

No. 24-1821

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

JANSSEN PHARMACEUTICALS, INC.,
Plaintiff-Appellant,

v.

XAVIER BECERRA, ET AL.,
Defendants-Appellees.

On Appeal from the United States District Court for the
District of New Jersey, No. 3:23-cv-3818 (Quraishi, J.)

**REPLY BRIEF OF APPELLANT JANSSEN
PHARMACEUTICALS, INC.**

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DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1.1(b), Appellant Janssen Pharmaceuticals, Inc. (“Janssen”) discloses the following.

The following are publicly owned corporations that own 10% or more of Janssen’s stock:

1. Johnson & Johnson, JNJ

The following are publicly owned corporations not a party to this appeal that have a financial interest in the outcome of the litigation and the nature of that interest:

1. Johnson & Johnson, JNJ (parent company of Janssen)

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GLOSSARY

Abrams Inst. Br.	Brief of Amicus Curiae Abrams Institute for Freedom of Expression in Support of Appellees, Nos. 24-1820 & 24-1821 (Sept. 16, 2024), ECF Nos. 139 & 136
BMS	Appellant Bristol Myers Squibb Co.
BMS Br.	Opening Brief of BMS, No. 24-1820 (July 12, 2024), ECF No. 27
BMS Reply Br.	Reply Brief of BMS, No. 24-1820 (Oct. 2, 2024), ECF No. 172
CMS	Centers for Medicare and Medicaid Services
Gov't Br.	Answering Brief of Appellees Xavier Becerra et al., Nos. 24-1820 & 24-1821 (Sept. 9, 2024), ECF Nos. 114 & 115
Gov't <i>Boehringer</i> Br.	Memorandum of Law in Opposition to Plaintiff's Mot. for Summ. Judgment, <i>Boehringer Ingelheim Pharms., Inc. v. HHS</i> , No. 3:23-cv-1103 (D. Conn. Dec. 20, 2023), ECF No. 48-1
HHS	U.S. Department of Health and Human Services
IFS Br.	Brief of Amicus Curiae Institute for Free Speech in Support of Appellants, Nos. 24-1820 & 24-1821 (July 19, 2024), ECF Nos. 64 & 68
IRA	Inflation Reduction Act, Pub. L. No. 117-169, 136 Stat. 1818 (2022)
JA	Joint Appendix, Nos. 24-1820 & 24-1821 (July 12, 2024), ECF Nos. 30 & 28
Janssen Br.	Opening Brief of Appellant Janssen Pharmaceuticals, Inc., No. 24-1821 (July 12, 2024), ECF No. 31
Manufacturer Agreement	Medicare Drug Price Negotiation Program Agreement, issued by CMS (JA676-688)

NAM Br.	Brief of Amicus Curiae National Association of Manufacturers in Support of Appellants, Nos. 24-1820 & 24-1821 (July 19, 2024), ECF Nos. 58 & 62
NCLA Br.	Brief of Amicus Curiae New Civil Liberties Alliance in Support of Appellants, Nos. 24-1820, & 24-1821 (July 19, 2024), ECF Nos. 51 & 55
Oral Arg. Tr.	Transcript of Oral Argument, Nos. 3:23-cv-03818 & 3:23-cv-0355 (D.N.J. Mar. 7, 2024), District Court ECF Nos. 107 & 97
Program	Medicare Drug Price Negotiation Program, as enacted by sections 1101–04 of the IRA
Teva Br.	Brief of Amicus Curiae Teva Pharmaceuticals USA, Inc. in Support of Appellants, Nos. 24-1820 & 24-1821 (July 19, 2024), ECF Nos. 69 & 73

INTRODUCTION

The Government defends a program that does not exist. At each step, it relies on sanitized descriptions of the Program that avoid the most challenging parts of the constitutional analysis. According to the Government, the Program is just like any negotiation between a purchaser and a seller; CMS is like any other market participant; Janssen can freely choose not to participate; and the Program's agreements are ordinary commercial contracts. Reality, however, is quite different. The persistent disconnect between the hypothetical program the Government defends and the program Congress enacted eviscerates the Government's arguments.

Start with CMS's role. The Government insists that CMS conducts arms-length negotiations with manufacturers over the drugs it will purchase, as in other federal programs. Unlike those other programs, however, CMS does not purchase drugs for Medicare through the Program. Instead, it sets a ceiling price and partially reimburses third-party payers who actually buy Janssen's products. Nor does CMS establish those prices through genuine negotiations. CMS wields sovereign, regulatory authority throughout the process, for example by prescribing rules Janssen must follow and imposing severe monetary penalties for noncompliance. Those penalties include a 1900% excise tax rising to hundreds of millions of dollars *per day* if Janssen fails to accept CMS's terms. Ordinary market participants have no such powers.

The Government’s description of the Program as a purely voluntary undertaking is equally divorced from reality. The lynchpin of the Government’s argument is that Janssen can opt out of the Program by withdrawing all of its products from Medicare and Medicaid. Yet that rationale ignores the Program’s forced tying arrangement (between Xarelto[®] and all of Janssen’s other drugs), which an ordinary market participant could not lawfully impose, and the “basic economic rationality” that prevents Janssen from being able to “wal[k] away.” *Nat’l Infusion Ctr. Ass’n v. Becerra*, — F.4th —, 2024 WL 4247856, at *13 (5th Cir. Sept. 20, 2024) (*NICA*). Undisputed record evidence shows that across-the-board withdrawal would devastate Janssen’s ability to innovate and compete—a “consequenc[e]” designed to be so “severe” that submission to CMS’s demands is “all but certain.” *Id.* at *5. That is coercion. And it triggers the longstanding rule that a theoretical “power of choice” is “illusory” where, as here, a program employs “economic coercion” to secure compliance. *United States v. Butler*, 297 U.S. 1, 70-71 (1936). The Government’s brief does not even acknowledge this body of binding Supreme Court precedent.

The Government likewise errs in characterizing the Manufacturer Agreement Janssen was forced to sign as doing nothing more than “establish[ing] prices.” Gov’t Br. 63. That agreement grants CMS authority to unilaterally revise the terms after the agreement is executed—a feature that underscores CMS’s regulatory role and

would render an ordinary commercial contract unenforceable. The agreement also goes much further than “regulat[ing] the amount” Janssen can charge for Xarelto[®]. Gov’t Br. 46 (cleaned up). It compels Janssen to endorse the Government’s views on drug pricing—a leading issue of public concern—including the way the Program’s prices are set and the fairness of those prices. Not only are those elements unnecessary to establish prices, but *none* of the procurement examples cited by the Government mandate performative negotiations or compel participants to use terms like “maximum fair price.” The Program is, in short, categorically different from the examples the Government invokes.

In addition to these mischaracterizations, the Government fails to grapple with the sweeping implications of its arguments. It asserts that federal programs are exempt from nearly all constitutional scrutiny so long as parties have a theoretical choice whether to participate, “regardless of th[e] magnitude” of coercion employed. Gov’t Br. 36. That proposition has no limiting principle. Indeed, if the Government were correct, CMS could offer manufacturers a binary choice between complying with the Program’s requirements or paying a tax equal to 100% of their assets. Neither this Court nor the Supreme Court has granted, or even suggested, such a vast exemption from compliance with the Constitution’s guarantees.

At bottom, the Government asks the Court to adopt a broad and troubling new rule that would allow Congress to use any amount of coercion to achieve its ends.

But precedent makes clear that the Government’s ability to “incentiv[ize],” Gov’t Br. 36, has its limits. The Program exceeds those limits. No matter how this case is analyzed—whether directly under the First and Fifth Amendments or indirectly under the unconstitutional conditions doctrine—the result is the same: The Program violates Janssen’s constitutional rights.

ARGUMENT

I. The Program Takes Janssen’s Property Rights in Xarelto®.

The Takings Clause prevents the Government from appropriating property for itself or others without providing just compensation. “Physical” (or *per se*) takings can occur in myriad ways, but they reduce to a simple question: Has government action stripped the owner of a property interest, such as the right to exclude? *See, e.g., Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149-50 (2021). That is what the Program does: It gives third parties a right to “access” Xarelto® products, appropriating Janssen’s rights to exclude others and control the disposition of its property. *See* Janssen Br. 23-26.

The Government resists that conclusion on three grounds. *First*, it seeks to restrict *per se* takings claims to physical seizures of property. *Second*, it argues that the Program cannot effect a taking because Janssen is not legally compelled to

participate. *Third*, it asserts that economic coercion—no matter how severe—is irrelevant to the constitutional analysis. All three arguments fail.¹

A. The Government’s Merits Defenses Do Not Withstand Scrutiny.

Physical takings occur whenever the Government “appropriat[es]” property rights, *regardless* of how that taking “comes garbed.” *Cedar Point*, 594 U.S. at 148-49. The Government disclaims (at 29) any taking because CMS will not “sen[d] trucks” to Janssen’s warehouses to “haul away” Xarelto[®] products.² But the absence of a physical seizure is not dispositive. As the Supreme Court has explained, the government need not take possession of the plaintiff’s property to effect a physical taking; appropriating the plaintiff’s right to exclude for the benefit of a third party suffices. *See Cedar Point*, 594 U.S. at 144, 149-50.

The statutory access requirement, 42 U.S.C. § 1320f-2(a), together with the rest of the Program’s provisions, meets that test by forcing Janssen to transfer its Xarelto[®] products to Medicare participants on terms dictated by CMS. *See Janssen*

¹ The Government acknowledges (at 24 n.1) that Janssen asserts only a physical-takings claim, but nevertheless tries to reframe Janssen’s claim as involving a regulatory takings theory (e.g., at 23-26, 30-31). The Government may prefer to avoid the constitutional issues raised by a physical-takings claim, but Janssen is entitled to choose the claims it is asserting.

² The Government also asserts that “Plaintiffs conceded at oral argument” that “the Program [does not] require a manufacturer to physically transmit or transport drugs at the agreed-upon price.” Gov’t Br. 29. That statement was made by the *Government’s* counsel, not Janssen’s. *See Oral Arg. Tr.* 58:7-20.

Br. 24-26; BMS Br. 13-14. In this respect, the Program is similar to the laws challenged in *Cedar Point*, which gave third parties access to private farmland, *see* 594 U.S. at 149, and *Horne v. Department of Agriculture*, 576 U.S. 350, 364 (2015), which stripped growers of the “right to control th[e] disposition” of their raisins. It did not matter in *Cedar Point* that California never took possession of the farmland because the law opened it up to union organizers. *See* 594 U.S. at 149. So too here: While CMS will not seize Janssen’s Xarelto[®] products, the Program nevertheless grants Medicare beneficiaries and their providers a right to obtain those products over Janssen’s objection.³

To be clear, Janssen has never argued that it has a right to “sel[l] [its] drugs to Medicare at any particular price.” Gov’t Br. 31. But just as Janssen cannot “force [CMS] to buy” Xarelto[®] at Janssen’s “preferred price,” *id.* at 32, the Program cannot force Janssen to sell Xarelto[®] at the Government’s. Indeed, the right to determine whether to allow a third party to occupy or possess one’s property “has traditionally been considered one of the most treasured strands in an owner’s bundle of property

³ A government-mandated transfer of property, which prevents an owner from exercising its “rights to possess, use and dispose of” its property, is not the same as a voluntary sale (an exercise of those rights). *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) (citation and quotation marks omitted). Nor does the ability to receive money from the forced transfer cure the taking. *See, e.g., Horne*, 576 U.S. at 363 (retention of “contingent interest in a portion of the value of ... property, set at the government’s discretion,” is insufficient to avoid takings liability).

rights.” *Loretto*, 458 U.S. at 435. Yet by coercing Janssen to participate, *see infra* Part I.C, and then obligating Janssen to grant third parties access to Xarelto[®], the Program appropriates that core property right.

The Government contends (at 29-31) that the Program at most mandates access to a *price*, not Janssen’s *product*, because “the statute does not require [Janssen] to make any sales to Medicare in the first instance.” This argument (and the related claim that Janssen could simply stop selling Xarelto[®] to Medicare participants) featured prominently in the Government’s papers below, but now tellingly receives only passing mention. And for good reason: The argument relies on a cramped reading of the IRA that circumvents the statute’s withdrawal provisions, flouts common sense, frustrates the IRA’s evident purposes, and contradicts the Government’s concession that the Program mandates access to *drugs*. *See* Janssen Br. 27-30 & n.16.⁴ The Government offers no response to these points.

B. Precedent Forecloses the Government’s Attempt to Impose a Legal Compulsion Requirement.

Aside from arguing that no taking has occurred, the Government makes the broader argument (at 26-28, 32-35) that a taking *cannot* occur because Janssen is not

⁴ *See also* Gov’t *Boehringer* Br. 43 (Program “obligat[es] ... manufacturers to provide selected drugs”); *NICA*, 2024 WL 4247856, at *2 (“[t]he *only* way for a manufacturer to avoid the tax (besides agreeing to HHS’s price) is to opt out of Medicare ... *entirely*,” i.e., stop selling *all* drugs through Medicare (emphases added)).

legally required to participate in the Program. But the Supreme Court has made clear that a statutory mandate to participate in the challenged program is not necessary to establish a taking.

1. In *Horne*, the raisin-grower plaintiffs were not required by law to enter the raisin market, and they too had options to avoid the appropriation of their crops. *See* 576 U.S. at 366, 370. For example, the growers could have kept their raisins and paid a penalty, planted different crops, or sold their grapes for other uses. *Id.* The Supreme Court nevertheless held that the reserve program effected a “per se taking,” and in doing so *rejected* the argument that there could be no taking because the “growers voluntarily ch[ose] to participate in the raisin market.” *Id.* at 365. In the same way, Janssen’s decision to participate in Medicare does not insulate every action—however confiscatory—that the Government might take with respect to Janssen’s property. *See* Janssen Br. 30-31.

The Government’s attempts to distinguish *Horne* fall short. *First*, the Government claims (at 37-38) that “the farmers were legally compelled to transfer the raisins” or “sto[p] selling raisins altogether.” But as explained above, that is not true: The growers entered the market voluntarily and could have paid a fine or sold the exact same grapes for other uses—options similar to those the Government presses here. *Second*, while the Government repeatedly cites Janssen’s ability to sell Xarelto[®] products to buyers outside of Medicare, *see, e.g.*, Gov’t Br. 64, that point

does not show that legal compulsion is necessary to establish a taking, and it also fails to account for the fact that the growers in *Horne* retained the ability to sell their grapes outside the raisin market. *Third*, the Government maintains (at 37) that it had nothing to offer to the growers in *Horne* but does have something to offer to Janssen here. Like the preceding argument, that point is irrelevant to whether legal compulsion is required, and it is inaccurate in any event because the reserve program provided growers with benefits. *See Horne*, 576 U.S. at 368 (reserve program generated “higher consumer demand for raisins” through its “promotional activities”).

2. The Government also cites out-of-circuit cases to argue that legal compulsion is necessary to raise a takings claim, and that Medicare participation lacks that compulsory character. *See* Gov’t Br. 26-28, 35-36. Yet Janssen (at 32-33) and BMS (at 48-49) have already explained why these cases are inapposite—most notably because they rely on a voluntariness rationale later rejected in *Horne*.⁵ Beyond those reasons, which the Government does not address, the cases are inapposite on several additional grounds. Because nearly all of the Government’s cases addressed regulatory-takings claims, *see, e.g., Garelick v. Sullivan*, 987 F.2d

⁵ The only post-*Horne* case cited by the Government, *Southeast Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016), mentions *Horne* only in passing and does not analyze the part of *Horne* that rejected a legal compulsion requirement.

913, 916-17 (2d Cir. 1993), it is “inappropriate to treat [them] ... as controlling precedents for the evaluation of” Janssen’s physical-takings claim, *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg’l Plan. Agency*, 535 U.S. 302, 323 (2002). Further, as one of the cases recognizes, “coercive financial incentive[s],” just as much as legal compulsion, can provide the basis for a takings claim. *Franklin Mem’l Hosp. v. Harvey*, 575 F.3d 121, 130 (1st Cir. 2009); *see also* BMS Reply Br. 17-19 (additional distinctions).

C. The Program Employs Economic Coercion to Secure Compliance, Negating the Government’s Voluntariness Defense.

The Program combines the sovereign power to impose penalties and set prices with economic leverage resulting from CMS’s “domina[nce in] the healthcare market.” *Sanofi Aventis U.S. LLC. v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). The end result is a coercive scheme that no ordinary market participant could lawfully impose, and that compels Janssen to acquiesce to CMS’s demands. *See* Janssen Br. 37-38. As the Fifth Circuit reasoned in *NICA*, “the consequences of failing to reach an agreement with [CMS] are [so] severe” that manufacturers are “all but certain” to accept whatever terms CMS offers, regardless of how “unprofitable” they might be. 2024 WL 4247856, at *5.

The Government nevertheless argues that the Program cannot effect a taking because it is voluntary. In the Government’s telling, the Program “does not require any pharmaceutical company to accept [CMS’s] terms,” and “[s]elling to Medicare

is a choice Plaintiffs can accept or not accept.” Gov’t Br. 33. That characterization ignores the Program’s structure and real-world effects. Janssen can reject CMS’s terms only by paying a confiscatory excise tax (more than \$90 billion in the first year alone⁶) or abandoning half the U.S. prescription drug market, nearly two-thirds of its sales, and millions of patients. *See* Janssen Br. 13, 26-27.⁷ That is no choice—by design. *See also NICA*, 2024 WL 4247856, at *2 (citing Congressional Budget Office estimate that excise tax “would raise no revenue because no manufacturer could afford to pay it”).

Longstanding precedent prevents the Government from claiming that participation secured through such severe coercion is voluntary. As one of the leading cases explains, Congress cannot impose burdens on regulated parties “by threat of [even greater] penalties” and then “declare the acceptance [of the burdens] voluntary.” *Union Pacific R.R. Co. v. Pub. Serv. Comm’n*, 248 U.S. 67, 70 (1918); *see also* Janssen Br. 33-35. In other words, laws that employ “coercion by economic

⁶ The Government attempts (at 12) to downplay the size of the tax, but has not disputed the sworn declaration documenting the amount Janssen would owe if the tax applied. *See* JA795-96.

⁷ The Government also asserts in passing (at 12) that there is no taking because Janssen could divest its interests in Xarelto[®]. But as one court recently observed, “[t]he Government cannot evade a Fifth Amendment challenge by requiring manufacturers to choose between losing their property rights ... through government appropriation and losing them through divestment.” *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103, 2024 WL 3292657, at *11 (D. Conn. July 3, 2024).

pressure” to force compliance are “not in fact voluntary” and the “power of choice” they purport to offer is “illusory.” *Butler*, 297 U.S. at 70-71; *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936).

The Government has no answer for that principle. Indeed, its brief conspicuously avoids any mention of *Butler*, *Carter*, or *Union Pacific*, all of which are binding precedents. As a result of that omission, the Government has forfeited any response to Janssen’s argument.

The Government does address *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*), arguing that its “gun to the head” rationale is limited to the federalism context. *See* Gov’t Br. 21-22, 52. But that argument misses the point: Although *NFIB* focused on constitutional protections afforded to state governments, it applied broader coercion principles that apply equally to private parties. *See* Janssen Br. 34 n.20; BMS Reply Br. 13-14.⁸ The federalism objection is nonresponsive to those broader principles. *See also* NCLA Br. 18-20 (addressing flaws in District Court’s analysis of *NFIB*). The Government also errs in asserting (at 52) that “[b]oth before and after *NFIB*, courts have uniformly rejected the idea that the lucrative nature of Medicare and Medicaid coerces private parties.”

⁸ These protections for private parties remain applicable even when Congress acts pursuant to its Spending Clause powers. *See, e.g., Butler*, 297 U.S. at 64-65, 74-75 (Congress “may not indirectly accomplish” unlawful “ends by taxing and spending to purchase compliance”).

None of the cases cited by the Government address *Butler*, *Carter*, or *Union Pacific*, and contrary to the Government’s claim of uniformity, at least one court has held that *NFIB*’s coercion analysis does apply to Medicare providers. *See Am. Health Care Ass’n v. Burwell*, 217 F. Supp. 3d 921, 929 (N.D. Miss. 2016).

The Government’s arguments regarding its general contracting authority fare no better. It is true, but irrelevant, that CMS may “determine those with whom it will deal, and ... fix the terms and conditions upon which it will make needed purchases.” Gov’t Br. 53 (quoting *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940)).⁹ That means CMS can choose not to buy if it does not agree with a seller’s price—not that CMS may impose massive penalties on the seller for failing to accept the agency’s terms.¹⁰ The key point is that CMS’s “terms and conditions” must

⁹ CMS does not purchase drugs under Medicare. Rather, as required by statute, it regulates prices and reimburses third parties. *See infra* Part III.A.

¹⁰ The Government’s defense contractor analogy (at 32) similarly ignores key aspects of the Program. In the defense context, both parties can walk away from the table without any further obligations or penalties. The Program, in contrast, requires Janssen to accept CMS’s terms or else incur devastating penalties. *See* Janssen Br. 34-35. Those provisions show that CMS does not operate as a mere market participant. Other parts of the Program reinforce that point. *See* BMS Reply Br. 15-16. For example, the Manufacturer Agreement states that CMS may unilaterally change its terms—a feature that would render an ordinary contract unenforceable. *See* Janssen Br. 12-13; *Morrison v. Amway Corp.*, 517 F.3d 248, 257-58 (5th Cir. 2008) (contract illusory under Texas law where one party retained unilateral authority to revise terms); *see also* Teva Br. 26-29 (Program’s “market-distorting effects” show that CMS “is not an ordinary market participant”).

comply with the Takings Clause because the Program is not truly voluntary. For the reasons given in Part I.A above, the access provision fails that test.

II. The Program Compels Janssen to Endorse the Government’s Message.

The IRA also violates the First Amendment by compelling Janssen to endorse the Government’s message that the Program involves genuine “negotiations” resulting in an agreed-upon “maximum fair price” for Xarelto[®]. 42 U.S.C. § 1320f-2(a); *see* Janssen Br. 41-42. The Government’s primary responses—that the Program is voluntary and has only an incidental effect on speech—are meritless. Voluntariness is not a defense because the Program applies “actual compulsion,” in the form of economic pressure, to secure participation. *Miller v. Mitchell*, 598 F.3d 139, 152 (3d Cir. 2010) (citing *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005)). The Government also glosses over key differences between the Program and “ordinary price regulation,” Gov’t Br. 45 (citation omitted), which show that the Program has far more than an incidental effect on speech.

A. The Government Misapplies the “Actual Compulsion” Test.

“Government action that requires stating a particular message favored by the government violates the First Amendment right to refrain from speaking.” *Miller*, 598 F.3d at 151 (collecting cases). That is precisely what the Program does. *See* Janssen Br. 40-46.

The Government challenges the premise of Janssen’s claim, asserting (at 42) that the Program “does not compel [Janssen] to do anything.” That wrongly equates the requirement that a plaintiff show “actual compulsion” in the First Amendment context with the “legal compulsion” standard discussed in Part I.B above. *See* Gov’t Br. 42.¹¹ As Janssen has explained (Janssen Br. 50), “actual compulsion” is not limited to a formal requirement imposed by statute or regulation, and it “need not take the form of a direct threat or a gun to the head.” *C.N.*, 430 F.3d at 189 (quoting *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1290 (10th Cir. 2004)). “[I]ndirect discouragement ... such as ... fines, injunctions[,] or taxes” is sufficient to show that speech has been compelled. *Axson-Flynn*, 356 F.3d at 1290 (cleaned up). The economic pressure applied by the Program is thus sufficient to support Janssen’s compelled-speech claim. *See* Janssen Br. 49-50; IFS Br. 6-12.

This Court’s decision in *Miller* is illustrative. There, a parent sued on behalf of her minor daughter when the district attorney threatened to bring criminal charges against the daughter for “sexting” unless she participated in an “education program.” 598 F.3d at 142. The program required students to prepare reports explaining “how [their] actions were wrong,” even though the daughter “d[id] not agree that appearing in the photograph was wrong.” *Id.* at 152. This Court recognized that the

¹¹ The Government’s amicus makes the same error. *See* Abrams Inst. Br. 9.

“choice” to “satisfactorily complete the education program” in lieu of prosecution was no choice at all, and held that the daughter was likely to succeed on her compelled-speech claim. *Id.* at 142, 152. Here, the economic pressure exerted on Janssen is similarly coercive. To avoid severe penalties, Janssen must “satisfactorily complete the [Program]” by signing a document that amplifies the Government’s preferred messages. *Id.* at 152; *see also Axson-Flynn*, 356 F.3d at 1283, 1290 (sufficient compulsion where student “would not be able to continue in [a training] program if she refused to” make statements “she found offensive”).

Even if legal compulsion were the appropriate test for compelled-speech claims, that test would be satisfied here. When CMS selected Xarelto[®] for the Program on August 29, 2023, there was not enough time for Janssen to withdraw from Medicare and Medicaid before the deadline to sign an “agreement” to “negotiate” on October 1, 2023. *See Janssen Br.* 50 n.29. In response to litigation, CMS issued guidance purporting to authorize expedited withdrawal from Medicare and Medicaid, but that guidance is inconsistent with the statutory text. *See id.* CMS cannot rewrite the statute to suit its litigating position.¹²

¹² Janssen’s disagreement with CMS’s guidance is hardly “academic.” Gov’t Br. 40 n.4. If Janssen’s view is correct, the guidance conflicts with the statutory timeline for withdrawal “[b]y a manufacturer,” 42 U.S.C. § 1395w-114a(b)(4)(B)(ii), and Janssen was legally compelled to sign the Manufacturer Agreement last October. Regardless of CMS’s views, this Court has a duty to “exercise independent judgment

The Government’s final defense (at 50) is that the Program is voluntary because “[i]n four instances, CMS directly accepted counteroffers proffered by manufacturers in connection with the negotiations.” As the Government knows, however, Janssen is not one of those four instances. CMS presented Janssen with a take-it-or-leave it offer, backed by severe penalties, which Janssen accepted under protest. The fact that CMS accepted other manufacturers’ counteroffers—in the midst of litigation challenging the sham “negotiation” process—does not render Janssen’s speech voluntary.

B. The Program’s Effect on Speech Is Not Incidental.

The Government does not argue that the Program’s speech mandates are narrowly tailored to serve a compelling interest. Having conceded this key point, the Government is forced to argue that the Program does not implicate the First Amendment *at all* because it regulates commercial conduct and has at most an incidental effect on speech. Gov’t Br. 44-47.

It is true that a “typical price regulation,” such as a law that “determine[s] the amount” a seller may “charg[e],” has only an incidental effect on speech and thus does not violate the First Amendment. Gov’t Br. 45 (quoting *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017)). But as *Expressions Hair Design*

in determining the meaning of” the withdrawal statute. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2262 (2024).

shows, that does not mean regulations are categorically exempt from First Amendment scrutiny merely because they relate to prices. *See* Janssen Br. 45-46. The exception invoked by the Government applies narrowly to laws whose effect on speech is “plainly incidental.” *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 62 (2006).

Here, the exception does not apply because the Program goes beyond “determin[ing] the price [Janssen] may charge for” Xarelto[®]. JA22. In addition to setting a maximum price, the Program requires Janssen to express controversial views regarding drug pricing—an issue front-and-center in public debate. *See* Janssen Br. 41-43; IFS Br. 13-18. Through the Manufacturer Agreement, the IRA forces Janssen to amplify the Government’s message that the Program involves “negotiation” of a price both parties agree is “fair.” The President and other senior government officials have repeatedly invoked these themes in public statements and on the campaign trail, illustrating their expressive nature.¹³ That connection between the compelled speech and the broader public dialogue confirms that the Program is far removed from “ordinary price regulation.” Gov’t Br. 45.

¹³ *See* Janssen Br. 44-45 & nn. 26-28; Nathaniel Weixel, *Biden, Harris Take Victory Lap on Drug Pricing During Joint Appearance*, The Hill (Aug. 15, 2024), <https://perma.cc/BZ4P-YYAP> (statement by President Biden, during campaign event held the same day CMS announced prices set through the Program, touting IRA’s provisions as “g[iving] Medicare the power to negotiate”).

Moreover, the Program would work just as well without the compelled statements targeted by Janssen’s claim. For example, if Congress had used the phrase “maximum price” instead of “maximum *fair* price,” the Program would have the same effect on drug prices. That dynamic demonstrates that the challenged parts of the Program target speech and have nothing to do with regulating commercial conduct. Similarly, CMS could “hear from manufacturers,” Gov’t Br. 50, without putting words in their mouths. Agencies routinely regulate prices without compelling regulated parties to engage in pretextual negotiations or endorse the resulting price caps. *See* Janssen Br. 47.

These features distinguish the Manufacturer Agreement from contracts that implement the other healthcare programs cited by the Government (at 47). The agreements that parties sign in those programs speak only to the price at which drugs will be sold and the rules the parties will follow. None of the programs require participants to communicate that the price-setting process involves a negotiation or that the resulting price is fair. *See* 42 U.S.C. §§ 1395cc (Medicare provider agreements), 1396r-8(b)-(c) (Medicaid rebate agreements and determination of rebate amounts), 1395w-102(b) (Medicare Part D coverage); 38 U.S.C. § 8126(a)(2) (Department of Veterans Affairs provider contracts).

The Government next contends that the Manufacturer Agreement’s use of statutory terms such as “maximum fair price” promotes consistency and clarity

rather than conveying a particular message. Gov't Br. 48. Yet Congress chose those terms, and the Government offers no compelling reason why Congress used phrases like "maximum fair price" if not to convey a message regarding the fairness of the prices established through the Program.¹⁴

Finally, it is no answer that "the IRA leaves participants at liberty to say what they wish about the Negotiation Program" in other settings. Gov't Br. 43. The Supreme Court has explained that the possibility of additional speech cannot defeat a compelled-speech claim. Otherwise, many canonical compelled-speech cases would have come out the other way. *See* Janssen Br. 48.

III. The Government's Attempts to Evade the Unconstitutional Conditions Doctrine Are Unpersuasive.

Even if the Program were voluntary, the unconstitutional conditions doctrine would prevent CMS from indirectly violating Janssen's First and Fifth Amendment rights. *See* Janssen Br. 51-56.¹⁵

¹⁴ The Government distances itself (at 48) from the District Court's reliance on *Meese v. Keene*, 481 U.S. 465 (1987), citing it only in passing. This Court should follow the D.C. Circuit, which rejected a theory similar to the District Court's on the ground that *Meese* "was not a compelled speech case." *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 529 (D.C. Cir. 2015); *see also* Janssen Br. 43-44.

¹⁵ Janssen adopts by reference the arguments presented by BMS on this issue. *See* BMS Reply Br. 7-16; Fed. R. App. P. 28(i).

A. There Is No Basis for the Government’s Proposed Limitation on the Unconstitutional Conditions Doctrine.

The Government contends that the unconstitutional conditions doctrine applies only to “the provision of government benefits” and thus should not govern procurement of drugs through the Program. Gov’t Br. 57-60. This argument mischaracterizes the Program and has no support in precedent.

1. The Government treats the Program as if it were no different from ordinary “procure[ment] [of] goods from private companies.” Gov’t Br. 41. But CMS does not purchase drugs for itself or Medicare beneficiaries. Instead, CMS “institute[s] a price structure” for selected drugs, consisting of a “maximum fair price” that manufacturers can charge the actual purchasers—patients and providers. *See* 42 U.S.C. § 1395w-111(i); *NICA*, 2024 WL 4247856, at *1 (outside the Program, “prices paid for drugs covered by” Medicare “are determined by the market”). CMS reimburses insurance plans for some of these drug costs, but that does not make the Program comparable to Government purchases of lightbulbs or even prescription drugs in other contexts.¹⁶ The Government’s repeated assertion that it “purchases

¹⁶ For example, the Departments of Veterans Affairs and Defense, unlike CMS, have authority to purchase drugs for use and distribution in their own medical facilities. *See* U.S. Dep’t of Veterans Affairs, Office of Procurement, Acquisition and Logistics, <https://www.va.gov/opal/nac/index.asp> (accessed Oct. 1, 2024) (agency awards contracts “for the *acquisition and direct delivery* of pharmaceuticals” (emphasis added)); *Avkare, Inc. v. United States*, 125 Fed. Cl. 11, 15-16 (2016) (explaining pharmaceutical procurement process).

[drugs] for beneficiaries,” Gov’t Br. 59, is thus untrue—meaning that even if there were a procurement exemption from the unconstitutional conditions doctrine, that exemption would not apply here.

The Government also errs in contending that participation in Medicare is not a benefit. *See* Gov’t Br. 59. Manufacturers *cannot* offer their products in or obtain reimbursement through Medicare without first entering into an agreement with CMS. *See* 42 U.S.C. §§ 1395w-153(a), 1396r-8(a). Courts and the Government have thus recognized that a provider’s ability to participate in Medicare constitutes a valuable benefit. *See, e.g., Fischer v. United States*, 529 U.S. 667, 676-78 (2000) (providers receive “benefits” under Medicare, including compensation for their services, as that “term is used in its ordinary sense”); Gov’t *Boehringer* Br. 31-32 (ability to “mak[e] sales of ... drugs to Medicare beneficiaries” is a “valuable government benefit”).

2. Regardless, the Government’s attempt to narrow the unconstitutional conditions doctrine conflicts with precedent. The Government argues (at 58-59) that the doctrine is designed to protect beneficiaries with “no ... leverage,” making it inapplicable whenever there is a “bargained-for exchange” and “each party comes to the table with something to offer.” But the Government does not cite a single case adopting that limitation, and so far as Janssen is aware, none exists. Unconstitutional conditions cases frequently involve private parties “bringing to the table” goods or

services that advance governmental objectives. For example, in *Dolan v. City of Tigard*, 512 U.S. 374, 377 (1994), the government sought “dedication of a portion of [a business’s] property for flood control and traffic improvements” in exchange for a building permit.¹⁷

Courts have consistently described the unconstitutional conditions doctrine as an “overarching principle” that exists to prevent the Government from “indirectly” achieving through coercion what it cannot mandate directly. *Speiser v. Randall*, 357 U.S. 513, 526 (1958). As one of the earliest cases reasoned: “It would be a palpable incongruity to strike down” a statute that expressly violates constitutional rights, but “uphold an act by which the same result is accomplished under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to withhold.” *Frost v. R.R. Comm’n*, 271 U.S. 583, 593 (1926).

The Government proposes such incongruities here. Congress could not directly require businesses to donate a portion of their revenues to a political candidate’s campaign without violating the First Amendment. Yet under the Government’s theory, Congress could achieve an identical result by conditioning the

¹⁷ See also *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205, 208 (2013) (*USAID*) (grant recipient’s program advanced government’s objective to “combat the spread of HIV/AIDS”); *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 605 (2013) (unconstitutional conditions doctrine applies where “government ... has broad discretion to deny a permit that is worth far more than property *it would like to take*” (emphasis added)).

purchase of goods from a business on the same donation requirement. Similarly, agencies cannot directly violate First Amendment rights by retaliating against someone's speech. Yet the Government's theory would mean that denying a bid based on the bidder's political speech would be "of no constitutional import." Gov't Br. 54.

The Government seeks to mitigate those troubling implications by noting that Due Process and Equal Protection Clause protections still apply to "procurement decisions." Gov't Br. 60 n.7. But that selective approach makes no sense. The Government cites no authority supporting its *ad hoc* exemption from the unconstitutional conditions doctrine, and precedent cuts in the opposite direction. *See, e.g., Koontz*, 570 U.S. at 604 (framing doctrine in broadly applicable terms).

The Government also ignores precedent that applies the unconstitutional conditions doctrine in the procurement context. *See, e.g., O'Hare Truck Serv., Inc. v. City of Northlake*, 518 U.S. 712, 721 (1996) (termination of services contract based on contractor's refusal to provide political contributions could not be "distinguish[ed] ... from the coercion exercised in ... other unconstitutional conditions cases"); *Bd. of Cnty. Comm'rs v. Umbehr*, 518 U.S. 668, 678-79 (1996) (extending unconstitutional conditions protections to "contract[s] for services"); *Oscar Renda Contracting, Inc. v. City of Lubbock*, 463 F.3d 378, 385 (5th Cir. 2006) (independent contractor "is protected by the First Amendment if its bid is rejected

in retaliation of its exercise of protected speech”). These cases show that a procurement exception would “invi[t] manipulation,” allowing governments to “avoid constitutional liability simply by” using indirect means to achieve unconstitutional ends. *O’Hare*, 518 U.S. at 722.

B. The Government Misapplies the Test for Determining When a Condition Is Unconstitutional.

The Government argues that under *Rust v. Sullivan*, 500 U.S. 173 (1991), the Manufacturer Agreement and associated statutory provisions do not impose unconstitutional conditions because they are integral to the Program and do not affect Janssen’s activities outside the Program. Gov’t Br. 61-65. That theory misapprehends the relevant tests in both the First and Fifth Amendment contexts.

For First Amendment rights, it is true that *Rust* distinguished between impermissibly placing conditions on a funding *recipient* and permissibly regulating the terms and scope of a federal *program*. See 500 U.S. at 197. *USAID*, however, provides two critical clarifications.

First, *USAID* explained that a condition “by its very nature” “defin[es] the recipient” when the condition requires the recipient to “adopt as [its] ow[n] the Government’s view on an issue of public concern.” 570 U.S. at 217-18. Where recipients are required “to pledge allegiance to the Government’s policy,” they “can express [contrary] beliefs only at the price of evident hypocrisy.” *Id.* at 220-21. Accordingly, the Government misses the mark by suggesting (at 64) that Janssen

could still express its views outside the Program. Not only does the ability to engage in counter-speech not ameliorate a First Amendment injury, *see* Janssen Br. 48, but courts applying *USAID* have reasoned that “condition[ing] ... funding on ...expression of [the Government’s] views” violates the First Amendment even if the recipient “remain[s] free to express its views in other ways,” *Bethel Ministries, Inc. v. Salmon*, No. 19-cv-1853, 2022 WL 111164, at *10-11 (D. Md. Jan. 12, 2022); *see also id.* at *5 (rejecting assertion that school could “say whatever it wants as long as it [also] says what the [government] want[s] it to say”).

Second, *USAID* rejected the view that conditions pass muster so long as they are “relevant to the objectives of the program.” 570 U.S. at 214. Such a loose standard would allow governments to “manipulat[e]” a program “to subsume the challenged condition,” reducing the First Amendment “to a simple semantic exercise.” *Id.* at 214-15 (cleaned up). This case shows why. The Government argues (at 62-63) that all of the Manufacturer Agreement’s terms “are integral to the functioning of” the Program. That may be true of the term stating the maximum price for Xarelto[®], but the provisions Janssen challenges “do something more,” *id.* at 218—for example, requiring Janssen to attest that the maximum price is “fair.” CMS could establish price caps for selected drugs without requiring manufacturers to engage in that additional speech, showing that the compelled speech does not define the scope of the Program under *USAID*.

With respect to Janssen’s Fifth Amendment rights, the Government’s argument (at 64) fails to grapple with the requirements of the nexus-and-proportionality test, which are not satisfied here. *See* Janssen Br. 53 n.31; BMS Br. 43-45; NAM Br. 21-26. Even if that test were limited to land-use cases, as the Government contends (at 57 n.6), the Program’s access provision would still fail because courts have applied a similar proportionality principle outside the land-use context. *See, e.g., Mem’l Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 257-63 & n.15 (1974) (comparing “the extent to which the” condition affected the plaintiffs’ rights and the strength of the government’s interests). Finally, the Government overlooks the parallels between the access provision and the Medicaid funding condition invalidated in *NFIB*, which like the Program leveraged large pre-existing revenue streams to coerce regulated parties into accepting significant new mandates. *See* Janssen Br. 54; BMS Br. 41-42.

CONCLUSION

This Court should reverse the District Court's judgment and hold that the Program violates the First and Fifth Amendments as applied to Janssen.

Respectfully submitted,

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October 2, 2024

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I hereby certify that on October 2, 2024, I caused the foregoing brief to be electronically filed with the United States Court of Appeals for the Third Circuit using the CM/ECF system for filing and transmittal of a Notice of Electronic Filing to counsel of record.

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