**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.)

# 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

| | |
|---|---|
| BMS Br. | Opening Brief of Appellant Bristol Myers Squibb Co., No. 24-1820 (3d Cir. July 12, 2024) |
| CMS | Centers for Medicare and Medicaid Services, a component of HHS |
| FDA | U.S. Food and Drug Administration, a component of HHS |
| HHS | U.S. Department of Health and Human Services |
| IRA | Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 |
| JA | Joint Appendix |
| Manufacturer Agreement | Medicare Drug Price Negotiation Program Agreement, issued by CMS (JA676-688) |
| Program | Medicare Drug Price Negotiation Program, as enacted by sections 1101–04 of the IRA |
| Revised Guidance | CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026* (June 30, 2023) (JA477-685) |

## INTRODUCTION

This appeal involves constitutional challenges to the Drug Price Negotiation Program, an unprecedented price-control scheme established by the Inflation Reduction Act of 2022. In 2023, the Centers for Medicare and Medicaid Services selected Xarelto®, a drug marketed by Plaintiff-Appellant Janssen Pharmaceuticals Inc., for the Program. As explained below, the Program violates Janssen's rights under the First and Fifth Amendments.

The Program authorizes CMS to impose prices for patent-protected medicines covered under Medicare. By statute, those prices must be well below market value. Aware that manufacturers would not voluntarily participate in the Program, Congress added coercive penalties to force compliance. Once CMS selects a drug for the Program, the manufacturer must provide Medicare participants "access" to the drug on terms dictated by the agency. 42 U.S.C. § 1320f-2(a)(1). A manufacturer that does not comply must pay an excise tax penalty equal to *nineteen times* the selected drug's sales. The only way a manufacturer can avoid that penalty is to withdraw its entire portfolio of medicines—not just the selected drug—from Medicare *and* Medicaid.

Congress acknowledged that the excise tax is so substantial that no manufacturer could pay it. Congress also knew that Medicare and Medicaid comprise "almost half the annual nationwide spending on prescription drugs," *Sanofi*

*Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023), and thus "dominat[e]" the market to such a degree that manufacturers cannot afford to withdraw from those programs entirely. Accordingly, the excise tax and withdrawal provision work together—by design—to leave manufacturers like Janssen with no choice but to acquiesce to CMS's demands.

Because top-down price controls are politically unpopular, Congress camouflaged the Program in the language of "negotiations" between manufacturers and CMS. That label is inaccurate: The Program does not involve actual negotiations or voluntary agreements, and the below-market prices it imposes do not provide just compensation. Nevertheless, the statute requires manufacturers to attest, in writing, that the Program involves "negotiation[s]" culminating in an "agreemen[t]" on a "maximum fair price" for the selected drug. 42 U.S.C. § 1320f-2(a)(1). Manufacturers that do not embrace that fiction must pay the excise tax, which for Xarelto® would exceed $90 billion in the first year alone. This framework allows the Government to proclaim that it is negotiating drug prices while avoiding the risk of a true negotiation: that CMS will not reach agreement with manufacturers, leaving tens of millions of Americans without insurance coverage for widely prescribed drugs.

The end result is a Program that relies on the Government's sovereign power—not its market participation—to impose terms on manufacturers against their will. That scheme violates Janssen's constitutional rights in two ways.

*First*, the Program effects a physical taking of Janssen's Xarelto® products. By granting third parties a statutory right to "access" those products over Janssen's objection, the Program appropriates the company's right to control the disposition of its property. *Id.* That access right, coupled with the Program's draconian penalties for noncompliance, has the same bottom-line effect as the raisin-reserve program invalidated in *Horne v. USDA*, 576 U.S. 350 (2015) (*Horne II*), and it constitutes a taking for the same reasons.

The district court disagreed, holding that the Program cannot effect a taking because it is voluntary. But the features that purportedly make the Program voluntary—the theoretical ability of manufacturers to pay the excise tax or withdraw their portfolios from nearly half of the U.S. prescription-drug market—are irrelevant as a matter of law and illusory as applied to Janssen. Indeed, while the Government contends that Janssen has voluntarily accepted the Program's terms, it does not dispute that the Program employs the sort of "economic dragooning" that the Supreme Court has repeatedly held makes federal programs *not* voluntary—and thus *not* immune from constitutional scrutiny. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 582 (2012) (*NFIB*); *United States v. Butler*, 297 U.S. 1, 70-71 (1936).

*Second*, the Program violates the First Amendment by compelling Janssen to endorse the Government's message that the Program involves "negotiate[d]" "agreement[s]" on a "maximum fair price." The Government has no legitimate interest (let alone a compelling one) in forcing Janssen to adopt that misleading narrative regarding drug pricing, an issue that is front and center in the national debate. Congress has enacted scores of other price-control schemes, none of which force regulated parties to vouch for the fairness of the agency's decisions.

The district court rejected this claim as well, concluding that the Program (1) is voluntary and thus does not compel Janssen to speak and (2) has only an incidental effect on protected speech. The first rationale fails for the reasons given above, and the second is foreclosed by binding precedent. Specifically, the Supreme Court has held that laws implicate First Amendment rights when they govern how businesses communicate their pricing, *see Expressions Hair Design v. Schneiderman*, 581 U.S. 37 (2017), and that agencies may not "compel" regulated parties to "adopt … the Government's view on an issue of public concern," *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc*., 570 U.S. 205, 206 (2013) (*USAID*).

Finally, even accepting the erroneous view that the Program is voluntary, it still violates the unconstitutional conditions doctrine, which prohibits the Government from using valuable benefits to "coerc[e] people into giving … up" their constitutional rights. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S.

595, 605 (2013). A voluntary Program would violate that rule by forcing Janssen to relinquish its property rights in Xarelto® and endorse the Government's narrative in order to continue participating in Medicare and Medicaid. These conditions are particularly harmful to Janssen because Medicare and Medicaid together comprise 65 percent of the company's sales. Janssen depends on that revenue to develop innovative drugs and remain competitive.

If Congress wants to reduce Medicare drug prices—which manufacturers already negotiate with the Part D insurance plans that pay for covered drugs—it has tools at its disposal. For example, Congress could authorize CMS to engage in true arms-length negotiations with manufacturers, without threatening multi-billion dollar penalties for noncompliance. But the Program takes a fundamentally different approach: the excise taxes, sham negotiations, and speech mandates set it apart from every other modern pricing statute. Those unique elements leave this case in uncharted constitutional waters and put the onus on the Government to prove that the Program does not take "a shorter cut than the constitutional way." *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415-16 (1922). Congress cannot appropriate Janssen's property rights without paying just compensation, as required by the Takings Clause. It cannot compel Janssen to endorse the Government's disputed narrative regarding the Program. And it cannot require Janssen to give up its constitutional rights as a condition on Medicare and Medicaid participation.

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

## JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. On April 29, 2024, the district court entered final judgment in favor of Defendants. JA28. On April 30, 2024, Janssen timely appealed. JA31-32. This Court has jurisdiction under 28 U.S.C. § 1291.

## ISSUES PRESENTED

1. Whether the Program violates the Takings Clause of the Fifth Amendment by appropriating Janssen's property rights in its Xarelto® products. JA5-18.

2. Whether the Program violates the First Amendment by compelling Janssen to amplify the Government's misleading narrative that the Program involves "negotiation[s]" culminating in an "agreement" on a "maximum fair price." JA18-25.

3. Whether the Program violates the unconstitutional conditions doctrine by conditioning Janssen's participation in Medicare and Medicaid (for 21 of the company's products) on Janssen surrendering its First and Fifth Amendment rights with respect to Xarelto®. JA25-26.

## RELATED CASES

In addition to Janssen, three manufacturers filed lawsuits challenging the Program in the District of New Jersey: *Bristol Myers Squibb Co. v. Becerra*, No. 23-

cv-3335 (*BMS*); *Novartis Pharmaceuticals Corp. v. Becerra*, No. 23-cv-14221; and *Novo Nordisk Inc. v. Becerra*, No. 23-cv-20814. The decision below disposed of *BMS* and *Janssen*, but did not address *Novartis* or *Novo Nordisk* (which remain pending). This Court consolidated Janssen's and BMS's appeals for purposes of scheduling, the joint appendix, Appellees' response brief, and disposition. ECF 3.

Another manufacturer unsuccessfully challenged the Program in the District of Delaware. *See AstraZeneca Pharms. LP v. Becerra*, No. 23-cv-00931, 2024 WL 895036 (D. Del. Mar. 1, 2024). This Court consolidated *AstraZeneca* with *BMS* and *Janssen* for disposition only. *See* ECF 28. AstraZeneca's claims do not overlap with those presented here.

The following cases outside the Third Circuit are also related:

- *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 3:23-cv-1103, 2024 WL 3292657 (D. Conn. July 3, 2024) (similar claims)
- *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156 (S.D. Ohio) (similar compelled-speech claim)
- *Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C.) (similar claims)
- *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-707, 2024 WL 561860 (W.D. Tex. Feb. 12, 2024), *appeal docketed*, No. 24-50180 (5th Cir.) (argued May 1, 2024) (no overlapping claims)

## STATEMENT OF THE CASE

### I. Pharmaceutical Development Depends on a Robust Innovation Ecosystem.

The United States leads the world in pharmaceutical development. In 2020, "almost half" the "medicines under development globally" came from the United States.[1] To develop innovative medicines, U.S. drug manufacturers must overcome significant risks. Only 1 in 5,000 compounds (0.02%) that enter preclinical testing ultimately receive FDA approval,[2] and only 20% of approved drugs ever recoup their development costs. The development process takes years and billions of dollars per drug.[3]

The United States' robust innovation ecosystem addresses these risks with two core incentives: (1) time-limited patent and regulatory protections for new and expanded treatments that give manufacturers exclusive rights over their pioneering medicines,[4] and (2) market-based pricing that reflects the value of groundbreaking

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[1] David H. Crean, *Is the USA's Innovation Leadership Position At-Risk?*, Pharma Boardroom (Nov. 13, 2020), https://perma.cc/2JN2-W7PC.

[2] Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Euro. Molecular Biology Org. 837, 837 (2004).

[3] *See id.*; Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 23 (2016), https://perma.cc/QB83-CBFZ.

[4] *See* Cong. Budget Off., *R&D in the Pharmaceutical Industry* (Apr. 2021), https://perma.cc/2ZC9-U2T3 (patent rights "increas[e] … incentives to invest in R&D").

drugs and funds development of many other promising drug candidates that fail to reach the market or achieve commercial success.[5] U.S. patients benefit from this ecosystem through broader and faster access to innovative treatments than patients in any other country.[6] This framework has allowed Janssen and its affiliates to invest more than $65 billion in pharmaceutical research and development since 2016, resulting in FDA approval for eight new medications and 52 additional indications or product formulations to serve patient needs. JA792.

Medicare and Medicaid play a crucial role in the innovation ecosystem,[7] accounting for 21% and 18%, respectively, of the U.S. pharmaceutical market in 2022.[8] This Court recently recognized that "domin[ant]" position, observing that Medicare and Medicaid comprise "almost half the annual nationwide spending on

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[5] *See* Alexander Shuhmaker et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Transl. Med. 105, 109 (2016) ("[T]he 4% of successful … drugs have to provide enough revenue to justify investment of the 96% failed compounds[.]").

[6] *See* Pharmaceutical Research and Manufacturers of America, *Global Access to New Medicines Report* 8, 11-26 (2023), https://perma.cc/PW8N-WEU8.

[7] Medicare principally provides health-insurance coverage for seniors. 42 U.S.C. § 1395 *et seq*. Medicare Part B provides benefits for physician-administered drugs, among other things. *Id.* § 1395j *et seq*. Medicare Part D provides benefits for self-administered prescription drugs. *Id.* § 1395w-101 *et seq*. Medicaid provides health-insurance coverage for low-income Americans. *Id.* §§ 1396 to 1396w-7. As explained below, the Program affects only certain Medicare Part D drugs in its first implementation year, yet exposes Janssen to adverse consequences in both Medicare and Medicaid for noncompliance.

[8] CMS, *NHE Fact Sheet*, https://perma.cc/8QFT-J9FU (updated Dec. 13, 2023).

prescription drugs." *Sanofi*, 58 F.4th at 699. Pioneering manufacturers thus depend on their ability to participate in these programs. Janssen, for example, sells 21 drugs in Medicare and Medicaid, accounting for approximately 50% of its U.S. prescriptions and 65% of its gross revenues in 2022. JA793. Medicare and Medicaid participation is crucial to Janssen's ability to compete and continue developing innovative treatments for serious medical conditions such as cancer, autoimmune conditions, cardiovascular disease, and HIV. JA794, 798-99.

Janssen's Xarelto® (rivoroxaban) is a product of this innovation ecosystem. Initially approved in 2011, Xarelto® treats and helps prevent blood clots and reduces the risk of stroke. Janssen continued to invest in research over the decade following initial approval, leading to five additional approvals for new dosage forms and indications of Xarelto®. In 2022, nearly 3 million U.S. patients filled nearly 11 million Xarelto® prescriptions, over half of which were reimbursed under Medicare or Medicaid. JA793.

## II. The Program Upends the Innovation Ecosystem.

In 2022, Congress made sweeping changes to Medicare Part D through the Inflation Reduction Act, including by fundamentally altering how certain drugs are priced. *See* Pub. L. 117-169, 136 Stat. 1818, §§ 11001-04. For nearly 20 years before the IRA, the Medicare statute precluded CMS from "institut[ing] a price structure for the reimbursement of covered part D drugs," instead allowing private

Part D insurance plans to negotiate market-based rates for covered drugs in arms-length transactions with manufacturers, without Government "interfere[nce]." 42 U.S.C. § 1395w-111(i) (2003). CMS would then reimburse the plans for these drug costs, up to an agreed-upon limit.

The IRA reverses that system by authorizing CMS to "institute a price structure for the reimbursement of" the most widely prescribed Part D drugs through the "Drug Price Negotiation Program." 42 U.S.C. § 1395w-111(i).[9] Under the Program, CMS, rather than the Part D insurers, establishes Medicare prices for a defined subset of drugs. That structure differs from the way prices are determined for Medicaid, the 340B program, and the Department of Veterans Affairs drug program. Each of those programs uses a formula that relies on average prices in market transactions—thus (in contrast to the Program) allowing manufacturers to predict and, to some degree, control the prices for their medicines. *See* 42 U.S.C. §§ 1396r-8(c), 256b(a)(2); 38 U.S.C. § 8126(a)(2).

The Program involves four steps: (1) CMS selects drugs for the Program; (2) a selected drug's manufacturer "enter[s] into" an "agreemen[t]" with CMS to "negotiate" the "maximum fair price" of that drug; (3) CMS and the manufacturer

[9] The Secretary of HHS delegated statutory authority to administer the Program to CMS. *See* 88 Fed. Reg. 1,390 (Jan. 10, 2023). Accordingly, this brief refers to CMS when discussing implementation of the Program.

"negotiate to determine" and "agree to" the "maximum fair price," which CMS publishes in the *Federal Register*; and (4) the manufacturer provides Medicare beneficiaries and their providers "access to" the selected drug at "such price." 42 U.S.C. §§ 1320f to 1320f-4.

**1. Selection.** For the first year of the Program, CMS was required to select the top ten drugs after ranking eligible Part D drugs by total Medicare spending. *Id.* § 1320f-1(a)(1), (d)(1)(A). On August 29, 2023, CMS selected Xarelto® and nine other drugs for the Program.[10]

**2. Agreement.** Once Xarelto® was selected, Janssen had until October 1, 2023, to "enter into" a "manufacturer agreemen[t]" with CMS. *Id.* §§ 1320f(d)(2)(B), 1320f-2(a). Under that agreement, the manufacturer must "agree" to "negotiate … a maximum fair price" for the selected drug, provide third parties "access to the maximum fair price … with respect to [the] selected drug," submit pricing data and any other "information that [CMS] requires," and "compl[y] with" any other "requirements determined by [CMS] to be necessary." *Id.* § 1320f-2(a)(1)-(5). CMS unilaterally drafted the Manufacturer Agreement and presented it to Janssen on a take-it-or-leave-it basis, *see* JA507, including a provision giving

[10] *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/88D4-3CA2. CMS also selected Stelara®, a drug marketed by Janssen Biotech, Inc. and not the subject of this case.

CMS "authority to amend this Agreement" without Janssen's consent even after Janssen signed it, JA680.

A manufacturer that fails to sign the Agreement is "noncomplian[t]" and subject to excise tax penalties. 26 U.S.C. § 5000D. The nonconforming manufacturer must pay an "excise tax" penalty on domestic sales of the selected drug starting at 186% and escalating to 1900% after nine months. *See id.* § 5000D(a), (b)(1), (d); JA703 (Congressional Research Service Report explaining computation of tax).

These penalties would far exceed Janssen's gross revenues for U.S. Xarelto® sales in the federal and non-federal markets: The penalty would begin at over $50 million daily, escalate to over $600 million daily after nine months, and surpass $90 billion in the first year. JA795-96. The Congressional Budget Office recognized that no manufacturer could ever willingly incur such enormous penalties, JA756, and Congress similarly estimated that a nearly identical penalty provision in a precursor bill would generate "no revenue," JA743.

The IRA provides only one way for a manufacturer to "suspend" the excise tax: by withdrawing *all* of its drugs—not just the selected drug—from Medicare *and* Medicaid. 26 U.S.C. § 5000D(c)(1). Undisputed record evidence shows that this is not an option for Janssen, because the company would lose 65% of its gross

revenues, with millions of patients losing coverage for 21 Janssen drugs they depend on. JA793, 796, 799.

The IRA also delays a manufacturer's withdrawal from Medicare and Medicaid for 11 to 23 months, depending on the timing of withdrawal. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). Thus, even if Janssen had initiated withdrawal as soon as CMS selected Xarelto®, January 2025 would have been the *earliest* point at which Janssen could have suspended the excise tax penalty. In other words, Janssen could not escape the Program until months after the deadlines for the Manufacturer Agreement, negotiation, and "maximum fair price" determination had passed, and also long after publication of the maximum fair price in September 2024 (a step that will immediately harm Janssen by affecting pricing for Xarelto® in commercial markets).

Facing the untenable prospect of paying more than $1 billion per week in penalties or losing access to almost half of the U.S. pharmaceutical market, Janssen had no choice but to sign the Manufacturer Agreement. It did so under protest.

**3. Negotiation.** After signing the Agreement, Janssen entered the "negotiation" phase. The statute required CMS to make an initial "offer," permitted Janssen to "counteroffer," and then required CMS to "respond in writing" with a final "maximum fair price offer." *Id.* § 1320f-3(b)(2).

In a true negotiation, parties can walk away from the table if they do not agree. But the Program works differently. The manufacturer "shall" agree to the "maximum fair price" established by CMS, *id.* § 1320f-2(a)(1), and failure to do so triggers the excise tax penalties or withdrawal consequences that initially compelled Janssen to sign the Manufacturer Agreement, *see* 26 U.S.C. § 5000D(b)(2).[11] Thus by design, the "negotiation" can end only one way: with CMS dictating the price. *See* 42 U.S.C § 1320f-3(b)(2)(E).

This will not be a "fair" price. By statute, the "maximum fair price" must be at least 25-60% below a benchmark market-based price that non-federal wholesalers pay for the selected drug. *See id.* § 1320f-3(c)(1)-(3). CMS must also "achieve the *lowest* maximum fair price for each selected drug" below that ceiling, *id.* § 1320f-3(b)(1) (emphasis added), with no relevant statutory floor. These provisions ensure that the prices will be well below market value.

The "negotiation period" ends on August 1, 2024, after which CMS will publish the "maximum fair price" and a short accompanying explanation in September 2024 and March 2025, respectively. *Id.* §§ 1320f(d)(2)(B) & (6), 1320f-4(a). Because Janssen has no choice, Janssen continues to participate in the "negotiation" process under protest.

[11] Janssen was also required to provide highly confidential business information to CMS under threat of daily $1 million penalties. *See* 42 U.S.C. § 1320f-6(c).

**4. Access.** Starting January 1, 2026, Janssen must grant Medicare beneficiaries and their providers "access" to Xarelto® at (or below) the "maximum fair price." *Id.* § 1320f-2(a)(3). The IRA also requires every Part D plan formulary[12] to include each selected drug, facilitating this third-party access to selected drugs. *Id.* § 1395w-104(b)(3)(I). Thus, when Medicare beneficiaries fill prescriptions for Xarelto®, they will take physical possession of the drugs on terms dictated by CMS, and to which Janssen would never voluntarily agree. Noncompliance would subject Janssen to civil monetary penalties, including daily $1 million penalties for violating certain Manufacturer Agreement provisions and penalties equal to ten times any amount charged over the maximum fair price. *Id.* § 1320f-6. This access obligation (and the threat of penalties) continues indefinitely until CMS determines that Xarelto® no longer qualifies for the Program—for example, because generic competition has entered the market. *See id.* §§ 1320f-1(c)(1), 1320f-2(b).

Record evidence documents the Program's harms to Janssen and patients. *See* JA798-99. For example, a sworn declaration not disputed in any respect by the Government explains that the Program will "significantly undermine Janssen's ability to innovate and compete over the long-term" by inhibiting Janssen's ability to "generate the revenues necessary to support development of the next generation

[12] A Part D formulary is a list of drugs covered by a Medicare Part D insurance plan. *See* 42 U.S.C. § 1395w-104(b)(3).

of transformational and accessible treatments" and ultimately "improve human health for patient populations with unmet medical needs." *Id.*

## III. Procedural History

Janssen filed suit in July 2023, asserting as-applied challenges to the Program. The complaint alleged that the Program violates (1) the Fifth Amendment by appropriating Janssen's property rights in its Xarelto® products, (2) the First Amendment by compelling Janssen's speech about the Program, and (3) the unconstitutional conditions doctrine by requiring Janssen to give up its rights with respect to Xarelto® in order to continue participating in Medicare and Medicaid (for all of the company's drugs). JA454-72.

On April 29, 2024, the district court granted the Government summary judgment on all of Janssen's claims. The court held that the Program does not effect a physical taking because, in its view, Janssen could have avoided the Program's requirements and because the Program differs factually from the regulation at issue in *Horne*. JA10-12. The court rejected Janssen's First Amendment claim, reiterating its view that the Program is voluntary and reasoning that the Program has only an "incidental" effect on speech. JA22-24. Finally, the court rejected Janssen's unconstitutional conditions arguments because it thought "no constitutional right [is] in danger of being trampled." JA25.

Janssen timely appealed.

## SUMMARY OF ARGUMENT

The Program is unconstitutional because it appropriates Janssen's property rights in Xarelto® and compels Janssen to endorse the Government's false characterization of the Program. The Government claims that Janssen's purported options to avoid these constitutional violations immunize the Program from scrutiny. But those options are both legally irrelevant and illusory. Even if the Program were voluntary, it would still violate the unconstitutional conditions doctrine.

**I.A.** The Program effects a physical taking of Janssen's rights in its Xarelto® products—i.e., the pills and their packaging. A physical taking can occur in many ways, including when the Government appropriates for itself or a third party property interests like the rights to control the disposition of property or to exclude others from that property. The Program effects such an appropriation: Janssen is required, on threat of significant penalties, to give third parties access to its Xarelto® products on terms imposed by CMS. The district court disagreed because, in its view, the Program does not map directly onto the facts of *Horne*. That rationale fails because an appropriation of property rights constitutes a physical taking however it comes garbed.

**B.** The district court also accepted the Government's argument that the Program does not effect a taking because Janssen purportedly has "options" to avoid the Program. None of those purported options is legally relevant. According to the

Government, Janssen could (1) pay an excise tax penalty in lieu of compliance; (2) divest Xarelto®; (3) remain in the Program but stop selling Xarelto® to Medicare participants; or (4) withdraw Xarelto® and all 20 of its other products from Medicare and Medicaid. But the "option" to pay penalties was irrelevant in *Horne*; a theoretical ability to divest has never shielded the Government from takings liability; the IRA's structure and purposes foreclose the existence of an option to stop selling Xarelto® to Medicare participants (while keeping Janssen's other drugs in Medicare and Medicaid); and *Horne* rejected the argument that an option to exit a market negates a takings claim.

**C.** The "options" cited by the district court are also unavailing because they are illusory as applied to Janssen. The Supreme Court consistently has held that when the Government relies on economic coercion to secure compliance, that compliance is not voluntary, and the underlying program is therefore not immune from constitutional scrutiny. That is the case here. Janssen submitted undisputed evidence demonstrating that each "option" is illusory given the sheer size of their economic consequences. For example, the excise tax would near $100 billion in penalties during the first year alone, and withdrawing from Medicare and Medicaid would eliminate 65% of Janssen's revenues, crippling its ability to innovate and compete.

**D.** Nor is the Program immune from scrutiny because CMS claims to be acting as a market participant or because the Program was enacted pursuant to the Spending Clause. CMS at times acts in a proprietary role in implementing the Program, but Congress augmented that role by granting CMS sovereign, regulatory powers as well—powers no ordinary market participant possesses and which would invite antitrust liability if an ordinary market participant exercised them. That regulatory authority sets this case apart from the others cited by the Government below. A private party with similar market power could not "tie" its continued purchase of all products to a single product as CMS does here. Moreover, the Supreme Court has explained that spending legislation is subject to constitutional scrutiny where, as here, a party has no choice but to accept the legislatively imposed funding conditions.

**II.A.** The Program also violates Janssen's First Amendment right not to speak. Where the Government compels a party to express a message, that compulsion is unlawful unless it satisfies strict scrutiny. The Program compels Janssen to speak in two ways: by forcing Janssen to (1) affix its signature to CMS-drafted agreements attesting that the CMS-imposed price is the maximum fair price for Xarelto®; and (2) participate in the "negotiation" process, giving credence to the Government's narrative that the Program involves genuine bargaining and voluntary agreements. The Program goes beyond merely establishing a price and incidentally

affecting speech, instead requiring Janssen to characterize what that price represents and how it was determined in a politically expedient way—all messages Janssen would not communicate but for the Program's coercive terms. The fact that these messages involve drug pricing—a matter of public concern in the national debate—makes it even more clear that the challenged provisions go far beyond an incidental effect on speech.

**B.** Because the Program compels speech, it must employ the least restrictive means of achieving a compelling government interest. But the Government has no valid interest (let alone a compelling one) in forcing manufacturers to amplify the Government's message or to deceive the public regarding the Program's true nature. Nor is the IRA narrowly tailored given the myriad other laws that set prices without forcing regulated parties to endorse the Government's policies.

**C.** Neither Janssen's ability to disavow its compelled speech nor the disclaimer language in the Manufacturer Agreement precludes Janssen's First Amendment claim. The Supreme Court and this Court have already rejected arguments that counter-speech or general disclaimers can justify speech mandates.

**D.** The Government's proposed "options" to avoid the Program likewise fail to negate the First Amendment violation. Again, those options are illusory, and the IRA requires Janssen to remain in the Program long enough to endorse the

Government's views. Additionally, this Court's precedent holds that speech can be compelled using the threat of noncompliance penalties, as the Program does here.

**III.A.** Even if the Program were voluntary, it would still violate the unconstitutional conditions doctrine, which prohibits the Government from using valuable benefits to coerce the relinquishment of constitutional rights. That protection applies even when persons seek a benefit that is wholly voluntary, and requires the court to assume that a funding condition is mandatory and then determine whether it is unconstitutional.

**B.** Here, a voluntary Program would violate the unconstitutional conditions doctrine by requiring Janssen to give up its First and Fifth Amendment rights in order to continue participating in Medicare and Medicaid. The required relinquishment of Janssen's property rights in its Xarelto® products is unconstitutional for the reasons stated in Part I.A. Similarly, the required endorsement of the Government's message is unconstitutional because it compels speech on a matter of public concern and thus inherently regulates conduct outside the scope of the Program. The Program also unconstitutionally conditions existing funding streams on the acceptance of new obligations.

## STANDARD OF REVIEW

This Court reviews the district court's grant of summary judgment *de novo*. *See Pichler v. UNITE*, 542 F.3d 380, 385 (3d Cir. 2008).

## ARGUMENT

### I. The Program Violates the Fifth Amendment's Takings Clause.

#### A. The Program Appropriates Janssen's Property Rights in Xarelto®.

The Takings Clause requires the Government to provide "just compensation" whenever it "take[s]" private property for public use. U.S. Const. amend. V.[13] The "essential question" is whether the Program effects a physical taking of Janssen's property rights by "appropriating" them "for itself or a third party." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148-49 (2021).[14] The answer here is yes. As explained below, the Program appropriates Janssen's rights to control the disposition of, and set the terms of access to, its Xarelto® products by granting Medicare participants access to those products over Janssen's objection.

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[13] Only Janssen's interest in its Xarelto® products—i.e., the physical doses that Janssen manufactures and sells—is at issue here. JA455, 467. Janssen retains additional property rights in its Xarelto® patents and regulatory exclusivities, *see* JA792-93, but Janssen has not alleged a taking of those rights.

[14] Because the Program appropriates Janssen's property rights, Janssen asserts only a physical takings claim. The Court therefore need not consider the "ad hoc, factual inquiry" associated with a regulatory takings claim. *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978); *see also Horne II*, 576 U.S. at 362.

*Horne* governs this case. There, federal law required raisin growers to reserve and transfer a portion of their crops "to the Government, free of charge" (the "reserve requirement"). 576 U.S. at 356. The Hornes failed to do so, "[t]he Government sent trucks … to pick up the raisins," "the Hornes refused entry," and the Government instead "assessed against the Hornes" penalties "for disobeying" the reserve requirement. *Id.* at 356. Although the Government did not physically seize the Hornes' raisins, the reserve requirement constituted "a clear physical taking" because of its effect on property rights: But for that requirement, growers would not have lost the right to "control [the] disposition" of their property. *Id.* at 361-62, 364.

*Cedar Point* presented different facts that nonetheless constituted a physical taking under the same effects-based analysis. California granted union organizers the "right [to] access … the premises of an agricultural employer" for several days each year. 594 U.S. at 144. This access right effected a taking because it appropriated property rights: Employers no longer retained "sole … dominion" over how others accessed their property because union organizers now had a "right to invade the [employers'] property" on the state's terms. In short, the state had "appropriate[d]" the employers' "right to exclude." *Id.* at 149-50. Regardless of the

specific mechanism by which the state appropriated that right, it had to "pay for what it t[ook]." *Id.* at 148.

The Program bears the hallmarks of the takings in *Horne* and *Cedar Point*. Under the Program, Janssen must provide Medicare beneficiaries and their providers "access to the maximum fair price … with respect to" Xarelto®. 42 U.S.C. § 1320f-2(a)(3). Moreover, because every Part D formulary must include Xarelto® on its list of selected drugs, the IRA ensures that *every* Medicare enrollee can demand access to, and take possession of, those drugs over Janssen's objection. *See id.* § 1395w-104(b)(3)(I). The noncompliance penalties for failing to agree to this access right or to transfer Xarelto® on CMS's terms reinforce the taking. *See* 26 U.S.C. § 5000D; 42 U.S.C. § 1320f-6. Janssen previously retained its rights to control the disposition of, and set the terms of access to, its Xarelto® products. The Program appropriates those rights and thus causes a physical taking.

The district court erroneously rejected the takings claim because the Program does not exactly match the facts of *Horne* by requiring Janssen to "set aside, keep, or otherwise reserve any of [its] drugs for the government's use." JA11-12. But any law that appropriates property rights constitutes a physical taking however the appropriation "comes garbed." *Cedar Point*, 594 U.S. at 149; *see also Ark. Game & Fish Comm'n v. United States*, 568 U.S. 23, 31 (2012) (recognizing "the nearly infinite variety of ways in which government actions or regulations can affect

property interests"). And the practical effect of the Program on Janssen's property rights is no different than if CMS physically seized Xarelto® products from Janssen. *See Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 322 (2002) (physical takings analysis focuses on whether Government "takes possession of an *interest* in property" (emphasis added)). Moreover, the district court did not explain how the factual differences it identified affect the takings analysis, and likewise failed to acknowledge the Program's similarities to the laws at issue in *Horne* and *Cedar Point*. *See infra* Part I.B. The critical question is not whether the Program maps directly onto the facts of *Horne* (or other physical takings cases), but whether it has the same effect of appropriating property rights.

### B. Janssen's Purported Options to Avoid the Taking Are Legally Irrelevant.

The district court also rejected the takings claim because it thought Janssen has "options" to avoid the Program. JA13-18. But precedent makes clear that these options are legally irrelevant.

**1.** Take Janssen's first "option" to retain its property by paying an excise tax penalty up to nineteen times Xarelto®'s daily sales. *See* 26 U.S.C. § 5000D. The laws in *Horne* and *Cedar Point* contained similar penalties. *See Horne II*, 576 U.S. at 356 (civil penalties); *Cedar Point*, 594 U.S. at 144 (sanctions). The Hornes, in fact, *were* assessed a penalty in lieu of a physical seizure, and they "argued that they could not be compelled to pay fines for refusing to accede to an unconstitutional

taking." *Horne v. USDA*, 569 U.S. 513, 519, 523-24 & n.4 (2013) (*Horne I*). Notwithstanding the penalty option, the Supreme Court held that the reserve requirement effected a "clear physical taking." *Horne II*, 576 U.S. at 361; *cf. Koontz*, 570 U.S. at 612 (2013) (fees "in lieu of" exacting property interests still trigger Fifth Amendment scrutiny).

**2.** Janssen's second "option" is to "divest" Xarelto®. JA12. Yet in *every* takings case, the owner can theoretically sell property before the Government takes it. Neither the Government nor the district court identified *any* case where the ability to divest negated a taking, and for good reason. There is no practical difference between a government-mandated transfer of property and divestment to avoid that mandate. In either instance, government action is the but-for cause of the owner "los[ing] the entire bundle of property rights." *Horne II*, 576 U.S. at 361 (cleaned up); *see also Cedar Point*, 594 U.S. a 155. At the very least, property rights would be "easily manipulated," *Horne II*, 576 U.S. at 365, if the Government could negate any taking by asserting that the owner could have sold off the property before it was appropriated. For this reason, the court in *Boehringer* rejected this option as "not relevant to the Fifth Amendment analysis." 2024 WL 3292657, at *11.

**3.** According to the Government, Janssen's third "option" is to "stop selling [Xarelto®] to Medicare beneficiaries" while remaining in the Program (and while continuing to market all 20 of its other drugs through Medicare and Medicaid)

because the IRA mandates access to a *price* rather than a *product*. JA12. The Government contrived this "option" during litigation, but the IRA's structure and purposes foreclose its availability. *See Univ. of Texas Sw. Med. Center v. Nassar*, 570 U.S. 338, 353 (2013) (rejecting interpretation that was "inconsisten[t] with the design and structure of the statute as a whole").[15]

*First*, the only way to suspend the excise tax under the IRA is for Janssen to withdraw *all* its drugs from Medicare and Medicaid. 26 U.S.C. § 5000D(c). Allowing a manufacturer to stop selling a selected drug to Medicare participants, while keeping all other drugs in Medicare and Medicaid, would render that statutory provision superfluous. Such a loophole, not mentioned anywhere in the statute, would allow any manufacturer to nominally participate in the Program without making a single sale at the "maximum fair price," evading the Program's core purpose and action-forcing penalties. The hidden exception advocated by the Government is thus at odds with the rule that the IRA must be interpreted "as a symmetrical and coherent regulatory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

*Second*, the Government's "price not product" distinction flouts the statute's plain meaning and common sense. Price is, by definition, what one pays to receive

[15] Janssen adopts by reference the arguments presented by BMS on this issue. *See* BMS Br. Part I.C; *see also* Fed. R. App. P. 28(i).

a product. *See Price*, Oxford English Dictionary (3d ed.) (defining "price" as "[t]he amount of money … given in payment *for* a commodity or service" (emphasis added)). Given that meaning, the mandate to provide "access to the maximum fair price … with respect to" Xarelto® is naturally understood as a requirement to offer the CMS-imposed price *in exchange for* the underlying product. 42 U.S.C. § 1320f-2(a)(3). Indeed, if a car dealer advertised a $10,000 price for new luxury sedans but then refused to provide the cars to interested customers on the ground that the offer was merely for a price, rather than the cars themselves, the dealer would likely find itself facing a lawsuit for deceptive trade practices. It is thus no surprise that the Government has repeatedly characterized the Program as providing access to *drugs*, both in this litigation and in other contexts.[16] Interpreting the Program as mandating access only to an abstract price would "defea[t]" the "obvious" (and repeatedly expressed) "intent of the statute." *Mather & Co. v. Comm'r*, 171 F.2d 864, 868 (3d Cir. 1949); *see also DIRECTV, Inc. v. Pepe*, 431 F.3d 162, 168 (3d Cir. 2005) (court

[16] *See* Defendants' Summary Judgment Br., No. 23-cv-3818, ECF 33-1, at 6 (D.N.J. Oct. 16, 2023) (Program will "provide Medicare beneficiaries access *to the drug* at the negotiated price" (emphasis added)), *id.* at 37 (manufacturer agreement establishes an "enforceable obligation for manufacturers to ultimately *provide their drugs* at the negotiated prices"); Statement by CMS Administrator Chiquita Brooks-LaSure, Press Release (Feb. 1, 2024), https://perma.cc/BR5L-J989 (Program will "*improv[e] access* to some of the most expensive *drugs* for people with Medicare" (emphases added)).

"must, whenever possible, read the statute in such a manner as to give effect to every part of it" and avoid rendering its purpose "meaningless").

*Third*, the IRA requires Part D plans to include every selected drug on their lists of covered drugs. *See* 42 U.S.C. § 1395w-104(b)(3)(I). Yet allowing a manufacturer to avoid Medicare coverage of its selected drug would "frustrate the evident purpos[e]" of the IRA to improve Medicare beneficiary access to selected drugs. *Romero v. SmithKline Beecham*, 309 F.3d 113, 119 (3d Cir. 2002); *cf. United States v. Barnes*, 295 F.3d 1354, 1364 (D.C. Cir. 2002) ("A statute should ordinarily be read to effectuate its purposes rather than frustrate them." (cleaned up)). And from a practical perspective, neither the Government nor district court has explained how Janssen could, given the complexities of the pharmaceutical market, actually prevent Medicare Part D beneficiaries from accessing Xarelto® while still selling the drug more broadly. Instead, the Government recently conceded the "logistica[l] difficult[ies]" of pursuing that approach, leading the court in *Boehringer* to question "whether any manufacturer can realistically make use of it." 2024 WL 3292657, at *11 n.10. A purported option that exists on paper, but that no manufacturer can "realistically make use of," is no option at all.

**4.** Janssen's final "option" is to withdraw all 21 of its drugs from Medicare and Medicaid and stop participating in those markets altogether. JA10, 17. The Supreme Court has rejected similar arguments on multiple occasions. For example,

in *Horne* the growers' ability to exit the raisin market did not immunize the reserve requirement from constitutional scrutiny: The district court rejected the takings claim because the plaintiffs were "not forc[ed] … to grow … or to market the raisins" but rather chose to pay "the admissions ticket" of participating in the market, *Horne I*, 569 U.S. at 522; the Ninth Circuit agreed because "the Hornes could [have] avoid[ed] the reserve requirement" by leaving the raisin market and "planting different crops," *Horne II*, 576 U.S. at 357, 365; and the Government denied any taking because growers could "plant different crops or sell their raisin-variety grapes as table grapes or for use in juice or wine," *id.* at 365 (cleaned up). The Supreme Court rejected these arguments as "wrong as a matter of law" and "prov[ing] too much" because permitting the Government to evade Fifth Amendment protections anytime someone "voluntarily ch[o]se to participate in [a] market" would allow "property rights [to] be easily manipulated." *Id.* (cleaned up); *see also Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 439 n.17 (1982) (ability to "avoid" taking "by ceasing to rent the building to tenants" did not negate a taking). Similarly here, Janssen's purported ability to "opt out" of the market, JA12, is not a defense.[17]

[17] The district court's treatment of *Horne* is also self-contradictory. While it correctly acknowledged the Hornes' voluntarily choice "to participate in the raisin market," it then asserted that Janssen's participation in the Program is voluntary and thus "[u]nlike *Horne*." JA10.

The district court dismissed the central reasoning in *Horne* by reiterating its erroneous conclusion, discussed above, that *Horne* is limited to its facts. *See* JA16. Regarding the withdrawal "option," the district court contrasted the law challenged in *Horne* (which the court characterized as requiring growers "to stop selling raisins altogether" to avoid a taking) with the Program (which it viewed as affecting only Janssen's "sales to Medicare," not all sales). JA12. But that rationale misreads *Horne*. The Supreme Court rejected the Government's voluntariness defense to avoid the "manipulat[ion]" of property rights, not because the growers were otherwise unable to sell raisins. 576 U.S. at 365. Moreover, the growers had the ability to sell the same grapes to other buyers—just as Janssen can (at least by the Government's telling) sell the same Xarelto® products to other patients. *See id.* Indeed, it would be absurd if the Government could take property without consequence by claiming that the property could have been sold elsewhere.

The district court also relied on a handful of out-of-circuit cases holding that participation in Medicare is voluntary and that absent a showing of legal compulsion to participate, there is no taking.[18] But those cases are distinguishable for the reasons given by BMS and are no longer good law because they rely on a voluntariness

[18] *See*, *e.g., Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719 (6th Cir. 1991); *Baptist Hosp. E. v. Sec'y of HHS*, 802 F.2d 860 (6th Cir. 1986); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442 (8th Cir. 1984).

rationale that *Horne* rejected. As the Supreme Court explained, treating voluntary market participation as foreclosing takings claims would allow the Government to manipulate property rights out of existence. *See Horne II*, 576 U.S. at 365. Instead, under *Horne*, Janssen's ability to exit Medicare and Medicaid to avoid the Program is irrelevant to the takings analysis.[19]

### C. The IRA Employs Economic Coercion to Force Janssen to Participate in the Program.

Even if Janssen's "options" to avoid the Program were relevant, the undisputed record evidence shows Janssen has no choice but to accede to the Government's demands.

The Supreme Court has held that economic coercion can render purported options to avoid Government demands illusory. In *NFIB*, Congress offered states the "choice" of accepting onerous new Medicaid requirements or losing federal funding comprising 10% of their budgets. *See* 567 U.S. at 588. That level of "economic dragooning" left the states "with no real option but to acquiesce." *Id.*

The Court has similarly held that private parties cannot be economically strongarmed into compliance. In *Union Pacific Rail Road Co. v. Public Service Commission*, 248 U.S. 67, 70 (1918), for example, the Court rejected attempts to

[19] For similar reasons, the district court erred by relying on *Dayton Area Chamber of Commerce*, which includes one cursory paragraph finding voluntariness based on the same out-of-circuit cases without addressing *Horne*, *see* 2023 WL 6378423, at *12, and *AstraZeneca*, which took a similar approach, 2024 WL 895036, at *15-16.

"impose an unconstitutional burden" on private railroads "by threat of [even greater] penalties" and then to "declare the acceptance [of that burden] voluntary." In *Butler*, the Court likewise held that using "coercion by economic pressure" to induce a regulated party to "surrender [its] independence of action" rendered the circumstances "not in fact voluntary" and the "asserted power of choice" "illusory." 297 U.S. at 70-71; *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) ("agreement" to participate in coal program was "coerce[d]" because it was backed by substantial noncompliance taxes); *Thompson v. Deal*, 92 F.2d 478, 484-85 (D.C. Cir. 1937) (cotton production quotas were not voluntary where Government offered "illusory" alternatives but used "coercion by economic pressure" to leave growers no real choice but "to accept" the quotas).[20]

That coercion principle applies here. Janssen submitted a sworn declaration explaining why the "options" cited by the Government are illusory and not in fact available to Janssen. Paying the excise tax would result in more than $90 billion in penalties during the first year of noncompliance alone. JA796. Similarly, complete withdrawal from Medicare and Medicaid would abandon roughly half of Janssen's

[20] *NFIB*'s coercion principles are not limited to the federalism context. Although *NFIB* involved the States' Tenth Amendment rights, the Court relied on broader coercion principles that apply equally in other contexts, as *Carter*, *Butler*, and the other cases cited above illustrate. *See also Am. Health Care Ass'n v. Burwell*, 217 F. Supp. 3d 921, 929 (N.D. Miss. 2016) (concluding that *NFIB*'s "basic point" "still stands" regarding coercive Medicare provisions governing nursing homes).

U.S. prescriptions and 65% of its gross revenues, JA793—several times the 10% "dragooning" in *NFIB*, 567 U.S. at 582, and the 15% "penalty to coerce compliance" in *Carter*, 298 U.S. at 239. Across-the-board withdrawal would also severely restrict Janssen's "continued ability to innovate and compete," and would harm millions of Medicare patients who rely on Janssen's drugs to treat serious medical conditions. JA794. The Government does not dispute that the Program is economically coercive as applied to Janssen.[21] The district court ignored this reality.

In short, the Program employs economic coercion to secure Janssen's participation. Janssen's purported options are a "financial … gun to the head" specifically designed to leave Janssen "with no real option but to acquiesce." *NFIB*, 567 U.S. at 581-82; *Thompson*, 92 F.2d at 333-34 (similar). In the face of such illusory choices, the Government cannot now "declare the acceptance [of the Program's unconstitutional burdens] voluntary" simply because Janssen acted under protest to avoid the "threat of [even greater] penalties." *Union Pacific*, 248 U.S. at 70. "One who does a thing in order to avoid a monetary penalty does not agree." *Carter*, 298 U.S. at 289. The upshot is that the Program is not exempt from scrutiny and must be evaluated on the merits. *See supra* Part I.A.

[21] Because the Government has not disputed any part of the declaration, the facts set forth in the declaration must be accepted as true at this stage of the litigation. *See* Fed. R. Civ. P. 56(c); *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

### D. The Government's Market Participant and Spending Clause Defenses Also Fail.

As a final line of defense, the Government contends that the Program is not a taking because (1) CMS is merely acting as a market participant, and (2) the Program is Spending Clause legislation and thus operates on the basis of consent. The district court agreed. *See* JA17. The first argument is untrue, and the second misapprehends precedent and the nature and limits of spending legislation.

**1.** CMS is not a mere market participant because it exercises significant *regulatory* authority. An agency is not acting as a market participant where it "employs … coercive mechanism[s], available to no private party." *Am. Trucking Ass'n v. City of Los Angeles*, 569 U.S. 641, 651 (2013); *see also Airlines for Am. v. City & Cnty. of San Francisco*, 78 F.4th 1146, 1152 (9th Cir. 2023) ("[C]ivil penalty provisions alone may amount to the force and effect of law rendering a government entity a regulator rather than a market participant.").

That is the case here. If CMS were truly acting in a proprietary role, it would simply refuse to purchase Xarelto® if the price were too high. But the Program goes further. It threatens Janssen with confiscatory taxes and other penalties in order to secure compliance. *See* 26 U.S.C. § 5000D; JA597-98, 606-08, 640, 644, 649. CMS can also order Janssen to "compl[y] with" any "requirements" it "determine[s] … to be necessary" to administer the Program, and has authority to impose penalties for noncompliance. 42 U.S.C. §§ 1320f-2(a)(5), 1320f-6; JA647-8. And it asserts

authority to amend the Manufacturer Agreement's terms without Janssen's consent, any time it sees fit, for as long as the Agreement remains in effect. *See* JA679, 680. Market participants cannot do these things; only regulators can. At a minimum, Congress's decision to augment CMS's purchasing power with sovereign power belies the notion that CMS is *solely* a market participant. *Cf. Cardinal Towing & Auto Repair, Inc. v. City of Bedford*, 180 F.3d 686, 691 (5th Cir. 1999) (state acts as sovereign when it "attempts to use its spending power in a manner 'tantamount to regulation'" (quoting *Wisc. Dep't of Indus., Labor and Human Rel. v. Gould*, 475 U.S. 282, 289 (1986)).[22]

Antitrust principles further undermine the Government's market-participant argument. Medicare and Medicaid account for almost half of the U.S. prescription drug market, which led this Court to observe in *Sanofi* that "[t]he federal government dominates" that market. 58 F.4th at 699. Under antitrust laws, a private party in that position would possess market power, *see Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 17 (1984), and would face serious antitrust scrutiny if it leveraged that power to tie the purchase of *all* Janssen's drugs to a favorable price on a single

[22] Below, the Government cited *Brooks v. Vassar*, 462 F.3d 341, 351 (4th Cir. 2006), for the proposition that regulating a market does not preclude the Government from being classified as a market participant. But *Brooks* involves a market-participant theory particular to the dormant Commerce Clause context, *see, e.g.*, *Gould*, 475 U.S. at 290, and does not address the federal government's regulatory powers outside that narrow context.

drug, *see U.S. Steel Corp. v. Fortner Enter., Inc.*, 429 U.S. 610, 620 (1977); *Century Aluminum of S.C. v. S.C. Pub. Serv. Auth.*, 278 F. Supp. 3d 877, 882 (D.S.C. 2017). In short, private market participants could not do what CMS is doing—leveraging its price-setting, regulatory authority from the IRA to tie all Medicare and Medicare participation to the relinquishment of one drug—undercutting the assertion that CMS is acting just like any other market participant.

**2.** Nor is legislation exempt from scrutiny merely because it was enacted pursuant to the Spending Clause. *See* JA7. The Government argued below that "[u]nlike ordinary legislation, which imposes congressional policy on regulated parties involuntarily," Spending Clause legislation "operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions."[23] Not quite. When legislation gives a party no choice, and therefore compels the party to accept conditions imposed by legislation, the legislation must pass constitutional muster. *See, e.g.*, *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981); *NFIB*, 567 U.S. at 580-82; *South Dakota v. Dole*, 483 U.S. 203, 211 (1987); *Cummings*, *v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 218-20 (2022) (same principles applied in private party context); *Butler*, 297 U.S. at 71,

[23] Defendants' Summary Judgment Reply Brief, No. 23-cv-3818, ECF 75, at 9 (D.N.J. Dec. 22, 2023).

74-75 (rejecting Congress's attempt to use "taxing and spending" power on private parties "to purchase compliance" through "coercion by economic pressure").

Here, Janssen had *no* opportunity to voluntarily accept the Government's conditions. CMS, not Janssen, selected Xarelto® for the Program and subjected Janssen to regulatory burdens backed by substantial noncompliance penalties. *See supra* Part I.C. Thus, the Program's intentional involuntariness removes this case from the considerations that ordinarily attend spending legislation.

## II. The Program Compels Janssen's Speech in Violation of the First Amendment.

Polling shows that negotiating Medicare drug prices is politically popular but government price-setting is decidedly unpopular.[24] Congress therefore presented the Program as authorizing negotiations rather than imposing price controls. To further that politically palatable fiction, the IRA requires manufacturers like Janssen to engage in sham negotiations and attest, in writing, that the Program involves voluntary negotiations resulting in a maximum fair price for selected drugs—or else incur massive penalties. Those requirements compel Janssen's speech in violation of the First Amendment.

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[24] *Compare* Morning Consult, National Tracking Poll #2109099, at 13 (Sept. 16-19, 2021), https://perma.cc/9XCL-JECJ (American public supports "allowing the federal government to directly negotiate with drug companies to get a lower price on medications"); *with id*. at 17 (less than half of Americans support "effectively allowing the federal government to set the prices of drugs.").

### A. The IRA Compels Janssen to Endorse Misleading Government Messages.

"[F]reedom of speech 'includes … the right to refrain from speaking at all.'" *Janus v. Am. Fed'n of State, Cnty. & Mun. Emps. Council 31*, 585 U.S. 878, 892 (2018). Requiring a person to express "a particular message favored by the government violates the First Amendment right to refrain from speaking," *Miller v. Mitchell*, 598 F.3d 139, 151 (3d Cir. 2010), because "[m]andating speech that a speaker would not otherwise make necessarily alters the content of the speech," *Riley v. Nat'l Fed'n. of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988). In such situations, government action will be invalidated unless it satisfies "the most exacting scrutiny," *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642 (1994)—i.e., the action must be a "narrowly tailored means of serving a compelling [governmental] interest," *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n.*, 475 U.S. 1, 17, 19 (1986) (plurality opinion) (*PG&E*).

The Program fails that demanding test. It compels Janssen to endorse the Government's narrative that manufacturers and CMS negotiate and agree on a maximum fair price for selected drugs. Janssen disagrees with those value-laden assertions. Specifically, the statute compels Janssen to speak in two ways: (1) by signing the Manufacturer Agreement to directly convey the Government's message, and (2) by participating in a performative "negotiation" process that supports the

Government's message. And the Government offers no compelling governmental interest to which the Program's compulsory speech is narrowly tailored.

**1.** The Supreme Court has recognized that signing a document can be expressive speech protected by the First Amendment. *See USAID*, 570 U.S. at 210, 218 (law compelled speech by requiring recipients of federal funds to "agree in the award document" to oppose prostitution); *John Doe No. 1. v. Reed*, 561 U.S. 186, 194-95 (2010) (rejecting argument that "signing a petition … does not involve any significant expressive element" (cleaned up)); *cf. Raiczyk v. Ocean Cnty. Vet. Hosp.*, 377 F.3d 266, 270 (3d Cir. 2004) ("signing a contract creates a conclusive presumption that the signer read, understood, and *assented to* its terms." (cleaned up; emphasis added)). Once CMS selected Xarelto®, Janssen was twice required to sign a Manufacturer Agreement with CMS: The first signature expresses Janssen's "agreemen[t]" to "negotiat[e]" a "maximum fair price" with CMS, and the second expresses that Janssen has "engaged in negotiation" with CMS and "now agree[s]" to a "maximum fair price" for Xarelto®. JA678, 683; 42 U.S.C. §§ 1320f-2(a)(1)-(3). By affixing its signatures, Janssen expresses messages core to the Government's preferred branding for the Program: (1) Janssen voluntarily "agree[s]" to the Program's terms; (2) the Program involves "negotiation[s]" culminating in Janssen and CMS "agreeing" on a price for Xarelto®; and (3) the price is not only "fair," but the "*maximum* fair price" for Xarelto®. 42 U.S.C. § 1320f-2(a) (emphasis added).

The constitutional problem arises because these expressions are neither Janssen's nor voluntarily made. They were coerced because a manufacturer that does not sign the Manufacturer Agreement is deemed to be in "noncompliance," subject to excise tax penalties that quickly balloon to nineteen times the total amount of a selected drug's sales. *See* 26 U.S.C. § 5000D(a). But for this coercive stick, Janssen would have never endorsed the Government's messages. In its view, the negotiations are cover for Government price-setting backed by noncompliance penalties, there is no volitional agreement, and the Program results in the imposition of unfair below-market prices. The Program thus violates Janssen's right to refrain from speaking.

The Program's expressive components are unique. Unlike typical government contracts, the Program coerces written agreement to blunt popular resistance to price controls and their effects on development of innovative new treatments. Speech must be "considered in the context in which it occurred." *Texas v. Johnson*, 491 U.S. 397, 405 (1989). While most government contracts are unlikely to violate the First Amendment, the Manufacturer Agreement is no ordinary contract. The provisions challenged by Janssen compel speech "on an issue of public concern" that is being actively debated at the highest levels of government,[25] against

[25] *See infra* notes 26-28 (citing statements by the President and CMS Administrator); 168 Cong. Rec. S4155-56 (Aug. 6, 2022) (remarks of Sen. Crapo) (advocating

the backdrop of a national discussion about the pricing of pharmaceutical products. *See USAID*, 570 U.S. at 218. By signing the Manufacturer Agreement, Janssen gives added weight to the Government's position on those issues.

The district court relied on *Meese v. Keene*, 481 U.S. 465 (1987), to hold that the compelled use of statutory terms cannot violate the First Amendment. JA24. But that overreads *Meese*. There, the plaintiff wished to show foreign films identified as "political propaganda" under the Foreign Agents Registration Act of 1938, a term the plaintiff claimed was pejorative and could "harm his chances for reelection." *Meese*, 481 U.S. at 468, 474. The Court rejected the speech claim because there was no evidence of harm to the plaintiff. *See id.* at 484. But the IRA context differs in important ways.

*First*, the statute did not compel the plaintiff to use the words "political propaganda." *Id*. at 471; *see also Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 529 (D.C. Cir. 2015) (recognizing that *Meese* "was not a compelled speech case"). In contrast, Janssen must sign its name to politically charged statutory terms like "maximum fair price." The D.C. Circuit distinguished *Meese* on precisely this ground, explaining—in the course of rejecting a nearly identical argument asserted by the SEC—that if the Government could use statutorily defined terms to compel

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against Program's "system of bureaucratic drug price controls" because it involves "negotiation in name only" and makes manufacturers "an offer [they] can't refuse").

speech, "there would be no end to the government's ability to skew public debate by forcing companies to use the government's preferred language." *Id.* at 530. *Second*, *Meese* is inapposite because two of the three terms challenged here—"agreement" and "negotiate"—are not defined by the IRA.

**2.** Janssen's forced participation in the Program exacerbates the compelled expression. The First Amendment protects "conduct" "inten[ded] to convey a particularized message" where "the likelihood [is] great that the message would be understood by those who viewed it." *Johnson*, 491 U.S. at 404 (cleaned up). Like the flag burning in *Johnson*, the "expressive, overtly political nature" of Janssen's forced participation in the Program is "both intentional and overwhelmingly apparent." *Id.* at 406. To the public, Janssen appears to have voluntarily signed agreements to negotiate prices with CMS that both parties agree are fair. *See* 42 U.S.C. §§ 1320f-4(a), 1320f(d)(6).

Indeed, the Government has already relied on Janssen's participation in the Program to express this very message. The President has said that the Program "giv[es] Medicare the power to *negotiate* drug prices,"[26] and after Janssen signed the Manufacturer Agreement, the White House proclaimed that manufacturers had

[26] State of the Union Address (Feb. 7, 2023) (emphasis added); *see also* Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022) ("Medicare will finally get the power to negotiate lower prescription drug prices.").

"com[e] to the negotiating table."[27] The CMS Administrator has likewise stated that the Program "is a voluntary process for manufacturers to negotiate with us directly."[28]

To be clear, Janssen has participated only because it had no other choice—the penalties that compelled Janssen to sign the Manufacturer Agreement at the outset loom over the entire process, compelling Janssen to do what CMS demands. *See* 26 U.S.C. § 5000D; 42 U.S.C. § 1320f-6. Just as the Government may not turn drivers into "mobile billboard[s]" for an ideological message, *Wooley v. Maynard*, 430 U.S. 705, 714 (1977), the Government cannot use Janssen's forced participation to amplify a political narrative that the Program involves voluntary price negotiations. By compelling Janssen to express "support for views [it] find[s] objectionable"—both through its statements in the Manufacturer Agreement and its participation in the performative "negotiation" process—the Program violates the First Amendment. *Janus*, 585 U.S. at 892.

The district court disagreed, holding that the Program is merely a conduct regulation with "incidental" effects on speech. JA20-22. But the Supreme Court

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[27] White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023), https://perma.cc/L9BG-EBJ3.

[28] Michael Erman & Patrick Wingrove, *U.S. Will Allow Drugmakers to Discuss Medicare Drug Price Negotiations*, Reuters (June 30, 2023), https://perma.cc/5CRE-KGXQ.

rejected a similar argument in *Expressions Hair Design*, distinguishing between restrictions that regulate "how sellers may *communicate* their prices" (not incidental) and "mine-run price regulation[s]" (incidental). 581 U.S. at 47-48 (emphasis added). The Program is not a "typical price regulation," *id.* at 47, because its requirements do not bear "only on product price," *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019). The political context dictates that the compelled statements go well beyond price, and regardless the compelled statements address issues other than the prices themselves—such as the fairness of the prices and the nature of the process used to adopt them. Indeed, the Manufacturer Agreement and "negotiation" process convey—and were *designed* to convey—that the Program consists of voluntary, arms-length bargaining. *See* JA22.

### B. The IRA's Compelled Speech is Not Narrowly Tailored to Serve a Compelling Government Interest.

Because the Program compels speech, it must satisfy "the most exacting scrutiny." *Turner*, 512 U.S. at 642. Yet the Government has no valid interest—let alone a compelling one—in forcing Janssen to amplify the Government's message. Nor does the Government have a compelling interest in deceiving the public regarding the true nature of the Program. To the contrary, government regulation of speech generally is limited to preventing deceptive or misleading public statements, not furthering them. *Compare Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-72 (1976) (government may regulate "deceptive or

misleading" commercial speech), *with Turner*, 512 U.S. at 641 (government may not "manipulat[e] the public debate through coercion rather than persuasion").

In any event, the Program fails to meet the narrow tailoring requirement because it could exist without forcing manufacturers to convey controversial messages. *See PG&E*, 475 U.S. at 17 (speech mandate must be narrowly tailored). Other laws allow federal agencies to set prices without forcing regulated parties to participate in performative negotiations or comment on the fairness of the agency's orders. *See, e.g.*, 42 U.S.C. § 1395w-4(b) (directing CMS to set fee schedule for physician services by regulation); 15 U.S.C. § 717d(a) (directing Federal Energy Regulatory Commission to "determine the just and reasonable rate" of natural gas for resale in interstate commerce); 49 U.S.C. § 10704(a)(1) (granting Surface Transportation Board authority to "prescribe the maximum rate" a rail carrier may charge "after a full hearing"). What makes the Program unique is the IRA's use of coerced agreements and sham negotiations to advance the Government's preferred narrative and avoid the political costs of adopting a price-setting regime. *Cf. Expressions Hair Design*, 581 U.S.at 47-48.

### C. The Option to Engage in Additional Speech Does Not Negate a Compelled Speech Violation.

The district court reasoned that even if the IRA compels Janssen to speak against its will, there is no First Amendment violation because Janssen can engage in additional speech to disavow the messages communicated through the negotiation

process and Manufacturer Agreement. That is not the law: The Government cannot "require speakers to affirm in one breath that which they deny in the next." *PG&E*, 475 U.S. at 15 nn.11, 16. Were it otherwise, the Government could compel citizens to endorse any message, simply by leaving compelled speakers free to engage in additional speech expressing their true beliefs. The argument that Janssen is free to engage in additional speech simply "begs the core question." *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 256 (1974).

For similar reasons, the "disclaimer" that CMS inserted into the Manufacturer Agreement (which is, in effect, additional compelled speech) does not cure the First Amendment violation. JA680. As this Court has recognized, "the fact that the [government] can issue a general disclaimer" accompanying a compelled message "does not erase the First Amendment infringement." *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). "Otherwise, the [government] may infringe on anyone's First Amendment interest at will, so long as the mechanism of such infringement allows the speaker to issue a general disclaimer." *Id*.; *see also W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 633 (1943) (finding compelled speech unconstitutional even when uttered "without belief and by a gesture barren of meaning").

### D. Janssen's Compelled Speech Claim Does Not Require Legal Compulsion.

The district court again accepted the Government's argument that Janssen is not required to speak because it has "options" to avoid the Program. JA19-20. For the reasons given above, these options are illusory. *See supra* Parts I.B-I.C. Moreover, circuit precedent holds that legal compulsion—that is, a formal legal prescription—is not the only way in which governments can compel speech.

Government action compels speech if it carries a punishment, or threat of punishment, that is "regulatory, proscriptive, or compulsory in nature." *Laird v. Tatum*, 408 U.S. 1, 11 (1972). But a party need not point to an affirmative legal obligation to bring a successful compelled speech claim; showing that the party is "indirect[ly]" subject to the *threat* of a specific collateral injury for failing to comply with the Government's speech mandate is sufficient. *Id.* at 12; *see also Phelan v. Laramie Cnty. Comm. Coll. Bd. of Trs.*, 235 F.3d 1243, 1248 (10th Cir. 2000); *Am. Comms. Ass'n v. Douds*, 339 U.S. 382, 402 (1950). Injuries of this nature range from denial of state bar admission, *Baird v. State Bar*, 401 U.S. 1, 5 (1971), to loss of employment, *Keyishian v. Board of Regents*, 385 U.S. 589, 592 (1967), to the conditioning of employment on a vague oath, *Baggett v. Bullit*, 377 U.S. 360, 361 (1964).

The district court relied on this Court's decision in *C.N. v. Ridgewood Board of Education*, 430 F.3d 159, 189 (3d Cir. 2005), for the proposition that compelled-

speech claims require a showing of "actual compulsion." JA19-20. But as this Court explained in *C.N.*, compulsion "need *not* take the form of a direct threat or a gun to the head." 430 F.3d at 189 (emphasis added) (quoting *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1290 (10th Cir. 2004)). "The consequence may be an indirect discouragement, rather than a direct punishment, such as imprisonment, fines, injunctions or taxes." *Axson-Flynn*, 356 F.3d at 1290 (cleaned up); *see also Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 189 (2024) (First Amendment prohibits government from relying on the "threat of invoking legal sanctions *and other means* of coercion … to achieve the suppression" of disfavored speech) (cleaned up; emphasis added).

In *C.N.*, the Court concluded that there was no compelled speech because, even if the school forced students to take a survey, there was no "disincentive or penalty if the survey was not completed." 430 F.3d at 189. Here, disincentives and penalties abound. Janssen faces enormous excise taxes for failing to participate in the "negotiation" process and sign the Manufacturer Agreement. *See supra* Part I.C; JA794-96. Thus, Janssen has sufficiently shown that its speech is, in fact, compelled.[29]

[29] Even if a legal obligation to speak were a necessary element, Janssen must remain in the Program for at least 11 to 23 months based on the IRA's delayed Medicare/Medicaid withdrawal provisions. *See* 26 U.S.C. § 5000D(c)(2); 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). Thus, to avoid having to sign the Manufacturer

## III. If Considered Voluntary, the Program Still Imposes Unconstitutional Conditions on Medicare and Medicaid Participation.

Even if Janssen's "options" to avoid the Program's requirements could be viewed as legally relevant and economically viable, the Program would still violate the unconstitutional conditions doctrine. This is so because a voluntary version of the Program would force Janssen to give up its First and Fifth Amendment rights in order to continue marketing its products through Medicare and Medicaid.

### A. The Government Cannot Place Unconstitutional Conditions on Benefits That Are Sought Voluntarily.

The unconstitutional conditions doctrine is an "overarching principle" of constitutional law that prevents the Government from using valuable benefits to "coerc[e] people into giving … up" their constitutional rights. *Koontz*, 570 U.S. a 604; *see also Perry v. Sindermann*, 408 U.S. 593, 597 (1972). The doctrine applies "in a variety of contexts," including to laws that implicate speech and property rights. *Koontz*, 570 U.S. at 604 (collecting cases).

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Agreement on October 1, 2023, Janssen would have needed to terminate its Medicare and Medicaid agreements no later than January 29, 2022—seven months *before* the IRA's enactment. To be sure, CMS has said in nonbinding guidance that it will shorten the withdrawal period to 30 days. *See* JA597-98. But the IRA suspends the excise tax only when a manufacturer terminates its Medicare and Medicaid agreements, *see* 26 U.S.C. § 5000D(c) (requiring "notice" to Secretary of manufacturer's "terminations of all applicable agreements"), and the IRA requires termination "by a *manufacturer*" to be delayed 11 to 23 months, *see* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii) (emphasis added).

The voluntary nature of a benefit is irrelevant to the unconstitutional conditions analysis. Indeed, the doctrine specifically applies when a person who "has *no* 'right' to a valuable governmental benefit" seeks that benefit voluntarily and encounters a demand to surrender constitutional rights in response. *Perry*, 408 U.S. at 597 (emphasis added). Thus, the Government may not use a voluntary benefit to coerce the relinquishment of rights, "produc[ing] a result which it could not command directly." *Id.* (cleaned up).

### B. A Voluntary Program Would Place Unconstitutional Conditions on Janssen's Participation in Medicare and Medicaid.

Unconstitutional conditions inquiries begin with a "predicate" question: whether "the government could not have constitutionally *ordered* … what it attempted to pressure that person into doing." *Koontz*, 570 U.S. at 612 (emphasis added). To answer this question, courts convert the challenged condition into a mandate and then assess its validity. *See id.* Thus, even if the Court were to view the Program as voluntary, the Court would apply the unconstitutional conditions doctrine by assuming that participation is mandatory and deciding whether the Program's requirements effect a taking of Janssen's rights in its Xarelto® products or unlawfully compel Janssen's speech. *See id.* The answer is yes on both counts.[30]

[30] The district court misunderstood this analysis, rejecting Janssen's unconstitutional conditions claim without assuming that the Program is mandatory. *See* JA25. Instead, the court reiterated its earlier conclusions that the Program does not effect a

**1.** In the takings context, *Horne* and *Cedar Point* show that a requirement to transfer property to third parties on Government-imposed terms would be a physical taking. And because the Government could not impose such a mandate "direct[ly]," the unconstitutional conditions doctrine precludes it from doing so "indirectly." *Speiser v. Randall*, 357 U.S. 513, 526 (1958); *see also Horne II*, 576 U.S. at 366 (Congress may not condition "basic and familiar uses of property" on "the waiver of constitutional protection"). Yet that is what the Program does (at least under the Government's misplaced voluntariness theory): Janssen must give up its rights to control the disposition of its Xarelto® products in order to continue offering its other medicines through Medicare and Medicaid. *See supra* Part I.A. "Extortionate demands of this sort frustrate the Fifth Amendment right to just compensation, and the unconstitutional conditions doctrine prohibits them." *Koontz*, 570 U.S. at 605.[31]

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taking or compel speech—conclusions that it reached, in large part, by characterizing the Program as voluntary. JA10, 13-18, 20.

[31] The result is the same under the nexus-and-proportionality test applied in *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994). Under the Program, Janssen must give up its property rights in Xarelto® or else lose the ability to sell *any* of its medicines through Medicare *and* Medicaid. *See* 26 U.S.C. § 5000D(c). That all-for-one tradeoff is disproportionate. Moreover, there is not a sufficient nexus between Janssen's sales of Xarelto® in Medicare Part D and the company's marketing of other medicines (which treat distinct health problems and serve distinct patient populations) in separate programs such as Medicare Part B and Medicaid. *See* BMS Br. Part III.B.1.

The Program is also an unconstitutional condition under *NFIB*. There, the Court explained that while Congress could place new conditions on new Medicaid funds, it could not "penalize [recipients] that choose not to participate in [a] *new* program by taking away their *existing* Medicaid funding," especially where recipients "ha[ve] no real choice" but to comply. 567 U.S. at 585, 587 (emphases added). Because the law at issue authorized the Government "to do just that" for recipients deemed "out of compliance" with the new Medicaid funding conditions, the Court struck down the law as unconstitutional. The same reasoning applies here for the reasons given by BMS. *See* BMS Br. Part III.A.

**2.** The Program also unlawfully conditions Janssen's ability to participate in Medicare and Medicaid on waiver of its First Amendment rights. A condition is unconstitutional if it requires program participants to "profess a specific belief" in order to receive a government benefit. *USAID*, 570 U.S. at 218-19. In *USAID*, for example, it was impermissible for Congress to condition federal grants on recipients "agree[ing] in the [funding] award document" that they are "opposed to prostitution and sex trafficking." *Id.* at 210 (cleaned up); *see also* 45 C.F.R. § 89.1 (HHS "shall include" in the "award documents" the "requirement that recipients agree that they are opposed to the practices of prostitution and sex trafficking"). The Court explained that while "conditions that … specify the *activities* Congress wants to subsidize" are constitutionally permissible, "conditions that seek … to regulate

speech outside the contours of the program itself" are not. *USAID*, 570 U.S. at 214-15. And while that "distinction … is not always self-evident," the Court was "confident" when the Government "demand[s] that funding recipients adopt—as their own—the Government's view on an issue of public concern, the condition *by its very nature* affects protected conduct outside the scope of the federally funded program." *Id.* at 217-18 (emphasis added; cleaned up).[32]

Similarly here, Janssen's continued ability to participate in Medicare and Medicaid depends on expressing messages it would not otherwise express and does not believe are true: that the Program involves an "agreement" to "negotiate" the "maximum fair price" for Xarelto®. The compelled speech also goes beyond the contours of the Program: Rather than merely determining and communicating a price for Xarelto®, the Program requires the speaker to endorse a government "characterization" of that price as stemming from a purportedly arms-length negotiation resulting in a price all agree is fair. *Nicopure*, 944 F.3d at 292 (discussing *Expressions Hair Design*, 581 U.S. at 47). Congress could have enacted a statute to set the price of selected drugs *without* requiring manufacturers "to pledge allegiance to the Government's policy" and to characterize the Program's prices in

[32] *Boehringer* overlooked this aspect of *USAID*. *See* 2024 WL 3292657 at *18. As the Supreme Court explained, "Congress cannot recast a condition on funding as a mere definition of its program in every case, lest the First Amendment be reduced to a simple semantic exercise." *USAID*, 570 U.S. at 215.

a politically favorable way. *USAID*, 570 U.S. at 220. Thus, the compelled speech "falls on the unconstitutional side of the line." *Id.* at 217.[33]

## CONCLUSION

The judgment of the district court should be reversed.

Respectfully submitted,

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[33] The Program's effects will be felt outside of Medicare as well. For example, CMS must publish the "maximum fair price" for Xarelto® by September 1, 2024, and publish an explanation for that price by March 1, 2025. 42 U.S.C. §§ 1320f(d)(2)(B) & (6), 1320f-4(a)(2). These public statements will cause—and no doubt were designed by Congress to cause—downward pressure on prices in commercial markets. They will also force Janssen to engage in additional speech to counteract the misleading statements compelled by the Program.

## CERTIFICATE OF COMPLIANCE

1. This Brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(b) because it contains 12,997, excluding the parts of the Brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This Brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point, Times New Roman font.

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/s/ *Kevin F. King*

July 12, 2024

## CERTIFICATE OF BAR MEMBERSHIP

Pursuant to Third Circuit Local Appellate Rule 28.3(d), I certify that the following attorneys whose names appear on the brief are members of the bar of this Court:

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*/s/ Kevin F. King*

July 12, 2024

## CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2024, I caused the foregoing document to be electronically filed with the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system for filing and transmittal of a Notice of Electronic Filing to counsel of record.

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