress routinely conditions Medicare and Medicaid funding on parties observing conditions 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 Cty.*, 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 its 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 for good reason: suggesting that Medicaid and Medicare conditions can be coercive 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. Plaintiffs provide no basis to believe that *NFIB* upset that settled law.

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.

4. Plaintiffs' failure to appreciate the options available to manufacturers under the Negotiation Program leads to another problem. "[U]nlike the situation in *NFIB* and like that in *Dole*," a manufacturer of a selected drug will "not risk losing *all* federal funding" from Medicare if it chooses to, for example, remain in Medicare but divest its interest in that drug. *Mississippi Comm'n*, 790 F.3d at 177. "Precisely how much less" money, if any, a manufacturer would then make "we do not know." *Id.* at 178. But "the burden of establishing unconstitutionality is on the challenger," and Plaintiffs' failure "to provide the necessary information" provides an independent "ground for rejecting" their claim. *Id.*; *see also NFIB*, 567 U.S. at 681 (joint opinion of Scalia, Kennedy, Thomas, and Alito, JJ.) ("[C]ourts should not conclude that legislation is

unconstitutional on this ground unless the coercive nature of an offer is unmistakably clear."); *see also United States v. Morrison*, 529 U.S. 598, 607 (2000) (requiring a "plain showing" of unconstitutionality). Especially on a facial challenge, where Plaintiffs "must establish that no set of circumstances exists under which" the Negotiation Program could be constitutionally valid, generalized fears of economic "coercion" are not enough. *Salerno*, 481 U.S. at 745; *see also Wash. State Grange*, 552 U.S. at 450 (explaining that "[f]acial challenges are disfavored" in part because they "run contrary to the fundamental principle of judicial restraint that courts should neither 'anticipate a question of constitutional law in advance of the necessity of deciding it' nor 'formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied'" (citation omitted)). So even if the coercion test were relevant here, Plaintiffs have failed to satisfy it.

* * *

Simply put, Plaintiffs cannot establish that the Negotiation Program is anything other than "completely voluntary." *Chamber*, *Chamber*, 2023 WL 6378423, at *11. And because it is voluntary, the Program "simply does not involve a forced taking of property by the state." *Minn. Ass'n*, 742 F.2d at 446. Plaintiffs may be dissatisfied with how the Negotiation Program differs from other voluntary conditions they are used to seeing in the Medicare statute. BMS Br. at. 31. But their dissatisfaction does not establish a constitutional claim.

II. PLAINTIFFS' TAKINGS CLAIMS FAIL EVEN ON THEIR OWN TERMS

Even setting aside the voluntary nature of the Negotiation Program, and the settled precedent rejecting Fifth Amendment challenges to Medicare reimbursement caps, Plaintiffs' takings claims still fail even as articulated.

The Supreme Court has made clear 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 v. Chevron U.S.A. Inc.*, 544 U.S. 528, 548 (2005). Plaintiffs do 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 Plaintiffs have 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, Plaintiffs assert that the Negotiation Program amounts to a *physical* taking of property. *See* BMS Br. at 15-16; Janssen Br. at 16. But Plaintiffs have no property interest in their current level of Medicare reimbursements—and the IRA does not require Plaintiffs to surrender their drugs.

A. Plaintiffs Have No Property Interest in Medicare Sales

A threshold inquiry in any takings claim is the existence of "a property interest protected by the Fifth Amendment's Taking Clause." *Ruckelshaus*, 467 U.S. at 1000. Protected "[p]roperty interests . . . are not created by the Constitution," but are instead "created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law." *Id.* at 1001 (quoting *Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 161 (1980), and *Bd. of Regents v. Roth*, 408 U.S. 564, 577 (1972)). To have a property interest, an individual must have "a legitimate claim of entitlement" to a particular benefit, not merely a "unilateral expectation" or "abstract need or desire" for it. *Bd. of Regents*, 408 U.S. at 577.

Neither Plaintiffs nor any other manufacturer has an inherent entitlement—and therefore no property interest—in selling their drugs *to Medicare* at any particular price. As a general matter, "[t]he 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.*, *Ruckelshaus*, 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"). As the *Chamber* court observed, "there is no constitutional right (or requirement) to engage in business with the government." *Chamber*, 2023 WL 6378423, at *11 (citing *Livingston Care*, 934 F.2d at 720). By extension, "providers do not have a property interest in a particular reimbursement rate" from Medicare or Medicaid. *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013); *see also Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019) ("[P]articipation in the federal Medicare reimbursement program is not a property interest."); *Painter v. Shalala*, 97 F.3d 1351, 1358 (10th Cir. 1996) (holding that a physician has no property interest in "having his [Medicare] reimbursement payments calculated in a specific manner").

Indeed, crediting Plaintiffs' claim that a reduction in Medicare reimbursement can constitute a taking would mean that a manufacturer has a *constitutional right* to dictate the government's expenditures. By the same logic, physicians and hospitals could challenge disfavored reimbursement rates under the Takings Clause—contrary to decades of precedent. *See, e.g.*, *Managed Pharmacy Care*, 716 F.3d at 1252; *Garelick*, 987 F.2d at 917. 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 rates the government is unwilling to pay. Not surprisingly then, courts have explicitly rejected the core premise of Plaintiffs' theory, noting that "those who opt to participate in Medicare are not assured of revenues." *Livingston Care*, 934 F.2d at 721.

B. The Negotiation Program Is Not a Physical Taking of Plaintiffs' Drugs

Endeavoring to overcome this precedent, Janssen and BMS seek to paint the Negotiation Program as a "'classic' or *per se*"—*i.e.*, a physical—taking of their actual

products, akin to the kind the Supreme Court examined in *Horne*, 576 U.S. 351. BMS Br. at 13, 15-16;[9] Janssen Br. at 16. 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 made clear, 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 Nursery v. Hassid*, 141 S. Ct. 2063, 2074 (2021) (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—as BMS itself acknowledges, BMS Br. at 14, 16—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, however, there is no "physical appropriation" at all. *Cedar Point Nursery*, 141 S. Ct. at 2074. Unlike the Department of Agriculture in *Horne*, CMS will not "sen[d] trucks to [Janssen's or BMS's] facility at eight o'clock one morning to" haul away drugs. *Horne*, 576 U.S. at 356. And, contrary to Plaintiffs' insistent claims, the IRA does not

[9] Unlike Janssen, BMS carefully (and tellingly) avoids using the term "physical" taking, but that is the only sort of taking that *Horne* and the other cases BMS relies on discuss. BMS Br. at 13, 16 (citing *Horne*, 576 U.S. at 358-64; *Cedar Point Nursery*, 141 S. Ct. 2063).

require manufacturers to provide "access" to their drugs against their will. Pl.'s Br. at 17-18 (citing *Cedar Point*, 141 S. Ct. at 2072). If BMS and Janssen do not wish to "deal with the Government on the Government's terms," they are free "not to sell [their] products" to Medicare beneficiaries. BMS Br. at 16. Neither the formulary provision Janssen 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)—nor anything else in the IRA requires manufacturers to *make sales* in the first instance. *Contra* Janssen Br. at 19-20; BMS Br. at 16.

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), (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 Janssen complains, Janssen Br. at 20, 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.* Plaintiffs' 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; *see also* BMS Br. at 16 (noting the distinction between "compulsory sales" and a "price cap"). And Plaintiffs' 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. BMS Br. at 15-16; Janssen Br. at 18-19.

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 on somewhat equal footing with public "utilities." *Garelick*, 987 F.2d at 916; *see* Pl.'s Br. at 15. 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 rate-setting is raised by rates, not methods." *Verizon*, 535 U.S. at 525. Plaintiffs, of course, are not challenging any "particular, actual . . . rate" yet—nor can they do so. *Id.* at 523-24. The negotiation schedule has barely started; neither CMS nor manufacturers will know what prices may result from these negotiations for many months more.

This uncertainty would have foreclosed any attempt Plaintiffs 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 Plaintiffs have eschewed a regulatory taking theory. But they fare no better with the theory they brought.

III. THE NEGOTIATION PROGRAM DOES NOT COMPEL MANUFACTURERS TO SPEAK

Plaintiffs' First Amendment claims fare no better. Those challenges rest entirely on the companies' unsupported assertions that (1) manufacturers will be "compelled" to sign agreements with CMS and that (2) entry into these agreements constitutes "speech" or "expression" protected by the First Amendment. BMS Br. at 23-24; Janssen Br. at 29-32. But neither is true.

As a threshold matter, because the Negotiation Program is entirely voluntary, it does not compel any manufacturer to do anything at all—either by signing an agreement or otherwise. For all the reasons detailed above, Plaintiffs' assertion that the manufacturer of a selected drug must either sign an agreement to negotiate or face a tax overlooks the various options the manufacturer has to exit or otherwise avoid the Negotiation Program. *See supra* Section II.B. The First Amendment does not prohibit the government from giving a company the *option* to sign an agreement pertaining to the program. *See, e.g.*, *Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 59 (2006) (*FAIR*) (noting that "Congress is free to attach reasonable and unambiguous conditions to federal" funds without triggering First Amendment scrutiny (citing *Grove City College v. Bell,* 465 U.S. 555, 575–576 (1984)). Just as there is no compulsion for manufacturers to sell drugs to Medicare, there is no compulsion for manufacturers to engage in activities that BMS and Janssen (incorrectly) describe as speech.

In any event, signing an agreement with CMS does not constitute compelled expression. Any speech implicated in the execution of an ordinary contract "is plainly incidental to the . . . regulation of conduct" that the contract would govern. *FAIR*, 547 U.S. at 62. As BMS itself acknowledges, contracts typically "do not express views or convey beliefs." BMS Br. at 25. Indeed, Medicare uses a myriad of agreements that health care providers and other entities are invited to sign to memorialize their voluntary acceptance of the terms for participation in the relevant programs; these agreements do

not compel providers to endorse the general fairness of the Medicare rate-setting process. *See, e.g.*, 42 U.S.C. §§ 1395cc, 1396r-8(b), (c). And the Negotiation Program agreements are no different.

Manufacturers who choose to sign agreements with CMS undertake a (voluntary) obligation to negotiate prices and, ultimately, to provide Medicare beneficiaries with an opportunity to purchase drugs at the negotiated price. *See* Revised Guidance at 118-20; *see also* BMS Mot., Decl. of Toni-Ann Citera, Ex. B (defining "CMS and Manufacturer Responsibilities" under the agreement) (Template Agreement). For First Amendment purposes, this is indistinguishable from run-of-the-mill price regulation that "simply regulate[s] the amount [of money] that a [manufacturer] [can] collect." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). As the D.C. Circuit has noted, the Supreme Court has "reaffirmed 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 Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 77 (1st Cir. 2013) ("[P]rice regulations and other forms of direct economic regulation do not implicate First Amendment concerns."). Contrary to Plaintiffs' suggestion, the agreements are "not directed at the communication of information" and any conduct restriction "is imposed 'for reasons unrelated to the communication of ideas,' so [it] would 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 (a "law's effect on speech [that is] only incidental to its primary effect on conduct" does not draw First Amendment scrutiny).

Indeed, the agreements' "character as a conduct restriction is underscored by [their] bearing *only* on product price." *Nicopure*, 944 F.3d at 292 (emphasis added). The Template Agreement states explicitly that, by signing it, a manufacturer neither professes 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"). Specifically, the agreement explains 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.* This language confirms the obvious: namely, that the agreement uses statutory terms merely as a way of ensuring that the counter-signing parties have the same understanding of their obligations.[10]

Unlike in the cases BMS cites, BMS Br. at 25, 28, the agreement manufacturers enter does not require them to say anything about the agreed-upon prices. *See, e.g.*, *Circle Schools v. Pappert,* 381 F.3d 172 (3d Cir. 2004) (analyzing state law mandating recitation of the Pledge of Allegiance); *see also New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145, 177–78 (2d Cir. 2020) (finding that state regulations governing adoption could plausibly compel a religious organization to make statements with which it disagreed); *303 Creative LLC v. Elenis*, 600 U.S. 570, 587 (2023) (finding that state anti-discrimination law was impermissible insofar as it would compel the creation of a website). Nor does the agreement restrict manufacturers' ability to say anything they want about the Negotiation Program, to characterize the negotiations as a "Hobson's choice" or otherwise illegitimate, or to generally criticize CMS or the IRA. BMS Br. at 10. Indeed, committing to contractual obligations does not require a manufacturer to adopt or express any viewpoint at all. *Contra Expressions Hair Design*, 581 U.S. at 47-48 (analyzing law that "is *not* like a typical price regulation" because it "tells merchants nothing about

[10] There is no merit to BMS's claim that the "disclaimer only underscores" that the contract *does* suggest an endorsement of CMS's views. BMS Br. at 28-29. The government, no less than a commercial party, is free to emphasize an already obvious point. Contracts do this routinely. BMS cites no canon of construction supporting its reading of such emphasis as a negation.

the amount they are allowed to collect" but instead "regulate[s] . . . how sellers may communicate their prices" (emphasis added)).

Notwithstanding all this, Plaintiffs suggest that—because the template agreement uses statutory terms like "agree" and "maximum fair price," which also have colloquial meanings—signing the agreement *could* be incorrectly perceived as a manufacturer agreeing with the government's message that the Negotiation Program is a *bona fide* negotiation that will culminate in prices that manufacturers consider "fair." *See* BMS Br. at 26, 27, 29; Janssen Br. at 30-32; *see generally* Template Agreement. Plaintiffs go so far as to suggest that creating that sort of false impression is the underlying motivation for the program. *See* Janssen Br. at 22. But this line of argument has no end point.

By Plaintiffs' logic, any seller of commercial goods could assert that *any* price regulation prohibits it from expressing the idea that its products are worth more—and that, by complying, it is forced to convey the government's message. But courts have declined to accept such arguments—and rightly so. *See, e.g.*, *Nicopure*, 944 F.3d at 291. As the D.C. Circuit explained in confronting a prohibition on the distribution of free samples of tobacco products, such arguments "would extend First Amendment protection to every commercial transaction on the ground that it 'communicates' to the customer 'information' about a product or service." *Id.* Yet "the Supreme Court has long rejected the 'view that an apparently limitless variety of conduct can be labeled "speech" whenever the person engaging in the conduct intends thereby to express an idea.'" *Id.* (quoting *United States v. O'Brien*, 391 U.S. 367, 376 (1968) and *Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 570 (1991)). Indeed, "[i]t is possible to find some kernel of expression in almost every activity a person undertakes—for example, walking down the street or meeting one's friends at a shopping mall—but such a kernel is not sufficient to bring the activity within the protection of the First Amendment." *City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989). Congress can, for example, "prohibit

employers from discriminating in hiring on the basis of race," and the "fact that this will require an employer to take down a sign reading 'White Applicants Only' hardly means that the law should be analyzed as one regulating the employer's speech rather than conduct." *FAIR*, 547 U.S. at 62

A manufacturer may, without a doubt, have numerous reasons for signing or not signing an agreement with CMS, and many of those reasons may pertain to the ideas it harbors or those it wants to communicate to others. But harboring such ideas "does not convert all regulation that affects access to products or services into speech restrictions subject to First Amendment scrutiny." *Nicopure*, 944 F.3d at 291. 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 *West Virginia Bd. of Ed. v. Barnette,* 319 U.S. 624 (1943); *Wooley v. Maynard,* 430 U.S. 705 (1977)).

In the end, if Plaintiffs are truly worried that a manufacturer's decision to sign an agreement will somehow "distort public debate," BMS Br. at 27, the answer is simple: BMS, Janssen, and other manufacturers of selected drugs are free to complain about the Negotiation Program to the public, to Congress, and to anyone else who will listen. Indeed, there has been no shortage of such complaints. *See, e.g.*, Giovanni Caforio, *The High Cost of Price Controls on Eliquis and Other Drugs*, Wall Street Journal (Aug. 29, 2023), available here (opinion editorial by CEO of BMS); *contra* BMS Br. at 27 (alleging that the IRA's agreements "insulates [CMS] from criticism"). These complaints make clear that the manufacturers disagree with the policy choices made by Congress. But such policy disagreements do not establish a constitutional claim.

IV. THE NEGOTIATION PROGRAM IS A VALID CONDITION ON FEDERAL FUNDS

Finally, both Janssen and BMS try to recast their Takings Clause and First Amendment grievances into one omnibus "unconstitutional condition[s]" argument. Janssen Br. at 36-39; BMS Br. at 37-39. As both companies acknowledge, however, 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). As a result, the "predicate for any unconstitutional conditions claim is that the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure the person into doing." *Id.* at 612; *see also FAIR*, 547 U.S. at 59-60 ("It is clear that a funding condition cannot be unconstitutional if it could be constitutionally imposed directly."). That predicate is absent here for all the reasons explained above.

And Plaintiffs' unconstitutional-conditions arguments fail for other reasons as well. Plaintiffs' central claim is that it is "disproportionate" for Congress to "threat[en] to terminate coverage for all of [Plaintiffs'] medicines" if a manufacturer declines to negotiate prices on a selected drug. BMS Br. at 37, 39; *see also* Janssen Br. at 38-39 (same). But Congress imposed no such "threat." As explained above, the option to exit Medicaid and Medicare belongs to the *manufacturer*—and is only one of several options that a manufacturer may exercise if it wishes to avoid the Negotiation Program. *See supra* at 15-17.[11] So Congress has not conditioned Medicare participation on manufacturers surrendering any property right.

[11] The same fact defeats Plaintiffs' passing reference to *Harris v. McRae*, in which the Supreme Court observed that a "substantial constitutional question would arise if Congress had attempted to withhold all Medicaid benefits" based on exercise of a constitutional right. 448 U.S. 297, 317 n.19 (1980). Simply put, it is the manufacturers who can choose to withdraw from Medicare. Further, as the *Chamber* court recognized, selling drugs to Medicare is not a constitutional right. *See* 2023 WL 6378423, at *11

Further, Janssen and BMS's arguments about "proportionality" are irreconcilable with Supreme Court precedent. The Supreme Court has explicitly rejected extending the "rough proportionality" test the companies advocate—which comes from a pair of land-use cases, *Nollan* and *Dolan*—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); *see also Koontz*, 570 U.S. at 604-05 (explaining that this test derives from the "special" circumstances that arise "when owners apply for land-use permits"). Other kinds of alleged takings are subject to different tests. *See, e.g.*, *Lingle,* 544 U.S. at 548 ("[A] plaintiff seeking to challenge a government regulation as an uncompensated taking of private property may" allege "a 'physical' taking, a *Lucas*-type 'total regulatory taking,' a *Penn Central* taking, or a land-use exaction violating the standards set forth in *Nollan* and *Dolan*."). Plaintiffs do not allege that the Program fails any of those other tests, however. *See* Janssen Br. at 16-20; BMS Br. at 15-17. And whatever else Janssen and BMS may say about selected drugs and the Negotiation Program, they have not claimed that CMS is trying to burden any manufacturer's land.

Meanwhile, in the First Amendment context, the Supreme Court has long upheld conditions on speech that pertain to the nature of the 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.*, 570 U.S. at 214-15; *see, e.g., United States v. Am. Lib. Assn.*, 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

("[T]here is no constitutional right (or requirement) to engage in business with the government").

to do so without federal assistance"); *Regan v. Taxation With Representation*, 461 U.S. 540, 546 (1983) (dismissing "the notion that First Amendment rights are somehow not fully realized unless they are subsidized by the State" (internal quotation marks omitted)). Conditions implicating speech may become suspect where those conditions "seek to leverage funding to regulate speech outside the contours of the program itself." *Agency for Int'l Dev.*, 570 U.S. at 214-15.

Here, of course, the supposed speech condition about which Plaintiffs complain is the signing of an agreement to negotiate. *See* Janssen Br. at 29-31, BMS Br. at 23-37. That agreement—again, entirely voluntary—is the core mechanism by which the negotiations proceed and the source of the enforceable obligation for manufacturers to ultimately provide their drugs at the negotiated prices. *See* Revised Guidance at 118-20. In this way, the agreement "define[s] the [Negotiation] program and" does not "reach outside it." *Agency for Int'l Dev.*, 570 U.S. at 217. And because the agreement is 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 agreement does not impose an unconstitutional condition on the use of federal funds. *Rust v. Sullivan*, 500 U.S. 173, 193, 196 (1991).

* * *

The IRA's Negotiation Program is nothing more, and nothing less, than an example of Congress exercising its constitutional authority to control the use of federal funds. Such control fits squarely within the bounds of established precedent. So Plaintiffs' constitutional challenges cannot succeed.

Additional briefing might be required to address the appropriate scope of remedy if the Court were to conclude otherwise. Among other things, the parties might have to brief how the Anti-Injunction Act, 26 U.S.C. § 7421, limits the relief that Plaintiffs can receive in this pre-enforcement lawsuit. Likewise, Plaintiffs' papers make clear that they are seeking relief only with respect to their own obligations under the Negotiation

Program. *See, e.g.*, BMS Br. at 40 (asking the Court to "enjoin Defendants from enforcing [the IRA] *against BMS"* (emphasis added)); BMS Proposed Order, Case No. 23-cv-3335, ECF No. 36-4 at 2 (same); Janssen Br. at 4, 36 (asking for relief only with respect to Plaintiff Janssen Pharmaceuticals, Inc.); Janssen Proposed Order, Case No. 23-cv-3818, ECF No. 30-11 at 2 (same). If, however, Plaintiffs were to expand the scope of the relief they seek, the parties would have to brief that too. *See, e.g.*, *Haaland v. Brackeen*, 143 S. Ct. 1609, 1639 (2023) (explaining that a "declaratory judgment" is only proper if it "conclusively resolves the legal rights of *the parties*." (citations omitted, emphasis in original)); *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018) ("A plaintiff's remedy must be tailored to redress the plaintiff's particular injury.").

The Court need not reach those issues at this stage, however, because Plaintiffs' challenges fail on the merits. Defendants are entitled to judgment as a matter of law.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion for summary judgment and grant Defendants' cross-motion.

Dated: October 16, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Alexander V. Sverdlov
ALEXANDER V. SVERDLOV
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 NEW JERSEY

BRISTOL MYERS SQUIBB CO., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 23-cv-03335-ZNQ
JANSSEN PHARMACEUTICALS, INC., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 23-cv-03818-ZNQ

[PROPOSED] ORDER

Upon consideration of the parties' cross-motions for summary judgment, 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**.

Date:

_____
ZAHID N. QURAISHI
United States District Judge