UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 1:23-cv-01615-CKK

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 statement of undisputed material facts and memorandum of law.

Dated: September 11, 2023

Respectfully submitted,

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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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INTRODUCTION

For more than 30 years, Congress has imposed limits on how much federal agencies pay for prescription drugs. Manufacturers who wish to sell their drugs to the Department of Defense and the Department of Veterans Affairs 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 August'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 some of the costliest, single-source, brand-name prescription drugs. *See* 42 U.S.C. § 1320f(a) (establishing the "Negotiation Program"). In this way, Congress sought to reduce government spending on pharmaceutical products that lack generic (or biosimilar) competition and account for a disproportionate share of Medicare's expense. 42 U.S.C. § 1320f-1(b), (d), (e).

Not surprisingly, drug manufacturers lobbied hard against legislative efforts to give the Secretary a seat at the negotiating table. And now that their lobbying failed, pharmaceutical companies and interest groups have filed multiple suits around the country challenging the statute on its face. This case, brought by Plaintiff Merck & Co., Inc. (Merck), is just one such lawsuit. But like the other suits, Merck's challenge rests on a number of misunderstandings regarding crucial elements of the IRA.

As an initial matter, Merck is not the proper plaintiff to bring this action. The Centers for Medicare & Medicaid Services (CMS) has made clear that it will negotiate and enter agreements only with the "Primary Manufacturer" of a selected drug: that is, the entity that holds the new drug application (NDA). CMS, Medicare Drug Price Negotiation Program: Revised Guidance at 118 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance). But Merck merely *markets* a drug CMS selected for negotiation, and the entity that holds that drug's NDA (a subsidiary of Merck) is not a plaintiff in this action. Under settled principles of the corporate form and shareholder standing, Merck cannot sue to vindicate an injury to another corporation, even if it owns a controlling stake.

Merck's misunderstandings of the IRA and CMS's implementation of the statute also doom its legal challenge on the merits. Contrary to Merck's assertions, drug manufacturers are not obligated to participate in the Negotiation Program. Rather, Congress "expressly connect[ed]" the Negotiation Program to a "manufacturer's *voluntary* participation" in Medicare and Medicaid. Revised Guidance at 120 (emphasis added); *see also* Pub. L. No. 117-169, § 11003 (enacting 26 U.S.C. § 5000D(c)). Manufacturers that do not wish to make their drugs available at negotiated prices can avoid doing so by forgoing sales of the relevant drugs to Medicare beneficiaries—including by withdrawing from the Medicare and Medicaid markets or by divesting their interests in the relevant drugs before 2026, when the negotiated prices would first take effect. Invoking these options allows manufacturers to avoid or exit the Negotiation Program without incurring any tax or penalty. And while Merck may be dissatisfied with the conditions the Negotiation Program imposes on future Medicare spending, precedent confirms that imposing such conditions is part of Congress's prerogative to ensure that federal funds are spent according to its view of the "general Welfare." U.S. Const., Art. I, § 8, cl. 1. Attaching such conditions to a voluntary program neither compels Merck to surrender its property in violation of the Fifth Amendment nor requires it to engage in speech in violation of the First. Both of Merck's constitutional claims fail on that basis.

Merck's constitutional arguments fail in other respects, too. The company's primary legal theory—that the Negotiation Program is a "classic" *physical* taking of its property—is untenable under the Supreme Court cases that Merck itself invokes. Pl.'s Mot. for Summ. J. Br., ECF No. 23-1 at 14 (Pl.'s 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 drug or other property. Nor does the IRA require a manufacturer to relinquish any drug it does not wish to sell. Merck's physical taking theory—the only type of taking Merck alleges—therefore fails outright.

Similar errors infect Merck's First Amendment arguments. Contrary to Merck's assertions, neither the agreements that a manufacturer might sign 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 agreements that pertain solely to the manufacturers' conduct. And Merck'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—recognition of First Amendment expression in every commercial act.

At bottom, Merck's objection to the Negotiation Program is "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.* Merck 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 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 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 Office (CBO), *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 leveraging market competition to reduce prices for beneficiaries and taxpayers. *Id.* at 120.

B. The IRA seeks to address these concerns. Pub. L. No. 117-169, §§ 11001-11003 (codifying 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 for price applicability years 2027 and 2028, and up to 20 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 a final 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 Medicare beneficiaries at non-negotiated prices and pay an excise tax. 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* Revised Guidance at 131-32. 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; 26 U.S.C. § 5000D(c)(1).

Like other market systems, the Negotiation Program thus gives a manufacturer a choice: it can sell its products at prices a buyer is willing to pay, or it can take its 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, Initial Guidance (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 who wish to remain in the Medicare and

Medicaid programs but who 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 intends to interpret the IRA's excise-tax provision. *See* IRS Notice No. 2023-52 (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.* For example, this means 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 Merck claims).[1] *Contra* Pl.'s Br. at 7. Notably, 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 construction the agency has articulated. IRS Notice at 5.

[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).

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. Januvia, in which Merck claims a financial interest, was among the drugs selected for negotiation. *Id.*

Manufacturers of the selected drugs are now expected to choose whether to enter into agreements to negotiate by October 1, 2023; those negotiations will conclude by August 1, 2024. Revised Guidance at 91-92; *see* 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b). Any agreed-upon prices for the selected drugs will take effect on January 1, 2026—about two and a half years from now. 42 U.S.C. §§ 1320f(b), 1320f-2(a); Revised Guidance at 92.

ARGUMENT

I. Merck Lacks Standing

In challenging the IRA, Merck has made a threshold error that deprives it of standing. Specifically, Merck alleges that it—*i.e.*, Merck & Co., Inc.—stands to suffer harm from the Negotiation Program because it "developed and markets" the drug Januvia, which is among the first 10 drugs selected for negotiation. Decl. of Patrick Davish, ECF No. 23-3 ¶ 5; *see also id.* ¶¶ 33, 50 (asserting without support that Merck would have to "'enter into' a 'manufacturer agreement'" under the Program, or else face the decision to either "terminate *all* of its Medicare Part D manufacturer-discount agreements and Medicaid rebate agreements" or pay "the IRA's excise[ ]tax"). But these assertions are incorrect, because an entity that merely develops and markets a drug is not subject to the obligations that accompany the Negotiation Program. *See, e.g.*, Compl., ECF No. 4 ¶ 28 (alleging that "affected *manufacturers*" must enter agreements "set[ting] forth the requirements governing the *manufacturer[s']* participation in the Program" (emphases added)).

The IRA instructs CMS to seek to negotiate with "the manufacturer" of a selected drug. 42 U.S.C. § 1320f-2(a)(1); *see also id.* §§ 1320f(b)(4), 1320f-2(a)(3), 1320f-3(a)(1), 1320f-4(a). As CMS's Revised Guidance makes clear, because the statute directs CMS to negotiate with one entity, the invitation to participate in negotiations—and option to sign any final agreement—will be extended exclusively to the "primary manufacturer" of the selected drug: that is, the holder of the new drug application (NDA) or biologics license application (BLA) for purposes of FDA approval. *See* Revised Guidance at 118 ("To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug . . . , CMS will designate the entity that holds the NDA(s) / BLA(s) for the selected drug to be 'the manufacturer[.]'"). And "[a]s the entity that is party to the Agreement, the Primary Manufacturer will be solely responsible for compliance with all provisions of the Agreement[.]" *Id.* at 119. Yet Merck has not alleged that it has been deemed the primary manufacturer for Januvia—and for good reason.

According to publicly available information, non-party Merck Sharp & Dohme (MSD)—not Plaintiff Merck & Co., Inc.—is the relevant manufacturer because MSD currently holds the NDA for Januvia.[2] *NDA 021995*, U.S. FDA: Drugs@FDA, https://perma.cc/HDS8-UNC6; *see also* Pl.'s Ex. D at 231, ECF No. 23-8 (listing "Merck Sharp & D[ohme]" as "[m]anufacturer" of Januvia). That means that MSD is the "primary manufacturer" within the meaning of the Revised Guidance. *See* Revised Guidance at 118. Accordingly, CMS has asked *MSD* to participate in the Negotiation Program—and *MSD* is the entity that faces the legal obligations that Merck supposedly fears. *See* Revised Guidance at 118.[3]

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[2] See also FDA Supplemental Approval (June 21, 2022), https://perma.cc/HYW7-DYFR (addressed to "Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc."). Further, the Januvia labeling states that the drug is "[d]istributed by: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc." Januvia Prescribing Information (rev. June 2022), https://perma.cc/Y2FL-VKXK.

[3] This is also true for the other drugs named in Merck's pleadings, which the company fears may be selected for negotiation in future years: MSD likewise holds the NDAs for Janumet and Janumet XR and a BLA for Keytruda. *See* Compl. ¶ 9; *see, e.g.*, *NDA 022044*, U.S. FDA: Drugs@FDA, https://perma.cc/D2L5-5XXS (Janumet); *NDA 202270*, U.S. FDA: Drugs@FDA,

Merck & Co., Inc., and its subsidiary MSD are distinct corporate entities. And, under basic principles of the corporate form and binding precedent, Merck cannot bring this suit on another corporation's behalf, even if that other corporation is a subsidiary. "A basic tenet of American corporate law is that the corporation and its shareholders are distinct entities." *Dole Food Co. v. Patrickson*, 538 U.S. 468, 474 (2003); *see also* 1 William Meade Fletcher *et al.*, Fletcher Cyclopedia of the Law of Corporations § 43 (2022 ed.) ("As a general rule, two separate corporations are regarded as distinct legal entities even if the stock of one is owned wholly or partly by the other."). On this basis, "[n]o shareholder—not even a sole shareholder—has standing in the usual case to bring suit in his individual capacity on a claim that belongs to the corporation." *Am. Airways Charters, Inc. v. Regan*, 746 F.2d 865, 873 n.14 (D.C. Cir. 1984). Accordingly, the shareholder standing rule "generally prohibits shareholders from initiating actions to enforce the rights of the corporation unless the corporation's management has refused to pursue the same action for reasons other than good-faith business judgment." *Franchise Tax Bd. of Calif. v. Alcan Aluminium Ltd.*, 493 U.S. 331, 336 (1990). This "longstanding equitable restriction," *id.*, "reflect[s] the established tenet that plaintiffs must demonstrate . . . standing by asserting their own legal rights and interests rather than resting claim[s] to relief on the legal rights or interests of third parties," *Bronner ex rel. Am. Stud. Ass'n v. Duggan*, 962 F.3d 596, 607 (D.C. Cir. 2020) (citation omitted).

A narrow exception to this general rule exists where the shareholder can show a "direct, personal interest in a cause of action" distinct from that of the corporation, as opposed to "claims [that] are purely derivative of the corporation's claims." *Cheeks v. Fort Myer Const. Co.*, 722 F. Supp. 2d 93, 108 (D.D.C. 2010) (citation omitted). But a "depreciation or diminution in the value of a shareholder's corporate stock" is "merely an indirect or incidental injury to an individual shareholder," which is not "the type of direct, personal injury . . . necessary to sustain a direct cause of action." *Gaff v. Fed. Deposit Ins. Corp.*, 814 F.2d 311, 315 (6th Cir.), *on reh'g in part*,

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https://perma.cc/8SCU-HV2M (Janumet XR); *BLA 125514*, U.S. FDA: Drugs@FDA, https://perma.cc/N89Y-LGN3 (Keytruda).

828 F.2d 1145 (6th Cir. 1987) (collecting cases). And a speculative diminution in value is the only sort of injury to Merck & Co., Inc. even hinted at in its filings. *See, e.g.*, Comp. ¶ 9 ("Merck invests billions of dollars every year to develop life-saving drugs. Among them is Januvia, which is used to treat type 2 diabetes."); *accord* Davish Decl. ¶¶ 4-5. *Merck*, as a shareholder of MSD, cannot bring suit on MSD's behalf unless it can allege (and substantiate) an exception to the general prohibition on shareholder standing. But Merck's filings make no mention at all of MSD—which in fact faces the choices and obligations under the Negotiation Program that Merck itself purportedly fears—much less make plausible allegations suggesting that Merck, as marketer of Januvia, would suffer any "separate and distinct" injury. Merck thus does not have standing to sue.

Enforcing this standing requirement is not a technical exercise. Rather, the "rule serves the noble function of preventing parent corporations from having their cake and eating it too." *Sec. Indus. & Fin. Markets Ass'n v. U.S. Commodity Futures Trading Comm'n*, 67 F. Supp. 3d 373, 406-07 (D.D.C. 2014) (collecting cases). "Where a parent corporation desires the legal benefits to be derived from organization of a subsidiary that will function separately and autonomously in the conduct of its own distinct business, the parent must accept the legal consequences," which may include "its inability later to treat the subsidiary as its alter ego because of certain advantages that might thereby be gained." *In re Beck Indus., Inc.,* 479 F.2d 410, 418 (2d Cir. 1973). This is no mere hypothetical; Merck has used its status as a parent corporation to its legal benefit. *See, e.g.*, *Mayne Pharma Int'l PTY Ltd. v. Merck & Co*., No. CV 15-438-LPS-CJB, 2015 WL 7833206 at *2 (D. Del. Dec. 3, 2015) (defendants Merck & Co. and two alleged subsidiaries, including MSD, moved to dismiss patent suit on the ground that plaintiff "failed to identify which entity is responsible for the alleged infringing activity by lumping together its allegations against the three Defendants"). The Court should not permit Merck to obscure in this case the same corporate distinction on which it relies to its advantage elsewhere. *Cf., e.g.*, *Williams v. Mordkofsky,* 901 F.2d 158, 164 (D.C. Cir. 1990) ("Had [the corporation] declared bankruptcy, it is certain that the [plaintiffs] would not be so quick to request that we disregard the corporate form."); *Pa. Eng'g*

Corp. v. Islip Res. Recovery Agency, 710 F. Supp. 456, 465 (E.D.N.Y. 1989) ("[A] parent corporation cannot create a subsidiary and then ignore [its] separate corporate existence whenever it would be advantageous to the parent." (citation omitted)); *Bross Utils. Serv. Corp. v. Aboubshait*, 618 F. Supp. 1442, 1445 (S.D.N.Y. 1985) ("[T]he courts will not allow a parent to pierce the corporate veil it created for its own benefit, so as to assert the claims of its subsidiary." (emphasis omitted)).

In short, Merck lacks standing to bring this suit on behalf of MSD, which is the true party to any negotiation and agreement under the Negotiation Program with respect to the drugs in which Merck asserts an interest. Accordingly, the case should be dismissed.

II. The Negotiation Program Is Not a Taking Because Participation Is Voluntary

Merck also misunderstands the IRA in ways that doom its merits arguments. For decades, courts analyzing reimbursement rates under Medicare have uniformly rejected takings claims like the one that Merck presses. *See, e.g.*, *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1279-80 (11th Cir. 2014); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir.), *cert. denied*, 510 U.S. 821 (1993). In doing so, those courts have emphasized that the Medicare program may limit how much the government pays participating providers—but these sorts of limits do not compel any entity to surrender property it does not wish to sell. *See Baker Cnty.*, 763 F.3d at 1279-80; *Garelick*, 987 F.2d at 916. The Negotiation Program works on the same principle.

Contrary to Merck's assertions, neither the IRA nor any other part of Medicare requires manufacturers to negotiate with CMS or to sell their drugs to Medicare beneficiaries. Rather than "compel[ling] the transfer of private pharmaceuticals for public benefit," Pl.'s Br. at 11, the IRA allows manufacturers to withdraw from the Negotiation Program if they do not wish to participate. The 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 Merck 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. am. 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). Where 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, 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 conditions on Medicare spending like the Negotiation Program.

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). 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 are voluntary—and therefore 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," like the Medicare statute, "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) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 16, 17 (1981)). 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. The IRA 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.*, 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* Revised Guidance at 33-34, 120-21, 129-31.[4] Alternatively, a manufacturer can divest its interest in the selected drug 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 Merck's claims, no manufacturer is being *forced* to make sales under the Negotiation Program. *Contra* Pl.'s Br. at 8, 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. The choice is the manufacturer's to make.

[4] Recognizing the viability of this option, some manufacturers have stated that this is exactly what they might do. *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.

B. Manufacturers Have Adequate Opportunity to Withdraw from the Program

Attempting to evade this well-settled precedent, Merck asserts 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." Pl.'s Br. at 42-44. But Merck's arguments about the process for withdrawal rest on a misunderstanding of the IRA's provisions.

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, 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] If manufacturers choose to withdraw from Medicare, the Social Security Act (SSA) provides that the relevant Medicare-participation agreements can be terminated by CMS within 30 days. *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 within 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 such as MSD flexibility to avoid any tax if they choose not to participate in the Negotiation Program. Under the IRA's schedule, a manufacturer

[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).

knew whether its drug was selected for the first set of negotiations 34 days before any tax liability (for selling the drug without signing a negotiation agreement) 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). The manufacturer of a selected drug will know how those negotiations are going far in advance of August 2, 2024, when it would be exposed to tax liability if it has not signed a final price agreement. *See* 26 U.S.C. § 5000D(b)(2). And if the manufacturer signs a final price agreement before the statutory deadline, there is still *at least 16 months* before January 1, 2026, when it would first be required to give effect to the negotiated prices—or face civil penalties (but no tax) for failing to do so. 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.[7] 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.

Merck fails to appreciate these various options—just as it fails to appreciate that the tax about which it complains attaches *only* to Medicare sales and does not exceed the total amount a manufacturer charges for the drug. *See, e.g.*, Pl.'s Br. at 7-8; 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, Merck merely makes a passing claim that CMS's use of its own authority to provide for the 30-day withdrawal option is "dubious." Pl.'s Br. at 43. But CMS's authority comes from other statutory provisions of the SSA—*not* the Negotiation Program provisions of the IRA. And

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

[7] Notably, a manufacturer can also provide this notice and then withdraw it within 30 days if it so chooses. *See* Revised Guidance at 121, 131. A manufacturer therefore can preemptively ask CMS to terminate its agreements out of an abundance of caution and then make a final decision about participation as the final deadline approaches.

Merck has not actually challenged CMS's interpretation, which operates to the manufacturers' benefit, and which Merck would therefore lack standing to contest.[8] Further, even putting aside CMS's Revised Guidance, Merck overlooks the 28-month period between a manufacturer's drug(s) being selected for negotiation and the January 2026 deadline for implementing negotiated prices. *See* Pl.'s Br. at 42. Even by Merck'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* Pl.'s Br. at 42 (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").

Merck is thus wrong to claim that the choice to withdraw from the Negotiation Program is "illusory" or that it is required to sell its drugs at negotiated prices. Pl.'s Br. at 42-43. 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). A manufacturer such as MSD has far more flexibility to withdraw from the Negotiation Program. Its choice to participate, or not, is real.

C. The Negotiation Program Does Not "Coerce" Merck

Unable to show that any manufacturer is *legally* compelled to participate in the Negotiation Program, Merck tries one final workaround. Relying on the Supreme Court's decision in *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*), Merck argues that the Negotiation Program is impermissibly "coercive" because Congress has improperly "leverage[d]" Medicare spending as means of compelling participation. Pl.'s Br. at 38-42, 45-48. But this argument reflects a basic misunderstanding of *NFIB*, on numerous levels.

[8] Indeed, Merck has not even alleged that it wishes to withdraw from Medicare to avoid the Negotiation Program. So its arguments about how CMS would administer the withdrawal timelines are purely academic.

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)); *see also Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Public Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) (holding that a "strong financial inducement to participate" in a regulated program does not render such participation involuntary); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983). 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 *NFIB* lead opinion emphasizes, the Spending Clause permits Congress to place "restrictions on the use of those 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 to ensure that Congress has not improperly infringed on state sovereignty—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).

These federalism-based principles are inapposite in evaluating whether Congress has overstepped its enumerated powers in dealing with private parties like Merck. *See, e.g.*, *Northport Health Servs. of Arkansas, 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 Arkansas, 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.").[9] After all, Merck is not a state and has no equivalent sovereign-based right to be free of 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 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))). Thus, in upholding a COVID-19 vaccination requirement for workers in facilities funded by Medicare or Medicaid, the Supreme Court emphasized that "healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy a host of conditions," without regard to whether those conditions were coercive. *Biden v. Missouri*, 142 S. Ct. 647, 652 (2022).

2. Further, 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 it will purchase goods in the market. *NFIB*, 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);

[9] Merck incorrectly suggests that the Third Circuit applied the "coercion" inquiry to private parties in *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020). Pl.'s Br. at 42. 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 nowhere analyzed whether the withdrawal of such funds would be impermissible (which the "coercion" inquiry would demand). *Id.* at 213.

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").

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. If a manufacturer is unwilling to sell its selected drugs to Medicare at the price that the government is willing to pay, it is free to withdraw from the Medicare program. Alternatively, if the manufacturer wishes to remain in Medicare but is for some reason unwilling to negotiate over the price of its

selected drugs, the IRA imposes an excise tax on sales *of those selected drugs* to Medicare. *See* 26 U.S.C. § 5000D(a); *see also* IRS Notice.[10]

These steps to limit how much the government expends 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. Merck may be dissatisfied with how Congress drafted those conditions or how those conditions differ from other conditions it is used to seeing in the Medicare statute. Pl.'s Br. at 36. But Merck's dissatisfaction does not establish a constitutional claim.

3. For similar reasons, the Negotiation Program would not be "coercive" under *NFIB*'s test even if that test were applicable. Unlike the challenged statutory provisions in *NFIB*, 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."); *see also Gruver v. La. Bd. of Supervisors*, 959 F.3d 178, 183 (5th Cir. 2020) ("conditions that do not directly 'govern the use of the funds'" are subject to "the coercion inquiry"). 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 the drug). *See* Revised Guidance at 131-32.

[10] Merck appears to misunderstand these two features of the tax—namely, its scope and amount. *See* Pl.'s Br. at 8. As detailed above, *supra* p. 7, the tax does not apply to sales of drugs beyond Medicare—and does not exceed the amount the manufacturer charges for the drug. *See* IRS Notice at 3.

True, manufacturers *also* have the option of leaving Medicare and Medicaid entirely.[11] For some manufacturers (particularly those that own only one drug) that may be a more straightforward option. But, contrary to Merck's characterization, the availability of this choice does not mean that Congress has offered manufacturers anything improper. For one thing, the option to exit Medicaid and Medicare still relates to Congress's spending on the drugs at issue—and thus does not trigger the "coercion" inquiry. *See, e.g.*, *Gruver*, 959 F.3d at 183. Further, the option is merely offered *in addition* to the other paths available to manufacturers, so it cannot create a constitutional problem. Rather than threatening entirely independent grants, *id.*, Congress has merely told manufacturers that Medicare will not necessarily continue paying manufacturers at current levels for their products, and left them free to choose whether they wish to continue selling the drug to Medicare on new terms. This is neither a "gun to the head" nor, in Merck's dramatic retelling, a "bazooka." Pl.'s Br. at 40. It is simply an offer made by a buyer to a seller who can agree to a price or forgo the sale.

4. Merck's 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*," the 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 Merck's failure "to provide the necessary information" provides an independent "ground for rejecting" Merck's 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*

[11] This is another reason why adhering to shareholder standing principles, *see supra* at p. 10-11, is important. Merck & Co., Inc.—the only Plaintiff in this case—is not even the entity that is now faced with the choice to participate in negotiations over the price of Januvia, divest its interest in Januvia, or withdraw from Medicare or Medicaid. That choice is now presented to MSD, and MSD alone.

also United States v. Morrison, 529 U.S. 598, 607 (2000) (requiring a "plain showing" of unconstitutionality). Especially on a facial challenge, where Merck "must establish that no set of circumstances exists under which" the Negotiation Program could be constitutionally valid, Merck's 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—which it is not—Merck has failed to satisfy it.

* * *

Simply put, Merck cannot establish that the Negotiation Program is anything other than voluntary. 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.

III. Merck's Takings Claim Fails Even on Its Own Terms

Even setting aside the voluntary nature of the Negotiation Program, and the settled precedent rejecting Fifth Amendment challenges to Medicare reimbursement caps, Merck's takings claim still fails 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). Merck does not allege a regulatory taking. Rather, Merck insists that the Negotiation Program amounts to a *physical* taking of selected drugs. Pl.'s Br. at 2, 14. Merck's reliance on the physical-taking framework is, in a way, not surprising: other forms of takings are evaluated on an "ad hoc" basis, and thus are not suitable for a facial challenge. *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). But Merck's physical-taking theory fails as a matter of law.

A. Merck Has No Vested 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.

Here, Merck asserts that manufacturers have such property interests in the drugs they *own* or in the patents on those drugs. *See* Pl.'s Br. at 16. But neither Merck nor any other manufacturer has an inherent entitlement—and therefore no property interest—in selling their drugs *to Medicare* at any particular price. *Contra id.* at 16-18. 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). 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"). So, as courts have repeatedly emphasized, "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 Merck's claim that a reduction in Medicare reimbursement can constitute a taking would mean that the manufacturer has a *constitutional right* to dictate the government's expenditures. By the same logic, physicians and hospitals could also challenge their reimbursement rates as takings. *Contra, e.g.*, *Managed Pharmacy Care*, 716 F.3d at 1252; *Garelick*, 987 F.2d at 917. But, as noted above, 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. 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 Merck's theory, noting that "those who opt to participate in Medicare are not assured of revenues." *Livingston Care Ctr*, 934 F.2d at 721.

B. The Negotiation Program Is Not a Physical Taking

Endeavoring to overcome this precedent, Merck seeks to paint the Negotiation Program as a "'classic' or *per se* taking" of the kind the Supreme Court examined in *Horne*, 576 U.S. 351. Pl.'s Br. at 14. Though Merck never uses the term "physical" taking, that is what *Horne* and the other cases Merck relies on discuss. *See* Pl.'s Br. at 14 (citing *Horne*, 576 U.S. at 358-64; *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063 (2021)). But the Negotiation Program has none of the features of a "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*, 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, however, there is no "physical appropriation." *Cedar Point Nursery*, 141 S. Ct. at 2074. Unlike the Department of Agriculture in *Horne*, CMS will not "sen[d] trucks to [Merck's] facility at eight o'clock one morning to" haul away drugs. *Horne*, 576 U.S. at 356. And, contrary to Merck's claims, the IRA does not 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). Nothing in the statute requires manufacturers to *make sales* in the first instance. 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 Medicare beneficiaries. 42 U.S.C. § 1320f-2(a)(1), (3) (emphasis added). In other words, Congress has sought to limit the prices at which drugs are to be made available under the Medicare program—but has not required manufacturers give physical "access" to property of the kind discussed in the cases Merck cites. *Cedar Point*, 141 S. Ct. at 2072. Merck's physical taking arguments therefore run aground on the "settled difference in [] takings jurisprudence between appropriation and regulation" even when the two may "have the same economic impact." *Horne*, 576 U.S. at 362; *contra* Pl.'s Br. at 19 (arguing that "[a]ppropriating 50% of one's inventory is materially identical" to "requisitioning that inventory at a 50% discount"). And Merck's efforts to conflate "access" to *prices* with "access" to *drugs*—which it does by omitting critical parts of the statutory language—reveals the conceptual problem with Merck's taking theory writ large.

In any event, as Merck appears to recognize, 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—contrary to Merck's suggestion, Pl.'s Br. at 15—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. Yet when it comes to utility ratemaking, the Supreme Court has made clear 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. That is, a utility alleging a taking is required to identify a "particular, actual . . . rate [that] is 'so unjust as to be confiscatory,' that is, . . . threatening [the utility's] 'financial integrity'"—and cannot merely challenge the rate-setting methodology on its face. *Id.* at 523-24 (quoting *Duquesne Light*, 488 U.S. at 307, 312). Merck, of course, is not challenging any specific rate yet—nor can it do so. 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 likewise have foreclosed any attempt Merck 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 Merck has eschewed a regulatory taking theory.

* * *

In short, the Negotiation Program is not a physical taking. And because Merck has not alleged any other kind of taking, its facial Fifth Amendment challenge fails.

IV. The Negotiation Program Does Not Compel Merck to Speak

Merck's attempt to assert a First Amendment challenge to the Negotiation Program likewise fails. That challenge rests entirely on Merck's unsupported assertion that (1) manufacturers will be "compelled" to sign agreements with CMS and (2) their entry into these agreements constitutes "speech" or "expression" protected by the First Amendment. Pl.'s Br. at 23. But neither assertion 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. Pl.'s Br. at 23. For all the reasons detailed previously, Merck's 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*). Just as there is no compulsion for manufacturers to sell drugs to Medicare, there is no compulsion for manufacturers to engage in activities that Merck (incorrectly) describes as speech.

In any event, signing an agreement with CMS does not constitute compelled expression. Pl.'s Br. at 27-28. 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 Merck puts it, "ordinary contracts do not express views or convey beliefs—they are promises to act, not professions of principle." Pl.'s Br. at 29. Indeed, Medicare uses a myriad of agreements that health care providers and other entities are invited to sign to demonstrate their voluntary acceptance of the terms for participation in the relevant programs; these agreements do not compel providers to endorse the 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 access to the

negotiated price. *See* Revised Guidance at 118-20; *see also* Roth Decl., ECF No. 23-6, Ex. B at 1-3 (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 Merck's 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). As Merck acknowledges, 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*. On its face, this language confirms the obvious: namely, that signing

a pricing agreement does not require a manufacturer to adopt or express any viewpoint.[12] Though the agreement uses statutory terms as a way of ensuring that the counter-signing parties have the same understanding of their obligations, signing the agreement does not commit the manufacturer to profess agreement with any broader principle. *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 the amount they are allowed to collect" but instead "regulate[s] . . . how sellers may communicate their prices"). Nor does the agreement restrict a manufacturer's ability to say anything it wants about the Negotiation Program, to characterize the negotiations as "Soviet" or illegitimate, or to otherwise criticize CMS or the IRA. Pl.'s Br. at 22.

Notwithstanding all this, Merck suggests that—because the template agreement uses statutory terms like "agree" and "maximum fair price," which also have colloquial meanings—signing the agreement *could* be perceived as a manufacturer agreeing with the government's message that the Program is a "*bona fide* negotiation" that will "culminate in an agreed price" that everyone considers to be "fair." *See* Pl.'s Br. at 27; *see generally* Template Agreement. Merck insists that creating such an impression is the secret motivation for the program. Pl.'s Br. at 30. But Merck provides no basis for this assertion. *See id.* at 9-10 & n.2 (citing over a dozen statements inconsistent with Merck's own theory, from the President, multiple Members of Congress, HHS, CMS, and the statute itself). And this line of argument has no end point.

By Merck's logic, any seller of commercial goods could assert that *any* price control prohibits it from expressing the idea that its products are worth more—and that, by complying with such price control, the seller is thus "dragooned into service as a political mouthpiece" for the legislature's ideas. Pl.'s Br. at 22. 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

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

prohibition on the distribution of free samples of tobacco products, these 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.* at 291. 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)); *see also FAIR*, 547 U.S. at 62 ("Congress, for example, can prohibit employers from discriminating in hiring on the basis of race. 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."). 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).

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. In the words of the Supreme Court, 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 Merck is truly worried that a manufacturer's decision to sign an agreement will somehow "distort" public debate, Pl.'s Br. at 32, the answer is simple: Merck and manufacturers of selected drugs are free to complain about the Negotiation Program to the public,

to Congress, and to anyone else who will listen.[13] As Merck acknowledges, the Revised Guidance contains no "gag order" and no prohibition on Merck expressing its ideas. *Id*. And if Merck believes that it would somehow be preferable for manufacturers to *not* have the option to negotiate—that Congress should have just imposed price controls directly—it can say that too. Pl.'s Br. at 30. But the IRA is not made constitutionally suspect by the choices that Congress has in fact made.

V. The Negotiation Program Is a Valid Condition on Federal Funds

Finally, Merck tries to recast both its Takings Clause and First Amendment grievances into one omnibus "unconstitutional condition[s]" argument. Pl.'s Br. at 35, 44-48. As Merck acknowledges, 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 ("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 Merck's unconstitutional-conditions argument fails for additional reasons. In the takings context, the Supreme Court has explicitly rejected extending the "rough proportionality" test Merck advocates, Pl.'s Br. at 45-46—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

[13] Indeed, there has been no shortage of such complaints. *See, e.g.*, *America's plan to cut drug prices comes with unpleasant side-effects*, The Economist (Aug. 29, 2023), available here (noting that the "backlash from the pharma industry has been fierce").

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*."). Merck does not even allege that the Program fails any of those other tests, however. So Merck's attempts to analogize the Negotiation Program to a city threatening to cut off utility services fails outright. *See* Pl.'s Br. at 12. Whatever else Merck may say about selected drugs and the Negotiation Program, it has not claimed that CMS is trying to burden any manufacturer's use of its own 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 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 Merck complains is the signing of an agreement to negotiate. *See* Pl.'s Br. at 45. 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. Merck's constitutional challenge cannot succeed.[14]

CONCLUSION

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

[14] Additional briefing might be required to address the appropriate scope of remedy if the Court were to conclude otherwise. Among other issues, the parties might have to brief how the Anti-Injunction Act, 26 U.S.C. § 7421, limits the relief that Merck can receive in this pre-enforcement lawsuit. The Court need not reach those issues, however, because Merck's challenge fails on the merits.

Dated: September 11, 2023

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., Plaintiff, v. XAVIER BECERRA, U.S. Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 1:23-cv-01615-CKK

DEFENDANTS' RESPONSE TO PLAINTIFF'S STATEMENT OF UNDISPUTED MATERIAL FACTS AND STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Civil Rule 7(h), Defendants Xavier Becerra, the U.S. Department of Health and Human Services (HHS), Chiquita Brooks-LaSure, and the Centers for Medicare & Medicaid Services (CMS), respectfully submit this combined response to Plaintiff Merck & Co., Inc.'s statement of undisputed material facts, ECF No. 23-2, and statement of undisputed material facts in support of Defendants' cross-motion for summary judgment.

I. Defendants' Response to Plaintiff's Statement of Undisputed Material Facts

1. Merck developed and markets JANUVIA® (sitagliptin) (Januvia), a medication to treat type 2 diabetes. Decl. of Patrick T. Davish (Davish Decl.) ¶ 5.

Defendants' Response: Defendants do not dispute that Merck & Co., Inc. developed and markets Januvia but aver that Merck & Co., Inc. does not currently hold the new drug application (NDA) for Januvia.

2. Januvia was first approved by the U.S. Food and Drug Administration (FDA) on October 16, 2006. Davish Decl. ¶ 7.

Defendants' Response: Undisputed.

3. Merck obtained multiple patents securing its intellectual property in Januvia, of which at least one patent remains operative. Davish Decl. ¶ 12.

Defendants' Response: Undisputed.

4. Januvia will be selected for negotiation under the Drug Price Negotiation Program (the Program), established through the Inflation Reduction Act (IRA), in September 2023. Davish Decl. ¶ 13; Decl. of Jacob Roth (Roth Decl.) Exh. D, S. Dickson & I. Hernandez, *Drugs likely subject to Medicare Negotiation, 2026- 2028*, 29 JMCP 229, 230–31 (Mar. 2023) (Dickson & Hernandez).

Defendants' Response: Defendants do not dispute that Januvia was selected for negotiation under the IRA Medicare Drug Price Negotiation Program but aver that the selection announcement was made on August 29, 2023. HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/C689-57WY.

5. Merck developed and markets JANUMET® (sitagliptin and metformin HCL) (Janumet), another medication to treat type 2 diabetes. Davish Decl. ¶ 14.

Defendants' Response: Defendants do not dispute that Merck & Co., Inc. developed and markets Janumet but aver that Merck & Co., Inc. does not currently hold the NDA for Janumet.

6. Janumet was first approved by the FDA on March 30, 2007. Davish Decl. ¶ 16.

Defendants' Response: Undisputed.

7. Merck obtained multiple patents securing its intellectual property in Janumet, of which at least one patent remains operative. Davish Decl. ¶ 20.

Defendants' Response: Undisputed.

8. Merck developed and markets Janumet XR, an extended-release formulation of Janumet first approved by the FDA on February 2, 2012. Davish Decl. ¶¶ 21, 23.

Defendants' Response: Defendants do not dispute that Merck & Co., Inc. developed and markets Janumet XR but aver that Merck & Co., Inc. does not currently hold the NDA for Janumet XR. Defendants do not dispute that the FDA first approved an extended-release formulation of Janumet on February 2, 2012.

9. Merck obtained multiple patents securing its intellectual property in Janumet XR, of which at least one patent remains operative. Davish Decl. ¶ 22.

Defendants' Response: Undisputed.

10. Janumet and Janumet XR (treated as a single product under the IRA) will be selected for the Program's 2027 cycle. Davish Decl. ¶¶ 24–25; Dickson & Hernandez, *supra*, at 321.

Defendants' Response: Defendants dispute Plaintiff's predictions about uncertain future events. CMS has neither promulgated program guidance applicable to, nor selected drugs for, initial price applicability year 2027 or future negotiation cycles. *See* 42 U.S.C. § 1320f(a), (b), (d).

11. Merck developed and markets KEYTRUDA® (pembrolizumab) (Keytruda), a cancer treatment for patients with unresectable or metastatic melanoma. Davish Decl. ¶¶ 26–27.

Defendants' Response: Defendants do not dispute that Merck & Co., Inc. developed and markets Keytruda but aver that Merck & Co., Inc. does not currently hold the biologics license application (BLA) for Keytruda.

12. Keytruda was first approved by the FDA on September 4, 2014. Davish Decl. ¶ 27.

Defendants' Response: Undisputed.

13. Merck obtained multiple patents covering Keytruda and related innovation, of which at least one patent remains operative. Davish Decl. ¶ 31.

Defendants' Response: Undisputed.

14. Keytruda will be selected for the Program's 2028 cycle. Davish Decl. ¶¶ 24–25; Dickson & Hernandez, *supra*, at 321–32.

Defendants' Response: Defendants dispute Plaintiff's predictions about uncertain future events. CMS has neither promulgated program guidance applicable to, nor selected drugs for, initial price applicability year 2028 or future negotiation cycles. *See* 42 U.S.C. § 1320f(a), (b), (d).

15. Once each of the foregoing products is selected for the Program, Merck will "enter into" a "manufacturer agreement" with HHS, 42 U.S.C. § 1320f–2(a), pronouncing Merck's purported "agreement" to participate in "negotiations" that will conclude in a "maximum fair price" for that product. Davish Decl. ¶ 33.

Defendants' Response: Defendants aver that CMS has asked Merck Sharp & Dohme (MSD), not Merck & Co., Inc., to participate in negotiations over Januvia for price applicability year 2026, because MSD currently holds the NDA for Januvia. *See* CMS, Medicare Drug Price Negotiation Program: Revised Guidance at 33-34, 131-32 (June 30, 2023), https://perma.cc/K6QB-C3MM ("Revised Guidance") (explaining that CMS will negotiate and enter agreements only with the "Primary Manufacturer" of a selected drug—that is, the entity that holds the NDA or BLA). Defendants also dispute that anything in the IRA requires any manufacturer to enter into an agreement, which is a legal question.

16. Merck will "enter into" such an "agreement" only because, if it fails to do so, the IRA will impose a daily penalty that begins at 186% and reaches 1,900% of each drug's daily revenues from all sources. Davish Decl. ¶¶ 33, 37, 39.

Defendants' Response: Defendants aver that CMS has asked MSD, not Merck & Co., Inc., to participate in negotiations over Januvia. *See* Revised Guidance at 33-34, 131-32. Defendants dispute that anything in the IRA requires any manufacturer to enter into an agreement, which is a legal question.

Defendants further dispute Plaintiff's characterization and construction of the tax provision, which is a legal question and is, in any event, contrary to the Treasury Department's construction of that provision. *See* IRS Notice No. 2023-52 ("IRS Notice") (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P.

17. For Januvia, that would amount to a penalty of tens of millions of dollars on the very first day of Merck's refusal to enter a "manufacturer agreement," soon escalating to hundreds of millions of dollars per day. Davish Decl. ¶ 37.

Defendants' Response: Defendants dispute Plaintiff's construction of the tax provision, which is a legal question and is, in any event, contrary to the Treasury Department's construction of that provision. *See* IRS Notice.

18. Merck's "ent[ry] into" any "manufacturer agreement" will be coerced by the threat of this penalty. Davish Decl. ¶¶ 33, 37, 39.

Defendants' Response: Defendants dispute that Merck & Co., Inc. will enter any agreement and aver that CMS has asked MSD, not Merck & Co., Inc., to participate in negotiations over Januvia. *See* Revised Guidance at 33-34, 131-32. Defendants also dispute that anything in the IRA requires or compels any manufacturer to enter into an agreement, which is a legal question.

19. By the applicable deadlines, Merck will "agree to" the "maximum fair price[s]" embodied in HHS's final offers, 42 U.S.C. § 1320f–2(a)(1), only because of the threatened penalties if Merck fails to do so. Davish Decl. ¶¶ 41, 47–48.

Defendants' Response: Defendants dispute that Merck & Co., Inc. will enter any agreement and aver that CMS has asked MSD, not Merck & Co., Inc., to participate in negotiations over Januvia. *See* Revised Guidance at 33-34, 131-32. Defendants also dispute that anything in the IRA requires any manufacturer to enter into an agreement, which is a legal question.

20. Merck will provide "access to such price" to eligible individuals and entities participating in Medicare, 42 U.S.C. § 1320f–2(a)(1), only because the IRA threatens civil monetary penalties for failure to provide such "access," *id.* § 1320f–6(a) & (c). Davish Decl. ¶¶ 47–48.

Defendants' Response: Defendants dispute that Merck & Co., Inc. will enter any agreement and aver that CMS has asked MSD, not Merck & Co., Inc., to participate in negotiations over Januvia. *See* Revised Guidance at 33-34, 131-32. Defendants dispute that anything in the IRA requires or compels any manufacturer to enter into an agreement or provide access to any prices to eligible individuals and entities, which is a legal question.

21. The daily penalty described above, *supra* ¶ 16, is suspended only when a manufacturer terminates all of its Medicare manufacturer-discount agreements and Medicaid rebate agreements. Davish Decl. ¶ 50.

Defendants' Response: Defendants dispute Plaintiff's characterization and construction of the tax provision, which is a legal question. *See* IRS Notice. Moreover, as a legal matter, a manufacturer of a selected drug will not be subject to the excise tax if it transfers its interest in the

selected drug to another entity, which can then make its own choices about negotiations. *See* Revised Guidance at 131-32.

22. Without those agreements, Merck cannot receive any payment for its products through Medicare Part B, Medicare Part D, or Medicaid. Davish Decl. ¶ 50.

Defendants' Response: Defendants do not dispute that, if Merck & Co., Inc. were to choose to withdraw from the Medicare and Medicaid programs, Merck & Co., Inc. would not receive payments through Medicare or Medicaid. *See* Revised Guidance at 33-34, 131-32. But Defendants aver that CMS has asked MSD, not Merck & Co., Inc., to participate in negotiations over Januvia, and Merck & Co., Inc. is therefore not faced with the potential choice of withdrawing from the Medicare and Medicaid programs. *See* Revised Guidance at 33-34, 131-32.

23. Together, these federal programs constitute nearly half of the prescription drug market in the United States. Davish Decl. ¶ 50.

Defendants' Response: Undisputed.

24. Exiting nearly half of the national prescription drug market would cost Merck billions of dollars in revenue and leave tens of millions of patients without access to their medications. Davish Decl. ¶¶ 51, 57.

Defendants' Response: Defendants do not dispute that if Merck & Co., Inc. were to choose to exit Medicare and Medicaid, it could lose revenue. Defendants aver that Merck & Co., Inc.'s exit from Medicaid and Medicaid would not necessarily lead to reduced access to specific medications for patients, depending on which entity holds the applicable NDA or BLA for the drugs in question. Defendants also aver that CMS has asked MSD, not Merck & Co., Inc., to participate in negotiations over Januvia, and Merck & Co., Inc. is therefore not faced with the

potential choice of withdrawing from the Medicare and Medicaid programs. *See* Revised Guidance at 33-34, 131-32.

25. Merck's compliance with the Program is coerced by the consequences of terminating all Medicare and Medicaid participation. Davish Decl. ¶¶ 50–51, 57.

Defendants' Response: Defendants dispute that Merck & Co., Inc. is being coerced and aver that CMS has asked MSD, not Merck & Co., Inc., to participate in negotiations over Januvia. *See* Revised Guidance at 33-34, 131-32. Further, Defendants dispute that anything in the IRA requires or coerces any manufacturer to enter into an agreement, which is a legal question.

26. Merck does not agree with (and does not wish to express) the message that drug selection under the Program initiates *bona fide* price negotiations. Davish Decl. ¶¶ 36, 43.

Defendants' Response: Defendants dispute that participating in the Negotiation Program forces any manufacturer to convey any message, which is a legal question. Further, the template agreement includes an explicit disclaimer, which makes clear that, by signing the agreement, a manufacturer is not endorsing the government's views. *See* Roth Decl., ECF No. 23-6, Ex. B at 4 (Template Agreement) (explaining that, by "signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views"); *see also id*. (explaining further than "[u]se of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms").

27. Merck does not agree with (and does not wish to express) the message that Merck and the Government will reach, or have reached, a meeting of the minds following *bona fide* negotiations. Davish Decl. ¶¶ 36, 43.

Defendants' Response: Defendants dispute that participating in the Negotiation Program forces any manufacturer to convey any message, which is a legal question. Further, the template agreement includes an explicit disclaimer, which makes clear that, by signing the agreement, a manufacturer is not endorsing the government's views. *See* Template Agreement at 4.

28. Merck does not agree with (and does not wish to express) the message that Merck's participation in the Program or its acceptance of the "maximum fair price" are voluntary. Davish Decl. ¶¶ 37, 44; *see also supra*, ¶¶ 15–25.

Defendants' Response: Defendants do not dispute that Merck may hold certain beliefs but dispute that participating in the Negotiation Program forces Merck to convey any message, which is a legal question. Further, the template agreement includes an explicit disclaimer, which makes clear that, by signing the agreement, a manufacturer is not endorsing the government's message. *See* Template Agreement 4.

29. Merck does not agree with (and does not wish to express) the message that the price HHS sets at the end of the Program's "negotiation" period represents the "maximum fair price" for any Merck product. Davish Decl. ¶¶ 38, 45.

Defendants' Response: Defendants dispute that participating in the Negotiation Program forces any manufacturer to convey any message, which is a legal question. Further, the template agreement includes an explicit disclaimer, which makes clear that, by signing the agreement, a manufacturer is not endorsing the government's views. *See* Template Agreement at 4. Defendants also dispute that HHS "sets" a price for selected drugs and aver that the Negotiation Program instead involves a price negotiated between HHS and the manufacturer.

30. The characterization of HHS's price as the only "fair" price contradicts Merck's strongly held views regarding drug pricing. Davish Decl. ¶¶ 38, 45.

Defendants' Response: Defendants dispute that the statutory language of the Negotiation Program forces any manufacturer to convey any message, which is a legal question.

31. Merck believes that its products must be priced to incentivize and support the expensive process of researching, developing, and securing FDA approval for new products. Davish Decl. ¶¶ 38, 45, 53–56.

Defendants' Response: Defendants do not dispute that Merck & Co., Inc. may hold certain beliefs about how to price its products.

32. Merck disagrees with (and does not wish to express) the message that, absent the Program, Merck would charge "unfair" prices. Davish Decl. ¶¶ 38, 45.

Defendants' Response: Defendants dispute that any aspect of the Negotiation Program forces any manufacturer to convey any message, which is a legal question. Further, the template agreement includes an explicit disclaimer, which makes clear that, by signing the agreement, a manufacturer is not endorsing the government's views. *See* Template Agreement at 4.

II. Statement of Undisputed Material Facts in Support of Defendants' Cross-Motion for Summary Judgement

1. On August 29, 2023, CMS published the list of drugs selected for negotiation for initial price applicability year 2026. *See* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/C689-57WY.

2. The drugs selected for price applicability year 2026 are Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and certain insulin products (comprising Fiasp, Fiasp FlexTouch, Fiasp PenFill, NovoLog, NovoLog FlexPen, and NovoLog PenFill). *See id*.

3. MSD holds the new drug application (NDA) for Januvia. *See NDA 021995*, U.S. FDA: Drugs@FDA, https://perma.cc/HDS8-UNC6; *see also* Pl.'s Ex. D at 231, ECF No. 23-8 (listing "Merck Sharp & D[ohme]" as "[m]anufacturer" of Januvia).

4. MSD is a separate corporate entity from Merck & Co., Inc. *See* FDA Supplemental Approval for NDA 021995, NDA 022044, NDA 202270 (June 21, 2022), https://perma.cc/HYW7-DYFR (addressed to "Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc."); Januvia Prescribing Information 26 (rev. June 2022), https://perma.cc/Y2FL-VKXK (stating on labeling that the drug is "[d]istributed by: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.").

5. CMS has asked MSD, not Merck & Co., Inc., to participate in negotiations over Januvia. *See* Revised Guidance at 33-34, 131-32.

Dated: September 11, 2023

Respectfully submitted,

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Counsel for Defendants

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC.,

Plaintiff,

v.

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

Defendants.

Civil Action No. 1:23-cv-01615-CKK

[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:

COLLEEN KOLLAR-KOTELLY
United States District Judge