

Nos. 25-749 and 25-751

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IN THE  
**Supreme Court of the United States**

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JANSSEN PHARMACEUTICALS, INC.,

*Petitioner,*

*v.*

ROBERT F. KENNEDY, SECRETARY OF  
HEALTH AND HUMAN SERVICES, *et al.*,

*Respondents.*

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BRISTOL MYERS SQUIBB COMPANY,

*Petitioner,*

*v.*

ROBERT F. KENNEDY, SECRETARY OF  
HEALTH AND HUMAN SERVICES, *et al.*,

*Respondents.*

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**On Petitions For Writ Of Certiorari To The  
United States Court Of Appeals For The Third Circuit**

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**BRIEF OF ATLANTIC LEGAL FOUNDATION  
AS *AMICUS CURIAE*  
IN SUPPORT OF PETITIONERS**

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**TABLE OF CONTENTS**

	<b>Page</b>
TABLE OF AUTHORITIES.....	ii
INTEREST OF THE <i>AMICUS CURIAE</i> .....	1
SUMMARY OF ARGUMENT .....	3
ARGUMENT.....	6
A. The unconstitutional conditions doctrine invalidates the Drug Price Negotiation Program .....	6
1. The Court repeatedly has held that the government cannot impose conditions that are unconstitutional in return for receiving a governmental benefit.....	8
2. “Consent” is irrelevant to whether government-imposed conditions are constitutional.....	9
3. The doctrine is not limited to land-use permitting.....	13
B. The public interest in fostering new drug R&D compels review.....	18
CONCLUSION.....	21

## TABLE OF AUTHORITIES

	<b>Page(s)</b>
<b>Cases</b>	
<i>Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.,</i> 570 U.S. 205 (2013) .....	14, 17
<i>Dolan v. City of Tigard,</i> 512 U.S. 374 (1994) .....	14-16
<i>Elrod v. Burns,</i> 427 U.S. 347 (1976) .....	14, 15
<i>Frost Trucking Co. v. R.R. Comm'n of Cal.,</i> 271 U.S. 583 (1926) .....	13
<i>Koontz v. St. Johns River Water Mgmt. Dist.,</i> 570 U.S. 595 (2013) .....	8, 9, 13-15
<i>Koslow v. Pennsylvania,</i> 302 F.3d 161 (3d Cir. 2002).....	13
<i>Nollan [v. Cal. Coastal Comm'n,</i> 483 U.S. 825 (1987)] .....	14-16
<i>Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC,</i> 584 U.S. 325 (2018) .....	8
<i>Perry v. Sindermann,</i> 408 U.S. 593 (1972) .....	8, 14

*Regan v. Taxation With Representation of Wash.,*  
461 U. S. 540 (1983) ..... 14

*Sheetz v. City and Cnty. of El Dorado, Cal.,*  
601 U.S. 267 (2024) ..... 14, 15

### **Statutes**

42 U.S.C. § 1320f *et seq.* ..... 1

42 U.S.C. § 1320f-1 ..... 2

42 U.S.C. § 1320f-2 ..... 2

### **Other Authorities**

CMS Press Release, HHS Announces 15 Additional  
Drugs Selected for Medicare Drug Price  
Negotiations in Continued Effort to Lower  
Prescription Drug Costs for Seniors (Jan. 17,  
2025) ..... 17

Data.CMS.gov, <https://tinyurl.com/yrj9kyak> (last  
visited Jan. 9, 2026) ..... 7

FDA, The Drug Development Process ..... 20

Kathleen M. Sullivan, *Unconstitutional Conditions*,  
102 Harv. L. Rev. 1413 (1989) ..... 8, 9

Kay L. Levine et al., *Protecting State Constitutional  
Rights from Unconstitutional Conditions*, 56 U.C.  
Davis L. Rev. 247 (2022) ..... 9, 12

Louis W. Fisher, <i>Contracting Around the Constitution: An Anticommodificationist Perspective On Unconstitutional Conditions</i> , 21 U. Pa. J. Const. L. 1167 (2019) .....	11, 13
Medicaid.gov, <a href="https://tinyurl.com/4krstnyb">https://tinyurl.com/4krstnyb</a> (last visited Jan. 9, 2026) .....	7
Philip A. Hamburger, <i>Unconstitutional Conditions: The Irrelevance of Consent</i> , 98 Va. L. Rev. 479 (2012) .....	9-12
PhRMA, Research & Development Policy Framework .....	19-20
Randy J. Kozel, <i>Leverage</i> , 62 B.C. L. Rev. 109, 124 (2021) .....	13
Richard A. Epstein, <i>Confiscation by Consent—The warped economics of price regulation for pharmaceuticals under the Inflation Reduction Act</i> , 30 Texas Rev. L. & Pol. (forthcoming) .....	11, 13
Ryan C. Williams, <i>Unconstitutional Conditions and the Constitutional Text</i> , 172 U. Pa. L. Rev. 747, 800 (2024) .....	12
White House, Interested Parties Memo: President Biden Takes On Big Pharma and Is Lowering Prescription Drug Prices (Feb. 1, 2024).....	18

## INTEREST OF THE *AMICUS CURIAE*<sup>1</sup>

Established in 1977, the Atlantic Legal Foundation (ALF) is a national, nonprofit, nonpartisan, public interest law firm. ALF’s mission is to advance the rule of law and civil justice by advocating for individual liberty, free enterprise, property rights, limited and responsible government, sound science in judicial and regulatory proceedings, and effective education, including parental rights and school choice. With the benefit of guidance from the distinguished legal scholars, corporate legal officers, private practitioners, business executives, and prominent scientists who serve on its Board of Directors and Advisory Council, ALF pursues its mission by participating as *amicus curiae* in carefully selected appeals before the Supreme Court, federal courts of appeals, and state supreme courts. *See atlanticlegal.org.*

\* \* \*

Petitioners Janssen Pharmaceuticals, Inc. and Bristol Myers Squibb filed these actions in New Jersey federal district court to challenge the constitutionality of the misleadingly named Drug Price Negotiation Program (“the Program”), 42 U.S.C. § 1320f *et seq.*, enacted as part of the Inflation Reduction Act of 2022.

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<sup>1</sup> Petitioners’ and Respondents’ counsel were provided timely notice of this brief in accordance with Supreme Court Rule 37.2. No counsel for a party authored this brief in whole or part, and no party, counsel for a party, or person other than the *amicus curiae* and its counsel made a monetary contribution intended to fund preparation or submission of this brief.

The petitioners are the innovative companies that developed Xarelto and Eliquis, respectively—blood clot-prevention medications that the Centers for Medicare & Medicaid Services (CMS) has selected as “negotiation eligible drugs” that can be sold within the enormous Medicare/Medicaid system *only* at a sharply discounted, government-dictated, “maximum fair price.” *See id.* §§ 1320f-1 & 1320f-2.

The Janssen and BMS certiorari petitions (Nos. 25-749 & 25-751), which seek review of the Third Circuit’s 2-to-1 opinion, squarely present the question of whether the Program is constitutional—specifically, whether it violates the Fifth Amendment’s Takings/Just Compensation Clause, or the First Amendment’s Free Speech Clause, or both.

Challenging the constitutionality of the Program’s extraordinarily oppressive, coerced-sales regime—the supposedly negotiated, so-called, “maximum fair price” that pharmaceutical manufacturers can charge within Medicare/Medicaid for their most innovative, widely prescribed, brand-name products—squarely aligns with ALF’s free-enterprise and limited-government missions.

These cases also implicate ALF’s long-standing mission of advocating for sound science in judicial and regulatory proceedings. The discovery and development of new life-saving drugs is an arduous, extraordinarily expensive, multi-phase scientific process. New drug R&D requires a continuous infusion of funds derived from sales of the tiny fraction

of potential products that survive extensive preclinical laboratory research, human clinical testing, and Food and Drug Administration (FDA) review. If the Drug Price Negotiation Program is allowed to stand, the stream of funds for new drug R&D will be severely disrupted and the public interest will be adversely affected.

ALF urges the Court to grant certiorari in both of these cases and reverse the Third Circuit's decision.

#### **SUMMARY OF ARGUMENT**

1. The Third Circuit majority opinion is predicated on the fiction that participation in the Program is voluntary. *See, e.g.*, Pet. App. 18a (“If the Companies dislike the prices the government is willing to pay, they are free to stop doing business with the government. So the Companies’ participation in the Program is voluntary, and there is no physical taking.”); *Id.* at 42a (“The Companies’ First Amendment challenge also fails because the Program only ‘compels’ them to speak if they choose to participate. As with their takings claims, the economic hardship that would result from declining to participate in the Program does not amount to unconstitutional compulsion.”).<sup>2</sup>

But as Circuit Judge Hardiman explained in his dissent, “[a]lthough participation in Medicare and

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<sup>2</sup> All references in this brief to Pet. App. are to the Appendix accompanying the BMS certiorari petition.

Medicaid is voluntary, participation in the Program is not. . . . The Act’s threat of excise taxes and civil penalties looms like a sword of Damocles, creating a de facto mandate to participate.” Pet. App. 56a-57a (Hardiman, J., dissenting). As Janssen’s petition emphasizes, “the Program relies on extraordinary economic coercion to secure compliance.” Janssen Pet. at 30; *see also* BMS Pet. at 1 (Congress “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.”).

Relying on the mistaken notion that participation in the Program is voluntary, the majority opinion circumvents the merits of petitioners’ constitutional claims.

Those claims warrant this Court’s immediate consideration regardless of whether participation in the program is voluntary. The “unconstitutional conditions doctrine” renders the Program invalid because it compels participants to forgo fundamental constitutional rights. Under this well-established doctrine, which the Court has applied in many contexts, pharmaceutical companies cannot be compelled to relinquish their constitutional rights as a condition for receiving a governmental benefit—here, the ability to sell their products within the enormous, financially crucial, Medicare/Medicaid system. Even if, contrary to reality, participation in the Program were voluntary, it still would be invalid: By depriving pharmaceutical companies of their rights

to just compensation and freedom of speech, the Program imposes unconstitutional conditions in return for a governmental benefit.

Although the Court cannot second guess Congress' wisdom in enacting the Program, it can and should declare the Program unconstitutional because of the way that it clashes with pharmaceutical companies' constitutional rights.

2. The Court's immediate review is needed also because there is a vital public interest in the question of whether the Program is constitutional. The public interest is not limited to whether government-selected brand-name drugs will be sold at lower prices within the Medicare/Medicaid system. Instead, the discovery, development, and availability of new life-saving drugs also is at stake. New drug R&D is a high-financial-risk, scientific and regulatory process. The Program's industry-crippling coerced-sales regime seriously undermines pharmaceutical companies' ability to engage in this high-stakes innovative activity. Because new drug R&D directly and indisputably benefits the public, the Court should take the public interest into account in deciding whether to grant certiorari and review petitioners' constitutional claims.

## ARGUMENT

### A. The unconstitutional conditions doctrine invalidates the Drug Price Negotiation Program

Petitioners persuasively argue that their constitutional rights are violated by the Program's built-in mandates—*e.g.*, the Program's requirement that a pharmaceutical manufacturer either participate in “negotiations” to reach “agreement” on a “maximum fair price” for its government-selected brand-name product or incur brutal if not fatal financial penalties. *See* Janssen Pet. at 15-20, 23-25; BMS Pet. at 14-20. Judge Hardiman's dissent agrees that the Program imposes unconstitutional conditions. *See, e.g.*, Pet. App. 56a (the Program “imposes a clear physical taking by forcing the Companies to turn over physical doses of Eliquis and Xarelto to Medicare beneficiaries at certain prices”); *Id.* at 77a-79a (“[T]he Companies are compelled to speak by the threat of ‘a direct punishment’: an enterprise crippling tax . . . [I]t forces the Companies to convey the government’s message about the Program—that it is a voluntary ‘negotiation that resulted in an agreement on a ‘maximum fair price.’”).

As a practical matter, a pharmaceutical company's participation in the Program is *not* voluntary. If a company fails to participate in the manner prescribed by the Inflation Reduction Act, the Program imposes a “confiscatory tax” that “Congress knew that no manufacturer would ever be able to pay.” Pet. App.

54a (Hardiman, J., dissenting). To avoid this punitive tax—which could rapidly grow to many billions of dollars, *see Janssen Pet. at 3, BMS Pet. at 2*—a non-compliant company would have to withdraw *all* of its products from Medicare/Medicaid. *See Pet. App. 16a*. Even assuming that it were timely, *Janssen Pet. at 7-8, BMS Pet. at 13*, exercising this supposed “opt-out option,” *Pet. App. 20a*, would be financial suicide that no rational, publicly held company would commit: As of December 2025 there were 69.4 million individuals enrolled in Medicare,<sup>3</sup> and as of September 2025, 69.8 million individuals in Medicaid.<sup>4</sup> This represents half of the U.S. market for prescription drugs. *See Janssen Pet. at 1; BMS Pet. at 3*. “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.” *Id. at 22*.

Even if the Program’s mandates somehow are viewed merely as conditions for “voluntary” participation in the Program—and by extension, for selling products within the Medicare/Medicaid system, *see Janssen Pet. at 1, 3, 6, 7, 10; BMS Pet. at 2, 7, 21-22*—they are *unconstitutional* conditions, and therefore render the Program invalid.

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<sup>3</sup> *See Data.CMS.gov, https://tinyurl.com/yrj9kyak* (last visited Jan. 9, 2026).

<sup>4</sup> *See Medicaid.gov, https://tinyurl.com/4krstnyb* (last visited Jan. 9, 2026).

**1. The Court repeatedly has held that the government cannot impose conditions that are unconstitutional in return for receiving a governmental benefit**

The unconstitutional conditions doctrine reflects an “overarching principle . . . 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). “[R]egardless of whether the government ultimately succeeds in pressuring someone into forfeiting a constitutional right, the unconstitutional conditions doctrine forbids burdening the Constitution’s enumerated rights by coercively withholding benefits from those who exercise them.” *Id.* at 606; *see also Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 584 U.S. 325, 342 n.4 (2018) (“The doctrine prevents the Government from using conditions ‘to produce a result which it could not command directly.’”) (quoting *Perry v. Sindermann*, 408 U.S. 593, 597 (1972)).

Even though “[v]irtually all of [the Supreme Court’s] unconstitutional conditions cases involve a gratuitous governmental benefit of some kind . . . [the Court has] repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights.” *Koontz*, 570 U.S. at 608; *see* Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 Harv. L. Rev. 1413, 1415 (1989) (“The doctrine of unconstitutional conditions holds that the government

may not grant a benefit on the condition that the beneficiary surrender a constitutional right, even if the government may withhold the benefit altogether.”).

In short, the doctrine “limits the ability of governments to force individuals to choose between retaining a right and enjoying a government benefit.” Kay L. Levine et al., *Protecting State Constitutional Rights from Unconstitutional Conditions*, 56 U.C. Davis L. Rev. 247, 249-50 (2022). It thus “reflects the triumph of the view that government may not do indirectly what it may not do directly over the view that the greater power to deny a benefit includes the lesser power to impose a condition on its receipt.” Sullivan, *supra*, at 1415.

## **2. “Consent” is irrelevant to whether government-imposed conditions are constitutional**

The unconstitutional conditions doctrine applies where, as here, companies must relinquish their constitutional rights as a condition for receiving a governmental benefit (e.g., selling their products within the Medicare/Medicaid system). See *Koontz*, 570 U.S. at 606. “Consent” to such conditions is irrelevant; it does not magically transform unconstitutional conditions into conditions that are constitutional. See Philip A. Hamburger, *Unconstitutional Conditions: The Irrelevance of Consent*, 98 Va. L. Rev. 479 (2012). In other words, even if petitioners’ participation in the Program

somehow were voluntary, the Program still would be invalid if, as petitioners contend, it requires them to forgo their constitutional rights.

Professor Hamburger's often-cited article on *The Irrelevance of Consent* explains that "consent is irrelevant for conditions that go beyond the government's power." Hamburger, *supra*, at 480. He asks:

Can consent justify the government in exceeding its power?

The key is to distinguish between the role of consent within and beyond the government's constitutional authority. . . . Undoubtedly the government can use consent within its authority, as defined by its various powers; but where these powers are limited, either in themselves or through the [Constitution's] rights and structures, the question is whether the government can rely on consent to justify going beyond these limits and thus beyond its authority. . . .

The answer can be found in the simple recognition that the Constitution is a law. Being a law and, indeed, a law made by the people, *its limits are not alterable by private or state consent*, but only by the consent of the people. . . . Accordingly, the *government cannot escape its constitutional bounds by getting, let alone*

*purchasing, the consent of any lesser body, whether individuals, private institutions, or states. For such purposes, their consent is irrelevant.*

*Id.* at 483 (emphasis added).

In other words, “waiver or voluntary consent is *never* sufficient to defeat an unconstitutional conditions claim.” Richard A. Epstein, *Confiscation by Consent—The warped economics of price regulation for pharmaceuticals under the Inflation Reduction Act*, 30 Texas Rev. L. & Pol. (forthcoming) (manuscript at 14).<sup>5</sup> “[T]he doctrine of unconstitutional conditions is always tied to the *irrelevance of consent*.” *Id.* (manuscript at 30) (emphasis added). The unconstitutional conditions doctrine thus establishes that the government cannot alter, much less ignore, the unalienable rights confirmed by the Bill of Rights on the theory that an individual or corporation has consented to forgo them in return for receiving a governmental benefit. See Louis W. Fisher, *Contracting Around the Constitution: An Anticommodificationist Perspective On Unconstitutional Conditions*, 21 U. Pa. J. Const. L. 1167, 1181 (2019).

“[T]here is a risk in allowing the government to accomplish indirectly that which it cannot do directly. If a constitutional provision prohibits the government

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<sup>5</sup> Manuscript (posted Apr. 28, 2025) available at <https://tinyurl.com/2sr6x69x>.

from violating a right, why can the government condition a valuable benefit on a person forsaking that right?” Levine, *supra* at 258; *see also* Ryan C. Williams, *Unconstitutional Conditions and the Constitutional Text*, 172 U. Pa. L. Rev. 747, 800 (2024) (“If the government conditions access to a particular benefit on waiver of a nonwaivable right, then the condition cannot be met without violating the Constitution.”).

Legal scholars debate the exact contours of the unconstitutional conditions doctrine. But with the growth of the administrative state,

the threat from unconstitutional conditions [has] become of central importance, for they have become a *means of evading much of the Constitution, including the Bill of Rights*. Only by recognizing this can one begin to understand the peril of casually assuming that the government can purchase its way out of constitutional rights and other limits.

Hamburger, *supra*, at 491 (emphasis added). The unconstitutional conditions doctrine is “charged with safeguarding liberty in the face of government’s ubiquitous programming and extraordinary resources,” and “is necessary to ensure that governments cannot circumvent constitutional imperatives simply by purporting to ask rather than

tell.” Randy J. Kozel, *Leverage*, 62 B.C. L. Rev. 109, 124 (2021).

### **3. The doctrine is not limited to land-use permitting**

a. From an historical perspective, the unconstitutional conditions doctrine goes back at least a century. *See, e.g., Frost Trucking Co. v. R.R. Comm'n of Cal.*, 271 U.S. 583, 598 (1926) (“a state is without power to impose an unconstitutional requirement as a condition for granting a privilege”); *Koslow v. Pennsylvania*, 302 F.3d 161, 173, 174 (3d Cir. 2002) (quoting *Frost*); *see generally* Fisher, *supra*, at 1176-79 (“Unconstitutional Conditions: Current Doctrine and Theories—A Brief Doctrinal History”).

“There are many complexities as to how the doctrine has been applied, but it has appeared among topics governing individual rights such as use of public roads and highways, land use regulation, licensing and permits, labor and employment contracts, tax exemptions, unemployment benefits, welfare benefits, and educational benefits.” Epstein, *supra* (manuscript at 14).

Indeed, “the modern administrative state [has] contributed to the proliferation of unconstitutional conditions problems.” Fisher, *supra*, at 1176. This escalation of governmental power is reflected by this Court’s numerous decisions applying the unconstitutional conditions doctrine in differing contexts. *See Koontz*, 570 U.S. at 608 (“We have said in a variety of contexts that ‘the government may not

deny a benefit to a person because he exercises a constitutional right.”) (quoting *Regan v. Taxation With Representation of Wash.*, 461 U. S. 540, 545 (1983)) (collecting cases).

Unconstitutional conditions cases include takings in violation of the Fifth Amendment. See, e.g., *Sheetz v. City and Cnty. of El Dorado, Cal.*, 601 U.S. 267, 275 (2024) (“Our decisions in *Nollan* [v. Cal. Coastal Comm’n, 483 U.S. 825 (1987)] and *Dolan* [v. City of Tigard, 512 U.S. 374 (1994)] address [the] potential abuse of the permitting process. There, we set out a two-part test modeled on the unconstitutional conditions doctrine.”); *Koontz*, 570 U.S. at 604 (“*Nollan* and *Dolan* involve a special application of this doctrine”) (internal quotation marks omitted).

The unconstitutional conditions doctrine also applies to government-imposed conditions that infringe on freedom of speech. See, e.g., *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.* (“AID”), 570 U.S. 205, 214 (2013) (“[W]e have held that the Government may not deny a benefit to a person on a basis that infringes his constitutionally protected freedom of speech even if he has no entitlement to that benefit.”) (cleaned up); *Elrod v. Burns*, 427 U.S. 347, 358 n.11 (1976) (noting the Court’s “[p]rotection of First Amendment interests” by “invalidation of conditions”); *Perry v. Sindermann*, 408 U.S. at 597 (the government “may not deny a benefit to a person on a basis that infringes his constitutionally protected interests—especially, his interest in freedom of speech”). “In *Perry*, the Court broadly rejected the validity of

limitations on First Amendment rights as a condition to the receipt of a governmental benefit . . . .” *Elrod*, 427 U.S. at 359.

b. The Third Circuit majority opinion erroneously rejects the applicability of the unconstitutional conditions doctrine to petitioners’ takings claims by conflating it with the *Nollan-Dolan* land-use permitting test. Noting that “the realities of land-use permitting have no bearing on Medicare contracts,” the opinion asserts that *Nollan-Dolan* is “a test the Supreme Court has applied only to takings claims involving land-use permits.” Pet. App. 32a-33a. Yet, the opinion readily acknowledges that the *Nollan-Dolan* test is a “special application” of the unconstitutional conditions doctrine. *Id.* at 32a (quoting *Koontz*, 570 U.S. at 604); *see also id.* (the test is “modeled on the unconstitutional conditions doctrine”) (quoting *Sheetz*, 601 U.S. at 275). So contrary to the majority opinion, even if the *Nollan-Dolan* test is inapplicable here, that does not resolve petitioners’ unconstitutional conditions claims.

The majority compounds its error by asserting that “[e]ven if an adaptation of the *Nollan-Dolan* test applied here, the Program would withstand scrutiny.” Pet. App. 33a n.21. According to the opinion, the Program not only has a nexus to Medicare, but also satisfies the proportionality prong of the test: “[T]he Program’s putative taking of property is proportional to the benefit conferred. In exchange for reduced profits from selected drugs, each company is able to

obtain Medicare reimbursements for numerous products that it manufactures.” *Id.*

But insofar as the *Nollan-Dolan* test can be applied to the Drug Price Negotiation Program, the majority’s inverted reasoning does not demonstrate proportionality. Continuing to sell products within the Medicare/Medicaid system by avoiding the Program’s draconian, government-imposed financial penalties for non-compliance, or avoiding being compelled by the government to withdraw all of a company’s products from Medicare/Medicaid, or both, is not a “benefit” for purposes of the *Nollan-Dolan* test. Instead, insofar as the test can be adapted to the Program, (i) the relevant benefit would be petitioners’ ability to continue selling Xarelto and Eliquis within Medicare/Medicaid, and (ii) the government’s *disproportionate* exaction (i.e., taking) of petitioners’ property would be the compulsory sale (i.e., physical transfer) of these products to Medicare/Medicaid beneficiaries at grossly unfair, drastically reduced prices.

c. As to petitioners’ First Amendment claims, the Third Circuit majority held that “the Program does not impose an unconstitutional condition on participation [because] [a]ny ‘compelled speech’ is squarely within the scope of the Program.” Pet. App. 46a.

This is incorrect. Aside from the opinion’s misinterpretation of this Court’s relevant free-speech case law, *see Janssen Pet. at 17-20, BMS Pet. at 26-27*, the majority errs by asserting that the Program does

not “leverage[] funding to regulate speech outside the contours of the program itself.” Pet. App. 46a-47a (quoting *AID*, 570 U.S. at 214-15). Judge Hardiman explained that the Program

orders the Companies to sign a document stating that they “agree” to “negotiate” a “maximum fair price” for their selected drugs. *See* 42 U.S.C. § 1320f-2(a)(1). By doing so, it *forces the Companies to convey the government’s message about the Program*—that it is a voluntary “negotiation” that resulted in an agreement on a “maximum fair price”—to incidentally set prices.

Pet. App. 79a (Hardiman, J., dissenting) (emphasis added).

This message is not limited to the “contours” of the Program. Instead, it is a key feature of a broader, highly politicized narrative intended for general public consumption. *See, e.g.*, CMS Press Release, HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors (Jan. 17, 2025) (“The Biden-Harris Administration continues to make history by announcing the latest round of drugs selected for the Medicare Drug Price Negotiation Program, with the goal of improving access to some of the costliest drugs while saving the American people

billions of dollars.”);<sup>6</sup> White House, Interested Parties Memo: President Biden Takes On Big Pharma and Is Lowering Prescription Drug Prices (Feb. 1, 2024) (“President Biden’s drug price negotiation program finally takes on Big Pharma’s exorbitant price gouging of seniors, allowing Medicare to put money back in the pockets of American families.”).<sup>7</sup>

As Judge Hardiman observed, “the Government’s message [is] about a subject of great political significance and debate: whether the Program is a voluntary negotiation or a forced sale at prices set by CMS.” Pet. App. at 84a (Hardiman, J., dissenting). The Program panders to the public by using the nation’s most research-oriented pharmaceutical companies as political pawns, threatening their financial survival—to the great detriment of the public—unless they convey the government’s false narrative about negotiated agreements and maximum fair prices for prescription drugs. This compelled speech is an unconstitutional condition that renders the Program invalid.

#### **B. The public interest in fostering new drug R&D compels review**

At the political sound bite level, forcing pharmaceutical companies to slash prices for their newest, most innovative, or widely used brand-name

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<sup>6</sup> Available at <https://tinyurl.com/kk7k7tn6>.

<sup>7</sup> Available at <https://tinyurl.com/4hvejezt>.

prescription drugs seems consistent with the public interest. But in reality, such government-compelled, highly discounted sales are *detrimental* to the public interest because they significantly diminish the financial resources that research-oriented companies like petitioners require to reinvest in new drug R&D.

The PhRMA (Pharmaceutical Research and Manufacturers of America) website emphasizes the societal importance of its members' financial investments in new drug R&D: "Over the past decade, PhRMA member companies have invested over \$850 billion in developing new treatments and cures, yielding groundbreaking results." PhRMA, Research & Development Policy Framework.<sup>8</sup> In fact, "[t]he biopharmaceutical sector is the most R&D-intensive industry in the U.S., investing six times more in research than other manufacturing sectors." *Id.*

- "On average, it takes 10-15 years and costs \$2.6 billion to develop one new medicine, including the cost of the many failures."
- "Only 12% of new molecular entities that enter clinical trials eventually receive U.S. Food and Drug Administration (FDA) approval."
- "Approximately 7,000 rare diseases exist today yet only 5% have an available treatment."

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<sup>8</sup> <https://tinyurl.com/2p8ns6dp> (last visited Jan. 10, 2026).

*Id.*

FDA's website provides an overview of the five, universally accepted stages of new drug development in the United States:

- Discovery and Development
- Preclinical Research
- Clinical Research
- FDA Review
- FDA Post-Market Safety Monitoring

FDA, The Drug Development Process.<sup>9</sup> Since human health and safety are at stake, each of these successive and arduous stages of new drug development involves rigorous scientific research or testing and evaluation of intensive evaluation of scientific data.

Given the enormous investment of scientific, financial, and human resources involved in developing a “winner,” pharmaceutical companies need to earn an acceptable return to continue engaging in new drug R&D. If allowed to stand, the Drug Price Negotiation Program will impair or impede the R&D process. This helps to explain why the need for the Court to review the Program’s constitutionality is urgent.

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<sup>9</sup> Available at <https://tinyurl.com/yc6wwcb4> (last visited Jan. 10, 2026).

## CONCLUSION

The Court should grant the petitions for a writ of certiorari.

Respectfully submitted,

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