No. _____

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

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The "Medicare Drug Price Negotiation Program," enacted in 2022, imposes new requirements for certain widely prescribed drugs. Under the Program, manufacturers must provide Medicare beneficiaries "access" to covered drugs at below-market prices set by the Centers for Medicare and Medicaid Services ("CMS") and sign "agreement[s]" describing those prices as "negotiate[d]" "maximum fair price[s]" for their drugs. 42 U.S.C. § 1320f-2(a). Manufacturers that do not comply with these requirements are subject to tens of billions in annual excise taxes or exclusion from Medicare and Medicaid, which together account for nearly half the U.S. drug market.

Petitioner Janssen Pharmaceuticals Inc. markets Xarelto®, a drug selected by CMS for the Program. Janssen alleged that the Program unlawfully compels the company's speech and effects a *per se* taking of the company's property. The Third Circuit rejected those claims, holding that the Program is lawful because participation is "voluntary." Judge Hardiman dissented, concluding that the Program's "enterprise-crippling" penalties unconstitutionally "force" Janssen "to turn over" its products on terms "set by CMS" and "misrepresent" that it "negotiated" a "fair" price for Xarelto®. The questions presented are:

1. Does the Program violate the First Amendment by compelling Janssen to express the Government's disputed messages regarding drug pricing?

2. Does the Program effect a Fifth Amendment taking by forcing Janssen to transfer its Xarelto®

products to third parties on the Government's terms?

3. Is the Program immune from constitutional scrutiny because it secures compliance through economic coercion?

PARTIES TO THE PROCEEDINGS

Petitioner (Plaintiff-Appellant below) is Janssen Pharmaceuticals Inc.

Respondents (Defendants-Appellees below) are Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; the United States Department of Health and Human Services ("HHS"); Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the Centers for Medicare and Medicaid Services.

CORPORATE DISCLOSURE STATEMENT

Janssen Pharmaceuticals Inc. is a wholly owned subsidiary of Johnson & Johnson (NYSE: JNJ). No other publicly held corporation owns 10% or more of Janssen's or Johnson & Johnson's stock.

RELATED PROCEEDINGS

The following proceedings are directly related to this petition under Rule 14.1(b)(iii):

Janssen Pharms. Inc. v. Sec'y of HHS, No. 24-1821 (3d Cir.) (judgment entered Sept. 4, 2025);

Janssen Pharms. Inc. v. Becerra, No. 3:23-cv-3818 (D.N.J.) (judgment entered Apr. 29, 2024);

Bristol Myers Squibb Co. v. Sec'y of HHS, No. 24-1820 (3d Cir.) (judgment entered Sept. 4, 2025);

Bristol Myers Squibb Co. v. Becerra, No. 3:23-cv-3335 (D.N.J.) (judgment entered Apr. 29, 2024).

The Third Circuit and District of New Jersey consolidated the *Janssen* and *Bristol Myers Squibb* cases for purposes of argument and decision, and thus issued a single opinion and judgment at each court level to resolve both cases.

Although not directly related under Rule 14.1(b)(iii), the following cases present related issues:

AstraZeneca Pharms. LP v. Kennedy, No. 25-348 (U.S.) (cert. petition filed Sept. 19, 2025);

Novartis Pharms. Corp. v. Becerra, No. 3:23-cv-14221 (D.N.J.) (judgment entered Oct. 18, 2024), *aff'd sub nom. Novartis Pharms. Corp. v. Sec'y of HHS*, No. 24-2968 (3d Cir.) (judgment entered Sept. 11, 2025);

Novo Nordisk Inc. v. Becerra, No. 3:23-cv-20814 (D.N.J.) (judgment entered July 31, 2024), *aff'd sub nom.*, *Novo Nordisk Inc. v. Sec'y of HHS*, No. 24-2510 (3d Cir.) (judgment entered Oct. 6, 2025);

Boehringer Ingelheim Pharms., Inc. v. HHS, No. 3:23-cv-1103 (D. Conn.) (judgment entered July 3, 2024), *aff'd*, No. 24-2092 (2d Cir.) (judgment entered Aug. 7, 2025); and

National Infusion Ctr. Ass'n v. Kennedy, No. 1:23-cv-707 (W.D. Tex.) (judgment entered Aug. 7, 2025, *appealed*, No. 25-50661 (5th Cir.) (oral argument held Oct. 7, 2025).

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INTRODUCTION

When Congress created the "Medicare Drug Price Negotiation Program" in 2022, it described the Program as a tool to reduce drug prices through voluntary negotiations with pharmaceutical manufacturers. Despite that framing, the Program is anything but voluntary. In true negotiations, parties can walk away from the bargaining table without reaching agreement. Yet as Judge Hardiman observed in dissent, the Program makes manufacturers "an offer [they can't] refuse" "by threatening them with unavoidable, enterprise-crippling tax liabilities" if they do not "agree" to turn over their drugs at below-market prices. App.69a, 46a. No voluntary program operates in that way.

Indeed, the Program compels manufacturers to participate in a performative negotiation process with a pre-determined result. The manufacturer "shall" sign an "agreemen[t]" to provide Medicare beneficiaries "access" to its medication at a "maximum fair price" set by the Centers for Medicare and Medicaid Services. 42 U.S.C. § 1320f-2(a)(1). Failure to participate in the sham negotiation subjects noncompliant manufacturers to a 1900% excise tax "that no manufacturer would ever be able to pay," App.50a (Hardiman, J., dissenting), or exclusion of *all* the manufacturer's drugs from Medicare and Medicaid, which together account for nearly half the U.S. market for prescription medications. In Janssen's case, the excise tax would have exceeded $90 billion in the first year alone, and either of the penalties would have eviscerated the company's ability to continue developing innovative medications.

These threatened penalties—which no mere market participant could impose—not only allow the Government to substitute market-based pricing with its own dictated rates. They also create a Program that crosses multiple constitutional lines.

To start, the Program violates the First Amendment by compelling Janssen to adopt the Government's narrative that the Program involves a "negotiat[ed]" "maximum fair price" for its selected drug. Janssen strongly disagrees with those statements, which involve "a subject of great political significance," App.79a (Hardiman, J., dissenting), and stifle the company's ability to advocate for the prices necessary to support development of innovative new treatments. But the Program nevertheless required Janssen to state in writing that it "agree[s]" with those statements, or else incur the devastating noncompliance penalties described above.

The Third Circuit majority upheld this extortionate scheme because manufacturers can criticize the Program *after* making the required statements, and because the Inflation Reduction Act ("IRA") defines "maximum fair price" in a non-expressive manner. Those rationales conflict with this Court's precedents and decisions from other courts of appeals, which reject the view that Congress may "require speakers to affirm in one breath that which they deny in the next," *Pac. Gas & Electric Co. v. Cal. Public Utilities Commission*, 475 U.S. 1, 16 (1986) (plurality opinion), and compel regulated parties to use normatively charged terms as long as it defines them in ways that obscure their ordinary meaning.

The Program also effects a *per se* taking of property by forcing Janssen to transfer its drugs to Medicare participants on terms dictated by CMS. The Third Circuit rejected that claim because manufacturers can continue to sell their drugs in the private market. But as Judge Hardiman recognized, *Horne v. Department of Agriculture*, 576 U.S. 350 (2015), "forecloses that argument." App.54a (dissenting opinion). The Third Circuit compounded that error by "declin[ing]" to consider whether the Program's access requirement unconstitutionally requires Janssen to hand over its Xarelto® products in order for the rest of its drug portfolio to be eligible for Medicare and Medicaid reimbursement. Although the Third Circuit concluded that the unconstitutional conditions doctrine applies only to takings claims that arise in the land-use context, this Court has never limited the doctrine in that way. On the contrary, the unconstitutional conditions doctrine is "an overarching principle" that protects all "enumerated rights." *Koontz v. St. Johns River Mgmt. Dist.*, 570 U.S. 595, 604 (2013).

More broadly, the Third Circuit adopted the Government's argument that Congress's Spending Clause powers are "unrestricted" so long as participation in a federal program is not legally mandated. The court concluded that the Program is "voluntary," and thus immune from constitutional scrutiny, because Janssen theoretically could have incurred tens of billions in excise taxes or withdrawn all 21 of its drugs from Medicare and Medicaid. That sweeping rationale defies common sense—and this Court's precedents. The Court has repeatedly held that voluntariness is no defense where, as here,

significant economic coercion renders a statute's purported opt-out provisions illusory. *See, e.g.*, *National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012) ("*NFIB*"); *United States v. Butler*, 297 U.S. 1, 70-71 (1936).

As Judge Hardiman explained, the issues in this case are "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." App.85a. The scale and scope of the Program alone, affecting hundreds of billions of dollars in the U.S. pharmaceutical market and millions of patients, make this case worthy of review. The Program also undermines patent protections that are enshrined in the Constitution and federal statutes by targeting revenues that flow from patented medications. Moreover, the implications of the Third Circuit's ruling sweep well beyond prescription drug markets by insulating federal spending programs from scrutiny. If the Third Circuit's decision stands, it will provide a roadmap for the Government to circumvent the constitutional rights of any business, individual, or organization that participates in federal benefits programs.

This Court should grant review to prevent that unconstitutional overreach.

OPINIONS BELOW

The court of appeals' opinion is reported at 155 F.4th 245 and reproduced at App.1a-86a. The district court's opinion is not reported, but is available at 2024 WL 1855054 and reproduced at App.87a-118a.

JURISDICTION

The court of appeals entered its judgment and opinion on September 4, 2025. App.2a. On November 6, Justice Sotomayor extended the deadline for filing a petition for a writ of certiorari to December 19. *See* No. 25A514. Pursuant to that extension, this petition was timely filed on December 19, 2025. The Court has jurisdiction under 28 U.S.C. § 1254(1).

RELEVANT PROVISIONS

The First Amendment to the U.S. Constitution provides, in relevant part, "Congress shall make no law … abridging the freedom of speech."

The Fifth Amendment to the U.S. Constitution provides, in relevant part, "nor shall private property be taken for public use, without just compensation."

The relevant statutory provisions governing the Program, *see* 42 U.S.C. §§ 1320f–1360f-7; 26 U.S.C. § 5000D, are reproduced at App.119a-78a. The form agreements that the IRA requires manufacturers to sign are reproduced at App.179a-92a.

STATEMENT

A. Statutory and Regulatory Background

Medicare provides health insurance coverage for seniors and individuals with disabilities. App.10a. Together with Medicaid, which principally covers needy families, the two programs "dominat[e] the healthcare market," accounting for "almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).

Medicare is divided into parts, including Part D, which subsidizes the cost of prescription drug coverage. Under Part D, CMS reimburses private insurance plans for their coverage of self-administered prescription drugs. *See* 42 U.S.C. § 1395w-101 *et seq.* When Congress established Part D in 2003, it forbade CMS from "institut[ing] a price structure for the reimbursement of covered Part D drugs" or otherwise "interfer[ing] with the negotiations between drug manufacturers" and Part D plans. *Id.* § 1395w-111(i). Instead, market forces determined pharmaceutical prices. For nearly 20 years, this arrangement helped sustain America's leading role in pharmaceutical innovation and patient access to lifesaving and life-improving medicines.

Congress changed course when it enacted the IRA in 2022. Among other changes, the IRA establishes the Program at issue here. *See* Pub. L. No. 117-169, §§ 11001-04, 136 Stat. 1818, 1833-64 (2022). The Program directs CMS to set "maximum fair price[s]" for drugs that account for the largest share of Medicare spending. 42 U.S.C. §§ 1395w-111(i), 1320f(a)(3).

CMS selects a prescribed number of drugs for the Program each year: 10 in the first year; an additional 15 in each of the second and third years; and another 20 each year thereafter. *Id.* § 1320f-1(a). Selected drugs remain in the Program until CMS removes the drug due to generic or biosimilar competition. *Id.* § 1320f-1(c)(1).

Once CMS selects a drug, the manufacturer has 30 days to begin participating in the Program. *See id.* § 1320f(d)(1)-(2). Manufacturers that fail to comply

are subject to an excise tax on all U.S. sales of the selected drug, starting at 186% of the sale price and escalating to 1900% after nine months. *See* 26 U.S.C. § 5000D(a)-(b). This tax is so severe that the Congressional Budget Office determined that no manufacturer would willingly incur it,[1] and the Joint Committee on Taxation estimated that the tax would generate "no revenue."[2]

A manufacturer can "suspend" the excise tax by terminating its participation in Medicare and Medicaid. 26 U.S.C. § 5000D(c)(1)(A)(i). In other words, to avoid the excise tax, the manufacturer must withdraw *all* its drugs—not just the selected drug—from Medicare and Medicaid. *See id.* Consequently, Medicare and Medicaid "w[ould] not reimburse patients or providers for *any* of the drugs that the manufacturer sells (whether or not those drugs are part of the [Program])." *National Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 495 (5th Cir. 2024) ("*NICA*").

Manufacturers cannot withdraw from Medicare and Medicaid immediately. Instead, there is a statutorily mandated delay between a manufacturer's notice of withdrawal and the effective date for that withdrawal. This delay period is 60 days for Medicaid,

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[1] *See* Cong. Budget Off., *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, at 11 (2023), https://perma.cc/C26R-WS35.

[2] Joint Comm. on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII—Committee on Ways and Means, of H.R. 5376, Fiscal Years 2022–2031*, at 8 (Nov. 19, 2021), https://perma.cc/SMC3-GZMF (calculating effect of similar tax provision in a precursor bill).

42 U.S.C. § 1396r-8(b)(4)(B)(ii), and 11 to 23 months for Medicare, depending on when the manufacturer gives notice, *id.* §§ 1395w-114a(b)(4)(B)(ii), 1394w-114c(b)(4)(B)(ii). Under these provisions, a manufacturer whose drug was selected for the first year of the Program on August 29, 2023, could not have withdrawn from Medicare and Medicaid until January 2025—well after the October 1, 2023 deadline to comply with the Program's initial requirements.[3]

A manufacturer begins participating in the Program by signing a form "agreement" written by CMS ("Agreement"). *Id.* § 1320f-2(a). This document states that the manufacturer "agrees" that the Program involves a "negotiat[ion]" regarding the "maximum fair price for the Selected Drug." App.181a. During the "negotiation" process, CMS makes an initial "offer," the manufacturer may "counteroffer," and CMS must then "respond in writing" with a final "maximum fair price offer." 42 U.S.C. § 1320f-3(b)(2). Manufacturers that do not engage in this "negotiation," or fail to provide the confidential information requested by CMS, are subject to a $1 million daily penalty for each violation. *Id.* §§ 1320f-3(b)(2)(A), 1320f-6(c).

Once CMS makes its final "offer," a manufacturer must sign a second "agreement" that establishes the "maximum fair price" for the selected drug in Medicare ("Addendum"). In the Addendum, the manufacturer represents that it "negotiated" with

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[3] To withdraw by October 1, 2023, a manufacturer would have needed to provide notice by January 29, 2022, months before the IRA was enacted. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii).

CMS and "now agree[s]" that the price set by CMS is the "negotiated maximum fair price" for the selected drug. App.190a. By statute, this "maximum fair price" must be at least 25-60% below a benchmark market-based price for the drug, and CMS must "achieve" the "lowest maximum fair price" possible below that ceiling. 42 U.S.C. § 1320f-3(b)(1), (b)(2)(B), (c). Manufacturers who do not sign the Addendum are subject to the excise tax described above. *See* 26 U.S.C. § 5000D(b)(2).

CMS then publishes the "maximum fair price" for each selected drug. 42 U.S.C. § 1320f-4(a). Medicare Part D insurance plans must include these drugs on their list of covered treatments, called a "formulary." *Id.* § 1395w-104(b)(3)(I). And each manufacturer of a selected drug must then provide Medicare beneficiaries and their providers "access" to the selected drug at or below the "maximum fair price." *Id.* § 1320f-2(a)(3). For drugs selected in the Program's first year, this "access" requirement takes effect on January 1, 2026. *See id.* §§ 1320f(b)(1), 1320f-1(c)(1), 1320f-2(b). If a manufacturer fails to provide Medicare beneficiaries with access to the drug on the Program's terms, it faces additional penalties, including a fine equal to ten times any amount charged over the "maximum fair price." *Id.* § 1320f-6.

B. Factual Background

Janssen markets Xarelto® (rivoroxaban), a widely prescribed drug used to prevent blood clots and reduce the risk of stroke. In 2022, nearly 3 million U.S. patients filled nearly 11 million Xarelto® prescriptions, most of which were reimbursed under Medicare or Medicaid.

On August 29, 2023, CMS selected Xarelto® for the first year of the Program.[4] Had Janssen refused to participate, it would have faced excise tax penalties starting at $600 million per day and surpassing $90 billion in the first year—more than triple the 2022 total adjusted net earnings of Janssen's parent company, Johnson & Johnson. App.197a-98a. Had Janssen instead withdrawn from Medicare and Medicaid, millions of Americans would have lost coverage for Xarelto® and 20 other Janssen medicines. App.195a, 198a. Janssen also would have lost 65% of its gross sales, crippling its ability to continue developing innovative treatments. App.195a. The statutory withdrawal delays would have also required Janssen to remain in Medicare until at least January 2025—well beyond the deadlines for signing the Agreement and Addendum (October 1, 2023, and August 1, 2024, respectively).

Facing these consequences, Janssen signed the Agreement under protest. And following the "negotiation" process with CMS under threat of additional penalties, Janssen signed the Addendum setting the "maximum fair price" for Xarelto® at a 62% discount from the prior year's list price,[5] an arrangement Janssen would not have entered into but for the Program's noncompliance penalties. Starting January 1, 2026, Medicare beneficiaries will have a

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[4] *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/88D4-3CA2.

[5] CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), https://perma.cc/WHU3-72LN ("*IPAY 2026 Negotiated Prices*").

right to "access" Xarelto® at the price set through the Program. *See* 42 U.S.C. § 1320f(b)(1).

C. Procedural Background

In July 2023, Janssen filed this lawsuit, alleging that the Program compels speech in violation of the First Amendment, effects a *per se* taking of Janssen's Xarelto® products under the Fifth Amendment, and imposes unconstitutional conditions on Medicare and Medicaid participation. *See* App.15a. Several other manufacturers challenged the Program on similar grounds. *See supra* pp. iii-iv.

In response, the Government asserted that the Program is not subject to constitutional scrutiny because participation is voluntary. App.94a-95a, 109a-10a. The Government maintained that Janssen could avoid the Program by paying the excise tax or withdrawing all its drugs from Medicare and Medicaid.

The District Court agreed and granted the Government's motion for summary judgment. App.87a-118a. A divided panel of the Third Circuit (Hardiman, Phipps, Freeman) affirmed. App.1a-86a.

The majority held that "legal compulsion" to participate in a federal program is necessary to support a takings or compelled-speech claim, and that the Program does not involve such compulsion because Janssen can withdraw from Medicare and Medicaid. App.18a-21a, 39a. The court disagreed that the IRA's 11- to 23-month withdrawal delay negates this option because CMS has promised, in guidance, to terminate a manufacturer's agreements within 30 days. App.25a-29a. And while the economic consequences of withdrawing from Medicare and

Medicaid exert "a strong influence on the company's choice," the court concluded that these consequences are irrelevant because they do not amount to legal compulsion. *Id.*

The majority separately held that the Program does not violate the First Amendment because it regulates conduct and has only an incidental effect on speech. App.35a-36a. The court gave two supporting rationales: manufacturers can criticize the Program after signing the Agreement and Addendum, and the challenged terms in those documents (*e.g.*, "maximum fair price") "lose the[ir] expressive weight" because the IRA defines them in a non-expressive way. App.37a.

Last, the majority held that the Program does not impose unconstitutional conditions on Medicare and Medicaid participation. The court determined that the statements required by the Program merely "effectuat[e] the government's policy choices" and do not restrict Janssen's counterspeech outside the Program. App.44a. Although Janssen argued that the Program places an unconstitutional condition on the company's property rights, the court "decline[d]" to "scrutin[ize]" the Program under the unconstitutional conditions doctrine because Janssen's claim does not arise in the land-use context. App.31a-32a.[6]

Judge Hardiman dissented. He disagreed that participation in the Program is voluntary, reasoning that Janssen was "compell[ed]" to "participate in the

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[6] The Third Circuit added in a footnote concluding that if the unconstitutional conditions doctrine did apply, the Program would still "withstand scrutiny." App.31a n.21.

Program" because the "enterprise-crippling tax liabilities" for noncompliance are "unavoidable" and "loo[m] like a sword of Damocles, creating a de facto mandate to participate." App.46a, 53a. He explained that CMS lacks authority to "rewrite the statute" and expedite Medicare and Medicaid withdrawal to ameliorate this compulsion, App.55a-69a, and that once Janssen signed the Agreement and Addendum, the company "could not have declined to participate in the first year of the Program," App.59a.

Judge Hardiman then explained how the Program impermissibly compels speech. The Program forces manufacturers to "sign an Agreement saying [that they] 'agree' to 'negotiate' a 'maximum fair price." App.77a. These forced "attest[ations]" effectively "represen[t] that [Janssen's] participation in the negotiation [is] voluntary" and that the higher prices Janssen has "previously charged" for Xarelto® were "unfair." *Id.* The Program thus requires Janssen "to convey the Government's message about" drug pricing, "a subject of great political significance and debate." App.79a.

Judge Hardiman also concluded that the Program effects a taking. "[B]y forcing [Janssen] to turn over physical doses of … Xarelto to Medicare beneficiaries," the Program appropriates Janssen's right to control the disposition of those products. App.53a-54a. Judge Hardiman disagreed that Janssen could have avoided the taking by paying the excise tax or removing Xarelto® from the market, observing that these arguments are "foreclose[d]" by *Horne*. App.54a-55a & n.4.

REASONS FOR GRANTING THE PETITION

Congress could have taken several constitutionally permissible approaches to reduce Medicare drug prices, for example by setting prices directly by statute. Instead, it took a "shorter cut than the constitutional way," *Horne*, 576 U.S. at 362, by relying on "enterprise-crippling" penalties to coerce manufacturers into accepting cut-rate prices. App.81a (Hardiman, J., dissenting). The Program "compels [Janssen] to speak in violation of the First Amendment," by conscripting the company to endorse the Government's narrative that the Program involves "negotiat[ed]" and "agree[d]" upon "maximum fair price[s]." App.46a (Hardiman, J., dissenting). It also effects a taking of Janssen's property without just compensation by compelling the company to turn over its Xarelto® products to Medicare beneficiaries on terms dictated by CMS.

The Third Circuit's contrary holding conflicts with decisions of this Court and other courts of appeals, providing a roadmap for Congress to evade constitutional protections through coercive spending programs. As Judge Hardiman observed, the questions presented here affect hundreds of billions in annual drug spending and are "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." App.85a. This Court's review is warranted.

I. The Third Circuit's Decision Conflicts With This Court's Precedents and Creates a Circuit Split.

A. The Decision Below Distorts First Amendment Doctrine.

The First Amendment safeguards "freedom of thought" by protecting the "right to speak freely and … to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). Accordingly, the Government cannot compel a person "to speak [the Government's] preferred messages," *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023), or to "affir[m] … a belief with which [the person] disagrees," *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 573 (1995). The same principle applies to conditions on federal funding: Recipients cannot be required to "adopt—as their own—the Government's views 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*").

The Program violates this principle by compelling manufacturers to express the Government's preferred messages. Under the Program, the manufacturer of a selected drug must (on pain of severe penalties) sign documents attesting that it "agree[s]" to the price set by CMS, that this price is the product of a "negotiation," and that the price is the "maximum fair price" for the selected drug. 42 U.S.C. § 1320f-2(a); *see also* App.178a-79a, 189a-90a. Janssen does not agree with *any* of those compelled statements—all of which make contested assertions on drug pricing, a leading issue of public concern.

The statements required by the Program meaningfully distort the marketplace of ideas. Once manufacturers signed these agreements, President Biden and senior Government officials cited that fact repeatedly—including during the State of the Union Address—to show manufacturers had "com[e] to the negotiating table."[7] The compelled statements have also led state regulators to incorrectly assume manufacturers "negotiated" and "are amenable to" the Program's prices.[8] And because the Program requires manufacturers to attest that its below-market rates are the "maximum fair price[s]," manufacturers must condemn their own conduct by implicitly "confes[sing]" that the higher prices they "previously charged" and continue to charge outside Medicare are "unfair." App.77a (Hardiman, J., dissenting). Moreover, forcing manufacturers to attest that the "maximum fair price" is the product of negotiation stifles their ability to advocate for the prices necessary to support development of innovative new treatments.

The Program's speech mandates are unique. Although Congress has enacted numerous price-

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[7] White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs* (Oct. 3, 2023), https://perma.cc/L9BG-EBJ3; Joseph R. Biden, State of the Union Address (Feb. 7, 2023), https://perma.cc/9MXK-WRS7 (asserting that Medicare is "negotiat[ing] drug prices" to end "exorbitant prices" paid "to Big Pharma"). These issues were the subject of significant debate in Congress as well. *See, e.g.*, 168 Cong. Rec. 84155-56 (Aug. 6, 2022) (remarks of Sen. Crapo) (criticizing Program as a "system of bureaucratic drug price controls" involving "negotiation in name only").

[8] Colo. Prescription Drug Affordability Rev. Bd., *Upper Payment Limit for Enbrel/Etanercept*, Rulemaking Hr'g 33:10-24, 1:05:14-20 (Aug. 22, 2025), https://tinyurl.com/5bkz55k7.

setting frameworks,[9] *none* require regulated parties to declare that the rates set by the Government are "fair." The IRA nevertheless "gratuitously" "force[s]" manufacturers, "in Orwellian fashion," to make "representations they have abjured from the start." App.79a, 82a (Hardiman, J., dissenting).

In holding that the Program complies with the First Amendment, the Third Circuit fashioned two exceptions that warrant this Court's review. *First*, it concluded that the Government may require manufacturers to express its preferred messages so long as they have the ability to engage in counterspeech. *Second*, the court held that Congress may compel manufacturers to make controversial statements if it defines the relevant terms in a non-expressive manner.

The first rationale conflicts with this Court's precedents, and the second rationale splits with *National Association of Manufacturers v. SEC*, 800 F.3d 518 (D.C. Cir. 2015) ("*NAM*"). Together, the Third Circuit's reasoning hands the Government a blueprint for converting federal spending programs into a powerful means of manipulating public debate.

1. The Third Circuit held that Janssen's ability to engage in counterspeech by "criticiz[ing] the Program outside of the contracts used to effectuate it" negates any First Amendment injury. App.38a, 44a. That ruling contravenes a considerable body of precedent.

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[9] *See, e.g.*, 15 U.S.C. § 717d(a) (directing Federal Energy Regulatory Commission to "determine the just and reasonable rate[s]" for natural gas).

For example, in *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241, 256 (1974), the Court held that compelling a newspaper to give political candidates a "right to reply to" criticism violated the First Amendment, even though the newspaper was "not prevented … from saying anything it wished." Similarly, a plurality of the Court reasoned in *Pacific Gas & Electric* that speech protections would be "empty" if "the government could require speakers to affirm in one breath that which they deny in the next." 475 U.S. at 16. The Court thus rejected the argument that a state may require utilities to transmit speech from an opposing party so long as the utility can disclaim the party's message. *See id.* at 15-16 & n.11; *see also id.* at 22-23 (Marshall, J., concurring in judgment). These decisions reflect an overarching principle: Counterspeech cannot cure a compelled-speech injury because being "forced" to "disseminat[e] … a view contrary to one's own" irretrievably compromises "the speaker's right to autonomy over [its own] message." *Hurley*, 515 U.S. at 576. Or as Judge Hardiman explained, manufacturers' "ability to criticize the Program does not erase the First Amendment infringement." App.81a.

USAID applied that principle in the unconstitutional conditions context. The Court distinguished between permissible federal funding conditions that regulate a "program" and impermissible conditions that regulate the "recipient" by "reach[ing] outside" the program. 570 U.S. at 213-18. Critically, the Court explained that conditions compelling a recipient to "adopt—as [its] own—the Government's view on an issue of public concern" "*by*

[their] very nature … g[o] beyond defining the limits of the federally funded program," and thus "fal[l] on the unconstitutional side of the line." *Id.* at 217-18 (emphasis added). The fact that participants in the *USAID* grant program could "communicate contrary views" was immaterial because, having been forced to "espouse a specific belief," participants could "express [contrary] beliefs only at the price of evident hypocrisy." *Id.* at 219-20.

The Third Circuit's decision conflicts with these precedents. According to the Third Circuit, Janssen's ability to engage in counterspeech "outside the … program" means that compelled speech within the Program is permissible. App.44a (cleaned up). But that is the opposite of what *USAID* held—*i.e.*, that compelling funding recipients to endorse the Government's views on a matter of public concern *always* reaches outside a program and regulates the recipient. *See* 570 U.S. at 217-19.

Foundational compelled-speech cases show why the Third Circuit's rationale is illogical. Were that rationale the law, New Hampshire could have mandated "Live Free Or Die" license plates because bumper stickers remained unregulated, *contra Wooley*, 430 U.S. at 714; Boston could have forced parade organizers to allow controversial parade floats because other floats could have expressed a different message, *contra Hurley*, 515 U.S. at 573; and West Virginia could have required students to recite the Pledge of Allegiance because recess remained an open forum for criticism, *contra W. Va. St. Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943). Under the Third Circuit's ruling, Congress can now condition eligibility for grants, contracts, benefits, and a raft of other

programs on recitation of its preferred messages so long as counterspeech remains an option.

2. The decision below also conflicts with decisions of other courts of appeals. According to the Third Circuit, Congress may require regulated parties to utter controversial statements as long as they are defined in non-controversial ways.

Relying on that rationale, the Third Circuit held that the statements required by the Program—*e.g.*, that it establishes the "maximum fair price" for selected drugs—"los[e] the[ir] expressive weight" because the Agreement incorporates "their statutory meaning" rather than "their colloquial meaning." App.37a. The court did not dispute that "maximum fair price" ordinarily means the highest price one could fairly charge. But the court concluded that the Program does not force manufacturers to convey that message because the IRA defines "maximum fair price" in a purportedly neutral way: as "the agreed-upon price for a selected drug during a specified pricing period." App.37a; *see* 42 U.S.C. § 1320f(c)(3). Thus, even though "a layman" or "someone who has not even read the statute" might understand "maximum fair price" as involving a normative judgment, the court disregarded that understanding and instead "construe[d] the term as defined in the IRA." App.37a (cleaned up).[10]

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[10] This rationale informed the Third Circuit's related conclusion that the Program regulates conduct with only an incidental effect on speech. App.33a-36a. But *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017), draws a critical distinction between "typical price regulation[s]" that govern "conduct alone" and laws that, like the IRA, regulate "how sellers (cont.)

The Third Circuit based that conclusion on *Meese v. Keene*, 481 U.S. 465, 467 (1987), which addressed a statute that used the term "political propaganda" to describe a category of foreign films. An individual who wished to exhibit covered films challenged the statute, arguing that its use of the loaded term "political propaganda" violated the First Amendment. But the Court rejected that claim, noting that the statute did not require the plaintiff to use the disputed phrase and defined the phrase in a "neutral" way. *Id.* at 471, 477-78.

The Third Circuit thus extended *Meese* to a new context: a framework in which the plaintiff *is* required to utter the challenged phrase. In doing so, the Third Circuit created a split with the D.C. Circuit's decision in *NAM*.

NAM addressed a regulation that required companies to label minerals derived from covered sources as "not conflict free." 800 F.3d at 530. The rule thus forced regulated parties to "tell consumers that [their] products are ethically tainted" by a regional conflict, despite "disagree[ment]" on the issue. *Id.* at 530 (citation omitted). The Government argued that under *Meese*, the "conflicts" label posed no First Amendment concern because "conflict free" was "statutorily defin[ed]." *Id.* at 529 (citation omitted). The D.C. Circuit rejected that argument, holding that *Meese* was inapplicable because it involved *the Government's* use of the term "political propaganda" and thus was "not a compelled speech case." *Id.*; *see*

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may communicate their prices" *Accord* App.75a (Hardiman, J., dissenting) (required statements "d[o] much more than" "outlining" Program's process and memorializing "price[s]").

Meese, 481 U.S. 474 (films "ha[d] been classified as 'political propaganda' by the Department of Justice").

The D.C. Circuit also explained why extending *Meese* to compelled speech cases would eviscerate the First Amendment. If the Government could require regulated parties to recite normatively charged terms as long as it defines them in a way that obscures their ordinary meaning, "there would be no end to [its] ability to skew public debate by forcing companies to use the government's preferred language." *NAM*, 800 F.3d at 530 (citation omitted). The Internal Revenue Service could require religious nonprofits to file paperwork describing their faith-based hiring as "discriminatory employment practices"; HHS could force clinics receiving federal funding to label abortion services "anti-life"; and the Interior Department could require energy companies that sign offshore drilling leases to describe their operations as "irresponsible polluting."

The Seventh Circuit's decision in *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641, 653 (7th Cir. 2006), accords with the analysis in *NAM*. *Blagojevich* held that a state law violated the First Amendment by compelling retailers to post signs describing certain video games as "sexually explicit." *Id.* at 651-53. Although the statute defined that term in a legalistic way, *see id.* at 643, the court concluded that the statute impermissibly required retailers to "communicat[e] a subjective and highly controversial message." *Id.* at 652. Even accepting that the State's definition was "precise," it was nevertheless the "State's definition" and retailers "may have [had] an entirely different definition of th[e] term." *Id.* Compelling use of the State's definition thus "force[d]"

retailers to "compromise th[eir own] message[s]" about the appropriateness "of various games for buyers of different age groups." *Id.* at 653. That reasoning is directly at odds with the Third Circuit's approach here.

The approach taken by the D.C. and Seventh Circuits is correct. This Court has never held that regulated parties may be "requir[ed]" to "utte[r] … a particular message favored by the Government" merely because a statute defines that message in a non-expressive way. *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994). Rather, this Court has held that laws violate the First Amendment where, as here, they compel speech in a way that "manipulate[s] the public debate." *Id.* Yet the decision below would permit just that.

B. The Decision Below Inappropriately Narrows This Court's Takings Clause Precedents.

The Third Circuit likewise committed consequential errors in assessing Janssen's takings claim.

The Fifth Amendment protects property rights, including the rights to "possess, use, dispose of" and "exclude" others from property. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982). When the Government appropriates those rights, a "*per se* taking" occurs, *Horne*, 576 U.S. at 360, and a "simple" rule applies: "The government must pay for what it takes," *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021).

As Judge Hardiman explained, the Program "imposes a clear physical taking by forcing [Janssen]

to turn over physical doses of … Xarelto® to Medicare beneficiaries." App.53a. As in *Cedar Point*, the Program grants third parties a right to "access" Janssen's drug on terms set by CMS, *i.e.*, access through every Medicare Part D formulary at or below the "maximum fair price." 42 U.S.C. § 1320f-2(a)(3). And that access right results in third parties taking physical possession of Xarelto®, just as in *Horne*. In other words, the Program appropriates Janssen's "right to decline to sell the doses of [its] dru[g] … to Medicare beneficiaries." App.53a (Hardiman, J., dissenting).

The Third Circuit's ruling conflicts with these precedents in two key respects.

1. The Third Circuit held that the Program does not effect a taking because manufacturers can exit Medicare and sell their drugs in the private market. *See* App.21a-23a. But that rationale is foreclosed by *Horne*.

When the growers in *Horne* argued that being forced to give up their raisins constituted a taking, the Government countered that there was no taking because the growers could "sell their raisin-variety grapes as table grapes or for use in juice or wine." 576 U.S. at 365. The Court held that this "[l]et them sell wine" argument failed "as a matter of law" under *Loretto*. *Id.* *Loretto* rejected the argument that a law appropriating portions of apartment buildings "was not a taking because" owners "could avoid the requirement by ceasing to be … landlord[s]." *Id.* (citing *Loretto*, 458 U.S. at 439 n.17). "[P]roperty rights," the Court observed, "cannot be so easily manipulated." *Id.*

In the Third Circuit, however, this sort of manipulation now gets a free pass: A forced sale no longer implicates the Takings Clause if the property owner could have sold the property to someone else (or put it to different uses). The Third Circuit sought to cabin *Horne* to situations where a property owner must "exit [a] market entirely" to avoid appropriation of his property. App.22a. But *Horne* rejected that reasoning. *See* 576 U.S. at 365. Just as it was irrelevant in *Horne* that growers could sell their grapes in other ways, it is irrelevant here that manufacturers can sell their drugs in other markets. The key point for Fifth Amendment purposes is that the Program strips manufacturers of their "right to *decline* to sell the doses of their drugs … to Medicare beneficiaries," App.53a (Hardiman, J., dissenting) (emphasis added)—an appropriation that occurs regardless of whether manufacturers can also sell to other patients.

At times, the Third Circuit characterized CMS as merely "negotiat[ing] prices" using its "sizable market share." App.10a, 21a. But as Judge Hardiman explained, CMS is not just a "dominant market participant"; the agency employs sovereign, *regulatory* authority to "compe[l]" participation through "unavoidable, enterprise-crippling" penalties, App.45a-46a, and therefore must comply with the Fifth Amendment, *see Am. Trucking Ass'n v. City of Los Angeles*, 569 U.S. 641, 651 (2013) (government does not act as a market participant when it "employs … coercive mechanism[s], available to no private party").

2. The Third Circuit also departed from this Court's precedents by improperly narrowing the

unconstitutional conditions doctrine. Janssen argued that the Program impermissibly conditions Medicare and Medicaid participation on relinquishment of the company's property rights in its Xarelto® products. *See* App.30a. But the Third Circuit "decline[d] … to subject the Program to scrutiny" under the unconstitutional conditions doctrine because, in its view, the nexus-and-proportionality framework articulated in *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987), and *Dolan v. City of Tigard*, 512 U.S. 374 (1994), applies only in the "land-use permitting" context. App.30a-31a.

That reasoning cannot be squared with this Court's precedents. The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz*, 570 U.S. at 604. And this Court has made clear that no "enumerated rights," *id.*, are "second-class" or "subject to an entirely different body of rules than the other Bill of Rights guarantees," *N.Y. State Rifle & Pistol Ass'n v. Bruen*, 597 U.S. 1, 70 (2022) (citation omitted). The Court has thus rejected approaches that would "relegat[e] the Takings Clause 'to the status of a poor relation' among the provisions of the Bill of Rights." *Knick v. Township of Scott*, 588 U.S. 180, 189 (2019) (quoting *Dolan*, 512 U.S. at 392).

Yet the Third Circuit's decision downgrades the Takings Clause in precisely that fashion. Unlike other enumerated rights, *see Koontz*, 570 U.S. at 605 (collecting cases), property rights outside the land-use context now receive no constitutional scrutiny so long as the Government uses conditions on federal spending to achieve its ends, rather than by

appropriating property directly. This Court has never recognized such a carveout to the unconstitutional conditions doctrine's "overarching" protection of *all* "enumerated rights." *Id.* at 605-06. The Third Circuit thus had no basis to "decline" to apply the unconstitutional conditions doctrine. App.31a.

Limiting that doctrine to the land-use context also contravenes this Court's broader takings precedent. The Court has rebuffed attempts to narrow takings protections to only real property, *see Horne* 576 U.S. at 359, or to specific contexts when "[n]othing in constitutional text, history, or precedent supports [an] exempt[ion] from ordinary takings rules," *Sheetz v. Cnty. of El Dorado*, 601 U.S. 267, 276 (2024); *see also Cedar Point*, 594 U.S. at 149 (Takings Clause applies however the taking "comes garbed"). The Third Circuit's decision presents another instance of lower courts artificially distinguishing among types of property despite this Court's directives to apply Takings Clause protections "equally." *Horne*, 576 U.S. at 360; *accord Sheetz*, 601 U.S. at 276-77 ("[T]he Takings Clause protects private property *without any distinction* between different types." (cleaned up; emphasis added)).

Indeed, the unconstitutional conditions doctrine is designed to protect against the very type of demands employed here. The doctrine "prohibits" the Government from "coercively withholding benefits" "worth *far more* than [the] property [the Government] would like to take" because "[e]xtortionate demands of this sort frustrate the Fifth Amendment" by "pressur[ing] an owner into voluntarily giving up property for which the Fifth Amendment would

otherwise require just compensation." *Koontz*, 570 U.S. at 605-06 (emphasis added).

The Program does just that. A manufacturer must either forgo reimbursements for all its drugs in Medicare and Medicaid, or give up its "right to decline to sell" a single drug to Medicare beneficiaries on CMS's terms. App.53a (Hardiman, J., dissenting). For Janssen, this means either losing Medicare and Medicaid coverage for 21 drugs or turning over Xarelto® products at the "maximum fair price." App.198a. Congress could have conditioned Medicare reimbursements for a selected drug on price concessions for only that drug. Instead, it made manufacturers "an offer they couldn't refuse," App.69a (Hardiman, J., dissenting) (cleaned up), by "leveraging" valuable and "unrelated" benefits "to exact private property without paying for it." *Sheetz*, 601 U.S. at 275-76.

In a brief footnote, the Third Circuit alluded to the nexus-and-proportionality test, *see* App.31a n.21, but it did not actually apply that test. Under this framework, a condition that demands property (*e.g.*, an easement) must be "rough[ly] proportiona[l]" to the "social costs" of the requested benefit (*e.g.*, a permit). *Koontz*, 570 U.S. at 605-06 (cleaned up). The Third Circuit, however, did not require the Government to make *any* showing on this issue. *See* App.31a n.21; *contra Dolan*, 512 U.S. at 395.

Moreover, the Third Circuit got the proportionality analysis backwards. The court asserted that manufacturers receive an outsized benefit for participating in the Program—*i.e.*, Medicare and Medicaid coverage for their drugs. App.31a n.21. But

the IRA does not condition Medicare coverage for Xarelto® on including that drug in the Program; instead, it holds hostage *all* of Janssen's drugs in Medicare *and* Medicaid to exact a steeply discounted price on a single drug. Preventing the Government from leveraging more valuable benefits to achieve unconstitutional ends is one of the core aims of the unconstitutional conditions doctrine. *See Koontz*, 570 U.S. at 605. Yet the Third Circuit's inverted analysis blesses such leveraging without limits. Indeed, under the decision below, Congress could have conditioned existing and future participation in *all* federal programs (healthcare related or not) on Janssen's acceptance of the Program's terms for Xarelto®. This Court has never endorsed anything resembling that boundless approach.

C. The Decision Below Misconstrues Constitutional Limits on the Government's Spending Power.

Throughout this litigation, the Government's main defense has been that the Program is largely immune from constitutional limitations because it is "voluntary." According to the Government, the Program cannot violate speech or property rights because manufacturers are not legally required to participate.

That argument fails for the reasons Judge Hardiman gave in dissent: Once CMS selects a drug for the Program, the manufacturer must sign the Agreement and Addendum under threat of enterprise-crippling noncompliance penalties. Manufacturers cannot avoid those penalties by withdrawing from Medicare and Medicaid because the withdrawal

process (which takes 11 to 23 months) cannot be completed before the deadline to sign the Agreement (30 days from drug selection). *See* App.55a-56a, 58a-69a.[11]

But even if manufacturers could quickly opt out, the Government's voluntariness defense would still fail because the Program relies on extraordinary economic coercion to secure compliance. That coercion involves the exercise of sovereign, regulatory powers that no market participant could wield. And the penalties for refusing to participate in the Program are so severe that Janssen had no choice but to acquiesce to CMS's demands. *See supra* p.10. The Third Circuit dismissed this economic coercion as irrelevant because it did not amount to legal compulsion (*i.e.*, participation formally mandated by statute or regulation). *See* App.18a-21a. But that flouts this Court's precedents, which have recognized that spending programs are subject to constitutional scrutiny when they compel compliance through economic coercion.

In *NFIB*, for example, Congress offered states a "choice" between accepting onerous new Medicaid requirements or forgoing existing federal funding that accounted for 10% of their budgets. 567 U.S. at 588.

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[11] Judge Hardiman also explained how the Government's attempts to "rewrite the statutory scheme" through guidance contradict the "best" reading of the statute. App.58a-68a (dissenting opinion). Although CMS's guidance purports to allow manufacturers to withdraw from Medicare and Medicaid in 30 days, Judge Hardiman correctly concluded that this guidance exceeds the agency's authority, contradicts the IRA, and renders the statutory manufacturer-initiated withdrawal provisions superfluous. *See* App.58a-66a (dissenting opinion).

The Court noted that Congress would violate the States' Tenth Amendment rights by mandating these new requirements directly, and it held that Congress could not achieve the same ends "indirectly" through coercion. *See id.* at 577-78. Using "financial inducements" to "economic[ally] dragoo[n]" the States into compliance amounted to a financial "gun to the head" that left the States "no real option but to acquiesce." *Id.* at 581-82, 588.

The Third Circuit incorrectly brushed aside *NFIB* as a federalism case. *See* App.23a-25a. The States' Tenth Amendment rights were at issue in the case—but the Court went further to analyze (and reject) Congress's attempt to use economic coercion as an indirect way to bypass those rights. *See* 567 U.S. at 578, 581. While the underlying rights are different here (Janssen's First and Fifth Amendment rights), *NFIB* still stands for the proposition that Congress cannot escape constitutional scrutiny by using economically coercive means.

This Court has applied identical reasoning in cases involving private parties. For example, in *United States v. Butler*, 297 U.S. 1, 53-57 (1936), Congress enacted a law authorizing the Secretary of Agriculture to use taxes and subsidies to regulate cotton production and prices. While the Government argued that the cotton program was "constitutionally sound" because of the farmers' "voluntary co-operation" through "agreements," the Court held that the program was "not in fact voluntary": "refus[al] to comply" resulted in "the loss of benefits … intended to be sufficient to exert pressure on [farmers] to agree to the proposed regulation" and avoid "financial ruin." *Id.* at 70-71. This "coercion by economic pressure"

made the "asserted power of choice" to participate in the program "illusory." *Id.* at 71. And because Congress lacked authority to impose direct mandates on cotton farmers (a "matte[r] of state concern"), Congress could "not indirectly accomplish" that same goal through economic coercion. *Id.* at 74-75.

Likewise, in *Union Pacific Railroad Co. v. Public Service Commission*, 248 U.S. 67, 68-69 (1918), the Court rejected Missouri's argument that a railroad had "voluntarily" purchased a certificate to issue bonds from the state for a fee that, according to the railroad, "unlawful[ly] interfere[d]" with interstate commerce. Because Missouri had threatened to impose "severe penalties" and "invalidat[e]" already issued bonds if the railroad did *not* purchase the certificate, the state could not "declare the acceptance" of the "unconstitutional burden" "voluntary" merely by threatening "worse" consequences so that the "party under duress" would "choose the lesser of two evils." *Id.* at 70. Similarly in *Carter v. Carter Coal Co.*, 298 U.S. 238, 281-82, 289, 297-304 (1936), the Court held that Congress could not "coerce" coal producers to enter "agreements" to comply with Government-set coal prices and labor regulations by taxing noncompliant producers at a rate ten times higher than compliant producers.

Given those precedents, the key consideration is not whether the Program is voluntary in theory, but whether it is voluntary "in fact." *Butler*, 297 U.S. at 70-71. The Third Circuit majority did not ask—and thus did not answer—that crucial question. But the answer is obvious, given the "enterprise-crippling" nature of the Program's noncompliance penalties. App.68a (Hardiman, J., dissenting). As in *NFIB*,

Butler, *Union Pacific*, and *Carter*, the Program relies on "basic economic rationality" to prevent manufacturers from "walk[ing] away." *NICA*, 116 F.4th at 500. Voluntariness is therefore no more a defense here than it was in those cases.

The Third Circuit's legal-compulsion requirement also undermines the purpose of the unconstitutional conditions doctrine. That doctrine exists to safeguard constitutional rights in the *absence* of legal compulsion—*i.e.*, where the Government has *not* directly mandated any action, but instead indirectly coerces what it "could not command directly." *Speiser v. Randall*, 357 U.S. 513, 526 (1958). And the doctrine applies with full force in the context of voluntary spending and procurement programs. *See, e.g.*, *Butler*, 297 U.S. at 71, 73-74; *USAID*, 570 U.S. at 213-21; *Bd. of Cnty. Comm'rs v. Umbehr*, 518 U.S. 668, 678-79 (1996).

II. This Case Presents Issues of Great Importance.

The questions in this case are important. At issue is the constitutionality of a statute that reshapes Medicare—a major federal program—by replacing market-based pricing with top-down price controls. But this case has implications that sweep well beyond drug pricing. The Third Circuit's decision grants the Government virtually "unrestricted" power when it acts through spending programs. App.18a (cleaned up). In today's economy—where the Government is the nation's largest spender in many sectors—that is a recipe for widespread constitutional evasion.

A. The Program Is of Great Importance to Producers and Consumers of Prescription Medicines.

As Judge Hardiman observed, the Program has profound effects on "consumers of pharmaceutical drugs, the companies that provide them, and the public at large." App.85a (dissenting opinion).

The Program's scale is apparent on the face of the statute. CMS must select drugs that account for the highest proportions of Medicare spending. *See* 42 U.S.C. § 1320f-1(a). And the Program will expand rapidly: Within five years, it will cover up to eighty drugs; and within ten years, one-*hundred*-and-eighty. Each selected drug remains in the Program until CMS determines that generic or biosimilar competition has entered the market. *Id.* § 1320f-1(c)(1). This framework erodes manufacturers' patent rights as well, by targeting medications that retain market exclusivity under the Intellectual Property Clause and other federal statutes.

If the Program proceeds, it will reshape the $600 billion pharmaceutical market.[12] In the Program's first year, CMS imposed price cuts of up to 79%, and 63% on average.[13]

Slashing drug prices by fiat will affect drug manufacturers, but the consequences will not end there. For decades, this country has led the world in pharmaceutical innovation, with "almost half" of new medicines originating in the United States in recent

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[12] Grand View Research, *U.S. Pharmaceutical Market Size & Trends* (2024), https://perma.cc/R8H7-L297.

[13] *See supra*, *IPAY 2026 Negotiated Prices*.

years.[14] Market-based drug pricing has played an essential role in fostering that innovation, mainly because developing new drugs is so expensive—requiring years of development and billions of dollars per drug.[15] For example, Janssen and its affiliates have invested more than $65 billion in pharmaceutical research and development between 2016 and 2022, resulting in FDA approval for eight new medications and 52 additional indications or product formulations to serve patient needs. App.194a. By replacing market-based pricing with Government-dictated prices, the Program destroys incentives to take the significant risks necessary to develop new treatments—thus reducing patients' access to innovative medicines. These adverse effects are not hypothetical: Manufacturers have already discontinued clinical trials because the Program will make it impossible to recoup the costs.[16] The Program's structure also undermines the incentives to develop generic and biosimilar drugs (as well as new indications for existing drugs), and will thus decrease competition.

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

[15] *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.

[16] *See, e.g.*, ATI Advisory, *Pharmaceutical Innovation and the Inflation Reduction Act: What Can We Learn from the First Half of 2023?* (Nov. 2023), https://perma.cc/6GPR-HWD9 (reporting cancellation of Eli Lilly Phase I oncology trial).

In sum, the Program's "effects on the life sciences industry and ultimately to patient treatment [will be] profound."[17]

B. The Third Circuit's Ruling Allows the Government to Leverage Its Spending Powers to Evade the Constitution.

The implications of the Third Circuit's decision extend well beyond the Program. If the Third Circuit's approach is allowed to stand, it would permit the Government to operate in a broad Constitution-free zone whenever it spends public money.

The Third Circuit determined that the Government's power is virtually "unrestricted" in the spending context. App.18a (cleaned up). Although the court acknowledged the possibility that some conditions on the receipt of federal funds could be unconstitutional, the court improperly limited that doctrine to narrow and specific contexts such as land-use restrictions and prohibitions on speech.

The Third Circuit's approach has far-reaching implications. The Government is by far the most significant purchaser of goods and services in the United States—indeed, "in the world."[18] In fiscal year 2024 alone, the "federal government spent about $755 billion on contracts for a wide variety of goods and

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[17] Luke Greenwalt, *The Impact of the Inflation Reduction Act on the Economic Lifecycle of a Pharmaceutical Brand*, IQVIA (Sept. 17, 2024), https://perma.cc/BRX6-6SXB.

[18] U.S. Gen. Servs. Admin., *Federal Acquisition Policy Division*, https://perma.cc/R9GY-6AJ5.

services."[19] Federal outlays for benefits programs are even larger. In fiscal year 2024, the Government spent $1.5 trillion on Social Security benefits, $865 billion on Medicare benefits, $618 billion on Medicaid benefits, $370 billion on income security programs, such as the Supplemental Nutrition Assistance Program, and approximately $120 billion on student aid for post-secondary education.[20]

Under the Third Circuit's framework, every one of these expenditures and disbursements is an opportunity for the Government to encroach on constitutional rights. This case illustrates how the Government can leverage its spending powers to infringe rights protected by the First and Fifth Amendments. *See supra* section I. And it is not difficult to imagine comparable violations in other contexts. For example, the Government could condition disability benefits on military veterans signing agreements attesting that they were wounded in "just and righteous causes."

The Third Circuit's ruling could readily be applied to subvert other constitutional protections as well. Federal contractors and benefits recipients could be required to sign away—partially or entirely—their Second Amendment right to own a firearm, their Fourth Amendment right against warrantless or unreasonable searches, or their Fifth Amendment due

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[19] U.S. Gov't Accountability Off., *Federal Contracting*, https://perma.cc/DYU4-KYE5.

[20] Cong. Budget Office, *The Federal Budget in Fiscal Year 2024* (Mar. 2025), https://perma.cc/U2NR-62K3; Fed. Student Aid, Fiscal Year 2024 Annual Report, at 8 (Nov. 14, 2024) https://perma.cc/J4XD-DB8P.

process rights. As long as the Government relies on its spending powers—and leaves open an illusory "choice" to decline the contract or benefit—these actions would all be permissible.

III. This Case Is an Excellent Vehicle for Resolving the Questions Presented.

This case provides an excellent vehicle for resolving the recurring constitutional questions presented by the Program's unprecedented scheme. As the Third Circuit acknowledged, the material facts are undisputed. *See* App.16a, 91a. The legal issues were squarely presented and the Third Circuit decided them on the merits. *See* App.16a-44a.

The issues are also outcome-determinative. If the Third Circuit erred in concluding that legal compulsion is required to bring a constitutional claim; *or* that the Program does not appropriate property in violation of the Takings Clause; *or* that the Program does not compel speech in violation of the First Amendment, then its decision upholding the Program cannot stand.

Finally, this case does not present threshold procedural or jurisdictional issues—meaning there is no obstacle to this Court's review of the merits. And because Janssen has asserted its claims on an as-applied basis, *see* Complaint ¶ 11, *Janssen Pharms. Inc. v. Becerra*, No. 3:23-cv-3818, ECF 1 (D.N.J. July 18, 2023), this Court can address the merits without applying the rigorous framework governing facial challenges.

CONCLUSION

For the foregoing reasons, the Court should grant the petition.

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