No. ____

IN THE

Supreme Court of the United States

BRISTOL MYERS SQUIBB COMPANY,

Petitioner,

v.

ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

On Petition For A 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

As part of the Inflation Reduction Act of 2022, Congress created the "Medicare Drug Price Negotiation Program." Under the Program, manufacturers of the Nation's leading prescription medications must expressly "agree" to sell selected products to Medicare beneficiaries at a below-market "maximum fair price." If a manufacturer declines to do so, it incurs an "enterprise-crippling" daily tax on all sales of the product that tops out at 1,900% of its total daily revenue. App.49a (Hardiman, J., dissenting). For petitioner Bristol Myers Squibb Company and its selected product Eliquis, that would mean up to $1 billion in daily liability. Other than "agreeing" to sell its product at a government-dictated below-market price, the only way for a manufacturer to avoid this massive penalty is to withdraw *every one* of its medicines from both Medicare and Medicaid—about half the American market.

A divided Third Circuit upheld the Program, reasoning that participation in it is wholly "voluntary" because a manufacturer can "choose" to avoid the IRA's crippling taxes by withdrawing entirely from Medicare and Medicaid—thereby destroying its domestic business. The questions presented are:

1. Whether the Program violates the Fifth Amendment's Takings Clause by forcing manufacturers to sell medicines to Medicare beneficiaries at below-market prices.

2. Whether the Program violates the First Amendment by compelling manufacturers to expressly "agree" with the government's narrative that its dictated amount is the medicine's "maximum fair price," set through a voluntary negotiation.

PARTIES TO THE PROCEEDING

Petitioner Bristol Myers Squibb Company (BMS) was the plaintiff-appellant below. Respondents Robert F. Kennedy, Jr., in his official capacity as the Secretary of the U.S. Department of Health and Human Services (HHS) and his predecessor; Mehmet Oz, in his official capacity as the Administrator of the Centers for Medicare & Medicaid Services (CMS) and his predecessor; HHS; and CMS were the defendants-appellees below.

RULE 29.6 STATEMENT

Petitioner Bristol Myers Squibb Company has no parent company, and no publicly held corporation owns 10% or more of its stock.

STATEMENT OF RELATED PROCEEDINGS

The following proceedings are directly related to this case within the meaning of Rule 14.1(b)(iii):

- *BMS v. Secretary, HHS*, No. 24-1820 (3d Cir.), judgment entered on September 4, 2025;
- *BMS v. Becerra*, No. 23-cv-3335 (D.N.J.), judgment entered on April 29, 2024;
- *Janssen Pharmaceuticals, Inc. v. Secretary, HHS*, No. 24-1821 (3d Cir.), judgment entered on September 4, 2025;
- *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 23-cv-3818 (D.N.J.), judgment entered on April 29, 2024.

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INTRODUCTION

In the Inflation Reduction Act of 2022 (IRA), Congress established the innocuous-sounding "Medicare Drug Price Negotiation Program." The name suggests that Congress just authorized Medicare to bargain over the prices it pays for prescription medicines. That is certainly how the Program was sold to the public.

That narrative is a false one. In reality, the Program involves no genuine negotiations—which, after all, can sometimes fail. Unwilling to take that risk (and the political heat for leaving millions of American seniors without their medicines), Congress instead used the threat of staggering tax penalties to compel pharmaceutical manufacturers to give Medicare "access" to their most valuable products at steeply discounted prices set by the government. Congress then required manufacturers to "agree," in writing, that those below-market prices represent negotiated "maximum fair prices" for their medicines. All this helped conceal the Program's central-planning approach—a radical departure from Medicare's traditional market-based design—under the guise of arms-length "negotiations."

This scheme violates the Constitution in multiple respects. *First*, the Program effects *per se* physical takings of private property without just compensation. It does not simply set the price at which the government will (or will not) purchase BMS's products. Instead, it *forces* BMS to sell its products at steep discounts. Indeed, that is its point: Congress wanted to obtain medicines for Medicare beneficiaries without paying fair market value. To that end, the Program hoists a menacing "sword of Damocles" over any manufacturer whose product has been chosen for "negotiation."

App.57a (Hardiman, J., dissenting). Refusing to "negotiate" or "agree" with the government would set off a cascade of tax liability that, for BMS, would quickly eclipse $1 billion *per day*. And once the government names its "maximum fair price," refusing to transfer the product to Medicare beneficiaries triggers further penalties. The Program thus requisitions BMS's property through a system of forced sales at below-market prices set by the government. The Fifth Amendment forbids such a regime.

Second, the IRA compels speech in violation of the First Amendment. Instead of just empowering HHS to set prices, Congress required manufacturers to peddle government-dictated propaganda about the Program. A manufacturer must first sign a written agreement to engage in a faux negotiation over its product's "maximum fair price." If it does not, the same tax penalties kick in. And when that "negotiation" ends, the manufacturer must again sign a form reciting that the parties have "agreed" on a "maximum fair price." The whole point of this, of course, is to bolster the political narrative that these are arms-length "negotiations" that result in a "fair price." But none of it is true, and BMS strongly disagrees with the speech it is compelled to utter under threat of massive penalties.

Despite these glaring constitutional defects, a divided Third Circuit upheld the Program over Judge Hardiman's dissent. In doing so, the majority did not seriously dispute that forcing manufacturers to hand over medicines at below-market prices—and to pretend they "agreed" to this "fair" deal—would defy the Constitution. Instead, the majority held that the Program is immune from any constitutional scrutiny because it represents a "voluntary exchange." App.19a.

But this Program is anything but voluntary. To the contrary, its "enterprise-crippling tax" can be suspended only if the manufacturer withdraws *all of its products* from Medicare and Medicaid. App.78a (Hardiman, J., dissenting); *see* App.24a (majority). As BMS has explained (without rebuttal), that would require it to abandon half of the U.S. market, which would devastate any manufacturer and the millions of Americans who rely on its products. The Program is thus the epitome of the proverbial "offer that can't be refused."

In holding otherwise, the decision below threatens to hollow out constitutional limits on federal authority. If Congress can coerce funding recipients into surrendering private property and mouthing government talking points while doing so, pharmaceutical manufacturers will not be its last target. American individuals and companies of all stripes depend heavily on federal funding in one form or another—from hospitals, defense contractors, and universities to the many retirees who rely on a Social Security check showing up each month. Under the Third Circuit's conception of "voluntariness," the political branches could tell any of them that they are free to keep their government funding streams so long as they fly an American flag, provide free housing, or endorse the President.

That is not our law. This Court has long admonished that the government cannot trample on constitutional guarantees—such as by seizing private property or conscripting private parties into carrying political water—whether it "directly commands" those results or "indirectly coerces" compliance. *NFIB v. Sebelius*, 567 U.S. 519, 578 (2012) (Roberts, C.J.); *see, e.g.*, *Frost & Frost Trucking Co. v. R.R. Comm'n of Cal.*, 271 U.S. 583, 593 (1926).

Unfortunately, that message was lost on the Third Circuit. And the stakes could not be higher: Pharmaceutical manufacturers, including BMS, stand at the precipice of a revolutionary system in which the government can simply take any product it does not wish to pay for. It merely has to frame that exaction as a condition on access to half of the U.S. market. Given the economic realities of that market—realities Congress legislated into existence—no manufacturer will be able to refuse. Instead, they have had to resort to litigation, filing at least 10 constitutional challenges to the Program across five different circuits. In the meantime, they have predictably been forced to reduce investments in new therapies to the detriment of all Americans.

In short, this case "is of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." App.90a (Hardiman, J., dissenting). It also comes to this Court free of any threshold obstacles that would impede review and with the benefit of two lengthy opinions exhaustively addressing the merits. It is therefore hard to imagine a better vehicle for this Court to address the Program's threat to innovation and the Constitution alike.

OPINIONS BELOW

The Third Circuit's panel opinion (App.1a-91a) is reported at 155 F.4th 245. The district court's opinion granting summary judgment to the government (App.92a-124a) is unreported but available at 2024 WL 1855054.

JURISDICTION

The Third Circuit entered its judgment on September 4, 2025. On November 6, 2025, Justice Alito extended the time to file this petition until December 19, 2025. No. 25A219. This Court has jurisdiction under 28 U.S.C. § 1254(1).

PROVISIONS INVOLVED

The constitutional and statutory provisions involved are reproduced at App.125a-181a.

STATEMENT

1. The federal government "dominates" the prescription drug 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 the largest federal health insurance program, covering "nearly 60 million aged or disabled Americans." *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019). It has two major prescription-medication programs relevant here. Part B covers medications administered by physicians. 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). And Part D allows beneficiaries to enroll in privately operated, federally subsidized plans for self-administered prescriptions. *Id.* § 1395w-101 *et seq.*; *see United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 744-45 (2023).

Historically, Medicare required market-based pricing for its coverage of prescription medicines. Part B reimbursement rates are based on an "average sales price" methodology. 42 U.S.C. § 1395w-3a. And when Congress enacted Part D, it forbade HHS to "interfere with the negotiations between drug manufacturers and pharmacies and [private plan] sponsors." *Id.* § 1395w-111(i)(1).

Congress recognized that this "fundamental protection" was necessary to prevent "price fixing." 149 Cong. Rec. 31043-44 (Nov. 23, 2003) (Sen. Grassley). Otherwise, the federal government's legislated "market power" as a purchaser would enable it to "dictate" prescription prices, *id.* at 31160 (Nov. 24, 2003) (Sen. Santorum)—and thereby "destroy" innovation, *id.* at 31051 (Nov. 23, 2003) (Sen. Frist).

2. Things changed in 2022, when Congress enacted the IRA, including the Medicare Drug Price Negotiation Program. That Program fundamentally transforms how the government sets prices for and acquires prescription medicines. It proceeds in five main stages.

First, HHS (through its sub-agency, CMS) selects products that will be subjected to the Program. In September 2023, CMS selected the first 10 medicines; in 2025, it added 15 new products; it will do the same in 2026; and in 2027 and beyond, it must add 20 new products annually. 42 U.S.C. §§ 1320f(b)(3), 1320f(d), 1320f-1(a). HHS is supposed to select products with the highest total historical cost to Medicare. *Id.* § 1320f-1(b)(1)(A). Selected medicines remain subject to the Program until HHS determines that a generic or biosimilar version of the product is approved and marketed. *Id.* § 1320f-1(c)(1).

Second, once products are selected for the Program, their manufacturers must "enter into agreements" to participate in an orchestrated "negotiation" geared towards setting what the government deems to be the "maximum fair price" for their products. *Id.* § 1320f-2(a). For the first round of selected products, manufacturers had until October 1, 2023, to enter those initial agreements. *See id.* § 1320f(a)(2), (d)(2).

To effectuate this requirement, CMS developed a standard contract (the Agreement) that manufacturers must sign. App.182a-194a. The Agreement states that "CMS and the Manufacturer agree" that they "shall negotiate to determine" and "agree to[] a maximum fair price for the selected drug." App.184a.

Failure to "agree" to begin this process triggers severe sanctions. If a manufacturer declines to go forward and continues selling the selected product—to *anyone*, not just Medicare beneficiaries—it incurs an escalating daily excise tax that starts at 186% and climbs to 1,900% of the medicine's daily revenues from all sources. *See* 26 U.S.C. § 5000D; Cong. Rsch. Serv., RL47202, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 4, tbl. 2 (2022). For a manufacturer like BMS, these penalties could quickly reach $1 billion per day. App.55a (Hardiman, J., dissenting). As Congress understood, this "tax"—which captures the product's entire economic value and then some—will raise "no revenue," because every manufacturer will be forced to comply. Joint Comm. on Tax'n, JCX-46-21, *Estimated Budget Effects of the Revenue Provisions of Title XIII—Committee On Ways And Means, of H.R. 5376, Fiscal Years 2022-2031* 8 (Nov. 19, 2021).

Third, once a manufacturer "agrees" to participate, HHS begins the supposed "negotiation" by issuing a "written initial offer." 42 U.S.C. § 1320f-3(b)(2)(B). The offered price cannot exceed a statutory ceiling that ranges from 75% of a market-based benchmark for the most recently approved medicines, down to 40% of the benchmark for medicines approved further in the past. *Id.* § 1320f-3(b)(2)(F), (c)(1)(C), (c)(3)-(5). In other words, the Program mandates a discount of at least 25%, and often much higher.

But there is no floor on the price HHS may set. The agency need only consider certain non-exclusive factors in deciding what price is "fair." *Id.* § 1320f-3(b)(2)(B), (b)(2)(C)(ii)(II), (e). Moreover, HHS must "aim[] to achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1). There is no formal procedure for setting the price, and the IRA purports to immunize the agency's pricing decisions (and drug selections) from judicial review. *Id.* § 1320f-7.

Fourth, negotiations "shall end" by a fixed statutory date—for the first round of selected products, August 1, 2024. *Id* § 1320f-3(b)(2)(E); *see id.* § 1320f(d)(5)(C). Although the IRA permits the manufacturer to make a "counteroffer," HHS is free to ignore it in favor of its "initial offer" or any other price below the IRA's cap. *Id.* § 1320f-3(b)(2)(C), (e). Regardless, by the deadline, a manufacturer must accept or reject the agency's price. But in reality, there is no choice. If a manufacturer rejects HHS's "offer," it triggers the same cascade of crippling excise-tax liability discussed above. *See* 42 U.S.C. § 1320f-2(a)(1); 26 U.S.C. § 5000D; *supra* at 7. The manufacturer must then sign a CMS-drafted "Addendum" to its initial agreement to participate in this process, which formalizes its "agreement" to sell at this "maximum fair price." App.195a-198a. HHS must then "publish" the price it "negotiated with the manufacturer," along with an "explanation" for that "maximum fair price." 42 U.S.C. § 1320f-4(a).

Finally, as a result of this process, the manufacturer must provide Medicare with "access" to the covered product at the dictated price. *Id.* § 1320f-2(a)(1). That duty ends only if HHS determines that a generic or biosimilar version is available, *id.* § 1320f-1(c)(1), or if it selects the product for "renegotiation," *id.* § 1320f-3(f).

Refusal to transfer the selected product at the "maximum fair price" would violate the "agreement," triggering two penalties. To start, the manufacturer would have to pay a $1 million noncompliance penalty per day. *Id.* § 1320f-6(c). It would also incur a penalty of 10 times the difference between the price charged and the "maximum fair price." *Id.* § 1320f-6(a).

3. There is only one way for a manufacturer to avoid the Program's penalties without incurring an obligation to sell its product at the "maximum fair price": It may terminate Medicare and Medicaid coverage for *all* of its products (not just the selected product). App.16a; App.54a (Hardiman, J., dissenting). Specifically, the IRA's excise tax is "suspend[ed]" on days when a manufacturer is not a party to a Medicare or Medicaid reimbursement agreement for *any* of its products. 26 U.S.C. § 5000D(c). In theory, then, a manufacturer could escape the Program by forfeiting its access to nearly half of the U.S. market for all of its products—and leaving millions of Americans without their medications.

But even this supposed option is illusory, at least as Congress designed it. The IRA prevented companies from withdrawing from Medicare in time to avoid the first round of forced sales. Under the statute, a manufacturer that gives notice to terminate its Medicare agreements must wait between 11 and 23 months before that termination takes effect. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii); 1395w-114c(b)(4)(B)(ii). So to avoid penalties for refusing to sign an agreement by October 1, 2023, a manufacturer would have needed to act by January 2022—months *before* the IRA was passed in August 2022. App.63a (Hardiman, J., dissenting).

4. In 2023, CMS published the list of 10 medications selected for "negotiation" in 2024 and forced transfers in 2026. App.17a. Among them was Eliquis, a BMS medication used to treat and prevent blood clots and strokes. *Id.* BMS was forced to "agree" to "negotiate" a "maximum fair price" for Eliquis, or else incur over $1 billion in daily penalties. That same threat compelled BMS to sign an agreement, to participate in the "negotiations," and to "agree" to the government's "maximum fair price" for Eliquis by signing the Addendum. *Id.* Starting in January 2026, BMS must provide Medicare "access" to Eliquis at that price. 42 U.S.C. § 1320f-2(a)(1).

5. In June 2023, BMS challenged the Program in district court, asserting violations of the Takings Clause and First Amendment.[1] Two weeks later, CMS issued "guidance" purporting to create an exit option from the Program. App.28a-30a. Invoking its power to terminate reimbursement agreements with 30 days' notice for a "violation" or other "good cause shown," CMS proclaimed that a manufacturer's desire to opt out of the Program is itself "good cause" to end its agreements without the statutory waiting period. *Id.*

Relying on that guidance, App.98a, the district court rejected BMS's claims on the premise that the manufacturer could simply withdraw from Medicare and Medicaid rather than comply with the Program. That option, the court concluded, rendered the Program "voluntary" and immunized it from any constitutional scrutiny. App.107a-114a.

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[1] Janssen Pharmaceuticals, Inc., brought a similar suit in the same court in July 2023. App.16a-17a. The cases were consolidated for disposition, including on appeal. App.17a.

6. A divided Third Circuit affirmed. App.1a-92a.

a. The majority did not deny that if Congress had prohibited manufacturers from "withdrawing" all their products from Medicare and Medicaid, then the Program would violate the Takings Clause. App.27a. Instead, it held that the availability of this "opt-out option" alone rendered participation in the Program entirely "voluntary." App.20a; *see* App18a-34a. And that was so even if "basic economic rationality dictates" that manufacturers must remain in Medicare and Medicaid, "making the exit option illusory." App.21a-22a. In the majority's view, the fact that manufacturers could *legally* "stop doing business with the government" meant "there is no physical taking." App.18a.

The majority rejected the First Amendment claim for the same reason, noting "the Program only 'compels' [manufacturers] to speak if they choose to participate." App.42a. While accepting manufacturers would suffer "hardship … from declining to participate," the majority held that "Congress can permissibly leverage funding in this way." App.42a-43a. It added that the "Program permissibly regulates conduct, with only an incidental effect on speech." App.35a.

b. Judge Hardiman dissented. He recognized that the Program seizes manufacturers' "property without just compensation in violation of the Fifth Amendment and compels them to speak in violation of the First Amendment." App.48a. As he observed, every party agreed that "Congress could have sought to reduce federal outlays simply by passing a law setting prices for the costliest Medicare drugs." App.49a. That would have left manufacturers free to decide whether or not to sell their products at the low prices.

Instead, the IRA strips manufacturers of that choice, forcing them to transfer their products at steep discounts. As Judge Hardiman explained, it does so through a "byzantine scheme" compelling manufacturers to not only "turn over" their medicines to Medicare beneficiaries at below-market prices, but to also "misrepresent that they agreed to such prices." App.91a. And the reason for this "Orwellian" framework, he explained, was that it freed the government to portray "a forced sale at prices set by CMS" as a true "voluntary negotiation." App.83a-84a. In reality, Judge Hardman observed, the government, "like Don Corleone in *The Godfather*," had simply made the manufacturers "an offer they couldn't refuse." App.73a (cleaned up).

REASONS FOR GRANTING THE PETITION

It is no secret that the government would like to pay less for prescription medications. And Congress has no shortage of constitutional strategies for pursuing that goal. In the IRA, however, Congress took "a shorter cut than the constitutional way." *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922). Its Program forces manufacturers to transfer their medicines to Medicare beneficiaries at a massive discount (a classic physical taking) and to express support for that seizure by signing faux "agreements" (a classic speech compulsion).

Despite these obvious problems, the Third Circuit did not merely *uphold* the Program; it ruled that it cannot be tested under *any* constitutional standard, simply because Congress dressed it up as a condition on funding. Specifically, the majority held Congress could exact both Eliquis and speech from BMS because it legislated the alternative "option" of withdrawing *all* of BMS's products from Medicare and Medicaid.

That theory is wrong—and dangerously so. To start, BMS would have needed to withdraw from Medicare and Medicaid *before* the IRA was even enacted—an obvious indicator that Congress was not extending a voluntary offer. More fundamentally, the so-called "choice" to abandon around half of the U.S. market is utterly "illusory." *United States v. Butler*, 297 U.S. 1, 71 (1936). Having legislated its own market dominance, Congress knew no manufacturer could destroy its domestic business in this way.

In short, the Third Circuit allowed Congress to "indirectly coerce" what the Fifth and First Amendments forbid it to "directly command." *NFIB*, 567 U.S. at 578 (Roberts, C.J.). But as this Court has held time and again, the government cannot "do indirectly what [it] is barred from doing directly." *E.g.*, *NRA v. Vullo*, 602 U.S. 175, 190 (2024). Left in place, the Third Circuit's decision will therefore empower the political branches to abuse the vast power of the purse to circumvent any limit on federal authority, including individual rights. And there is no reason to think the government would wield that newfound power against pharmaceutical companies alone. Any individual, household, or business reliant on federal funds would be at risk.

This case presents the ideal vehicle to address that threat—before it can metastasize—by reviewing the most consequential healthcare law since the Affordable Care Act. Every member of the panel below agreed the fundamental questions here were both cleanly presented and deserving of thorough consideration. And while Judge Hardiman has rejected other challenges to the IRA, he recognized that "[t]his appeal" was of such "great importance" that it merited a 43-page dissent. App.90a.

I. THE DECISION BELOW IS DANGEROUSLY WRONG.

By leveraging the threat of unbearably high tax penalties, the Program compels manufacturers not only to turn over their property, but to say they agreed to it. The court of appeals' only real defense of this unconstitutional scheme was to assert that manufacturers could "avoid" it by withdrawing their entire portfolio of medicines from Medicare and Medicaid. App.16a. Put differently, the law in the Third Circuit now is that Congress can say: "Give up your rights, or we will cut you out of other programs, benefits, or contracts." That theory is both profoundly wrong and deeply chilling. Yet without it, the Program cannot survive.

A. The Program violates the Takings Clause by compelling below-market sales.

The Program takes prescription medicines without paying just compensation. That is its point. Having promised Medicare beneficiaries it would cover the cost of their medications, Congress decided it no longer wanted to pay market prices. Its "solution" was to coerce manufacturers to transfer doses of those products to Medicare beneficiaries at a cut-rate discount to CMS. That is a physical taking.

1. The Takings Clause provides that "private property" shall not "be taken for public use, without just compensation." U.S. Const. amend. V. In doing so, it creates "a simple, *per se* rule: The government must pay for what it takes." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021). That is true whether the government takes property "for itself or someone else" and no matter what "means" it uses to do so. *Id.* at 149. A "statute" that "appropriates property" through "compelling" a transfer is therefore a "physical taking." *Id.*

By the same token, a forced transfer of property remains a taking even when dressed up as a "sale." *See, e.g.*, *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307-08 (1989). That the previous owner may receive some money does not erase the taking; it affects only the *amount of compensation* owed. In *Horne v. Department of Agriculture*, 576 U.S. 350 (2015), for example, this Court found a *per se* taking where a statute required farmers to "turn over a percentage of their raisin crop," even though they retained a contingent right to partial payment if their raisins were resold. *Id.* at 358, 361-62, 368-69.

2. The Program is materially indistinguishable. All agree that units of Eliquis are BMS's property protected by the Takings Clause. App.19a; *see Horne*, 576 U.S. at 358. It is equally clear that the Program compels BMS to transfer that property to Medicare beneficiaries at a price of the government's choosing. "Like th[e] reserve requirement" in *Horne*, the IRA forces BMS "to turn over physical doses of Eliquis" to "Medicare beneficiaries" at dictated prices by threatening "ruinous excise tax liability." App.57a (Hardiman, J., dissenting).

That the IRA launders these transfers through the façade of an "agreement" is immaterial. The Constitution does not care how a physical taking "comes garbed." *Cedar Point*, 594 U.S. at 149. BMS is penalized if it does *not* sign the "agreement" to fork over its medicines, just as the farmers in *Horne* were fined for refusing to relinquish their raisins. *See* 576 U.S. at 356. An owner's "'option' to pay a major financial penalty" is irrelevant as to "whether the government has taken property." App.58a (Hardiman, J., dissenting).

Because it effects a taking, the Program triggers a duty to pay "fair market value." *United States v. Reynolds*, 397 U.S. 14, 16 (1970). But the IRA is written to *prevent* the government from doing so. It caps the "maximum fair price" at 75% of a genuine market price (or lower, for older medicines), and permits HHS to impose steeper discounts still. 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C), (c)(3)-(5). By definition, that cannot be just compensation. *Horne*, 576 U.S. at 368-69.

As Judge Hardiman understood, the Program is therefore no different than the reserve requirement in *Horne*. App.57a. Like the IRA, the law in *Horne* used penalties to coerce owners to turn over their property. *Id.* at 356, 358, 362. The government in *Horne* took a fraction of the farmers' raisins, while here it is taking BMS's medicines for a fraction of their fair value, but that distinction is immaterial. Seizing 50% of a company's inventory is no different from seizing that inventory at a 50% discount. And the Program's below-market payments bear only on the amount of damages, just like the partial proceeds the farmers stood to earn from resale of their requisitioned raisins. *See id.* at 364. Accordingly, there as here, any taking of the property "requires just compensation." *Id.* at 358. Because the Program refuses to do so by design, it violates the Takings Clause.

3. Notably, Congress could have avoided this constitutional defect by simply enacting a price cap for Medicare. A price cap *forbids* sales above certain prices but does not *compel* sales at any price—leaving open other uses of the property. *See, e.g.*, *Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992). A forced sale, by contrast, leaves the owner with no choice but to hand over its property.

Congress, however, deliberately declined to adopt a price cap in the IRA. The Program does not merely set maximum prices for covered medicines. That constitutional regime would have been simpler to set up, but politically toxic. Aside from using controversial price controls, that approach would create the risk that Medicare beneficiaries might lose access to their medicines if sellers refused the offered terms. After all, price controls leave manufacturers with a choice: sell at the mandated price or keep their products. The Program, in contrast, mandates "access" for a preferred class of buyers by forcing manufacturers to turn over their medicines to them on the dictated terms. That "access" requirement defies the Takings Clause. *Cedar Point*, 594 U.S. at 149.

B. The Program violates the First Amendment by compelling manufacturers to convey the government's political narrative.

Not content to merely requisition Eliquis and other medicines, Congress disguised the Program as a politically palatable "negotiation" over a "maximum fair price"—and compelled manufacturers to express that same false narrative. Economically, this aspect of the Program is useless: Congress could have imposed price controls to achieve the same result. Instead, it erected a charade of sham "negotiations" that requires manufacturers to sign "agreements" confessing that the government-dictated prices are "fair." The only purpose served by this kabuki is political deception—it allows the government to pretend that it hashed out voluntary agreements with businesses who agree that the below-market prices are fair. But the First Amendment forbids conscripting private businesses to parrot government spin.

1. Freedom of speech "necessarily compris[es] the decision of both what to say and what *not* to say." *Riley v. Nat'l Fed'n of the Blind of N.C.*, 487 U.S. 781, 797 (1988). The government therefore "may not compel a person to speak its own preferred messages." *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023).

That includes coercing speakers into feigning "agree[ment] with" the government's stance. *Agency for Int'l Dev. v. All. for Open Soc'y Int'l*, 570 U.S. 205, 213 (2013) (*AOSI*). In *AOSI*, for instance, this Court made short work of a regime that barred funding "to any group … that does not have a policy explicitly opposing prostitution and sex trafficking." 22 U.S.C. § 7631(f). Under that program, any recipient had to "agree in the award document that it is opposed to" those activities or lose its funds. *AOSI*, 570 U.S. at 210. By "mandat[ing] that recipients … explicitly agree with the Government's policy," this requirement "plainly violate[d] the First Amendment." *Id.* at 213.

2. The Program here is no different. As described above (at 6-9), manufacturers must first "enter into" an "agreement[]" promising to "negotiate" toward a "maximum fair price" for their medicines. 42 U.S.C. § 1320f-2(a)(1). After the sham "negotiation" concludes (as it must by a fixed deadline, *id.* § 1320f-3(b)(2)(E)), the manufacturer must then "agree to" the "maximum fair price" CMS dictated, *id.* § 1320f-2(a)(1). Indeed, CMS's agreement recites over 20 times that the parties do or will "agree." App.182a-194a. And its Addendum proclaims that the parties have "negotiated," and "agree[d]" upon, a price that is the "maximum fair" one. App.195a-198a. Refusal to sign any of these agreements results in the horse's head—financially ruinous tax penalties. *See* 26 U.S.C. § 5000D.

In sum, any manufacturer hoping to avoid the IRA's crippling tax must—quite literally—sign on the dotted line of an "agreement" that falsely states the price "agreed" to is "fair." And by doing so, it expresses obvious messages: these are voluntary negotiations; this give-and-take will and did in fact end in "agreement"; and the resulting price is the "maximum fair" one. That expression is the inevitable result of the IRA's design. *See Doe v. Reed*, 561 U.S. 186, 194-95 (2010) (signing document "expresses" messages therein); *New Hope Family Servs. v. Poole*, 966 F.3d 145, 178 (2d Cir. 2020) (signing placement agreement "communicat[es]" state's "viewpoint" on adoptee's best interests).[2]

BMS, of course, does not "agree" with any of this. The Program involves no "negotiation" because BMS would incur enormous penalties for walking away. More fundamentally, BMS rejects the agreement's "'overtly political'" message that the government's dictated price—as opposed to a genuinely negotiated one—is the "maximum fair price" for Eliquis. App.82a (Hardiman, J., dissenting). Indeed, parroting that message is akin to a forced confession: It tells the world that BMS has long been charging more than the "maximum fair price" for Eliquis. *Id.* Instead, BMS believes sharply discounting crucial medicines like Eliquis far below the market price will only undermine BMS's ability to develop new life-saving medicines.

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[2] It does not matter that the IRA "defines 'maximum fair price' and uses the terms 'agree' and 'negotiate.'" App.82a n.13 (Hardiman, J., dissenting). Otherwise, "there would be no end to the government's ability to skew public debate." *Id.* (quoting *NAM. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015)); *but see* App.40a (majority) (using statutory definition to negate "expressive weight").

The IRA's compelled "Agreements" are thus nothing like "'ordinary commercial contracts'" with the government involving "non-expressive … conduct." App.78a (Hardiman, J., dissenting). The latter merely memorialize voluntary transactions; they do not require the government's counterparty to proclaim "agreement" with a political narrative. And while the government is free to persuade the public that higher prices would be "unfair," it cannot conscript BMS into doing so.

Yet that misimpression is the only evident purpose of the Program's convoluted framework. There is no *policy* reason to channel forced sales through "agreements" to sell at a so-called "maximum fair price." But there is a *political* reason to do so: It allows the government to pretend the Program entails politically palatable "negotiation" and mutually agreeable "fair" prices (as opposed to top-down, innovation-crippling mandates). And it ensures that BMS "could disclaim" those falsehoods "only at the price of evident hypocrisy." App.84a n.14 (Hardiman, J., dissenting) (quoting *AOSI*, 570 U.S. at 219); *see Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 576 (1995) (freedom of speech "'would be empty'" if the government could "'require speakers to affirm in one breath that which they deny in the next'").

The proof is in the pudding. As Judge Hardiman documented, President Biden repeatedly relied on signed IRA "agreements" to assert that manufacturers had voluntarily "'com[e] to the negotiating table to lower prices'" so that "'we can give seniors the best possible deal.'" App.82a-83a. The First Amendment, however, prohibits any scheme forcing the regulated to carry political water for their regulators.

C. The Program is not a "voluntary exchange" free from constitutional scrutiny.

Despite its flagrant Fifth and First Amendment defects, the IRA survived review in the Third Circuit—but not because the court read the statute differently, nor based on a serious disagreement with BMS on the substance of takings or compelled-speech doctrine. Instead, it immunized the Program from constitutional scrutiny based on its view that the Program is part of a "voluntary exchange" between BMS and the government. App.19a. That reasoning is dangerously flawed.

1. The majority below did not dispute that, without the supposed "option" to abandon Medicare and Medicaid, the Program would be unconstitutional. App.20a. Instead, it focused on one feature of the excise tax: its "suspen[sion]" on days when a manufacturer is not a party to a Medicare or Medicaid reimbursement agreement. 26 U.S.C. § 5000D(c). That provision, the majority reasoned, converts the *entire Program* into a "voluntary exchange." App.19a. In the majority's view, BMS had a *bona fide* choice, because rather than surrender units of *one* product at CMS's cut-rate price, it could withdraw *all* of its products from half of the U.S. pharmaceutical market. App.20a-23a. In short, even if the IRA would otherwise violate the Constitution, Congress could secure *the same result* just by providing an financially ruinous alternative. App.16a.

Aa Judge Hardiman explained, the imagined "escape hatch" does not exist even as a legal fiction: A manufacturer could *not* have abandoned Medicare and Medicaid in time to "suspend" the tax before the Program compelled it to "agree." App.54a-55a. As drafted by Congress, the IRA delays the effectiveness of a

manufacturer's termination of its federal reimbursement agreements by between 11 and 23 months. *Supra* at 9. To avoid forced sales of Eliquis, BMS thus would have had to begin the process *before* the IRA became law. App.54a-55a. And while CMS purported to fix that issue in guidance, the *agency's* atextual rescue mission is unlawful (as Judge Hardiman detailed) and only confirms that *Congress* did not make an offer manufacturers could willingly refuse. App.58a-71a.

More fundamentally, that purported option—even if available *in theory*—is utterly illusory *in fact*. Today, government programs account for nearly half of all domestic spending on prescription drugs. Withdrawing wholesale from Medicare and Medicaid would therefore cripple a manufacturer's domestic business and leave millions of Americans without access to their prescription medications. In a sworn declaration, BMS explained that this Hobson's choice does not present a feasible alternative—and the government has never claimed otherwise. App.203a-215a. Yet the Third Circuit dismissed this existential threat to a manufacturer's business as a routine "[e]conomic factor[]" that "may … strong[ly] influence" its choice "to do business with the government." App.23a. Two related lines of precedent, one addressing congressional power and the other constitutional rights, dictate otherwise.

2. Start with Congress's power. Because Spending Clause legislation like the IRA "rests not on" Congress's "sovereign authority to enact binding laws, but on" a recipient's "consent" to the deal, the law must present a truly "'voluntar[y]'" exchange. *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022). That is true whether a private party or State is on the other side. *Id.*; *see also, e.g.*, *Butler*, 297 U.S. at 70-71.

As a result, conditions on receipt of government funds are unconstitutional when "persuasion gives way to coercion." *NFIB*, 567 U.S. at 585 (Roberts, C.J.). In *NFIB*, for instance, this Court held that Congress could not force a State to expand Medicaid by "threatening to withhold all of [its] Medicaid grants." *Id.* at 575; *accord id.* at 681 (joint dissent). Three features rendered that condition too coercive. *First*, Congress "threaten[ed] to withhold" "*existing* Medicaid funding" from States that did not accept "*new* conditions," which showed that it was using its spending power "as a means of pressuring" recipients. *Id.* at 575, 579-581 (Roberts, C.J.) (emphases added). *Second*, the pressure was unconstitutionally coercive due to its size: It threatened over 10% of a State's budget. *Id.* at 581-82. *Third*, Congress upset reliance interests developed over "many decades" by imposing "postacceptance … retroactive conditions" that States "could hardly [have] anticipate[d]." *Id.* at 581, 583-84 (cleaned up).

It is hard to imagine a closer analogy to *NFIB* than the Program. As in *NFIB*, manufacturers face the loss of existing funding streams if they do not bow to the Program's new demands. As in *NFIB,* those preexisting funding streams are economically critical, leaving only the illusion of choice. And as in *NFIB,* the new "conditions" work a major revision to the original bargain. Medicare Part D long forbade government interference in negotiations between manufacturers and plan sponsors—a feature its proponents called a "fundamental protection" against "price fixing by the CMS bureaucracy." 149 Cong. Rec. 31043-44. The Program breaks that promise. All told, the IRA coerces manufacturers to participate in the Program just as the Affordable Care Act coerced States to expand Medicaid.

The majority below dismissed all this as irrelevant to cases where the government "contracts with private parties." App.27a. In other words, although Congress cannot use a coercive funding condition to "trampl[e] on a State's prerogatives under the Tenth Amendment," the majority saw *no check* on Congress's ability to abuse that same spending authority to trample on a private party's rights under the Fifth and First Amendments. App.26a. But this Court has emphasized that the same "principles" govern funding offers to "state and private recipients," *Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 374 n.5 (2025), and that private recipients, too, must be able to "'voluntarily'" accept, *Cummings*, 596 U.S. at 219.

3. The Third Circuit's analysis is likewise at odds with "the unconstitutional conditions doctrine," the overarching rule "that vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). By holding hostage manufacturers' access to half of the market, the IRA compels them to both hand over their property and parrot a political narrative.

a. When it comes to the Takings Clause, this doctrine forbids the government from leveraging its array of benefits to "exact private property without paying for it." *Sheetz v. Cnty. of El Dorado*, 601 U.S. 267, 275 (2024). To that end, the government may tie a benefit to the forfeiture of a property right only if the condition has an "'essential nexus'" to the benefit and is "'rough[ly] proportional[]'" to it. *Id.* at 275-76. Neither condition is met by the Program's attempt to leverage *all of a manufacturer's sales* to Medicare and Medicaid to coerce its submission to the seizure of *one* product.

To provide an "essential nexus," *id.*, the Program could have conditioned Medicare coverage for Eliquis on BMS's agreement to a mutually acceptable price for *that* medicine. Instead, if BMS does not agree, it must either pay impossibly high penalties or "remove *every* drug that it produces from Medicare coverage, not just the drug that is the subject of the negotiation." *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 500 (5th Cir. 2024) (*NICA*). In other words, the IRA leverages the government's legislated monopsony over *other* products to "exact" *one* product "without paying for it." *Sheetz*, 601 U.S. at 275. That kind of cross-collateralized condition is akin to "'extortion.'" *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837-38 (1987).

Nor is the threat to strip reimbursement from all of a manufacturer's products "roughly proportional" to the demand to transfer a single medicine at a discount. Being barred from selling to half the national market for prescription drugs would crush a manufacturer (and its patients), which is why the Program's demands cannot be rationally resisted. That "basic economical rationality" ensures that "an agreement" is "all but certain." *NICA*, 116 F.4th at 500.

The Third Circuit nevertheless refused "to subject the Program to scrutiny" on the theory that this analysis applies "only" to "land-use permits." App.32a-33a. But this "two-part test" is just one application of "the unconstitutional conditions doctrine," not a quirk of land-use law. *Sheetz*, 601 U.S. at 275; *see id.* at 279. And the implications of the Third Circuit's theory are startling: The government can now extort property concessions at will—no matter how disproportionate the "condition"—provided it does not involve "land-use permits." App.32a.

That cannot be correct. Perhaps recognizing as much, the majority added a cursory footnote asserting that the Program "would withstand scrutiny" under this framework. App.33a n.21. But that only makes its decision *more* dangerous: If the threat of denying "Medicare reimbursements for numerous products" is somehow "proportional to" the command to turn over a single medicine at a paltry price, then not even the realm of land-use permitting is safe. *Id.*

b. The problem is even more obvious for the IRA's speech mandate. This Court has "broadly rejected the validity of limitations on First Amendment rights as a condition to the receipt of a government benefit." *Elrod v. Burns*, 427 U.S. 347, 359 (1976) (plurality). In particular, requiring "recipients to adopt—as their own—the Government's view on an issue" as a condition of funding "by its very nature affects 'protected conduct outside the scope of the federally funded program.'" *AOSI*, 570 U.S. at 218. Yet that condition is central to the Program's operation: manufacturers must publicly "profess a specific belief"—namely, that they have "negotiated" and "agree" the government's prices are the "maximum fair" ones—or lose a stream of funds. *Id.*

While *AOSI* should have made this an easy case, the Third Circuit held that this "speech compulsion does not reach outside the contours of the program" because the agreements "effectuate the drug price negotiation process." App.44a-46a. But this Court has rejected the argument that constitutionality turns on a condition's relevance "to the objectives of the program," because the "definition of a particular program can always be manipulated to subsume the challenged condition." *AOSI*, 570 U.S. at 214-15.

Rather, by "requiring recipients to profess a specific belief," the IRA inherently "goes beyond defining the limits of the federally funded program to defining the recipient." *Id.* at 218. The opinion below proves the point. In the Third Circuit's view, "[a]ny expressive content in the contracts" would be constitutional merely because "it effectuates the government's policy choices." App.47a. That is not the law. Again, Congress had constitutional means of limiting Medicare expenditures on prescription drugs. But this regime of pretend "negotiations" and "agreements"—backed by economic exile for any manufacturer that does not play along—is necessary only for extorting manufacturers' speech. Congress's choice to design the Program this way is the First Amendment *problem*, not its *solution*.

* * *

In short, after (mis)characterizing the Program as a routine funding condition, the Third Circuit was unwilling to accept the consequences of that framing. Instead, it blessed all government efforts to leverage the vast power of the federal purse to coerce the surrender of individual rights. That holding cannot stand.

II. THIS CASE IS EXCEPTIONALLY IMPORTANT.

This case is one of the most significant constitutional challenges to major legislation in decades. Legally, it raises fundamental questions at the heart of our constitutional order. Factually, the Program's disruption of the free market—and the precedent it sets—is of utmost "importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." App.90a (Hardiman, J., dissenting).

A. The decision below has far-reaching legal ramifications.

The Program unambiguously forces transfers of a manufacturer's private property—and also compels speech along the way. But the Third Circuit brushed aside these flagrant constitutional flaws by reimagining the Program as a "voluntary" one that manufacturers can "choose whether to participate in." App.13a, 18a. To the majority, it did not matter that no manufacturer could "voluntarily" abandon half of the American market.

In short, the Third Circuit now permits Congress to *require*—on pain of massive penalties—precisely what the Constitution *prohibits*, provided it tacks on an utterly infeasible "escape hatch" in the form of a funding condition. App.54a (Hardiman, J., dissenting). Even if that condition is coercive, simply reciting it immunizes the statute from constitutional scrutiny.

No constitutional right is safe under such a regime. To the contrary, Congress has every incentive to accept the majority's blank check. When a nominal funding "condition" is in reality a "gun to the head," "economic dragooning" is costless for Congress—the target will always "acquiesce." *NFIB*, 567 U.S. at 581-82. And given Congress's unique sovereign power to tax and spend, there are few constraints on its ability to "leverage funding in this way." App.43a.

Nor is there is any reason to expect Congress or the Executive to limit themselves to wielding this novel power against pharmaceutical companies. After all, Congress can accrue monopsony power in *any* area of the economy by enacting spending programs. And once it has, it is apparently free to extort property, compel

speech, or infringe other rights enjoyed by any individual or business that finds itself operating in a federally dominated market. All of that, under the decision below, would be "permissibl[e]." *Id.*

Given the existential threat that federal debarment would pose in many sectors, the potential for abuse is endless. For example, the government funds the majority of research-and-development spending at American universities. Nat'l. Sci. Found., NSF 25-313, *Higher Education R&D Expenditures Increased 11.2%, Exceeded $108 Billion in FY 2023* (Nov. 25, 2024), https://perma.cc/W3JC-4XZX. Under the Third Circuit's logic, Congress can leverage that power to extort valuable discoveries or infringe on First Amendment "academic freedom." *Keyishian v. Bd. of Regents of Univ. of N.Y.*, 385 U.S. 589, 603 (1967).

Many technology companies, especially those specialized in military innovation, likewise rely on government contracts for a large percentage of their revenues. I. Kolchev, *How Much Do Government Contracts Contribute to Defense Suppliers' Revenue Share?* TenderAlpha (Nov. 7, 2024), https://perma.cc/C89S-2LY2. If Congress decides it no longer wishes to pay for their cutting-edge products, it could mandate "access" to valuable weapon systems—and, in the Third Circuit, evade constitutional scrutiny by adding an "option" for a contractor to instead place itself on a Pentagon blacklist. Other technology firms could be compelled to muzzle criticism of the government, or else face the termination of lucrative federal investments in artificial intelligence. *See Murthy v. Missouri*, 603 U.S. 43, 51-53 (2024).

Closer to this case, Medicare and Medicaid account for over 40% of hospital spending. Z. Levinson et al., *Key Facts About Hospitals*, KFF (Feb. 19, 2025), https://perma.cc/4U96-B4Y3. The government could coerce the surrender of equipment or building space—and, in the Third Circuit, a hospital's nominal "choice [not] to do business with the government" would defeat a Takings claim. App.23a.

It is not difficult to imagine other troubling scenarios. Despite the unconstitutionality of state-sponsored racial discrimination, the government could condition access to federal contracts or licenses on discriminatory hiring practices. *SFFA v. President & Fellows of Harvard Coll.*, 600 U.S. 181, 205-06 (2023); *see, e.g.*, *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13 (D.C. Cir. 2001). Despite the unconstitutionality of compelled political speech, the government could require contractors "to pledge allegiance" to a policy or officeholder. *AOSI*, 570 U.S. at 220. Congress could even require retirees dependent on Social Security benefits to rent out their basements to ameliorate a housing crisis, provided it offered the alternative of opting out from future checks. All of that would be "voluntary"—and thus, immune from review—in the Third Circuit.

In short, the decision below refuses to recognize *any limits* on congressional attempts to extort away rights or otherwise circumvent limits on federal authority. It thus violates the bedrock principle that, under our Constitution, "what cannot be done directly cannot be done indirectly." *SFFA*, 600 U.S. at 230 (cleaned up). And it arms the political branches with a potent weapon for coercing businesses and individuals into surrendering their constitutional liberties.

This Court should grant review and reaffirm that the power of the federal treasury cannot be used to extort private property or speech. Our "'Constitution deals with substance, not shadows,'" and is not so easily circumvented. *Id.*

B. The Program will inflict serious harm.

America's pharmaceutical companies, including BMS, are working to develop thousands of innovative new lifesaving treatments. That research-and-development process requires massive investments in time, money, and experimentation. On average, an estimated $2.5 billion in revenue is required to support the invention of one new drug product. P. Dubois et al., *Market Size and Pharmaceutical Innovation*, 46 RAND J. of Econ. 844, 861 (2015).

But despite these huge investments, there is no guarantee of success. The vast majority of new projects do not even result in testable products. Indeed, only a fraction of 1% of the projects that enter preclinical testing secure FDA approval—and only a fraction of *those* recoup their investments. J. Vernon & J. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 9-12 (2008).

The ability to bring groundbreaking therapies to market thus depends on the returns generated by just a handful of successful products. But rather than encouraging the risky investments necessary to develop new life-saving treatments, the IRA penalizes those efforts: It targets *precisely* those rare breakthroughs that not only reach but revolutionize the market. *See supra* at 6.

With the IRA's regime of forced sales about to take full effect, BMS and other manufacturers must operate on the expectation that their most successful future products will soon be seized by the government at below-market prices. The consequences are already rippling across the industry. One company suspended development of a treatment for a rare eye disease that would have fallen within the IRA's crosshairs; another announced that certain blood cancer research "no longer met [the] threshold for continued investment." J. Grogan, *The Inflation Reduction Act is Already Killing Potential Cures*, Wall St. J. (Nov. 3, 2022)

Nor are these isolated examples. The Program's enactment has been followed by an estimated 38.4% decline in industry-sponsored trials involving approved medicines—a crucial area of study that often reveals additional therapeutic uses for drugs already on the market. H. Zhang et al., *The Inflation Reduction Act and Drug Development: Potential Early Signals of Impact on Post-Approval Clinical Trials*, 59 Therapeutic Innovation & Reg. Sci. 781, 784 (2025). For instance, by disincentivizing this research, the IRA threatens the development of non-opioid pain relievers. W. Smith & R. Popovian, *The Left-Hand Doesn't Know What the Right-Hand is Doing: The Federal Government and Opioids* 9-11, Pioneer Inst. (Apr. 2024), https://perma.cc/ZLJ9-48YG. Meanwhile, one State has already used the CMS-dictated "maximum fair price" to benchmark *market-wide* price caps, extending the IRA's reach even beyond Medicare. S. Wilson, *Colorado Becomes First State to Cap Price of Prescription Drug*, Colorado Newsline (Oct. 7, 2025), https://perma.cc/M232-ACZ4 (noting state regulators' "reli[ance] on Medicare's 'maximum fair price'").

This pattern will only grow more pronounced as the IRA's grip extends to an ever-growing list of groundbreaking products. And that is the *best-case* scenario: If the government can seize what it wants using sky-high penalties and coercive conditions, it will not stop with the current Program. Why use this tactic to seize a mere 20 new products annually, rather than *all* medications? Expansion efforts are already underway. *Klobuchar, Welch, Colleagues Introduce Legislation to Boost Medicare Prescription Drug Price Negotiation, Lower Costs for Americans*, Off. of Senator Amy Klobuchar (Apr. 24, 2023), https://perma.cc/2Q6K-8DAM.

Notably, too, while President Biden signed the IRA into law, the Trump Administration has not only continued to defend the Program's constitutionality, but proposed to extend the Program in new and damaging ways. CMS, *Draft Guidance on the Medicare Drug Price Negotiation Program* 13 (May 12, 2025), https://perma.cc/BVZ2-9EEC (proposing to treat as a single "drug" for IRA purposes co-formulations with different clinically important ingredients). The problems here are not going away any time soon.

III. THIS CASE IS AN IDEAL VEHICLE.

Shortly after Congress enacted the IRA, nearly all of the Nation's leading pharmaceutical manufacturers with selected drugs and trade groups brought constitutional challenges. *See Janssen Pharms. Inc. v. HHS*, 155 F.4th 245 (3d. Cir. 2025); *Novartis Pharms. Corp. v. HHS*, 155 F.4th 223 (3d. Cir. 2025); *Novo Nordisk Inc. v. HHS*, 154 F.4th 105 (3d Cir. 2025); *Boehringer Ingelheim Pharms., Inc. v. HHS*, 150 F.4th 76 (2d Cir. 2025); *Dayton Area Chamber of Com. v. Kennedy*, 147

F.4th 626 (6th Cir. 2025); *AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116 (3d Cir. 2025); *NICA*, 116 F.4th 488; *Teva Pharms. USA, Inc. v. Kennedy*, No. 25-cv-113, 2025 WL 3240267 (D.D.C. Nov. 20, 2025), *appeal filed*, No. 25-5425 (D.C. Cir.); *Merck & Co., Inc. v. Kennedy*, No. 23-cv-1615 (D.D.C.).

Given the Program's profound consequences for the industry and consumers alike, that is unsurprising. But this case is the ideal vehicle for resolving the central constitutional concerns raised by the Program. As the Third Circuit observed, "[th]e parties have stipulated that no material facts are in dispute," and this case presents pure "questions of law." App.17a-18a. This Court can therefore evaluate the legal merits of BMS's constitutional claims without determining the Program's effects on BMS (such as the infeasibility of paying the IRA's tax penalties or voluntarily abandoning both Medicare and Medicaid). And unlike other challenges to the Program, this case does not involve disputes over standing or other threshold, non-merits issues. *See Novartis*, 155 F.4th at 231-34; *Dayton Area Chamber of Com.*, 147 F.4th at 629; *AstraZeneca*, 137 F.4th 116; *NICA*, 116 F.4th at 494.

Most importantly, BMS's Fifth and First Amendment claims cut to the IRA's unconstitutional core: Its whole purpose is to compel manufacturers to transfer private property to third parties without just compensation under the pretense of "voluntary" "agreements" expressing a political message. Other challenges to the Program, by contrast, concern defects in its implementation—for example, whether Congress gave CMS excessive price-setting latitude. *See, e.g.*, No. 25-348 Pet. As explained by Judge Hardiman, however, this suit targets the Program's most fundamental errors.

This Court may wish to review the full suite of petitions in IRA challenges as it weighs which to grant. Provided the Court remains sensitive to the January 2026 start of "maximum fair price" transfers, BMS does not object to that approach. Either way, this case represents the most compelling vehicle.

CONCLUSION

This Court should grant the petition.

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