IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

JANSSEN PHARMACEUTICALS, INC., *Plaintiff*, v. XAVIER BECERRA, Secretary of Health and Human Services, *et al.*, *Defendants*.	Civil Action No. 23-cv-03818-ZNQ-JBD

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

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INTRODUCTION

At its core, the Drug Price Negotiation Program constitutes government price-setting: A federal agency, the Centers for Medicare & Medicaid Services ("CMS"), unilaterally imposes price caps for innovative and widely prescribed drugs, including Janssen's drug Xarelto®. To make the Program more popular with voters—and to avoid accountability for its destructive effects on scientific research and development—Congress cloaked those price caps in the fiction of voluntariness, characterizing them as "negotiated agreements" between manufacturers and CMS. But no voluntary agreement is reached under threat of billion-dollar penalties for refusing the Government's "offer." And no Program is voluntary where failure to comply means losing access to nearly half the U.S. healthcare market. Congress knew that in a truly voluntary framework manufacturers could refuse CMS's below-market prices. To prevent that outcome, Congress designed the Inflation Reduction Act ("IRA") to make the Program voluntary in theory but mandatory in fact.

As Janssen explains in its opening brief, that scheme is unconstitutional in multiple ways. It violates the Fifth Amendment by effecting a physical taking of Xarelto® products through the Program's statutory "access" right, and also infringes Janssen's First Amendment rights by compelling Janssen to endorse the Government's misleading message that the Program merely involves "negotiating" "fair" prices. *See* Janssen Opening Brief ("Janssen Br."), ECF 30-1, at 16–35.

The Government's cross-motion for summary judgment doubles down on the IRA's central fiction, insisting that the Program is immune from Janssen's claims because it is "entirely voluntary." Government Opposition Br. ("Govt Br."), ECF 33-1, at 38. That argument is incorrect on the law and the facts. The Program is structured so that Janssen is compelled to make its Xarelto® products available at whatever price CMS unilaterally decides to pay. Failing to do so would subject Janssen to a punitive excise tax equal to *19 times* the sale price of Xarelto®. Although the Government contends that Janssen has the "option" of withdrawing *all* twenty-one of its medicines (not just Xarelto®), from Medicare and Medicaid, that is no option at all. Janssen's undisputed evidence shows that an across-the-board withdrawal from Medicare and Medicaid would deprive millions of patients of insurance coverage for their critical medicines and deprive Janssen of approximately 65 percent of its gross revenues—revenues that are essential for Janssen to continue innovating and competing in the marketplace.

The Government's remaining voluntariness arguments are equally unavailing. The Supreme Court has rejected the Government's contention that legal (as opposed to economic) compulsion is required to establish a constitutional violation. *See, e.g.*, *Horne v. U.S. Dep't of Agric.*, 576 U.S. 350, 365–66 (2015). Even if legal compulsion were necessary, Janssen has made that showing here given the IRA's requirement that Janssen comply with the Program's requirements for at least a

minimum period or else pay the excise tax. With respect to economic coercion, the Government errs in arguing that the Program is voluntary because Janssen could sell its rights in Xarelto® to a hypothetical buyer. That argument relies on speculation that a willing buyer exists for a drug subject to the Program's draconian requirements, and also ignores the harm to Janssen even if such a buyer could be found. The Government's assertion that it is merely a "market participant" likewise fails because CMS acts as a regulator in carrying out the Program—for example, by issuing directives backed by civil monetary penalties and claiming the right to amend the "agreement" that implements the Program without Janssen's consent. Moreover, CMS possesses significant market power in the prescription drug sector and wields that power in a way that would expose any private market participant to antitrust enforcement, further underscoring that the Program is not voluntary.

The Government defends the Program on additional grounds beyond voluntariness, but none of those defenses withstands scrutiny.

As to Janssen's Fifth Amendment claim, the Government relies on the fact that the Program does not haul away physical doses of Xarelto® from Janssen's facilities. But the Supreme Court has reasoned that appropriation of property rights is a taking no matter how it is garbed. *See Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021). Here, the Program eviscerates Janssen's right to control the disposition of its Xarelto® products by authorizing Medicare participants to "access"

those products over Janssen's objection. *See Horne*, 576 U.S. at 363. Because that scheme produces the same result as if a fleet of government trucks seized the doses of Xarelto® and delivered them to third parties, the takings analysis leads to the same conclusion.

With respect to Janssen's First Amendment claim, the Government does not argue that the Program's requirements can survive any form of heightened scrutiny, let alone strict scrutiny. Instead, the Government contends that the Manufacturer Agreement Janssen was required to sign is not speech at all. That argument is not tenable. The First Amendment protects a broad range of speech, including "creation and dissemination of information." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 570 (2011). Here, the compelled speech goes well beyond simple contract terms: The IRA forces Janssen to amplify the Government's message that the Program involves an "agreement" to "negotiate" a "fair" price. Such statements would be compelled speech if Janssen were required to make them in a *New York Times* advertisement. *See, e.g.*, *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 17–19 (1986) ("*PG&E*"). They are equally compelled speech when Janssen is required to sign a document that can be, and is, used by the President and other high-ranking officials to advance a narrative on a contested issue of public concern. The Government's additional arguments that the First Amendment violation is cured by a "disclaimer"

drafted by CMS, and by Janssen's ability to engage in additional counter-speech, are foreclosed by binding precedent.

Finally, even if the Program could be viewed as voluntary, it would still violate the unconstitutional conditions doctrine. Under that doctrine, the Government may not burden constitutional rights by coercively withholding benefits from those who exercise those rights. *See Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013). The Program imposes exactly such a burden by forcing Janssen to surrender its property rights in Xarelto® and engage in compelled speech in order to continue participating in Medicare and Medicaid.

The Court should grant Janssen's motion for summary judgment and deny the Government's cross-motion.

ARGUMENT

I. The Program is Not Voluntary.

The Government devotes most of its brief to arguing that the Program is voluntary and therefore immunized from First and Fifth Amendment scrutiny. *See* Gov't Br. 11–25. That argument fails because the Program is *not* voluntary. Rather, the IRA compels Janssen, both legally and economically, to comply with the Program's terms. The purported alternatives cited by the Government either do not

exist or are not viable as applied to Janssen.[1] Because the Government's voluntariness argument fails, the Court must evaluate Janssen's First and Fifth Amendment claims under the same standards that would apply in any other case.

A. Legal Compulsion Is Not Required to Establish Constitutional Injury, and Even if It Were, Janssen Has Made That Showing.

On August 29, 2023, CMS issued an order selecting Janssen's drug Xarelto® for the Program.[2] That order triggered an obligation for Janssen to "enter into [an] agreemen[t]" to "provide access to" Xarelto® at the "maximum fair price" imposed by CMS. 42 U.S.C. § 1320f-2(a). The Government nevertheless argues that the Program is voluntary because there is no "statutory provision requir[ing] entities to participate in Medicare or to sell their property." Gov't Br. 12–13 (citing *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993)). And because there is no express "legal compulsion," the Government argues, the IRA cannot violate Janssen's constitutional rights. *Id.* at 12. That argument contradicts Supreme Court precedent, which instructs that legal compulsion is *not* necessary for Janssen to prevail on its

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[1] Contrary to the Government's repeated assertion (at 11, 25, 26, 30), Janssen has not brought a facial challenge. Instead, Janssen asserts as-applied challenges to the Program based on undisputed facts concerning Janssen and Xarelto®. *See, e.g.*, Janssen Compl. ¶¶ 11, 132 (IRA "is unconstitutional *as applied to Janssen* in at least three ways[.]" (emphasis added)); Janssen Br. 22–23.

[2] *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html. CMS also selected Stelara®, a drug marketed by Janssen Biotech, Inc., for the Program. *See id*.

First and Fifth Amendment claims. Even if legal compulsion were required, the Government's argument would fail on its own terms because Janssen is legally required to comply with the Program's requirements for at least a minimum period.

1. The Supreme Court has rejected the notion that legal compulsion is necessary to establish a constitutional violation. In *Horne*, farmers brought a physical takings claim even though they were not required by law to enter the raisin market and could pay a penalty in lieu of giving up their property. 576 U.S. at 366, 370. The Government seized on these "options" to argue that there was no taking because the farmers could "plant different crops" or "sell their raisin-variety grapes as table grapes or for use in juice or wine." *Id.* The Court rejected that argument, holding that the Government had effected a taking even if the "raisin growers *voluntarily ch*[*ose*] to participate in the raisin market." *Id.* at 365 (emphasis added). If legal compulsion had been necessary (as the Government now contends), the Court would have reached the opposite result. *See also Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 439 n.17 (1982) (ability to "avoid [challenged law] by ceasing to rent the building to tenants" did not defeat landlord's takings claim because property rights "cannot be so easily manipulated").[3]

[3] Although the Government suggests (at 18) that *Yee v. City of Escondido*, 503 U.S. 519 (1992), supports its position, subsequent takings decisions, such as *Horne* and *Cedar Point*, foreclose that argument. *See, e.g.*, *307, 712, 2103 & 3151 LLC v. City* (continued…)

The Government relies (at 12–13) on a handful of out-of-circuit cases to support its legal compulsion argument, but those cases are inapposite for several reasons. *First*, nearly all of them predate *Horne*.[4] To the extent those cases contradict *Horne* by imposing a legal compulsion requirement, they have no precedential weight in this (or any) Court—*Horne* controls. *Second*, those cases are factually distinct. None of the cases involved a situation like the one presented here, in which CMS selected Janssen for the Program—exposing Janssen to coercive penalties if it does not comply. The plaintiffs in the Government's cases, in contrast, were free to enter or exit the various programs without penalty. *Third*, several of the cases—including the Government's primary authority, *Garelick*—are inapposite because they involved *regulatory* takings claims, rather than physical takings claims. As the Supreme Court has explained, regulatory takings cases should not be used as "controlling precedents" when evaluating physical takings claims. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan Agency*, 535 U.S. 302, 323 (2002). *Finally*, some of the cases do not support the Government's argument that legal compulsion is always required. *See, e.g.*, *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 129–

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of Minneapolis, 27 F.4th 1377, 1381–83 (8th Cir. 2022) (questioning whether *Yee*'s "voluntariness rationale" remains good law in light of *Horne*).

[4] The sole exception is *Southeast Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016), which in a single sentence contrasted the "voluntar[y]" Medicare hospice program with the raisin program challenged in *Horne*.

30 (1st Cir. 2009) (considering whether *financial inducement*, not legal compulsion, made MaineCare involuntary for participating hospitals).

The recent order in *Dayton Area Chamber of Commerce v. Becerra*, No. 3:23-cv-156 (S.D. Ohio Sept. 29, 2023), lacks persuasive force for similar reasons. As a threshold matter, the decision is preliminary and addresses a due process claim not at issue here. The order concludes that "at this initial stage in the litigation process, it is too early to know—with the degree of certainty necessary for a preliminary injunction—that Plaintiffs have a strong likelihood of success on the merits." *Id.* at 24. Moreover, the decision's voluntariness discussion consists of a single paragraph based on the same out-of-circuit, pre-*Horne* cases addressed above to suggest that manufacturers "are not legally compelled to participate in the [IRA] Program." *Id.* at 23. That conclusion rests on a mistaken premise for the reasons given above. In addition, the *Chamber* decision does not address *Horne* or any of the other coercion arguments advanced in this brief.

To be sure, the Supreme Court has recognized one limited situation that can mitigate a takings claim: the "voluntary" relinquishment of property in exchange for "a valuable Government benefit." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984); *accord Horne*, 576 U.S. at 366. The Government mentions this principle in passing (at 12), and several of the cases it cites rely on similar logic. But there is no exchange here. Janssen receives *no* benefit from the Program: it can either lose (by

participating in the Program with its unconstitutional demands) or lose even more (by incurring excise tax penalties for noncompliance). *See Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023) (rejecting voluntary exchange argument where plaintiff "receive[d] no additional benefit for the [property] they [were required to] forfeit").[5]

The IRA also changes the federal healthcare markets in such a way that even if the Program could be construed as an exchange for benefits, it cannot be considered a *voluntary* exchange. When Janssen entered the Medicare Part D market, CMS was statutorily precluded from interfering with drug price negotiations. *See* 42 U.S.C. § 1395w-111(i) (2022). *That* was the market around which Janssen structured a significant portion of its business. *See* Penkowski Decl., ECF 30-10, ¶¶ 4–11. The IRA fundamentally alters that regulatory landscape by creating a new Program, giving CMS authority to dictate Medicare drug prices "[f]or the first time," Gov't Br. 1, and imposing seismic economic consequences for noncompliance. The Government cannot point to Janssen's participation in a prior regulatory regime that has since been replaced and claim that participation in the new regime is voluntary. This is especially so where the Program is specifically

[5] The Law Scholar *amici* argue (ECF 48-3, at 14) that the Program is a voluntary exchange because Janssen received patents and other regulatory benefits before the IRA's enactment. But *none* of those benefits stem from the Program, making them irrelevant to the voluntariness analysis. *See, e.g.*, *Monsanto*, 467 U.S. at 1007.

designed to leverage reliance interests in the prior regime to compel compliance with the new scheme. *Cf. Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 585 (2012) ("*NFIB*") ("Congress is not free … to penalize States that choose not to participate in that new program by taking away their existing Medicaid funding.").

2. Even if the Government were right that legal compulsion is necessary, Janssen has made that showing here. The IRA is structured in such a way that once CMS selected Xarelto®, Janssen became subject to the Program: it could either comply or pay crushing excise taxes as a penalty for noncompliance. Indeed, it would make no sense to impose an excise tax on Janssen for "noncompliance," 26 U.S.C. § 5000D, unless Janssen was, in fact, legally obligated to comply. Janssen is thus compelled by law to "enter into agreements," "negotiate to determine a maximum fair price," provide "access" to Xarelto® at that price, submit confidential data, and "compl[y]" with any other requirements CMS deems to be "necessary." 42 U.S.C. § 1320f-2(a).

The Government's response to this legal compulsion is that Janssen can withdraw from Medicare and Medicaid to avoid the Program's requirements and noncompliance penalties. But even then, the IRA requires Janssen to remain subject to the Program for at least some period of time. The IRA suspends the excise tax only *after* a manufacturer has provided notice of termination of all its Medicare and Medicaid agreements and terminated its Medicare agreements, *see* 26 U.S.C.

§ 5000D(c)—a process that, by statute takes at least 11 months (and as long as 23 months) to complete, *see* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii).

Following several lawsuits raising this issue,[6] CMS promulgated nonbinding guidance stating that the agency will treat "[t]ermination … [b]y a manufacturer," which is required to avoid the excise tax, *id.* §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii), as "[t]ermination … [b]y the Secretary," *id.* §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i); *see* Revised Guidance (Chiesa Decl. Ex. A, ECF 30-3) § 40.6. The effect of that regulatory sleight of hand is that the termination timeline conveniently shortens to 30 days. That approach contradicts the statute in numerous ways: It collapses the statutory distinction between manufacturer-initiated and CMS-initiated termination; ignores the fact that the IRA suspends the excise tax only upon "the manufacturer" providing "notice" that its Medicare and Medicaid agreements have been "terminat[ed]" and the effective termination of any Medicare agreements; and transgresses statutory limits, which allow CMS to terminate such agreements only upon a manufacturer's "knowing and willful violation of the requirements of the agreement or other good cause" related

[6] *See, e.g.*, *Merck v. Becerra*, No. 23-cv-01615, ECF 1 ¶¶ 6, 82 (D.D.C. June 6, 2023); *Dayton Area Chamber of Com. v. Becerra*, No. 23-cv-00156, ECF 1 ¶¶ 96, 98–100 (S.D. Ohio June 9, 2023).

thereto. 26 U.S.C. § 5000D(c); 42 U.S.C. §§ 1395w-114a(b)(4)(B), 1395w-114c(b)(4)(B). But even under the Government's atextual theory, Janssen still cannot extricate itself from the Program for at least 30 days. *See* Revised Guidance § 40.6. Whether for one month or 23, Janssen must comply with the Program or be penalized for not doing so. That mandate amounts to legal compulsion.

B. The "Choices" Available to Janssen Are Illusory.

In addition to the legal coercion described above, Janssen has provided company-specific evidence showing that the Program is not voluntary because it employs *economic* coercion to force Janssen into compliance. *See* Penkowski Decl. ¶¶ 9, 11, 17–22, 27. For example, failing to comply with the Program's requirements while remaining in Medicare and Medicaid would subject Janssen to billions of dollars in penalties, which, over the course of only one year, would amount to more than three times the 2022 adjusted net earnings of Janssen's parent company. *See id.* ¶¶ 18–20. Withdrawing entirely from Medicare and Medicaid would not be feasible either; doing so would force Janssen to give up approximately 65 percent of its gross sales and would leave millions of patients without insurance coverage for the medicines on which they depend. *See id.* ¶¶ 9, 21. In short, no rational actor in Janssen's position could seriously consider, let alone adopt, the courses of action that the Government contends make the Program voluntary.

The Government ignores Janssen's evidence entirely. Instead, the Government asserts that the Program is lawful because the IRA leaves Janssen theoretical "choices" other than participation in the Program. Gov't Br. 6; *see also id.* 11–19. But those purported choices do not support the Government's argument. Some of them do not exist. Others rely on litigation-driven contortions of the IRA's structure that fail as a matter of law. Still others may exist in theory but are not available as applied to Janssen.

1. The Government maintains that "[a] manufacturer that does not wish to sign" CMS's Program agreement can "pay an excise tax." Gov't Br. 6. The Government devotes little attention to this supposed choice, and it is easy to see why: paying the tax would leave Janssen in a *worse* economic position than submitting to the CMS-imposed price for Xarelto®. *See* Penkowski Decl. ¶ 20. A demand to "give us an arm or we will take an arm and a leg" does not make handing over an arm voluntary. *See NFIB*, 567 U.S. at 582 ("threatened loss of over 10 percent of a State's overall budget" was "economic dragooning that le[ft] the States with no real option but to acquiesce in the Medicaid expansion"). The Government's attempts to dodge that straightforward conclusion are unavailing.

First, the Government seeks to downplay the size of the excise tax by asserting that the Internal Revenue Service ("IRS") "intends to propose regulations" that would, if adopted, limit the tax to "only those drugs dispensed, furnished, or

administered to Medicare beneficiaries." Gov't Br. 8. But the IRS has not proposed, much less finalized, those regulations—and there is no guarantee that they will ever go into effect. The mere *possibility* of future regulations cannot convert the tax into an acceptable choice. *Cf. In re Murray Energy Corp.*, 788 F.3d 330, 334 (D.C. Cir. 2015) ("[p]roposed rules" have no "legal consequences" (citation omitted)). Even if IRS did adopt the new rules, they would leave Janssen exposed to massive (just not quite *as* massive) penalties. And even that step would contravene the text of the IRA itself, which subjects *all* domestic sales of selected drugs to the excise tax. *See* 26 U.S.C. § 5000D(a) ("impos[ing]" the tax "on *the sale* by the manufacturer … of any designated drug" (emphasis added)).[7]

Second, the Government resorts to additional interpretive gymnastics to obscure the tax's scope, contending (at 8) that the tax applies at a 95 percent rate, rather than 1900 percent. The Government's 95 percent figure refers to the proportion of the total invoice amount attributable to the excise tax. Thus, under the Government's approach, when a manufacturer invoices a wholesaler $100 for a selected drug, the tax makes up $95 of that sum, while the manufacturer retains the

[7] The statute's exclusion for exports, *see id.* § 5000D(g), reinforces this conclusion: Because Medicare and Medicaid are domestic programs, the exemption would be surplusage if "the sale[s]" covered by the tax were only sales to those programs. *See Obduskey v. McCarthy & Holthus LLP*, 139 S. Ct. 1029, 1037 (2019) (applying principle that "courts generally presume that statutes do not contain surplusage" (cleaned up)).

remaining $5. *Id.* at 8–9 & n.1. But a $95 tax on a $5 sale and a $1900 tax on a $100 sale reflect exactly the same confiscatory rate of taxation: 1900 percent, or 19 times, the revenue earned by the taxpayer. A true 95 percent tax on a $5 sale would be $4.75—a far cry from the $95 the Government would take from Janssen in the Government's own example. *See also* Chiesa Decl. Ex. D, ECF 30-6, at 4 (Congressional Research Service report explaining that the tax "range[s] from 185.71% to 1900% of the selected drug's price").

At bottom, the Government's hypothetical regulations and accounting maneuvers are a distraction. The Program is not voluntary because the IRA forces Janssen to comply with its terms or pay excise taxes that would extract an even greater economic toll. *See, e.g.*, Penkowski Decl. ¶¶ 17–20. The Congressional Budget Office recognized as much, observing "that drug manufacturers will comply with the negotiation process because the costs of not doing so are greater than the revenue loss from lower … prices." Chiesa Decl. Ex. F at 12.

2. The Government further relies (at 15) on Janssen's supposed "choice" to withdraw all of its drugs—not just Xarelto®—from both Medicare and Medicaid. Once again, the Government has not addressed Janssen's evidence that this "purported choice is no choice at all." Janssen Br. 11. The problem is straightforward: Medicare and Medicaid account for roughly half of prescriptions for Janssen drugs and 65 percent of Janssen's gross revenues. Penkowski Decl. ¶ 9.

As a result, "Janssen's ability to participate in [Medicare and Medicaid] is critical to its continued ability to innovate and compete." *Id.* ¶ 11. Across-the-board withdrawal would require removing all 21 of Janssen's drugs from those programs and depriving millions of Americans of coverage for these medications. *Id.* ¶ 21.[8]

Courts have recognized for nearly a century that a government program is not voluntary when it employs that sort of economic dragooning. In *NFIB*, for instance, the Supreme Court recognized that sufficiently strong economic coercion leaves the regulated party "with no real option but to acquiesce." 567 U.S. at 582. Applying that principle, the Court held that Congress had coerced the States into accepting new Medicaid requirements by making compliance with them a prerequisite for receipt of Medicaid funds equal to "10 percent of a State's overall budget." *Id.* at 582. The magnitude of that penalty distinguished *NFIB* from prior cases in which smaller inducements left program participants with the "prerogative to reject Congress's desired policy, not merely in theory but in fact." *Id* at 581 (cleaned up).

Earlier decisions applied the same commonsense principle. For example, in *Union Pacific Rail Road Co. v. Public Service Commission*, the Supreme Court

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[8] The Government suggests in passing that Janssen could simply "stop selling [Xarelto®] to Medicare beneficiaries." Gov't Br. 14. But the IRA requires a manufacturer to withdraw *all* its products—not just the selected drug—from Medicare or Medicaid to escape the Program's penalties. *See* 26 U.S.C. § 5000D(c); *see also* Revised Guidance § 40.6.

recognized that the Government may not "impose an unconstitutional burden" on a private railroad "by threat of [even greater] penalties" if the railroad "fail[s] to accept [that burden], and then … declare the acceptance voluntary." 248 U.S. 67, 70 (1918). Such economic "duress" would negate any purported "choice" between compliance and "grave penalties" because it would be "practically impossible *not to comply* with the terms of the law." *Id.* (emphasis added). Likewise, the Court in *United States v. Butler* held that a "regulation [was] not in fact voluntary," and the "asserted power of choice … illusory," where Congress had used "coercion by economic pressure" "to induce [a regulated party] to surrender [its] independence of action." 297 U.S. 1, 70–71 (1936); *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (concluding that a purportedly voluntary "agreement" to participate in a coal regulation program was "coerce[d]" and "lack[ed] the essential element of consent" because it was backed by provisions imposing substantial taxes for noncompliance, and observing that "[o]ne who does a thing in order to avoid a penalty does not agree").

In circumstances starkly similar to Janssen's, the D.C. Circuit held that a comparably structured federal program restricting cotton production was involuntary. *See Thompson v. Deal*, 92 F.2d 478 (D.C. Cir. 1937). That program was structured such that existing cotton farmers had "options" to (1) not produce or sell cotton; (2) sell their cotton subject to a 50 percent tax on each bale; (3) sell their

cotton without paying the 50 percent tax and be subject to *even greater* fines and imprisonment; or (4) receive an allotment from the Secretary of Agriculture to sell cotton tax- and penalty-free. *Id.* at 329, 333. Yet to take the fourth "option" and receive an allotment, a farmer had to sign an agreement with the Secretary of Agriculture "to comply with the limitations on production … not only as to cotton but as to all other agricultural commodities." *Id.* And for any cotton produced in excess of that allotment, a farmer would have to purchase additional allotment certificates at 40 percent of the cotton bales' value (i.e., 10 percent less than the tax the farmer would otherwise have to pay). *Id.* at 329, 333. Given these "options," the court held that "[t]he asserted power of choice [was] illusory" because the program exercised "coercion by economic pressure": "No farmer … was in position to refuse to sign the agreement … to accept his allotment as the Secretary made it," and any purchase of excess cotton certificates was similarly "made under compulsion" to avoid a higher noncompliance tax. *Id.* at 333–34. The parallels with the IRA's use of illusory "options" and economic coercion to compel Janssen's compliance with the Program are clear.[9]

[9] *See also, e.g.*, *Philip Morris, Inc. v. Harshbarger*, 159 F.3d 670, 678–79 (1st Cir. 1998) ("forc[ing] a party to make a Hobson's choice" between disclosing "valuable trade secrets without adequate safeguards to remain in business" or "ceas[ing] … business in an important market" was "the essence of legal compulsion").

The Government responds only to *NFIB* and improperly writes off that case. According to the Government, the economic coercion principle does not apply here because it "is derived exclusively from cases analyzing … *federalism* principles." Gov't Br. 20. It is true that federalism concerns played a role in *NFIB*. *See* 567 U.S. at 577–78. But the Government goes too far in suggesting that economic coercion matters in the federalism context alone. *Union Pacific*, *Carter*, *Butler*, *Thompson*, and *Philip Morris* applied the same principles to private parties. Janssen is situated similarly to the businesses that were coerced into compliance in those cases, and the economic coercion principle applies equally here.[10]

3. The Government also suggests that Janssen has the "option" of avoiding the Program by divesting Xarelto®. Gov't Br. 2, 14, 17, 23, 24.[11] That argument disregards common sense and economic reality. Contrary to the Government's speculation, it is doubtful that a willing buyer would emerge for a drug burdened by the Program. Further, any hypothetical buyer of the rights to Xarelto® would

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[10] The fact that Janssen has signed the Manufacturer Agreement does not make this issue "purely academic." Govt Br. 15. Janssen signed the Agreement under protest. In doing so, Janssen proceeded in the same fashion as the challengers in the other cases surveyed above—it complied, but only out of necessity. Such coerced compliance is not evidence of voluntariness. *See, e.g.*, *Butler*, 297 U.S. at 70–71.

[11] The Government asserts (at 14) that Janssen can "divest its interest in the selected drug to a subsidiary" and avoid the portfolio-wide consequences of declining to sell to Medicare. But doing so would violate CMS's directive that a divestiture only affects application of the excise tax if "the transfer … was made to an entity that is *not a related party*." Revised Guidance at 132.

immediately face the same obligations that the Program currently imposes on Janssen and therefore would discount the price it is willing to pay in light of those burdens. The transaction would, in other words, be a "fire sale" that could impose on Janssen the same harm as would participation in the Program. The possibility of such a transaction thus does not mitigate the Program's coercive effects.[12]

C. The Government Is Not Acting as a Market Participant.

Finally, the Government seeks to excuse the Program's coercive terms on the ground that CMS is simply exerting economic "pressure" by using its "leverage" as "any well-funded market participant" would do. Gov't Br. 21–22. Not so.

The Government is acting as a regulator here, not a market participant. Market participants cannot impose confiscatory taxes on counterparties who do not accept their demands. *See* 26 U.S.C. § 5000D; Revised Guidance §§ 40.1, 40.6, 60.8, 90.1, 100.2. Nor do market participants have the right to unilaterally establish regulations that govern the conduct of counterparties or to impose civil monetary penalties when counterparties fail to comply with those regulations—powers the IRA grants CMS here. *See, e.g.*, 42 U.S.C. § 1320f-6; Revised Guidance § 100

[12] The Government does not cite a single case in which the possibility of divestiture barred a First Amendment claim, and there are scores of cases that would have come out differently if the Government's theory were correct. To take just one example, the plaintiff in *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241 (1974), could have sold its newspaper rather than complying with the challenged regulation, but that did not insulate the regulation from First Amendment scrutiny.

(adopting a "structure for enforcement actions" regarding "violations" of CMS directives). Ordinary market participants cannot revise a contract unless the other party accepts the changes; CMS, in contrast, retains the right to amend the Manufacturer Agreements that govern the "negotiation" process at any time, without the manufacturer's consent. *See* Manufacturer Agreement (Chiesa Decl. Ex. B, ECF 30-4) §§ II(e), IV(b).

That CMS exercises those powers through the Program highlights its quintessentially regulatory role. Congress could have authorized CMS to leverage its significant share of the healthcare market to negotiate drug prices—without layering on excise taxes, regulations, civil monetary penalties, and the rest of the Program's elaborate structure. But that framework would have left open the possibility that some manufacturers would decline CMS's offer—thus leaving Medicare beneficiaries without coverage for the selected drugs (which, given the Program's design, are among the most widely prescribed drugs in the market). Congress enacted the coercive provisions described above—thus augmenting CMS's economic power with *sovereign* power—to prevent that politically unacceptable outcome. No amount of litigation posturing by the Government can change that fact.

Antitrust principles further undermine the Government's market-participant analogy. Medicare and Medicaid together account for nearly 40 percent of the U.S.

prescription drug market—a fact that recently led the Third Circuit to observe that "[t]he federal government dominates the healthcare market." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023); *see* Janssen Br. 6 n.8. Under the antitrust laws, a party in that position possesses market power. *See Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 26–29 (1984); U.S. Dep't of Justice & Federal Trade Commission, Draft Merger Guidelines 19 (2023). If a private market participant were in CMS's position—leveraging its market power by tying the purchase of all Janssen's drugs to obtain one drug on favorable terms—that conduct would face a serious antitrust challenge. *See Century Aluminum of S.C. v. S.C. Pub. Serv. Auth.*, 278 F. Supp. 3d 877, 882 (D.S.C. 2017) ("tying arrangement[s]" involving the sale of "one product … only on the condition that a buyer also purchases a different product" are "forbidden"). No true market participant could do what the Program allows without implicating the antitrust laws.[13]

[13] The Government claims (at 6, 24) that the Program is "routin[e]" by analogizing it to other federal programs. But the programs the Government cites differ in important ways. For example, none allows the Government to single out individual drugs for participation or punish manufacturers for noncompliance by imposing enormous taxes on all sales of selected drugs.

II. The Program Effects an Unconstitutional Taking of Janssen's Xarelto® Products.

The IRA inflicts a physical taking by granting Medicare participants a statutory right to "access" Janssen's Xarelto® products over Janssen's objection. *See* Janssen Br. 16–22.[14]

Beyond its erroneous voluntariness arguments, the Government offers little response to Janssen's takings claim. The Government's primary argument is that mandated access to Xarelto® is not a taking because manufacturers are not required "to surrender their drugs." Gov't Br. 25, 27. That defense is contrary to settled takings jurisprudence and the Program's structure.

The critical question on a physical takings claim is whether the Government has deprived the plaintiff of its property rights. Janssen Br. 17 (citing *Cedar Point*, 141 S. Ct. at 2071). Those rights include the rights to control the "possess[ion], use[,] and dispos[ition] of" one's property, *Horne*, 576 U.S. at 360, and "to exclude others" from accessing the property, *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979). When the Government appropriates these rights for its own benefit or the benefit of others, a "simple, *per se* rule" applies: "The government must pay for what it takes." *Cedar Point*, 141 S. Ct. at 2071.

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[14] Janssen's claim concerns *physical doses* of Xarelto®—i.e., the pills themselves. *See, e.g.*, Janssen Compl. ¶¶ 90, 93; Janssen Br. 15. As a result, the Government's argument (at 26–27) that Janssen does not have a right to "sel[l] [its] drugs to Medicare at any particular price" is irrelevant to the takings analysis.

Here, the Program appropriates Janssen's rights to control the disposition of its Xarelto® products and to set the terms on which third parties can access those products. The IRA requires that Janssen "shall … provid[e]" third parties in Medicare "access to the maximum fair price … with respect to" Xarelto®. 42 U.S.C. § 1320f-2(a)(3). In other words, the IRA obligates Janssen to give third parties access to its drugs on the Government's terms, and thereby "appropriates a right to physically invade [Janssen's] property—to literally 'take access' as the [statute] provides." *Cedar Point*, 141 S. Ct. at 2074. That appropriation of property rights is a *per se* physical taking under *Cedar Point* and *Horne*. *See* Janssen Br. 20.

The Government next protests that "CMS will not send trucks to Janssen's … facility … to haul away drugs" as the Government did in *Horne*, Gov't Br. 28 (cleaned up), but that argument misses the key constitutional point. What mattered in *Horne* is that the Government's action, regardless of its form, resulted in the raisin growers losing "the rights to possess, use and dispose of" their property. *Id.* at 361–62. As the Supreme Court later explained in *Cedar Point*, an appropriation of property rights "constitutes a *per se* physical taking" regardless of whether the taking involves physical seizure or instead "comes garbed" as a regulation. 141 S. Ct. at 2071. The Government's suggestion that only a fleet of trucks can inflict a physical taking misunderstands the inquiry, which focuses on the

challenged law's *effects* on property rights, not *how* the law causes those effects. *See id.* (collecting cases involving physical takings through various mechanisms).

The Government again exalts form over substance in arguing (at 29) that the IRA's access provision mandates only access to *price* rather than access to *product*. The access provision, no matter how artfully worded, will result in third parties taking possession of Xarelto® products—again, the pills themselves—on terms set by the Program. The Government does not (and cannot) dispute this reality. It makes no sense for a beneficiary to have "access" to a price without the associated product. Reading the IRA as the Government suggests would defeat the Program's core purpose of providing access to *drugs* at lower prices. The Government's own brief acknowledges as much by stating (repeatedly) that under the Program, Janssen will "provide Medicare beneficiaries access *to the drug* at the negotiated price," and that the Manufacturer Agreement is "the source of the enforceable obligation for manufacturers to ultimately provide their *drugs* at the negotiated prices." Gov't Br. at 6, 37 (emphases added); *see also id.* at 32.

The Government's final line of defense relies on a flawed analogy to public utilities cases. According to the Government, Janssen is on "somewhat equal footing with public utilities"—a sector in which "the Supreme Court has not treated … rate-setting as *physical* takings." *Id.* at 30 (cleaned up). That body of case law is inapplicable here. As the Government acknowledges, Janssen is "*not* challenging

any particular rate." *Id.* (cleaned up & emphasis added). Rather, Janssen's claim concerns the IRA's statutory right to access physical Xarelto® products, not the "maximum fair price" issued by CMS for those products. Nor can the Government plausibly argue that Janssen is a public utility: Any "evolution of takings jurisprudence" to treat public utilities differently, *id.*, stems from "th[e] *partly public, partly private status* of utility property [which] creates its own set of questions under the Takings Clause," *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989) (emphasis added). Janssen, however, is purely private—and the same is true for the Xarelto® products it markets. *See Horne*, 576 U.S. at 358–60. The Government does not cite a single case in which Janssen or any other drug manufacturer has been classified as a public utility for Takings Clause purposes, and there is no reason for this Court to break new ground on that issue here.

III. The IRA Violates the First Amendment by Compelling Janssen to Endorse the Government's Message That the Program Involves "Negotiations" Regarding "Fair" Prices.

The IRA also violates Janssen's First Amendment right not to be compelled to endorse the Government's favored message. "[T]he principle that each person should decide for himself or herself the ideas and beliefs deserving of expression" is "[a]t the heart of the First Amendment." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994). Accordingly, "[g]overnment action that requires stating 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); *accord Janus v. AFSCME Council 31*, 138 S. Ct. 2448, 2463 (2018). Government efforts to "compel speakers to utter or distribute speech bearing a particular message" are subject to "the most exacting scrutiny," *Turner*, 512 U.S. at 642, and are permissible only in rare circumstances when the government demonstrates that the compelled speech is "a narrowly tailored means of serving a compelling [government] interest," *PG&E*, 475 U.S. at 17, 19 (plurality opinion).

Here, the IRA has compelled Janssen to sign an "agreement" stating that it will "negotiat[e]" with CMS to determine a "maximum fair price" for Xarelto®. Janssen believes that each of these statements is false and does not wish to express support for any of them. In Janssen's view, there is no genuine "agreement" because it has no viable option not to comply with the Program's requirements; there is no "negotiation" because Janssen must accept whatever price CMS sets for Xarelto®; and the price will not be "fair" because it will be set below market levels, based on CMS's unilateral determination.

By signing the Manufacturer Agreement, Janssen has been compelled to endorse the Government's preferred narrative that the IRA provides for negotiated drug prices rather than government-imposed price controls. *See* Janssen Br. 29–33. That narrative gives the Government the best of both worlds: it can effectively impose price controls (which are politically unpopular), while maintaining that it is

merely engaging in price negotiations (which are more palatable). *See id.* 27 n. 21 (citing polling data). The Government has repeated this narrative at every turn. For example, soon after Janssen and other manufacturers signed Program "agreements" drafted entirely by CMS, the President announced that manufacturers "are coming to the negotiating table."[15] Earlier, the President stated that the IRA "give[s] Medicare the power to *negotiate* drug prices," *see* Janssen Br. 27 n.22, and CMS's guidance and legal briefs frequently repeat this message.[16] Even the Government draws conclusions about Janssen's and other manufacturers' subjective intentions from the Manufacturer Agreements they signed—illustrating the communicative value of the speech compelled by the IRA. *See* Gov't Br. 15 ("Neither Janssen nor BMS has *indicated that it wishes* to withdraw from the Negotiation Program or from Medicare; to the contrary, both companies have signed agreements to negotiate." (emphasis added)). The Government is free to advance its preferred narrative, but

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[15] President Biden, X (Oct. 3, 2023, 8:05 AM), https://twitter.com/POTUS/status/1709177956285759844?s=20; The 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://www.whitehouse.gov/briefing-room/statements-releases/2023/10/03/biden-harris-administration-takes-major-step-forward-in-lowering-health-care-costs-announces-manufacturers-participating-in-drug-price-negotiation-program/.

[16] *See, e.g.*, Govt. Br., *Merck & Co. v. Becerra*, No. 23-cv-1615, ECF 24-1, at 12, 15–18 (D.D.C. Sept. 11, 2023); Gov't Br., *Dayton Area Chamber of Commerce v. Becerra*, No. 23-cv-156, ECF 34, at 4–6, 10 (S.D. Ohio Aug. 11, 2023).

cannot constitutionally require Janssen to endorse that message "by word or act." *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943).

The Government's responses to Janssen's First Amendment claim fall short. At the outset, it is important to note that the Government does *not* argue that requiring Janssen to sign a contract reciting that it is engaging in a "negotiation" with CMS to set a "fair price" is narrowly tailored to serve a compelling government interest. Indeed, the Government does not argue that it can survive *any* form of heightened scrutiny. Any such argument would be doomed because the Government has no valid interest, let alone a compelling interest, in conscripting manufacturers to amplify its political message, and the Government could achieve its goal of lowering drug prices through a variety of means that do not infringe manufacturers' First Amendment rights. *See* Janssen Br. 33–35.

Having effectively conceded that it cannot survive First Amendment scrutiny, the Government reprises its argument that the First Amendment is not implicated because the Program is "entirely voluntary." Gov't Br. 31. But the Program is not "voluntary," *see supra* Part I, and, at any rate, the Supreme Court has "rejected the validity of limitations on First Amendment rights as a condition to the receipt of public benefits," *Elrod v. Burns*, 427 U.S. 347, 359 (1976) (plurality opinion); *see also infra* Part IV.

The Government next retreats to an even more radical, untenable argument: Janssen's signing of the Manufacturer Agreement is not "'speech' or 'expression' protected by the First Amendment" at all. Gov't Br. 31. The Supreme Court has recognized that the scope of the "speech" protected by the First Amendment is extremely broad and includes expressive conduct as well as spoken or written language. *See, e.g.*, *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 505 (1969) (wearing armbands to protest Vietnam War is protected by First Amendment); *Texas v. Johnson*, 491 U.S. 397, 406 (1989) (flag burning "sufficiently imbued with elements of communication" to implicate First Amendment (cleaned up)). Government mandates applicable to "the written or spoken word" are subject to even more demanding First Amendment scrutiny. *Johnson*, 491 U.S. at 406.

There can be no real debate that signing the Manufacturer Agreement constitutes "speech" within the First Amendment's broad protective sweep. *See Sorrell*, 564 U.S. at 570 (recognizing that the "creation and dissemination of information are speech within the meaning of the First Amendment"). The Manufacturer Agreement goes further than a run-of-the-mill contract that merely sets forth the terms of a transaction: It repeats and amplifies the Government's message—a controversial *political* message—that the Program involves "negotiation" with manufacturers resulting in a "fair price," rather than top-down government price-setting. Just as "[a]n individual expresses a view on a political

matter when he signs a petition," *John Doe No. 1 v. Reed*, 561 U.S. 186, 194–95 (2010), a manufacturer endorses the Government's political message by signing an "agreement" to "negotiate" a "maximum fair price."

The Government's brief does not cite a single case holding that agreements are not speech protected by the First Amendment.[17] Instead, it falls back to an argument that any speech "implicated by the execution of an ordinary contract 'is plainly incidental to the … regulation of conduct' that is governed by the contract." Gov't Br. 31 (quoting *Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 547, 47, 62 (2006) ("*FAIR*")). But as already explained, the Manufacturer Agreement is not an "ordinary contract" because it goes *beyond* regulating conduct and coopts Janssen to endorse the Government's message that the IRA involves "negotiations" on a "fair price." The validity of that message is an issue of public concern that is not merely incidental to the regulation of conduct, as demonstrated by the title of the "Drug Price Negotiation Program," debate regarding the Program

[17] One of the Government's amici incorrectly asserts that *Ohralik v. Ohio State Bar Association*, 436 U.S. 447 (1978), "provides numerous examples of speech *exempt from* First Amendment scrutiny." Abrams Institute Amicus Br. 10 n.10 (emphasis added). *Ohralik* merely observed that "the State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity," not that the First Amendment is inapplicable to certain forms of speech. *Id*. at 456.

in Congress,[18] and the repeated statements of government officials, including the President, prominently employing the same message. The IRA's requirements are thus quite different from a statute requiring that military recruiters have access to college campuses. *See FAIR*, 547 U.S. at 59. Nor is this case like *Nicopure Labs, LLC v. FDA*, which involved a statutory ban on distribution of free e-cigarette samples—thus effectively prohibiting manufacturers from offering e-cigarettes at "zero dollars." 944 F.3d 267, 292 (D.C. Cir. 2019). Here, unlike in *Nicopure*, the IRA's requirements do not bear "only on product price," *id.*, but instead convey that the process leading to the price is a "negotiation" that will achieve a "fair" result.

After manufacturers raised First Amendment claims in litigation, CMS responded by adding a "disclaimer" to the Manufacturer Agreement. The disclaimer does not cure the First Amendment violation. For one thing, the compelled speech arises from the IRA itself, rather than from CMS's implementation of the statute. The IRA bases the Program entirely on "agree[ments]" to "negotiat[e]" "maximum fair price[s]." 42 U.S.C. § 1320f-2(a). Moreover, the Government cannot insulate speech mandates from First Amendment scrutiny merely by including a disclaimer

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[18] *See, e.g.*, 168 Cong. Rec. S4155–56 (Aug. 6, 2022) (remarks of Sen. Crapo) (advocating against the Program's "system of bureaucratic drug price controls" because it involves "negotiation in name only" and makes manufacturers "an offer [they] can't refuse"); 168 Cong. Rec. S4500 (Sept. 8, 2022) (remarks of Sen. Thune) (advocating against IRA because the Program's "price controls … will discourage medical innovation and reduce the number of new treatments and cures").

(which is, in effect, additional compelled speech) stating that the speaker might not agree with the message it is being compelled to convey. As the Third Circuit explained in another case involving a disclaimer, "the fact that the schools can issue a general disclaimer along with the [required] recitation does not erase the First Amendment infringement at issue here, for the schools are still compelled to speak the Commonwealth's message. Otherwise, the state 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." *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004).

For similar reasons, the Government's argument (at 35) that Janssen is free to engage in additional speech expressing its views on the Program does not resolve the First Amendment problem. 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 government message, simply by leaving compelled speakers free to engage in additional speech expressing their true opinions. The Government's argument that Janssen is free to engage in additional speech simply "begs the core question." *Miami Herald*, 418 U.S. at 256.

Contrary to the Government's suggestion (at 34), recognizing the validity of Janssen's First Amendment claim will not open the floodgates to a stream of First

Amendment challenges to government contracts. The IRA's statutory scheme is highly unusual, and therefore a ruling in Janssen's favor will not cast all government contracts or price regulation schemes into doubt. What makes the Program unique is the Government's use of coerced agreements and faux negotiations to avoid the political costs of adopting a price-setting regime.[19] The other agreements that the Government cites (at 32) lack the Program's artificial negotiation overlay. *Compare* 42 U.S.C. §§ 1395cc, 1396r-8(b), (c) (governing typical Medicare provider agreements and Medicaid rebate agreements, which do not require counterparties to "agree" that the price CMS pays is "fair" or the result of "negotiations").

Because violations of the First Amendment "constitut[e] irreparable injury," injunctive relief is warranted here. *Elrod*, 427 U.S. at 373. Courts routinely award injunctive relief in compelled speech cases, *see* Janssen Br. 35–36 (collecting cases), and the Government does not challenge that well-settled principle. Instead, it suggests that "[a]dditional briefing might be required to address the appropriate scope of remedy" if the Court agrees that IRA unconstitutionally compels speech. Gov't Br. 38. The Court should reject that procedural gambit: The Government had

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[19] Other laws charge federal agencies with setting prices, without relying on agreements or negotiations between regulator and regulatee. *Compare* 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 (granting Surface Transportation Board the power to "prescribe the maximum rate" a rail carrier may charge "after a full hearing").

an obligation to raise whatever arguments it wished to make in its opening brief, and thus has forfeited any arguments on the scope of injunctive relief. *See, e.g.*, *United States v. Boggi*, 74 F.3d 470, 478 (3d Cir. 1996) (declining to consider arguments raised for the first time in a reply brief).

IV. Even if the Program Were Voluntary, It Would Violate the Unconstitutional Conditions Doctrine.

The Government hinges its defense on the notion that a manufacturer's entry into the Program and underlying participation in Medicare are voluntary. *See* Gov't Br. 11–25; *supra* Part I. But even if the Program were voluntary (it is not), application of its coercive provisions to Janssen would still be unconstitutional.

The "unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them." *Koontz*, 570 U.S. at 606; *see also* Janssen Br. 36–39 (citing cases). In other words, the doctrine forbids the IRA from requiring Janssen to give up its First and Fifth Amendment rights "in exchange for a discretionary benefit conferred by the government." *Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994).

The Government errs in suggesting (at 36, 38) that the unconstitutional conditions doctrine does not apply because participation in Medicare is voluntary. The fact that Janssen lacks a right to participate in Medicare and Medicaid, and (on the Government's misguided view) may "choose to withdraw from Medicare," Gov't Br. 36 & n.11, is "immaterial" to a claim under the unconstitutional conditions

doctrine, *Perry v. Sindermann*, 408 U.S. 593, 598 (1972). Instead, the doctrine applies where, as here, the Government conditions access to a valuable benefit on surrender of a participant's constitutional rights, even when the participant voluntarily seeks the benefit in the first place. *See id.*; *Dolan*, 512 U.S. at 385.

By the Government's own reasoning, the Program forces Janssen to "choose between," *id*. at 385–86, remaining in the critical Medicare and Medicaid markets and the exercise of Janssen's constitutionally protected property and speech rights.[20] The unconstitutional conditions doctrine recognizes that, even if the Program is considered to be voluntary as a legal matter, the practical reality is that Janssen has "no choice, except a choice between the rock and the whirlpool—an option to forego a privilege which may be vital to [its] livelihood or submit to a requirement which may constitute an intolerable burden." *Frost v. R.R. Comm'n*, 271 U.S. 583, 593 (1926) (finding state law unconstitutional where it conditioned permit for private carrier to operate on public highways on acceptance of common carrier obligations). The Program is unconstitutional because the government "may not impose

[20] *See, e.g.*, Gov't Br. 2 ("Plaintiffs may be dissatisfied with the *conditions* this program imposes on future Medicare spending[.]"), 6 ("These *conditions* parallel those Congress has long attached to other government healthcare programs."), 13 ("If a provider dislikes the *conditions* offered by the government, it can simply withdraw from the program.") (all emphases added).

conditions" on a valuable privilege "which require the relinquishment of constitutional rights." *Id.* at 593–94.

The Government's remaining arguments fare no better. With respect to Janssen's First Amendment right to refrain from endorsing messages it opposes, the Government argues that the Program's speech mandates merely "pertain to the nature of the government program" and therefore permissibly "define" the Program. Gov't Br. 37, 38 (quoting *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 217 (2013) ("*USAID*")). The Supreme Court's decision in *USAID* does not support the Government's position. Although the Court noted that the line between conditions that properly "define the federal program" and conditions that improperly "reach outside it … is not always self-evident," the Court was "confident" that when the Government "compel[s]" the recipient of a benefit to "adopt … 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, 218 (emphasis added).

Here, because the Program does not involve actual "negotiation" or a bona fide "agreement," coercing Janssen to endorse those messages "must be doing something more." *Id.* at 218. The Program uses CMS's control of the prescription drug market to "leverage" an endorsement of its political narrative "outside the contours of the program itself." *Id.* at 214–15. The Program thus "falls on the

unconstitutional side of the line." *Id.* at 217; *see also id*. at 215 ("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." (cleaned up)).

With respect to the Fifth Amendment, the Government cannot justify the taking of Janssen's Xarelto® products as a condition on Janssen's participation (for all of its products) in Medicare and Medicaid. That requirement violates the unconstitutional conditions doctrine because it is not proportional to the benefit sought. *See Koontz*, 570 U.S. at 605–06 (setting out this test); Janssen Br. 38 (applying the test here). Although the Government contends (at 37) that the proportionality principle is limited to the land-use context, that argument proves too much. While cases articulating the proportionality test involved "misuse of the power of land-use regulation," *Koontz*, 570 U.S. at 599, that does not mean the test is inapplicable to other types of governmental action. Indeed, the land-use cases relied on precedent across the range of enumerated constitutional rights, *see Dolan*, 512 U.S. at 385 (citing cases), and cases outside the land-use context have applied similar proportionality principles, *see, e.g.*, *Mem'l Hospital v. Maricopa County*, 415 U.S. 250, 258–59 & n.13 (1974).

Regardless, even if the proportionality test did not apply here, it is clear that the unconstitutional conditions doctrine *does* apply. *See, e.g.*, *Koontz*, 570 U.S. at 604 (explaining that the unconstitutional conditions doctrine "reflect[s] an

overarching principle … that vindicates the Constitution's enumerated rights"); *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434 (6th Cir. 2005) (unconstitutional conditions doctrine applies broadly across "constitutional provisions, including the Takings Clause"). Thus, at a minimum, the Program is unlawful if the condition it imposes—requiring Janssen to grant Medicare participants "access" to Xarelto® products—would violate the Fifth Amendment if required outright. *See, e.g.*, *Maricopa County*, 415 U.S. at 258 (applying same test to condition burdening constitutional right as law infringing that right directly); *R.S.W.W.*, 397 F.3d at 436 (same).[21] The Program fails that test, *see supra* Part II, and thus violates the unconstitutional conditions doctrine even if it is voluntary.

CONCLUSION

For the foregoing reasons, and those set forth in Janssen's Opening Brief, the Court should grant summary judgment in favor of Janssen.

Respectfully submitted,

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[21] *Horne* suggests an even more stringent test: When the Government requires the "relinquish[ment of] specific, identifiable property as a 'condition'" on market participation, it effects a "per se taking." 576 U.S. at 364–65.

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November 24, 2023