No. _____

IN THE

Supreme Court of the United States

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Petitioner,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

On Petition for Writ of Certiorari to the U.S. Court of Appeals for the Second Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Inflation Reduction Act of 2022 established the "Medicare Drug Price Negotiation Program," which imposes new, top-down mandates for leading prescription drugs. The Centers for Medicare and Medicaid Services ("CMS") selects drugs for the Program and sets a below-market "maximum fair price" for each selected drug. Manufacturers must then provide Medicare beneficiaries "access" to the drugs at that price and attest that they "negotiate[d]" and "agre[e]" to CMS's terms. Failing to comply subjects manufacturers to severe sanctions—billions of dollars in annual tax penalties or complete exclusion from Medicare and Medicaid, which account for nearly half the U.S. prescription drug market.

The Second Circuit upheld the Program, but it never engaged with the substance of Petitioner Boehringer Ingelheim Pharmaceuticals, Inc.'s constitutional claims. The court instead held that the Program cannot violate the First or Fifth Amendments because it is "voluntary": A manufacturer can "choose" to avoid the Program's mandates by incurring crippling tax penalties or withdrawing its entire drug portfolio from Medicare and Medicaid. The questions presented are:

1. Is the Program immune from scrutiny under the First and Fifth Amendments because it relies on economic coercion to secure participation?

2. Does the Program unconstitutionally condition Medicare and Medicaid participation on manufacturers giving up their constitutionally protected speech, property, and due process rights?

PARTIES TO THE PROCEEDINGS

Petitioner (Plaintiff-Appellant below) is Boehringer Ingelheim Pharmaceuticals, Inc.

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

CORPORATE DISCLOSURE STATEMENT

Petitioner Boehringer Ingelheim Pharmaceuticals, Inc. is a nongovernmental corporation that is wholly owned by Boehringer Ingelheim USA Corporation. Both corporations are privately owned, and no publicly held company owns 10% or more of those corporations' stock.

RELATED PROCEEDINGS

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

Boehringer Ingelheim Pharms., Inc. v. HHS, No. 24-2092 (2d Cir.) (judgment entered Aug. 7, 2025);

Boehringer Ingelheim Pharms., Inc. v. HHS, No. 3:23-cv-1103 (D. Conn.) (judgment entered July 3, 2024).

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

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

Janssen Pharms. Inc. v. Kennedy, No. 25-749 (U.S.) (cert. petition filed Dec. 19, 2025);

Bristol Myers Squibb Co. v. Kennedy, No. 25-751 (U.S.) (cert. petition filed Dec. 19, 2025);

Novo Nordisk Inc. v. Kennedy, No. 25-761 (U.S.) (cert. petition filed Dec. 22, 2025);

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

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

Teva Pharms. USA, Inc. v. Kennedy, No. 1:25-cv-113 (D.D.C.) (judgment entered Nov. 20, 2025); *appealed*, No. 25-5425 (D.C. Cir.) (appeal docketed Nov. 30, 2025).

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INTRODUCTION

The "Medicare Drug Price Negotiation Program"—enacted in 2022 as part of the Inflation Reduction Act ("IRA")—sounds reasonable enough. What could be wrong with merely allowing the federal government to negotiate with manufacturers regarding the prices it pays for drugs? That is no doubt why Congress designed the Program to *resemble* an arms-length negotiation: The Centers for Medicare and Medicaid Services ("CMS") makes an "offer" to pay a particular price for a particular drug; the manufacturer makes a "counteroffer"; and this back-and-forth ends with the manufacturer signing an "agreement" stating that it "negotiate[d]" to provide Medicare beneficiaries "access" to the drug at a "maximum fair price."

But that is all a politically expedient charade. In reality, the Program establishes a series of obligations with which manufacturers are forced to comply. In an actual negotiation, both parties are free to walk away from the bargaining table. The Program, on the other hand, deploys the federal government's sovereign, regulatory powers to impose terms without consent.

Companies that manufacture drugs selected by CMS for the Program—including Petitioner Boehringer Ingelheim Pharmaceuticals, Inc.—*must* participate in the "negotiation" and *must* "agree" to the "maximum fair price" set by CMS. Otherwise, the IRA subjects them to a 1900% excise tax on sales of the selected drug, or complete exclusion from both Medicare *and* Medicaid, which together make up nearly half of the American prescription drug market. When CMS selected Boehringer's Jardiance® for the Program, failing to comply would have subjected

Boehringer to $5.5 billion in excise tax penalties *per week* or required Boehringer to withdraw Jardiance® and over 20 other drugs from Medicare and Medicaid, forfeiting more than half the company's net domestic sales and leaving millions of patients without coverage for their medications. As Judge Hardiman observed in a related case, the Program's "enterprise-crippling" penalties for noncompliance "loo[m] like a sword of Damocles, creating a de facto mandate to participate." *Bristol Myers Squibb Co. v. Sec'y of HHS*, 155 F.4th 245, 273, 289 (3d Cir. 2025) (dissenting opinion) ("*BMS*").

This unprecedented scheme violates Boehringer's rights under the First and Fifth Amendments. It unlawfully compels speech by forcing the company to express the Government's disputed message that prices set through the Program are both "negotiate[d]" and "fair." It works a *per se* taking of property by forcing Boehringer to transfer Jardiance® products to Medicare beneficiaries on terms the company would never willingly accept. And it deprives Boehringer of due process by granting CMS nearly unfettered discretion to determine prices, while at the same time barring judicial review of those determinations.

But the Second Circuit never engaged with the substance of those claims. Instead, it rejected Boehringer's challenge with two sweeping holdings that cut across all of Boehringer's claims. Both rulings contradict this Court's precedents and carry alarming implications.

First, the Second Circuit held that the Program is immune from constitutional scrutiny because a manufacturer theoretically can "choose" not to

participate. In the court of appeals' view, it is immaterial that this choice subjects a manufacturer to billions of dollars in penalties or exclusion from half the American prescription drug market. Relying on a categorical rule set forth in circuit precedent, the court reasoned that federal programs cannot "directly" violate constitutional rights unless participation is mandated by law. Although the court acknowledged that the IRA employs economic coercion to force Boehringer into accepting the Program's mandates, it treated that coercion as irrelevant because Boehringer could withdraw from Medicare and Medicaid.

That rationale disregards this Court's precedents, which establish that a formal legal mandate is not necessary to trigger constitutional scrutiny. The Constitution still applies even when Congress relies on economic coercion to secure compliance. *See, e.g.*, *National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 578, 582 (2012) ("*NFIB*"); *United States v. Butler*, 297 U.S. 1, 53-57, 70-71 (1936). Where, as here, "economic pressure" renders a program's opt-out mechanisms "illusory," regulated parties' theoretical "power of choice" is no defense. *Butler*, 297 U.S. at 71.

Second, the Second Circuit held that the Program does not impose unconstitutional conditions on Medicare and Medicaid participation because the conditions "relat[e]" to the Government's objectives and apply "within" the Program. But that is a mere shadow of the standard this Court has applied in its unconstitutional conditions precedents. For example, this Court has made clear that conditions requiring funding recipients to adopt the Government's views on matters of public concern "by [their] very nature"

impose unconstitutional conditions, even when they are relevant to a grant program's objectives. *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 218 (2013) ("*USAID*"). The Second Circuit's ruling flouts that principle by upholding the Program's speech mandates.

The Second Circuit's errors have far-reaching implications. As Judge Hardiman observed in *BMS*, the issues presented here are "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." 155 F.4th at 289 (dissenting opinion). The Program's scope and scale alone make this case worthy of review, as it will affect hundreds of billions of dollars in the U.S. pharmaceutical market and millions of patients. Further, the implications of the Second Circuit's ruling sweep well beyond the pharmaceutical sector, creating a blueprint for the Government to use federal spending programs to circumvent constitutional protections without meaningful scrutiny. This Court should grant review.

OPINIONS BELOW

The opinion of the court of appeals is reported at 150 F.4th 76 and reproduced at App.1a-46a. The opinion of the district court is not reported, but is available at 2024 WL 3292657 and reproduced at App.47a-104a.

JURISDICTION

The court of appeals entered its judgment and opinion on August 7, 2025. App.1a, 45a-46a. On September 29, 2025, Justice Sotomayor granted Boehringer's application for a 60-day extension of the

deadline to file a petition for writ of certiorari. *See* No. 25A357. Pursuant to that order, this petition is timely filed on January 5, 2026. The Court has jurisdiction under 28 U.S.C. § 1254(1).

RELEVANT PROVISIONS

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

The Fifth Amendment to the U.S. Constitution provides, in relevant part, "nor shall any person … be deprived of life, liberty or property without due process of law; nor shall private property be taken for public use, without just compensation."

The relevant statutory provisions governing the Program, *see* 42 U.S.C. §§ 1320f–1360f-7; 26 U.S.C. § 5000D, are reproduced at App.105a-64a. The form agreements that the IRA requires manufacturers to sign are reproduced at App.165a-78a.

STATEMENT

A. Statutory and Regulatory Background

This case implicates two federal health insurance programs. Medicare provides coverage for seniors and eligible individuals with disabilities. *See* 42 U.S.C. § 1395 *et seq*. Medicaid provides free or low-cost coverage to individuals based on financial need. *See id*. § 1396 *et seq*. Together, these programs account 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 comprises several parts that provide different types of benefits. Under Part D, private insurance plans provide coverage for self-administered prescription drugs and CMS partially reimburses the plans. *See* 42 U.S.C. § 1395w-101 *et seq*. For nearly 20 years, market forces determined drug prices in Part D: Plans and drug manufacturers negotiated drug prices, and CMS was prohibited from "institut[ing] a price structure" or otherwise "interfer[ing] with the negotiations" between drug manufacturers, pharmacies, and Part D plans. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, § 101(a)(2), 117 Stat. 2092, 2098.

That changed in 2022 when Congress established the Program. *See* Inflation Reduction Act of 2022, Pub. L. 117-169, §§ 11001-11004, 136 Stat. 1818, 1833-64 (codified at 42 U.S.C. § 1320f *et seq*.). CMS now "select[s]" the drugs that account for the highest gross expenditures in Medicare; "negotiate[s]" with manufacturers to set "maximum fair prices" for those drugs; and requires manufacturers to provide Part D beneficiaries "access" to the drugs at those prices. 42 U.S.C. §§ 1320f(a), 1320f-2(a), 1395w-111(i). The IRA authorizes CMS[1] to select 10 drugs for the first year of the Program, 15 for each of the second and third years, and 20 for every subsequent year. *Id.* § 1320f-1(a). A selected drug generally remains subject to the Program until CMS determines that the drug is

[1] The IRA grants these powers to the Secretary of Health and Human Services, *see* 42 U.S.C. § 1320f-1(a), who has delegated them to CMS.

subject to generic or biosimilar competition. *Id.* § 1320f-1(c)(1).

After CMS selects a drug for the Program, the agency presents the drug's manufacturer with a CMS-drafted form "agreement" ("Agreement"). *See id.* § 1320f-2(a); *see also* App.165a-78a. The Agreement states that the manufacturer "agree[s]" to participate in a "negotiat[ion]" with CMS "to determine … a maximum fair price for the [s]elected [d]rug." App.166a-67a. The manufacturer is required to provide confidential information to CMS about the selected drug on pain of a daily $1 million penalty for noncompliance. 42 U.S.C. §§ 1320f-3(b)(2)(A), 1320f-6(c). CMS then makes an "offer," which must be at least 25-60% below a benchmark market-based price for the selected drug. *See id.* § 1320f-3(c).[2] If the manufacturer makes a counteroffer, CMS responds with its final offer. *Id.* § 1320f-3(b)(2).

The "negotiations" must end by a statutory deadline, *id.* § 1320f-3(b)(2)(E), at which point the manufacturer must sign a CMS-drafted addendum to the Agreement ("Addendum"), *see* App.176a-78a. The Addendum states that the manufacturer "negotiated" with CMS and "now agree[s]" to a maximum fair "price for the [s]elected [d]rug." App.176a.

If a manufacturer does not sign the Agreement or the Addendum, it becomes subject to an enormous excise tax on all domestic sales of the selected drug. *See* 26 U.S.C. § 5000D. The tax starts at 186% of the drug's sale price and increases to 1900% after nine

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[2] The IRA also requires CMS to "achieve" the "lowest maximum fair price" below the statutory ceiling. 42 U.S.C. § 1320f-3(b)(1).

months. *See id.* § 5000D(a), (b)(1), (d). The tax is so grossly excessive that no manufacturer could afford to pay it, as reflected by Congressional Budget Office and Joint Committee on Taxation estimates that it would raise no revenue.[3]

A manufacturer can "suspend" the excise tax only by terminating its participation in Medicare *and* Medicaid for *all* of its drugs (not just the selected drug). *See* 26 U.S.C. § 5000D(c).[4] In that scenario, CMS would no longer "reimburse patients or providers for *any* of the drugs that the manufacturer sells." *National Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 495 (5th Cir. 2024) ("*NICA*"). In other words, the manufacturer of a selected drug must remain subject to the Program for any of its drugs to be eligible for Medicare and Medicaid reimbursement. Because Medicare and Medicaid account for roughly

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[3] *See* Congressional Budget Office, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, at 11 (2023), https://perma.cc/C26R-WS35; Joint Comm. on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII—Committee on Ways and Means, of H.R. 5376, Fiscal Years 2022–2031*, at 8 (Nov. 19, 2021), https://perma.cc/SMC3-GZMF (calculating revenue effect of nearly identical tax provision in a precursor bill).

[4] By statute, manufacturers must wait 11 to 23 months before terminating their Medicare and Medicaid participation agreements, depending on when the manufacturer notifies CMS of the terminations. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii); App.37a-38a. CMS has argued that it can terminate the agreements in only 30 days, but Boehringer and other manufacturers dispute that interpretation. *Compare* App. 37a-38a (concluding that CMS has authority to expedite withdrawal) *and BMS*, 155 F.4th at 259-61 (same), *with id.* at 275-79 (Hardiman, J., dissenting) (concluding CMS's lacks such authority).

half of the country's prescription drug market, "basic economic" logic makes it "all but certain" that manufacturers will remain in the Program and "reac[h] an agreement" with CMS. *Id.* at 500.

Once CMS completes the "negotiat[ion]" process, the agency "publish[es] the maximum fair price for [each selected] drug." 42 U.S.C. § 1320f-4(a). Manufacturers must then provide Medicare beneficiaries "access" to the selected drug at that price. *Id.* § 1320f-2(a). Every Part D plan must also include the selected drug on its list of covered medicines (known as a "formulary"), reinforcing Medicare beneficiaries' statutory right to obtain the selected drug on CMS's terms. *See id.* § 1395w-104(b)(3)(I). This "access" right took effect on January 1, 2026, for the Program's first "price applicability" year. *Id.* §§ 1320f(b)(1), 1320f-1(c)(1), 1320f-2(a)(3) & (b). Manufacturers who fail to provide such "access" are subject to additional penalties, including a fine equal to ten times any amount charged in excess of the "maximum fair price." *Id.* § 1320f-6(a).

B. Factual Background

Boehringer's Jardiance® (empagliflozin) is widely prescribed to millions of patients throughout the United States to reduce the risk of cardiovascular death, lower blood sugar in adults with type 2 diabetes, and prevent chronic kidney disease from worsening. App.180a ¶ 5, 181a ¶ 8. It is one of the many innovative medicines that Boehringer has researched and developed over the years, and one of the nearly two dozen drugs that Boehringer offers through Medicare and Medicaid. *See* App.180a ¶ 4, 181a ¶ 7.

On August 29, 2023, CMS selected Jardiance® for the first year of the Program.[5] Boehringer signed the Agreement under protest to avoid excise taxes that would have started at over $500 million per week and increased to more than $5.5 billion per week. App.183a ¶ 16. Had Boehringer withdrawn from Medicare and Medicaid, the company would have lost more than half of its domestic net sales, crippling the company's ability to continue developing innovative new medications, and millions of patients would have lost coverage for drugs they rely on to treat serious, often life-threatening medical conditions. App.183a ¶ 17, 184a ¶ 18.

At the end of the "negotiation" process, Boehringer signed the Addendum, which stated that the company "negotiated" and "agrees to" the "maximum fair price" set through the Program. App.176a; *see also* App.7a. CMS then published the "maximum fair price" for Jardiance®, which is 66% less than the prior year's market-based price.[6] Boehringer would not have entered into this arrangement with CMS had it not been compelled to do so by the threat of the Program's coercive penalties. Under the Addendum, Boehringer must now grant all Medicare beneficiaries and their providers "access" to Jardiance® at the price set through the Program. *See* 42 U.S.C. § 1320f(b)(1).

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

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

C. Procedural Background

Boehringer filed this suit in August 2023, asserting as-applied challenges to the Program's constitutionality. The company alleged that the Program violates (1) the First Amendment by compelling Boehringer to express the Government's disputed narrative regarding prices set through the Program; (2) the Fifth Amendment's Takings Clause by forcing Boehringer to transfer physical doses of Jardiance® to third parties on CMS's terms; (3) the Fifth Amendment's Due Process Clause by depriving Boehringer of its property interests without adequate procedural safeguards; and (4) the unconstitutional conditions doctrine by making Medicare and Medicaid participation contingent on compliance with these unconstitutional demands. *See* App.19a.[7] In response, the Government argued that the Program cannot compel speech, take property, or violate due process because it is "voluntary." App.63a, 71a-82a.

The District Court ruled for the Government, granting it summary judgment on each of Boehringer's claims. *See* App.104a. On appeal, the Second Circuit (Leval, Bianco, Nardini) affirmed. App.1a-46a. In affirming, however, the court did not address the substance of Boehringer's constitutional claims. Instead, it rejected those claims at the threshold, on two cross-cutting grounds.

First, the Second Circuit held that Boehringer could not assert a "direct" violation of its constitutional rights because Program participation is

[7] Boehringer's complaint also asserted other claims not at issue here.

not "legally compelled." App.23a. Relying on a categorical rule adopted in *Garelick v. Sullivan*, 987 F.2d 913 (2d Cir. 1993), the court observed that a federal program cannot violate a plaintiff's constitutional rights if participation is not formally required by law. App.26a. In other words, a program is "voluntary" and thus immune from constitutional scrutiny even when it employs economic coercion to ensure compliance. *Id.*

Applying that standard, the Second Circuit concluded that Boehringer's participation in the Program is not "legally compelled" because the company could theoretically avoid it by "opt[ing] out of Medicare and Medicaid." *Id.* Based on that rationale, the court held that it was unnecessary to confront the merits of Boehringer's claims. App.31a n.11.

Second, the court held that the Program does not impose unconstitutional conditions on Medicare and Medicaid participation. App.39a-44a. The Second Circuit acknowledged that even a "voluntar[y]" federal program can violate the unconstitutional conditions doctrine. App.40a. But the court limited that doctrine's protections to situations where conditions extend beyond "the four corners of [a] federally funded progra[m]" and "burden" participants' "constitutionally protected conduct" "in the private market." App.43a. Under this narrowed standard, the Program's conditions pass muster because they are "related to the government's legitimate goal of controlling Medicare costs" and affect drug sales only "within … Medicare." *Id.*

REASONS FOR GRANTING THE PETITION

This Court should grant review because the decision below exempts federal spending programs from constitutional scrutiny, contrary to this Court's precedents.

First, the court of appeals determined that federal programs *never* violate the First or Fifth Amendments if they present regulated parties with an illusory opt-out mechanism—no matter how coercive the penalties for noncompliance. *Second*, the court narrowed the unconstitutional conditions doctrine beyond recognition, holding that federal funding conditions are valid so long as they "relat[e]" to the Government program and apply "within" it. App.43a.

Those flawed doctrinal moves allowed the Second Circuit to turn a blind eye to the Program's serious constitutional defects. As Judge Hardiman explained in *BMS*, the Program violates the First Amendment by compelling manufacturers to "represen[t] that their participation … was voluntary" and to "confes[s] to having previously charged unfair prices." 155 F.4th at 285 (dissenting opinion). The Program also "imposes a clear physical taking by forcing [manufacturers] to turn over physical doses of [their selected drugs] to Medicare beneficiaries" on terms "set by CMS." *Id.* at 273. And the Program violates Boehringer's due process rights by depriving the company of core procedural safeguards, including an impartial decisionmaker, ascertainable standards to guide CMS's decisions, and the ability to seek judicial review of those decisions.

But the consequences that flow from the Second Circuit's decision extend well beyond Boehringer's

rights. By ushering in a draconian regime of forced transfers at below-market rates, the Program will chill U.S. pharmaceutical development and impede patient access to lifesaving and life-improving medicines. And those adverse effects will snowball over time as more and more drugs are subjected to Program each year. More broadly, the Second Circuit's reasoning removes critical checks on federal spending powers, creating a roadmap for the Government—the nation's single-largest spender—to use federal benefits programs as a tool to trample constitutional rights.

I. The Second Circuit's Decision Conflicts with This Court's Precedents.

A. The Decision Below Improperly Makes Legal Compulsion a Prerequisite to Constitutional Review.

The Second Circuit rejected Boehringer's constitutional claims because it concluded that participation in the Program is "voluntary" as a matter of law. The court relied on its decision in *Garelick*, 987 F.2d 913, for the principle that a federal program cannot "entail an unlawful deprivation of rights" unless participation is "legally compelled." App.8a, 23a-26a. Under this rationale, the economically coercive consequences of leaving a federal program are irrelevant, no matter how extreme. *See* App.27a. That holding conflicts with this Court's precedents, which have repeatedly applied constitutional scrutiny to economically coercive Government programs even when participation is not required by legal mandates.

1. Economic Coercion—Not Just Legal Compulsion—Triggers Constitutional Scrutiny.

There is no basis for the Second Circuit's categorical distinction between legal mandates and economic coercion. When a proper plaintiff challenges the constitutionality of a federal statute, the court's role is to "say what the law is." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). Consistent with that principle, this Court has repeatedly assessed the merits of laws that secure compliance through economic coercion—*i.e.*, where the consequences for noncompliance (or non-participation) are so severe that the opt-out mechanism is illusory. In those cases, the challenged program is subject to the same rule that applies to statutes generally: it must comply with the Constitution. That principle governs here.

For example, in *NFIB*, 567 U.S. at 577, 582, the Court held that Congress could not use "financial inducements" to "economic[ally] dragoo[n]" the States into compliance with "no real option but to acquiesce." States were required to "either accept a basic change in the nature of Medicaid, or risk losing all Medicaid funding." *Id.* at 588. Even though the States had a theoretical option to forgo Medicaid funding (which amounted to ten percent of their annual budgets), they had no "genuine choice" in the matter because Congress had "forc[ed] them to accept [new federal demands] by threatening the funds for the existing Medicaid program." *Id.* at 582, 588. Similarly here, the Government has threatened Boehringer's longstanding participation in Medicare and Medicaid in order to guarantee Boehringer's compliance with the Program's terms. Fully withdrawing from

Medicare and Medicaid is no real option because it would erase more than 50 percent of Boehringer's domestic net sales and eviscerate the company's ability to compete. *See* App.183a ¶ 17, 184a ¶ 18. Just as in *NFIB*, the Program's coercive penalties have forced Boehringer to comply with the Government's demands.

The Second Circuit confined *NFIB* to the federalism context, *see* App.26a-27a, but that misreads the decision. In *NFIB*, federalism principles supplied the underlying substantive right. *See* 567 U.S. at 578. But the Court proceeded to analyze whether Congress had impermissibly violated that right by "indirectly" using an *economic* "gun to the head" to achieve an otherwise unconstitutional result. *Id.* at 578, 581. The same principle applies here, even though the underlying rights are grounded in the First and Fifth Amendments rather than in federalism principles.

Besides, *NFIB* was hardly the first time that the Court recognized that economically coercive legislation can violate the Constitution. In *United States v. Butler*, 297 U.S. 1, 53-57, 70-71 (1936), for example, cotton farmers argued that federal production quotas exceeded Congress's enumerated powers. The Government defended the program by arguing that it involved "voluntary co-operation": farmers could accept the quotas and receive significant subsidies to offset an onerous cotton "processing ta[x]," or they could reject those quotas, forgo the subsidy benefit, and bear the full tax. *Id.* at 55-57, 70. The Court rejected the Government's voluntariness argument. Although farmers could "refuse to comply," "the price of such refusal [wa]s the

loss of benefits" large enough "to exert pressure" on farmers to accept the quotas—meaning that the program was "not in fact voluntary." *Id.* at 70-71. Instead, the Government had employed "coercion by economic pressure" to make the famers' "asserted power of choice … illusory." *Id.*; *see also id.* at 71 (program's "coercive purpose" was "to induce" farmers "to surrender their independence of action" and "keep … non-cooperating" farmers "in line").

Similarly, in *Union Pacific Railroad Company v. Public Service Commission of Missouri*, 248 U.S. 67, 68-70 (1918), the Court concluded that a railroad had not "voluntar[ily]" paid an in-state operating fee because a regulator had threatened "grave" economic consequences (canceling all of the railroad's already-issued bonds) if the railroad did not pay up—thus forcing the railroad to "choose the lesser of two evils." And in *Carter v. Carter Coal Co.*, 298 U.S. 238, 281-82, 288-89, 297-304 (1936), the Court determined that a coal program was involuntary where the operative statute threatened to withhold substantial tax credits from producers if they did not comply with "maximum prices" and labor regulations prescribed by a federal agency. Because the tax provisions served "to compel compliance with the regulatory provisions of the" program, the "agreement[s]" signed by producers "lack[ed] the essential element of consent" and were not a defense to the producers' constitutional challenges. *Id.* at 289. Summing up the operative principle, the Court observed that "[o]ne who does a thing in order to avoid a monetary penalty does not agree; he yields to compulsion precisely the same as though he did so to avoid a term in jail." *Id.*; *see also*

id. at 310 (challenged statute was "compulsory" "in fact").

In each of these cases, the use of economic coercion to secure participation did not immunize the program from constitutional scrutiny. Instead, the Court assessed the merits of each program after rejecting the Government's voluntariness defense. *See Butler*, 297 U.S. at 70, 74-75; *Union Pac.*, 248 U.S. at 70; *Carter Coal*, 298 U.S. at 309-10.

The Second Circuit's voluntariness rationale is irreconcilable with these decisions. Indeed, the court entirely ignored *Butler*, *Carter Coal*, and *Union Pacific*, despite substantial discussion of those cases in Boehringer's briefs.[8] Together with *NFIB*, these cases establish that a federal program is not voluntary—and is not exempt from constitutional analysis—when it employs severe economic coercion to force participants to comply. Here, the Program coercively prevents manufacturers from "walk[ing] away," *NICA*, 116 F.4th at 500, by threatening them with "enterprise-crippling excise tax liabilities" and complete exclusion from Medicare and Medicaid, *BMS*, 155 F.4th at 269 (Hardiman, J., dissenting). In other words, CMS, "like Don Corleone in *The Godfather*, made [manufacturers] 'an offer [they] [couldn't] refuse.'" *Id.* at 281.

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[8] *See also* App.81a (district court decision declining to follow these precedents and questioning whether they "remain good law").

2. Voluntariness Is No Defense to First Amendment, Takings, and Due Process Claims.

The Second Circuit's decision also conflicts with foundational cases addressing the substantive claims at issue here. In the takings, due process, and First Amendment contexts, this Court has evaluated the merits of constitutional challenges even when the plaintiff was not formally required to participate in the underlying program or market.

For example, in *Horne v. U.S. Department of Agriculture*, 576 U.S. 350, 355 (2015), raisin growers asserted a *per se* takings challenge to a program that called on growers to turn a portion of their crops over to the Government. In response, the Government argued that there was no taking "because raisin growers voluntarily choose to participate in the raisin market" and retained the option to "sell their … grapes as table grapes or for use in juice or wine." *Id.* at 365 (citation omitted). The Court rejected that argument "as a matter of law," warning that "property rights 'cannot be so easily manipulated.'" *Id.* (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 439 n.17 (1982)). The Court then analyzed the constitutional claim on its merits, holding that the raisin reserve program effected a *per se* taking. *See id.* at 361-62.

The Second Circuit fundamentally misread *Horne*. It limited *Horne* to situations where the Government "actual[ly] seiz[es]" property, App.30a, but in *Horne*, the growers' raisins were *not* actually seized; the growers instead paid a penalty, *see* 576 U.S. at 356. Regardless, this Court has made clear that a seizure

is not required for a *per se* taking to occur. *See, e.g.*, *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021) (Fifth Amendment applies however the taking "comes garbed"). The Second Circuit also sought to limit *Horne* to situations where a property owner's only alternative is to exit the market entirely. *See* App.32a. But as just discussed, the growers could have continued to market their grapes for other purposes, and the Court rejected "as a matter of law" the argument that the theoretical option to leave a market negates a taking. *Horne*, 576 U.S. at 365.

This Court has applied similar reasoning in the due process context. In *Bowles v. Willingham*, 321 U.S. 503 (1944), for example, the Court evaluated the merits of a due process challenge to a rent control statute even though there was "no requirement that the apartments in question be used for purposes which br[ought] them under the Act." *Id.* at 516-17; *see also id.* at 519-21. Similarly, in *Yakus v. United States*, 321 U.S. 414, 421-22, 431-32 (1944), the Court analyzed the plaintiffs' due process challenge to wholesale beef price controls despite the fact that plaintiffs "were … not required by the Act, nor so far as appears by any other rule of law, to continue selling meat at wholesale," and could have instead engaged in retail sales. *Id.* at 431.

Nor is legal compulsion a prerequisite to scrutiny under the First Amendment. In *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557 (1995), for instance, state law required a private organization to include messages it opposed in its annual parade. *See id.* at 560-65. The group was under no legal obligation to organize the parade. But the Court still concluded that the law had violated the

group's "autonomy to control [its] own speech." *Id.* at 568-81.

In each of these cases, the party asserting the constitutional claim was not required by law to participate in the challenged program or market. But that did not stop the Court from analyzing the constitutionality of the Government's actions. Indeed, were the Second Circuit's framework the law, each of these cases would have come out the other way. The option to stop producing raisins would have negated Takings Clause protections in *Horne*. The option to cease renting apartments or selling beef wholesale would have defeated the due process claims in *Bowles* and *Yakus*. And the option to stop organizing the parade would have doomed the First Amendment challenge in *Hurley*. But a formal legal mandate is not a prerequisite to constitutional review, and the Second Circuit disregarded this Court's precedents by holding otherwise.

B. The Decision Below Conflicts with This Court's Unconstitutional Conditions Precedents.

Even if a legal mandate were required to show that a federal program *directly* infringes constitutional rights, the lack of a mandate would not end the inquiry. The unconstitutional conditions doctrine prohibits the Government from imposing conditions on benefits to "coerc[e] people into giving … up" their constitutional rights, *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013), achieving *indirectly* what the Government "could not command directly," *Speiser v. Randall*, 357 U.S. 513, 526 (1958); *see also Perry v. Sindermann*, 408 U.S. 593, 597 (1972)

(Government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests"). Thus, even when a program is truly voluntary, the unconstitutional conditions doctrine provides a meaningful check to "vindicat[e] the Constitution's enumerated rights." *Koontz*, 570 U.S. at 604.

The Second Circuit applied a watered-down version of the unconstitutional conditions doctrine that departs in significant ways from settled law. It held that federal spending conditions pass muster as long as they are "related" to a program's purposes and operate within the "four corners" of the program. App.43a. But that test cannot be squared with this Court's unconstitutional conditions precedents or the doctrine's underlying purposes.

1. Consider *USAID*. There, Congress had placed several conditions on participation in a grant program created to "combat the spread of HIV/AIDS around the world." 570 U.S. at 208. The Court invalidated one of those conditions because it required funding recipients to "agree in the award document" that they are "opposed to prostitution and sex trafficking." *Id.* at 210 (cleaned up). That condition would have survived the Second Circuit's test because it was "related" to the "legitimate goal" of combatting HIV/AIDS, and it formally operated "within the four corners" of the program because only those who participated needed to adopt an anti-prostitution policy. App.43a. Indeed, the *USAID* dissent—just like the Second Circuit panel here—would have held that this condition was permissible because it was "relevant to the objectives of the program" and "nothing more" than a criterion to select grant

recipients. *USAID*, 570 U.S. at 214; *see also id.* at 221, 223 (Scalia, J., dissenting).

But the *USAID* majority rejected that approach. It refused to reduce the unconstitutional conditions doctrine to a mere relevance test because such "limited" protections would allow the Government to "manipulat[e]" a program's scope "to subsume the challenged condition" and "reduc[e] [constitutional rights] to a simple semantic exercise." *Id.* at 214-15 (majority opinion). The majority also disagreed that conditions requiring recipients to "adopt—as their own—the Government's view on an issue of public concern" could fall within the contours of a federal program. Compelled endorsements impermissibly go beyond regulating the use of funds and instead regulate the funding recipient by requiring recipients to "pledge allegiance to the Government's policy"—a step that recipients could disavow outside the grant program "only at the price of evident hypocrisy." *Id.* at 217-20.

The Program imposes the type of condition that *USAID* held is impermissible. It requires Boehringer, as a condition of maintaining Medicare and Medicaid coverage for its drugs, to endorse the Government's views—*i.e.*, that the Program involves voluntary "negotiat[ions]" resulting in an "agree[ment]" on a "maximum fair price" for Jardiance®. 42 U.S.C. § 1320f-2(a). Those compelled statements "by their very nature affec[t] protected [speech] outside the scope of the" Program, *USAID*, 570 U.S. at 218-19 (citation omitted), because they compromise Boehringer's "right to autonomy over [its own] message," *Hurley*, 515 U.S. at 576. By compelling Boehringer "to affirm in one breath that which [it

would] deny the next," *Pac. Gas & Elec. Co. v. Cal. Pub. Utils. Comm'n*, 475 U.S. 1, 16 (1986), the Program prevents the company from advocating for higher Jardiance® prices outside Medicare except "at the price of evident hypocrisy," *USAID*, 570 U.S. at 218-19. As Judge Hardiman explained in *BMS*, compelling manufacturers to "stat[e] that they have 'agree[d]' that the price" set by CMS is the "maximum fair price" forces them to "confes[s]" that the higher prices they "previously charged" in Medicare (and continue to charge in the private market) are "unfair." 155 F.4th at 285 (dissenting opinion).

The Second Circuit disregarded those speech mandates because the Program does not govern Boehringer's Jardiance® *sales* in "the private market." App.43a-44a. But that does not change the fact that the Program *also* compels Boehringer to speak. *USAID*, 570 U.S. at 218. The Program "does much more than" regulate prices; it "forces" manufacturers, "in Orwellian fashion," to "convey the Government's message 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"—"representations [manufacturers] have abjured from the start." *BMS*, 155 F.4th at 283-86 (Hardiman, J., dissenting). The Program thus imposes an unconstitutional condition on Boehringer's First Amendment rights, and the Second Circuit contradicted *USAID* in holding otherwise.

2. The Second Circuit's approach also conflicts with this Court's precedents applying the unconstitutional conditions doctrine in the takings context. Those cases make clear that, in order to pass constitutional muster, "conditions must have an

essential nexus to" the government's interest and be "rough[ly] proportiona[l] to" the effect of the property owner's proposed action on that interest. *Sheetz v. County of El Dorado*, 601 U.S. 267, 275-76 (2024) (cleaned up). While this test arose in the land-use permitting context, it draws from the principles that make up the "overarching" unconstitutional conditions doctrine. *Koontz*, 570 U.S. at 604.

Indeed, this Court has applied similar proportionality principles in other contexts. *See, e.g.*, *Mem'l Hosp. v. Maricopa County*, 415 U.S. 250, 257-63, 260 & n.15 (1974) (comparing "the extent to which" restrictions on healthcare benefits burdened plaintiffs' right to travel with the strength of the State's interest). These cases go beyond evaluating the factors addressed by the Second Circuit here, *see* App.43a-44a, by scrutinizing conditions to ensure they "further [the government's] stated purpose" and do not "requir[e] [individuals] to give up more than is necessary" to justify granting a benefit. *Sheetz*, 601 U.S. at 275-76.

The Second Circuit disregarded those principles entirely. *See* App.43a-44a. Indeed, if the Second Circuit's watered-down test were the law, foundational unconstitutional conditions cases would have come out the other way. For example, in *Dolan v. City of Tigard*, 512 U.S. 374, 378, 380, 387 (1994), the challenged condition—which required a building permit applicant to dedicate property to improve storm drainage—was "obvious[ly]" related to the city's interest in counteracting flooding risks from increased urbanization, and the regulated conduct fell within the four corners of the city's development program. The condition thus would have passed muster under

the Second Circuit's test. Yet *Dolan* concluded that relevance is not enough; the condition was impermissible because it "demanded more" than necessary to achieve the city's interests. *Id.* at 393. Similarly in *Maricopa County*, the residency condition on healthcare benefits was relevant to the State's interest in reducing the cost of its "free medical care" program. 415 U.S. at 253. But the Court nevertheless held that the condition was unconstitutional because its burden on the right to travel outweighed the State's budgetary interest. *See id.* at 269.

3. The Second Circuit's framework also conflicts with the core purpose of the unconstitutional conditions doctrine. The doctrine serves to prevent the "palpable incongruity" that would occur if the Government could achieve unconstitutional ends by "withhold[ing]" a "valuable privilege" to pressure program participants into "surrender[ing] … a [constitutional] right," *Frost v. Cal. R.R. Comm'n*, 271 U.S. 583, 593 (1926), thereby "produc[ing] a result which [the Government] could not command directly," *Speiser*, 357 U.S. at 526. This sort of "extortionate" leveraging is especially problematic when "the government … has broad discretion to deny a [benefit] that is worth far more than [the right] it would like to take," because participants are "likely to accede to the government's demand, no matter how unreasonable." *Koontz*, 570 U.S. at 605.[9]

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[9] *See also, e.g.*, *USAID*, 570 U.S. at 214-15 (rejecting attempts to "leverage funding to regulate speech outside the contours of the program"); *NFIB*, 567 U.S. at 581 (rejecting attempt to threaten "*all*" "existing Medicaid funding" to coerce States into expanding the coverage of their Medicaid programs); *Sherbert v. Verner*, 374 (cont.)

Yet the Second Circuit's test would authorize the federal government to "leverag[e] its … monopoly" on valuable benefits in exactly the ways the unconstitutional conditions doctrine was designed to prohibit. *Sheetz*, 601 U.S. at 275. Congress structured the Program to present manufacturers "an offer they [can't] refuse," *BMS*, 155 F.4th at 281 (Hardiman, J., dissenting) (cleaned up), by ransoming existing Medicare and Medicaid coverage for a manufacturer's entire drug portfolio unless the manufacturer submits to CMS's demands regarding a single selected drug. *See* 26 U.S.C. § 5000D. In Boehringer's case, this dynamic means that the company had to accede to CMS's demand for a massive discount on Jardiance®, or else lose Medicare and Medicaid coverage for more than 20 other drugs. App.180a ¶ 4, 181a ¶ 7. By leveraging benefits "worth far more" than the cost of compliance to strip regulated parties of their constitutional rights, *Koontz*, 570 U.S. at 605, the Program violates the unconstitutional conditions doctrine.

Notwithstanding this precedent, the Second Circuit suggested that the Government could "leverage its purchasing power to get a better bargain" because it is "act[ing] as a market participant, not a regulator." App.31a n.11. But it strains credulity to characterize CMS as a mere market participant when it "threatens [manufacturers] with unavoidable,

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U.S. 398, 404-05 (1963) (refusing to permit withholding of unemployment benefits for individuals who did not abandon Saturday worship practices); *Sheetz*, 601 U.S. at 275-76 (warning against "leveraging [the Government's] permitting monopoly" to "requir[e] a landowner to give up more than is necessary" and "exact private property without paying for it").

enterprise-crippling" penalties if they try to walk away from the negotiating table. *BMS*, 155 F.4th at 269 (Hardiman, J., dissenting). "[C]oercive mechanism[s]" like penalties, taxes, and exclusion from federal programs are exercises of sovereign power, not negotiating tactics "available to … private part[ies]," belying the notion that the Government is simply leveraging its dominant market share. *Am. Trucking Ass'n v. City of Los Angeles*, 569 U.S. 641, 651 (2013). Indeed, private market participants would face serious antitrust scrutiny if they attempted to do what the Program does here—*i.e.*, tying the purchase of all Boehringer drugs to a price concession on a single drug. *See, e.g.*, *U.S. Steel Corp. v. Fortner Enters.*, 429 U.S. 610, 620 (1977). Regardless, even when the Government acts as a market participant in a truly voluntary context, the unconstitutional doctrine still acts as a meaningful check to prevent unconstitutional overreach. *See, e.g.*, *O'Hare Truck Serv., Inc. v. City of Northlake*, 518 U.S. 712, 721 (1996); *Bd. of Cnty. Comm'rs v. Umbehr*, 518 U.S. 668, 678-79 (1996). In short, the Second Circuit's market-participant theory cannot shield the Program from constitutional scrutiny.

II. This Case Presents Issues of Great Importance.

The questions presented are of profound national significance. At stake is the constitutionality of a statute that fundamentally transforms Medicare by replacing market-based prescription drug pricing with forced transfers on Government-dictated terms. Moreover, the implications of this case extend far beyond drug pricing. By holding that federal programs are categorically exempt from First and

Fifth Amendment analysis whenever they offer an illusory exit option, and then diluting the unconstitutional conditions doctrine, the Second Circuit's decision grants the Government virtually unrestricted authority to achieve unconstitutional ends through spending programs. In an economy where the Government is the largest spender in many sectors, that approach is a roadmap for widespread constitutional evasion.

A. The Program Affects Tens of Millions of Americans and Deters Development of Innovative New Treatments.

The constitutional questions presented by the Program's coercive structure are "of great importance to consumers of pharmaceutical drugs, the companies that provide them, and the public at large." *BMS*, 155 F.4th at 289 (Hardiman, J., dissenting).

The Program's vast scale is apparent on the face of the statute. More than 50 million Americans are enrolled in Medicare Part D.[10] The Program will affect the vast majority of those beneficiaries because it targets the most successful and widely prescribed drugs. *See* 42 U.S.C. § 1320f-1(a), (c)(1) (requiring CMS to select medications that account for the highest share of Medicare spending). The Program will also steadily expand over time as CMS selects drugs for each "initial program applicability year." 42 U.S.C. § 1320f-1(a), (c)(1). It will encompass up to 80 drugs within five years and 180 within ten years.

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[10] *See* Juliette Cubanski, *A Current Snapshot of the Medicare Part D Prescription Drug Benefit*, Kaiser Family Foundation (Oct. 7, 2025), https://perma.cc/8CCM-539Y.

Each of these drugs will remain subject to the Program until CMS determines that the drug faces generic or biosimilar competition. *Id.* § 1320f-1(c)(1).

The Program will have vast economic effects on the $600 billion pharmaceutical market as well.[11] For decades, the United States has led global pharmaceutical innovation, with "almost half" of new medicines originating here in recent years.[12] American consumers have reaped the benefits, gaining early and widespread access to life-saving medicines.[13] The innovation of new drugs has been possible in part due to market-based pricing, previously guaranteed by statute. *See supra* p.6. The revenues generated by that market-based model are critical because drug development is extraordinarily costly—requiring years of research and billions of dollars in investments for each new product.[14] The Boehringer Ingelheim family of companies, for example, invested $7 billion into new drug development over the course of 2024 alone.[15] Further,

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

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

[13] *See* Andrew W. Mulcahy, *Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries* (Feb. 1, 2024) https://perma.cc/FKE2-4TDY.

[14] *See id.*; Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 23 (2016), https://perma.cc/QB83-CBFZ.

[15] *See* Boehringer Ingelheim, *Boehringer Ingelheim Reaches More Patients in 2024 and Prepares New Medicine Launches* (Apr. 2, (cont.)

the overwhelming majority of new drugs never make it to market, so manufacturers must rely on revenues from a small number of successful drugs to cover the research and development costs for their entire portfolio.[16]

By slashing drug revenues, the Program also chills pharmaceutical innovation. In the Program's first year, the "maximum fair price[s]" set by CMS were as much as 79% below the market-based benchmark price, with an average discount of 63%.[17] Those reductions will hinder pharmaceutical innovation. By replacing market-based pricing with CMS-mandated rates, the Program dramatically reduces the incentives to undertake the substantial risks necessary to develop new treatments. These harms are not hypothetical: Some manufacturers have already terminated clinical trials because the Program undercuts their ability to recoup research and development costs.[18] In short, the Program's

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2025), https://www.boehringer-ingelheim.com/about-us/who-we-are/2024-results-research-and-development-investment-rise (accessed Nov. 24, 2025); *see also* App.180a.

[16] Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://perma.cc/EH2Q-Y83B.

[17] *See IPAY 2026 Negotiated Prices*, *supra* n.6.

[18] *See, e.g.*, ATI Advisory, *Pharmaceutical Innovation and the Inflation Reduction Act: What Can We Learn from the First Half of 2023?*, at 5 (Nov. 2023), https://perma.cc/6GPR-HWD9 (reporting cancellation of Eli Lilly Phase I oncology trial).

"effects on the life sciences industry and ultimately to patient treatment [will be] profound."[19]

B. The Second Circuit's Decision Allows the Government to Leverage Its Vast Spending Powers to Evade Constitutional Protections.

The Second Circuit's ruling has consequences that reach far beyond the Program and the pharmaceutical sector. Under the decision below, the Government effectively operates in a Constitution-free zone whenever it spends public funds. Indeed, the Second Circuit characterized the law as granting the Government virtually "unrestricted" authority in the Spending Clause context. App.32a.

That approach has alarming implications. The Government is the largest purchaser of goods and services in the United States—indeed, "in the world."[20] In fiscal year 2024, it spent approximately $755 billion on contracts for goods and services.[21] Federal outlays for benefits programs are even greater: $1.5 trillion for Social Security, $865 billion for Medicare, $618 billion for Medicaid, $370 billion for income security programs like the Supplemental

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

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

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

Nutrition Assistance Program, and roughly $120.8 billion for post-secondary student aid.[22]

Under the Second Circuit's framework, each of these expenditures is an opportunity to skirt the Constitution. This case demonstrates how the Government can exploit its spending power to violate rights protected by the First and Fifth Amendments. *See supra* Part I. And it is clear that the Second Circuit's approach could, if allowed to take root, lead to the erosion of other constitutional guarantees as well. For example, federal contractors and benefit recipients might be compelled to waive—partially or entirely—their Second Amendment right to bear arms, their Fourth Amendment protection against unreasonable searches, or other enumerated rights. So long as the Government invokes its spending authority, broadly defines the scope of the program, and offers an illusory "choice" to decline the benefit or contract, these actions would be permissible.

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

This case is an excellent vehicle for addressing the important constitutional questions presented by the Program's unprecedented scheme. The material facts are undisputed, *see* App.60a n.5, and the legal issues were squarely raised and decided by the Second Circuit, *see* App.45a-46a.

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

The issues are also outcome-determinative. The Second Circuit grounded its ruling in only two holdings, which correspond to the issues presented: that (1) the Program is not subject to constitutional scrutiny because it relies on economic coercion to secure compliance; and (2) the Program's spending conditions are permissible because they are "relevant" to governmental objectives and operate "within" the four corners of the Program. *Both* of those holdings were necessary to the Second Circuit's ruling, such that reversing *either* of them would at a minimum require a remand to address the merits of Boehringer's claims. Those claims are worthy of careful review for the reasons given in Judge Hardiman's carefully reasoned *BMS* dissent.

Finally, this case presents no procedural or jurisdictional obstacles to review. And because Boehringer asserts its claims on an as-applied basis,[23] this Court can resolve the merits without applying the demanding framework for facial challenges. *Cf. Moody v. NetChoice, LLC*, 603 U.S. 707, 718 (2024).

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[23] *See* Compl., *Boehringer Ingelheim Pharms. Inc. v. HHS*, No. 3:23-cv-1103, ECF 1, at 60-61 (D. Conn. Aug. 18, 2023).

CONCLUSION

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

Respectfully submitted,

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