No. 25-749

IN THE

Supreme Court of the United States

JANSSEN PHARMACEUTICALS INC.,

Petitioner,

v.

ROBERT F. KENNEDY, JR., ET AL.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

REPLY BRIEF FOR PETITIONER

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CORPORATE DISCLOSURE STATEMENT

The corporate disclosure statement accompanying the petition for a writ of certiorari remains accurate.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTRODUCTION

The Government and the decision below rely on the same dangerous fiction in defending the Program: that Congress can require participants in federal programs to give up their constitutional rights under threat of massive penalties, so long as it offers an illusory opt-out mechanism. Such programs, the Government asserts, are "voluntary" and therefore immune from constitutional scrutiny. That rationale is wrong twice over. *First*, this Court has repeatedly held that economically coerced compliance is not voluntary. *Second*, the unconstitutional conditions doctrine applies even when government programs are optional. The Third Circuit disregarded these principles, placing the Program—and vast swaths of federal spending activity—in a Constitution-free zone.

As Judge Hardiman explained in dissent, the decision below also conflicts with First and Fifth Amendment precedents. The Government never offers a persuasive response. It characterizes the Program as merely setting Medicare prices for selected drugs. But the Program goes further by compelling manufacturers to make normative statements about those prices—something this Court and two circuits have held violates the First Amendment. Similarly, the Government insists that the Program cannot violate the Takings Clause because Janssen can sell Xarelto® in other markets, despite the Court's rejection of that defense in *Horne v. USDA*, 576 U.S. 350 (2015).

The Government acknowledges the high stakes here and concedes that the Program imposes substantial economic burdens. Because the questions

presented are "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large," App.85a (Hardiman, J., dissenting), this Court should grant review.

ARGUMENT

I. The Decision Below Conflicts with Decisions of This Court and Other Courts of Appeals.

A. The Compelled-Speech Question Warrants Review.

According to the Government, the Program complies with the First Amendment because it merely "memorializes" "the maximum amount that Medicare will pay for" selected drugs. Opp.20-22. That nothing-to-see-here defense papers over the Program's most problematic elements. It also disregards clear conflicts between the decision below and precedent from this Court and two other circuits. Review is warranted to resolve those conflicts and address the Program's manipulation of the marketplace of ideas.

1. Congress has enacted countless laws that regulate prices and expenditure of public funds. The Program differs from those laws in a critical respect: It requires manufacturers, on pain of "enterprise-crippling" penalties, App.46a (Hardiman, J., dissenting), to participate in a performative "negotiation" and "agree" that the resulting price is the "maximum fair price" for their patented medications. 42 U.S.C. § 1320f-2(a). No other pricing law forces regulated parties to weigh in on disputed matters of public concern in that way, and Congress could have limited Medicare spending without compelling these statements. Pet.16-17. The

Program thus departs from typical pricing laws by "gratuitously" "forc[ing]" manufacturers to amplify the Government's preferred narrative "in Orwellian fashion." App.79a, 82a (Hardiman, J., dissenting).

The Government insists that there is no First Amendment violation because the Program does not "compe[l] [Janssen's] speech" through a formal legal mandate. Opp.20-21. But that sort of mandate is not necessary for a First Amendment claim; laws remain subject to constitutional review when they coerce compliance through economic pressure. *See infra* section I.C. "[I]ndirect 'discouragements' undoubtedly have the same coercive effect upon the exercise of First Amendment rights as … fines, injunctions[,] or taxes." *Am. Commc'ns Ass'n, C.I.O., v. Douds*, 339 U.S. 382, 402 (1950). And unconstitutional conditions on federal programs violate the First Amendment even when participation is voluntary. *See U.S. Agency for International Development v. Alliance for Open Society International, Inc.*, 570 U.S. 205, 214 (2013) ("*USAID*").

2. Precedent also forecloses the Government's argument that the Program is a "typical price regulation" that governs "non-expressive, commercial conduct" and has only "incidental" effects on speech. Opp.21-22. A law "cannot avoid searching First Amendment review just because it mostly regulates non-expressive conduct." *Chiles v. Salazar*, No. 24-539, slip op. 9 (U.S. Mar. 31, 2026). Instead, the question is whether the law "goes a step further" by regulating speech. *Id.* at 13.

This Program does. The challenged provisions "d[o] much more" than set a price. App.75a

(Hardiman, J., dissenting). They require Janssen to describe that price as the product of "negotiation" and the "maximum fair price" for Xarelto®. The Program is thus "not exempt … from demanding First Amendment review." *Chiles*, *supra*, at 16.

Expressions Hair Design v. Schneiderman, 581 U.S. 37 (2017), reinforces that conclusion. *Expressions* distinguished laws that *set* prices (which raise no First Amendment concern) from laws that dictate what must be said *about* prices (which do). *Id.* at 47-48. The Program falls into the latter category: manufacturers must make normative statements about the nature of the price-setting process and endorse the fairness of the resulting prices. These statements are not "integral to the functioning of" Medicare or necessary to "determin[e] the amount charged" for Xarelto®. Opp.22, 29 (citation omitted). Instead, they were designed (and have been used) to "g[o] a step further," *Chiles*, *supra*, at 13, by buttressing the Government's contested narrative about drug pricing, Pet.16 (collecting examples).

The Government's attempt to justify the term "fair" by analogy to other contracting schemes fails as well. Opp.24-25. None of its examples involved laws that compelled regulated parties to make normatively charged statements. For example, *United States v. General Dynamics Corp.*, 19 F.3d 770 (2d Cir. 1994), addressed a law that required shipbuilders to submit cost data to the Secretary of Transportation, who then "determined" whether their prices were "fair and reasonable." 46 U.S.C. app. § 1152(a) (2000). Shipbuilders were not required to utter that phrase, and the case did not involve a First Amendment claim. Federal agencies may determine *for themselves*

whether a price is "fair" before spending public funds, but the First Amendment prohibits them from requiring counterparties to "misrepresen[t]" that evaluative judgment as their own. App.81a (Hardiman, J., dissenting).

3. Like the Third Circuit, the Government argues that counterspeech cures the Program's infirmities. Opp.23-24. That position runs headlong into cases like *Pacific Gas & Electric Co. v. California Public Utilities Commission*, 475 U.S. 1, 16 (1986), which establish that counterspeech cannot cure the First Amendment harm caused by compelled statements. Pet.17-18; *see Chiles*, *supra*, at 13-14 (allowing regulated parties "to say other things" or "criticiz[e] [the relevant] law" is no defense (citation omitted)).

The Government retorts that, under *Pacific Gas*, the Manufacturer Agreement's disclaimer defeats compelled-speech claims by "avoid[ing] … the mistaken impression" that manufacturers are expressing the Government's views. Opp.24. Not so. The disclaimer in *Pacific Gas* prevented mistaken impressions only because a third party was involved, *see* 475 U.S. at 6-7; here Janssen signed the Agreement on its own behalf. Moreover, *Pacific Gas* concluded that disclaimers "d[o] *not* suffice to eliminate" harms caused by compelled speech, 475 U.S. at 15 n.11 (emphasis added), which the Government concedes, Opp.24. Were the law otherwise, foundational First Amendment cases would have come out the other way. Pet.19-20.

The decision below disregarded *USAID*, and the Government repeats that error. It asserts that there is no First Amendment violation because Janssen can

"exercise [its] rights outside of the" Program. Opp.29. But as Janssen explained, Pet.18-19, *USAID* held that compelling a funding recipient to "adopt—as [its] own—the Government's views on an issue of public concern" "by its very nature … goes beyond defining the limits of the federally funded program" and "falls on the unconstitutional side of the line," 570 U.S. at 217-18. The Government offers no response.

4. Nor does the Government refute the circuit split regarding the role of statutory definitions in compelled-speech cases. The Third Circuit applied *Meese v. Keene*, 481 U.S. 465 (1987), to hold that statutory definitions cause the Program's value-laden terms to "los[e] the[ir] expressive weight," App.37a; Pet.20-23. Yet the D.C. Circuit refused to extend *Meese* in that way because it "was not a compelled speech case," and warned that the Government otherwise could "skew public debate," *National Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 529-30 (D.C. Cir. 2015) ("*NAM*"). The Seventh Circuit reached a similar conclusion in *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641, 653 (7th Cir. 2006).

The Government denies any split, claiming that the Third Circuit merely invoked *Meese* for the principle that statutory definitions control when incorporated in a contract. Opp.31. That only confirms the split with *NAM*, which held that statutory definitions do *not* control over the ordinary meaning of expressive terms in the compelled-speech context. The Government's argument also fails on its own terms: *Meese* did not involve contracts, *see* 481 U.S. at 469-72, and the Third Circuit relied on *Meese* to disregard the "normative" implications of the phrase "maximum fair price," App.37a. The

Government embraces the same faulty logic, arguing that "maximum fair price" is not expressive because it is statutorily "defined." Opp.23.

B. The Takings Question Warrants Review.

The Program also takes property without just compensation. It appropriates Janssen's "right to decline to sell" its patented Xarelto® products by giving Medicare beneficiaries a right to access and take possession of those products on CMS's terms. App.53a (Hardiman, J., dissenting). This compelled transfer "from A … to B" is just as much a taking, *Kelo v. City of New London*, 545 U.S. 469, 478 n.5 (2005) (citation omitted), as "sending trucks" to "haul away" Janssen's products, Opp.16.

Like the Third Circuit, the Government's chief rejoinder is that manufacturers' "option" to withdraw from Medicare and Medicaid negates any taking. Opp.18. That ignores precedents holding that participation is not voluntary where, as here, coercion renders the purported opt-out illusory. *See infra* section I.C. Moreover, *Horne* held that a property owner's theoretical ability to exit the regulated market does not defeat a Takings Clause claim. Pet.24-25.

The Third Circuit's takings analysis also narrowed the unconstitutional conditions doctrine into nonexistence, Pet.25-28, and the Government offers no meaningful defense. Even if the nexus-and-proportionality test—a "specific application" of the unconstitutional conditions doctrine—were inapplicable, Opp.29-30, the Program would not be exempt from the underlying doctrine, which protects

all "enumerated rights." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013).

The unconstitutional conditions doctrine prohibits governments from "coercively withholding benefits" "worth *far more* than [the] property [they] would like to take." *Id.* at 605-06 (emphasis added). The Program does just that by ransoming reimbursements for *all* of Janssen's drugs to exact a single drug without paying just compensation.

C. The Government's Voluntariness Argument Confirms the Need for Review.

The Program is exempt from constitutional scrutiny, the Government claims, because manufacturers can withdraw from Medicare and Medicaid. Opp.17, 21. That premise is false. As Judge Hardiman reasoned, the Program makes it impossible for manufacturers to withdraw in time to avoid massive penalties. App.54a-69a.

Even if withdrawal were formally available, it would be economically ruinous because Medicare and Medicaid together account for nearly half of the nation's prescription drug market. The Program thus makes manufacturers "an offer they can't refuse." App.69a (Hardiman, J., dissenting) (cleaned up).

The fact that participation in a program is voluntary *in theory* does not confer talismanic immunity from constitutional limits. What matters is whether the program is voluntary *in fact*—i.e., whether purported opt-out mechanisms are illusory. Under *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) ("*NFIB*"), *United States v. Butler*, 297 U.S. 1 (1936), and similar cases, spending programs are subject to constitutional

scrutiny when they employ significant economic pressure to compel participation. That's exactly what the Program does.

The Government seeks to avoid this principle by characterizing *Butler* as a federalism case. Opp.27. But that misreads *Butler*, which held that *private farmers'* participation in a cotton production program was "not in fact voluntary" where noncompliance triggered "the loss of benefits" and potential "financial ruin" to "exert pressure … to agree." 297 U.S. at 70-71. Not once did *Butler* limit its "coercion by economic pressure" principle to state governments. *See id.* Besides, the Government ignores other cases that apply the same framework to private parties. *See Carter v. Carter Coal Co.*, 298 U.S. 238 (1936); *Union Pacific R.R. Co. v. Pub. Serv. Comm'n*, 248 U.S. 67 (1918).

Indeed, the Government concedes that Janssen's claims implicate the "rule that 'Spending Clause legislation operates based on consent,' and that, accordingly, recipients must 'voluntarily and knowingly accept the terms' of the funding contract." Opp.27 (quoting *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022)). *NFIB* applied the same test: the Medicaid expansion was not "voluntarily and knowingly" accepted *because* it involved an economic "gun to the head." 567 U.S. at 577. The Government does not explain why *NFIB*'s consent principle applies to private parties but *not* the

necessary corollary that economic coercion vitiates consent.[1]

The Government relatedly contends that the Program is voluntary because CMS is simply "driving [a] hard … bargain" "[l]ike any other private party seeking to leverage its purchasing power." Opp.16, 25. The analogy is absurd: CMS wields sovereign powers no market participant could possess, including authority to impose punitive excise taxes and exclude manufacturers from federal healthcare markets. Pet.25.

Moreover, an ordinary market participant would face serious antitrust scrutiny if it tied the continued purchase of an entire portfolio of products to concessions on a single drug. *See U.S. Steel Corp. v. Fortner Enters., Inc.*, 429 U.S. 610, 620 (1977). In short, CMS is not "simply [expressing] what Medicare will offer to pay for certain drugs," Opp.16; it employs regulatory powers to "threat[en]" manufacturers with taxes and other penalties that "loo[m] like a sword of Damocles, creating a de facto mandate to participate." App.53a (Hardiman, J., dissenting).[2]

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[1] Concluding that a program is involuntary negates a voluntariness defense, but does not mean that the program is unconstitutional. Challengers must still show that the program infringes their rights. Thus, rejecting the voluntariness defense here will not (contra Opp.17, 33) give contractors "a constitutional right to dictate the government's expenditures."

[2] The fact that CMS accepted counteroffers from other manufacturers (Opp.11)—not Janssen—is irrelevant. Just as consent is invalid when obtained under duress, *see* Pacific Research Institute Amicus Br.19, agreement procured under threat of severe penalties does not show that the process was a "real negotiatio[n]." Opp.26.

The Program also differs fundamentally from other federal drug procurement programs cited by the Government. Opp.18. Among other things, those programs rely on average prices in market transactions, giving manufacturers a degree of predictability and control over drug prices. For instance, under Medicaid, prices flow from a statutory formula tied to a drug's "average sales price" in the broader market. 42 U.S.C. § 1396r-8(b)(3)(A)(iii)(I). Additionally, although other statutes allow agencies to negotiate prices, those statutes do not penalize manufacturers who refuse to sell below the statutory, market-based rate. *See, e.g.*, 38 U.S.C. § 8126.

II. The Questions Presented Are Exceptionally Important.

Contrary to the Government's characterization, the Program structurally overhauls Medicare drug reimbursement, making it the most consequential change to the Nation's healthcare laws since the Affordable Care Act.

The Government seeks to downplay the Program's importance by framing it as "govern[ing] only the prices that Medicare pays" for selected drugs. Opp.6. But that ignores the statute's design. Because Medicare and Medicaid together account for nearly half of prescription-drug spending, rejecting CMS's terms would eliminate coverage not merely for Xarelto®, but for all 21 of Janssen's medicines. Pet.10.

The Program also has spillover effects on private-market negotiations.[3]

Further, the Program will expand rapidly. CMS selected 15 new drugs for 2027 and 2028, and will select 20 additional drugs each year thereafter. Pet.6. Thus, the Program will soon cover many clinically and commercially significant drugs. The Government does not dispute that this scheme undermines incentives to develop new treatments and indications, weakening Americans' access to novel medicines.

The Third Circuit's decision will also reach far beyond the pharmaceutical sector. Under its reasoning, the Government can insulate vast categories of spending programs from constitutional limits. Pet.36-38. Janssen's argument is narrower: When a program secures compliance through economic coercion, constitutional scrutiny applies as with any other law.

III. This Case Is an Excellent Vehicle.

The Government does not dispute that this case squarely presents outcome-determinative legal issues. Nor does it identify procedural or jurisdictional obstacles to this Court's review.[4]

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[3] *See* Pet.16 (reliance on Program's compelled statements by Colorado regulator); Minn. Stat. § 62J.92 (2025) (prescribing an "upper payment limit" for selected drugs "at the Medicare maximum fair price"); H.B. 483, 2026 Gen. Assemb., 164th Sess. (Va. 2026) (capping drug prices for all Virginia payers—public and private—at Program's "maximum fair prices").

[4] CMS will remove Xarelto® from the Program effective January 1, 2027, due to generic competition. *See* L. Strawbridge, CMS, *Removal of Entresto, Stelara, and Xarelto from the Selected Drug* (cont.)

There is no reason for delay. *Contra* Opp.34. It makes sense to consider this case alongside the other pending petitions that challenge the Program. But there is no reason for further percolation merely because additional challenges are pending in the lower courts.[5] Those cases do not involve Takings Clause or First Amendment claims.[6] Delay would also come at a serious cost, given the Program's sharp reduction of incentives to develop innovative treatments. Where the cost of waiting for additional percolation is substantial and the benefit marginal at best, delay "should count[] for little." Henry J. Friendly, *The "Law of the Circuit" and All That*, 46 St. John's L. Rev. 406, 407 (1972) (cleaned up).

List Effective January 1, 2027 (Nov. 25, 2025), https://perma.cc/97GE-RTU9. That step will not remedy Janssen's claims for injuries suffered before 2027. Janssen's forced endorsement of a "maximum fair price" will also continue to cast a shadow over price negotiations for Xarelto® in the private sector and in other government programs, allowing the company to advocate for higher prices "only at the price of evident hypocrisy." *USAID*, 570 U.S. at 219.

[5] *See National Infusion Ctr. Ass'n v. Kennedy*, No. 25-50661 (5th Cir.) ("*NICA*") (argued Oct. 7, 2025); *Teva Pharm., USA, Inc. v. Kennedy*, No. 25-5425 (D.C. Cir.) (argument scheduled May 5, 2026).

[6] *NICA* involves separation-of-powers, excessive fines, and due process claims. *Teva* involves a due process claim and challenges to CMS guidance documents.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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April 8, 2026