

No. 25-799

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

REPLY BRIEF FOR PETITIONER

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CORPORATE DISCLOSURE STATEMENT

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

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INTRODUCTION

On the Government’s telling, the Program is a voluntary enterprise involving “real negotiation[s]” and “ordinary commercial contract[s].” Opp.18, 25.

That sanitized, made-for-litigation account calls on the Court to “exhibit a naiveté from which ordinary citizens are free.” *Department of Commerce v. New York*, 588 U.S. 752, 785 (2019) (quoting *United States v. Stanchich*, 550 F.2d 1294, 1300 (2d Cir. 1977) (Friendly, J.)). The Court should decline the invitation.

In reality, the Program forces manufacturers to surrender valuable products at cut-rate prices, forgo basic procedural protections, and support the Government’s politically expedient narrative—all under the threat of enterprise-crippling penalties. “[L]ike Don Corleone,” the Program makes manufacturers “an offer they c[an’t] refuse.” *Bristol Myers Squibb Co. v. Sec’y of HHS*, 155 F.4th 245, 281 (3d Cir. 2025) (“BMS”) (Hardiman, J., dissenting) (cleaned up).

The Government disagrees, but its arguments defy this Court’s precedents. For more than a century, the Court has held that spending programs are not voluntary when they rely on economic coercion to secure compliance. Such programs, the Court has explained, are subject to constitutional scrutiny. Rather than confronting the disconnect between that principle and the Second Circuit’s reasoning, the Government waves the issue away based on a series of flimsy (and often irrelevant) distinctions. The Government’s efforts to evade the unconstitutional conditions doctrine are equally flawed—for example,

they rely on a relevance test this Court rejected in *Agency for International Development v. Alliance for Open Society International, Inc.*, 570 U.S. 205 (2013) (“*USAID*”), a case the Government never bothers to address.

If left to stand, the Second Circuit’s decision will convert spending programs into a vast Constitution-free zone. Given the sweeping implications of that rationale, the Program’s seismic effects on a major sector of the economy and tens of millions of Americans, and the numerous conflicts between the decision below and longstanding precedent, this Court should grant review and reverse.

ARGUMENT

I. The Questions Presented Warrant Review.

A. The Decision Below Contravenes This Court’s Coercion Precedents.

The Second Circuit’s decision rests on a dangerous categorical rule: government programs are “voluntary,” and thus exempt from constitutional scrutiny, when participation is not “legally compelled.” App.22a-27a. That rule has no limiting principle: Under the Government’s logic, no amount of economic coercion is too much.

That has never been the law. Instead, this Court has long recognized that when a program threatens severe economic consequences to secure compliance, participation is not voluntary and the ordinary rules of constitutional review apply. *See National Federation of Indep. Bus. v. Sebelius*, 567 U.S. 519, 578 (2012) (“*NFIB*”); *United States v. Butler*, 297 U.S.

1, 70-71 (1936). The Second Circuit misread *NFIB* and completely disregarded *Butler*. Pet.15-18.

1. The Government responds by distorting precedent and mischaracterizing the Program.

a. Contrary to the Government’s assertion, the coercion analysis in *NFIB* and *Butler* is not limited to the federalism context. Opp.22.

NFIB recognized that the Tenth Amendment barred Congress from requiring States to accept the proposed Medicaid expansion. 567 U.S. at 577-78. But the Court separately analyzed whether Congress could indirectly coerce the same result by threatening to terminate existing Medicaid funding, an economic “gun to the head.” *Id.* at 580-82. The Court based that inquiry on consent principles—*i.e.*, “voluntar[y] and knowin[g]” acceptance—that extend beyond federalism cases and apply to *all* Spending Clause conditions. *Id.* at 577 (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)). The Government effectively concedes as much, quoting precedent that applies the same test to private parties. Opp.16-17 (quoting *Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022)). There is no reason—and the Government offers none—to require “voluntary and knowing” assent by States and private parties alike, but to protect only States from economic threats that invalidate that consent.¹

¹ The Government’s approach is especially arbitrary because individuals “lac[k] th[e] formidable institutional resources” of States and so are *more* vulnerable to economic coercion. *Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002).

Butler illustrates the point. The plaintiffs there were farmers, not state governments. 297 U.S. at 1, 70-71. But the Court nonetheless concluded that the challenged program was “not in fact voluntary” because it threatened non-participating farmers with the loss of benefits and “financial ruin,” rendering the “choice” to participate “illusory.” *Id.* The Court then assessed the merits of the plaintiffs’ claims, just as the Second Circuit should have done here.

The Government protests that *Butler* is different because the plaintiffs’ claims relied on federalism principles. Opp.22. That argument conflates the Court’s threshold coercion analysis with its downstream merits ruling. *Butler* held that constitutional scrutiny applied because the program coerced private parties, not because it exceeded Congress’s authority, and nothing in *Butler* says the coercion principle is limited to federalism cases.

Union Pacific Railroad Co. v. Public Service Commission, 248 U.S. 67 (1918), and *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936), take a similar approach. True, the condition challenged in *Union Pacific* would have “wholly excluded” an interstate railroad from operating in Missouri. Opp.22. But the railroad was free to continue operating in other states. *See* 248 U.S. at 69. That distinction proves Boehringer’s point: Exclusion from a significant *portion* of the market can constitute “duress” when it leaves no meaningful choice but “the lesser of two evils.” *Id.* at 69-70. *Carter Coal* similarly did not turn on the plaintiffs’ inability to produce or sell “any coal” without penalty. Opp.22. The coal program lacked “the essential element of consent” because it threatened to withhold

relief from severe taxes *unless* producers accepted federal quotas. 298 U.S. at 289.

Put simply, what counts is voluntariness “in fact.” *Id.* at 310. Where, as here, a program eliminates choice through economic coercion, voluntariness is no defense and constitutional scrutiny applies. Pet.15-18.

b. The Government does not deny that this Court has evaluated takings, due process, and compelled-speech claims even when plaintiffs faced no legal mandate to participate in the underlying program or market. *See* Pet.19-21. For each case, the Government offers marginal distinctions but no material differences.

It dismisses *Horne v. USDA*, 576 U.S. 350 (2015), because growers had to exit the market “entirely” to avoid confiscation of their property. Opp.23. But that argument proceeds from a false premise. The growers could have avoided the challenged program (or any fee) by selling their grapes for other uses. *Horne*, 576 U.S. at 364-65. That possibility did not stop this Court from finding a violation of the Takings Clause. *Id.* The same logic holds here: Manufacturers’ theoretical ability to sell drugs in private markets does not justify uncompensated takings within Medicare. Pet.19-21.

Similarly, the Government observes that *Bowles v. Willingham*, 321 U.S. 503 (1944), addressed “a statute of general applicability” regulating all rental prices, while the Program regulates only Medicare. Opp.23-24. That misses the point: *Bowles* addressed the merits of a due process claim even though landlords were not legally required to rent their property and

could have used it for other purposes. *See* 321 U.S. at 517.

As for *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557 (1995), parades no doubt involve “inherent[ly] expressiv[e]” activity. Opp.24. But so do the Program’s mandatory statements and performative negotiations. *See infra* pp.8-9. Besides, arguments regarding whether the Program involves expressive activity go to the merits of Boehringer’s First Amendment claim, not whether the First Amendment applies at all. The key point, overlooked by the Second Circuit, is that *Hurley* analyzed the compelled-speech claim even though the plaintiffs were not legally required to organize the parade. Pet.20-21. As the Government elsewhere acknowledges (Opp.21), First Amendment scrutiny applies when a plaintiff faces “actual compulsion”—a standard satisfied by indirect threats and similar pressures, *see, e.g., Miller v. Mitchell*, 598 F.3d 139, 152 (3d Cir. 2010); *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1290 (10th Cir. 2004); *cf. Am. Commc’ns Ass’n, C.I.O. v. Douds*, 339 U.S. 382, 402 (1950) (“indirect discouragements” can have “the same coercive effect upon the exercise of First Amendment rights as ... fines, injunctions[,] or taxes” (cleaned up)).

2. Is the Program just a run-of-the-mill procurement scheme, as the Government suggests? Not even close. Unlike the examples cited by the Government, the Program relies on sovereign, regulatory powers that no mere market participant possesses. Pet.27-28. When a widget manufacturer objects to the Government’s price, it can simply walk away from the table. The Program does not give Boehringer that option: It cannot refuse CMS’s terms

regarding Jardiance® without triggering a catastrophic 1,900% excise tax (\$5.5 billion *per week* in liability), or an equally catastrophic exclusion of all Boehringer drugs from Medicare and Medicaid (which together account for more than half of Boehringer's domestic net revenues). Pet.7-10.

Those coercive features also set the Program apart from other federal healthcare programs. Opp.5, 15-18. Agencies like the Department of Veterans Affairs rely on market-based benchmarks and do not force manufacturers to adopt the Government's controversial characterization of the pricing process. *See, e.g.*, 38 U.S.C. § 8126. Unlike the Program, these frameworks do not leverage a manufacturer's entire portfolio to obtain concessions on a single drug. In short, the Program goes well beyond what Congress has done before.

More broadly, there is no merit to the Government's suggestion that faithfully applying this Court's coercion precedents will cause the federal bureaucracy to come tumbling down. Opp.17-18. Courts, including this Court, have assessed the constitutionality of government procurement schemes in the past. *See, e.g., O'Hare Truck Serv., Inc. v. City of Northlake*, 518 U.S. 712, 721 (1996). The Government never explains why that analysis poses an existential threat here, and common sense confirms that it does not. There is a difference between constitutional *review* and constitutional *invalidity*; *Butler* and similar precedents merely preclude a voluntariness defense when a program coerces parties into participating. In that scenario, courts still must separately determine whether the challenged regulation complies with the Constitution.

Accounting for economic coercion thus would not require “bespoke deals” or invalidate the hospice-care conditions cited by the Government. Opp.17. The same is true for the Government’s “bargaining terms” in the defense-contracting context. Opp.18. Scrutinizing coercive conditions poses no threat unless the Government takes a “shorter cut than the constitutional way,” as it has here. *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922).

3. As a fallback, the Government contends that Boehringer’s claims fail on the merits. Opp.19-21. Those contentions largely collapse into the voluntariness point addressed above. The Government’s remaining merits arguments simply highlight the Program’s unprecedented nature.

First, regarding due process, the Government attacks a strawman. Boehringer does not claim a right to sell Jardiance® to Medicare at a particular price. *Contra* Opp.20-21. Instead, Boehringer claims that the Program deprives it of the rights to exclude others from accessing its patented products and to refuse forced transfers of its property on terms dictated by CMS. Pet.13-14; *see Bowles*, 321 U.S. at 519-21. The Government does not address those property interests or deny that the Program deprives manufacturers of core procedural safeguards—*e.g.*, by barring judicial review and omitting ascertainable standards to guide CMS’s action. Pet.13

Second, the Government claims that the Program regulates non-expressive conduct and only incidentally burdens speech. Opp.21. But a law that regulates speech is not immune from “searching First Amendment review just because it mostly regulates

non-expressive conduct.” *Chiles v. Salazar*, 146 S. Ct. 1010, 1022 (2026). When laws go beyond *setting* prices and dictate what must be said *about* prices, the First Amendment applies with full force. *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47-48 (2017). The Program “does much more than” merely set prices. *BMS*, 155 F.4th at 284 (Hardiman, J., dissenting). It “goes a step further,” *Chiles*, 146 S. Ct. at 1024, by “forc[ing] [manufacturers] to convey” normative statements “about the Program,” its processes, and the fairness of the resulting prices, *BMS*, 155 F.4th at 283 (Hardiman, J., dissenting).

B. The Decision Below Disregards This Court’s Unconstitutional Conditions Precedents.

Even if the Program were voluntary, it would be subject to scrutiny under the unconstitutional conditions doctrine. The Program violates that doctrine by leveraging valuable benefits to achieve indirectly outcomes that Congress “could not command directly.” *Speiser v. Randall*, 357 U.S. 513, 526 (1958); Pet.21-28.

The Government never squarely confronts that problem. Instead, it repeats the Second Circuit’s missteps by watering down the unconstitutional conditions doctrine in conflict with this Court’s precedents.

1. According to the Government, Congress may impose conditions on spending programs so long as they are “relevant to [a] program’s purpose” and limited to regulating in-program “activities.” Opp.25 (citation omitted). That argument tracks the *dissenting* view in *USAID*, 570 U.S. at 214; *see id.* at

221, 223 (Scalia, J., dissenting). The *USAID* majority rejected a relevance test because it would reduce the unconstitutional conditions doctrine to a “simple semantic exercise”; Congress could always “manipulat[e]” “the definition of a ... program ... to subsum[e] the challenged condition.” *Id.* at 215. To avoid that problem, the Court held that when a condition requires funding recipients to “adopt a particular belief” “on an issue of public concern,” the condition—even if relevant to the program’s purpose—“by its very nature” goes “beyond” regulating the *use* of federal funds and improperly regulates the *recipient’s* speech. *Id.* at 218. That principle applies here given the Program’s “Orwellian” requirement that manufacturers “conve[y] a politically charged message” they “have abjured from the start,” *BMS*, 155 F.4th at 285-87 (Hardiman, J., dissenting). Like the Second Circuit, the Government inexplicably ignores this central holding in *USAID*.

The Program does not, as the Government suggests, leave Boehringer “unfettered in its other activities.” Opp.25 (quoting *Rust v. Sullivan*, 500 U.S. 173, 196 (1991)). Having been forced to publicly proclaim that the price set through the Program is the “negotiated” “maximum fair price” for Jardiance®, Boehringer can advocate for higher prices in the private market “only at the price of evident hypocrisy.” *USAID*, 570 U.S. at 219. And the Program’s spillover effects constrain Boehringer in other ways that extend beyond the Program’s boundaries. For example, state governments have latched onto the Program’s terms by adopting laws

that apply the “maximum fair price” to non-federal markets.²

2. The Second Circuit compounded the problem by refusing to address the lack of proportionality between the Program’s conditions and related benefits. Pet.24-26. Although the Government maintains that proportionality principles are relevant only in land-use cases, Opp.25-26, that argument fails several times over. To start, it overlooks decisions *outside* the land-use context that apply proportionality principles. Pet.25-26. Moreover, the Government fixates on one “special application” of the unconstitutional conditions doctrine, while failing to address the doctrine’s “overarching” principles that apply to all “enumerated rights.” *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013).

The Program contravenes those overarching principles by ransoming existing Medicare and Medicaid coverage for a manufacturer’s *other* drugs to exact speech, property, and due process concessions for a single selected drug. Pet.27. That scheme mirrors the extortionate bargains condemned by this Court’s decisions—*i.e.*, where a regulator obtained otherwise unconstitutional concessions by threatening to withhold or rescind benefits worth more than the rights it sought to take. *See Frost v. Cal. R.R. Comm’n*, 271 U.S. 583, 593 (1926); *Koontz*, 570 U.S. at 605; Pet.26 n.9.

² *See, e.g.*, Md. Code of Regs. § 14.01.07.02 (proposed Apr. 13, 2026) (imposing upper payment limit for Jardiance® based on Program’s “maximum fair price”); Minn. Stat. § 62J.92 (2025) (prescribing an “upper payment limit” for selected drugs “at the Medicare maximum fair price”).

II. This Case Presents Important, Recurring Questions.

The Government does not dispute that this litigation presents questions “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). Rather, it maintains that the harms inflicted by the Program are less significant than its effect on Medicare spending. Opp.26-27. That policy argument does not justify turning a blind eye to the Program’s “byzantine scheme,” *BMS*, 155 F.4th at 289 (Hardiman, J., dissenting), which upends two of the Nation’s largest healthcare programs and slashes the incentives to invest in development of innovative new treatments, Pet.30-32. Moreover, because the Program will expand rapidly in the years ahead, Pet.29-30, the optimal time to take up the questions presented is *now*, before the Program’s distortion of the market becomes widespread.

The far-reaching implications of the Second Circuit’s decision give this case even greater significance. The court applied a broad rule that insulates federal spending programs from constitutional review whenever Congress offers a theoretical opt-out, no matter how coercive or illusory that mechanism may be. App.22a-27a.³ The Government embraces that novel rule, asserting that

³ The Second Circuit’s voluntariness rationale also threatens a broad range of rights outside the Medicare context. *See, e.g., 74 Pinehurst LLC v. New York*, 59 F.4th 557, 563 (2d Cir. 2023) (“voluntar[y]” entry into housing market foreclosed Takings Clause challenge to rent control statute).

Congress has “unrestricted” authority to adopt spending conditions. Opp.20. But if that were true, federal contractors, veterans, and others could be compelled to surrender their constitutional rights to obtain government benefits, without meaningful judicial review. Pet.33. The decision below warrants review because it arms the Government with a blueprint to evade constitutional constraints.

III. This Case Is an Excellent Vehicle.

This case is well suited for the Court’s review. The Government does not contest that it presents pure legal issues that are outcome-determinative and unobstructed by procedural or jurisdictional issues. Pet.33-34.

The Government instead calls for delay. Opp.27. That argument is meritless. All pending petitions that present challenges to the Program are now fully briefed,⁴ and the D.C. and Fifth Circuit cases cited by the Government present only one overlapping issue: due process. Thus, further percolation would likely provide little, if any, benefit. At the same time, delay would impose serious constitutional and practical costs on manufacturers and the public.

⁴ See Nos. 25-348, 25-749, 25-751, 25-761, 25-902.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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