

United States Court of Appeals for the Third Circuit

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

On Appeal from the United States District Court for the
District of New Jersey, Nos. 3:23-cv-03335 & 3:23-cv-03818

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INTRODUCTION

Congress had to act, the government says, to combat “unsustainable” prices for certain high-cost medicines covered by Medicare. Govt.1. It could easily have done so in a constitutional way. Indeed, the government highlights two such ways in the first paragraph of its brief—setting “limits on the amounts that federal agencies will pay” for these medicines, or giving CMS “authority to negotiate prices.” *Id.* But neither of those approaches would have *guaranteed* that manufacturers would provide these critical medicines while still saving Medicare from paying their fair market value. So Congress took “a shorter cut than the constitutional way.” *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922). It ordered the manufacturers to provide “access” to their most valuable medicines at marked-down prices, or else face punishment that would be *even worse*—either impossibly high tax penalties, or wholesale exclusion of the company’s entire portfolio of medicines from coverage under both Medicare and Medicaid.

Everything hinges on that last point. The government does not seriously dispute that if the only options were to fork over the medicines or pay up, that would effect a taking. Its defense of the Program thus reduces to a manufacturer’s theoretical ability to avoid both the appropriation and the penalties by withdrawing all its products from the nearly half of the U.S. prescription-drug market that the government controls. That legal right to withdraw, the government insists, makes any condition Congress imposes “voluntary.” Govt.30. Put a different way, its theory is that Congress is free to say: “Give up your rights, or we will cut you out of other programs, benefits, or contracts.”

That position is profoundly wrong and deeply chilling. The government is open that, in its view, there are *no constitutional limits* on Congress's use of its Spending Clause power to induce the transfer of property or the surrender of other rights. Govt.60. But the Spending Clause is not a blank check. For over a century, the Supreme Court has policed it by requiring that conditions on federal funds be targeted and proportional, and by looking beneath the surface to distinguish voluntary conditions from coercive ones. Those principles do not go out the window when the government buys things. That supposed gap in the unconstitutional-conditions doctrine, which is the fulcrum of the government's brief, flouts both precedent and common sense. And without it, the Program cannot survive. Leveraging billions of dollars in unrelated Medicare and Medicaid spending, all beyond the scope of the Program, to demand one medicine on special terms—that exemplifies an extortionate, coercive, disproportionate condition.

Congress again took a politically expedient but unconstitutional path by compelling manufacturers to publicly “agree” that the government-mandated discounts are the “maximum fair prices” for their medicines, and that those prices were reached through “negotiation.” Here too, the government claims any Medicare condition is *ipso facto* voluntary. Govt.21. That is even more wrong when it comes to the First Amendment. And the government's fallback defenses—that a direct mandate is incidental; these contracts are not speech; and “confessing” to price-gouging is not expressive—are a master class in gaslighting. Congress compelled manufacturers not only to turn over their property, *but to say they agreed to it*. That is anathema to the Constitution.

BMS appreciates that this case involves significant federal legislation that addresses an important matter of public policy. But that makes independent judicial review more critical, not less. This novel Program uses governmental power to appropriate private property and coopt the victims to deceive the public about what happened. Because that scheme doubly violates the Constitution, this Court should reverse.

ARGUMENT

I. THE PROGRAM EFFECTS PHYSICAL TAKINGS BY COMPELLING THE TRANSFER OF DISCOUNTED MEDICINES UNDER THREAT OF PENALTIES.

The government appears to accept that if the Program required BMS to hand over Eliquis at a discount or pay penalties—with no other options—it would constitute a taking. That would be an “appropriation,” no less than compelling farmers to turn over raisins, and so must be compensated. *Horne v. Dep’t of Agric.*, 576 U.S. 350, 358 (2015). Instead, the government rests its entire defense of the Program on the notion that framing this otherwise-unconstitutional scheme as an implicit “condition” on Medicare and Medicaid coverage immunizes it from constitutional scrutiny.

Unsurprisingly, the government cites no authority for that absolutist position. The consequences would be frightening indeed, leaving those dependent on government benefits with no protection against attempts to strip away their constitutional rights. That is not the law: The Supreme Court requires a closer look to ensure the government has not abused the power of the purse. Here, even a cursory glance beneath the surface exposes the Program as a quintessential abuse.

A. The “Access” Mandate Requires Manufacturers To Transfer Selected Medicines to Government-Insured Buyers.

The government agrees that it takes property whenever it compels the owner to transfer possession to a third party. Govt.24, 26. That is precisely what the Program does. It *commands* BMS to provide Medicare beneficiaries with “access” to Eliquis at whatever price CMS dictates. *See* 42 U.S.C. § 1320f-2(a)(3) (ordering that “access to the maximum fair price ... *shall* be provided” by manufacturer (emphasis added)). Refusal triggers “escalating fines ranging from 187.5% to 1,900% of the drug’s price.” *Nat’l Infusion Ctr. Ass’n v. Becerra*, No 24-50180, 2024 WL 4247856, at *1 (5th Cir. Sept. 20, 2024) (*NICA*). The Program thus requires BMS to “physically surrender” Eliquis to Medicare beneficiaries, losing “any right to control the disposition” of medicines that everyone agrees are private property. Govt.24-25 (quoting *Horne*, 576 U.S. at 361, 364).

The government never contests this account of the Program’s “access” mandate. Instead, it suggests the Program involves no taking because it does not authorize CMS to send “trucks” to BMS’s warehouse to “haul away” Eliquis. Govt.29. That artificial distinction does not help the government, because the Constitution does not care how an appropriation “comes garbed.” *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021). The Program’s regime of forced sales backed by severe penalties is functionally and constitutionally equivalent to directing manufacturers to load the medicine onto CMS trucks under threat of sanctions. It merely cuts out the middleman by forcing the transfer to be made directly to the third parties for whom Medicare is the payor.

Consequently, the government must pay “fair market value” for the medicines BMS is forced to distribute. *United States v. Reynolds*, 397 U.S. 14, 16 (1970). The government does not dispute that the Program will pay BMS only steeply below-market payments. The Program therefore effects uncompensated takings.

Instead of contesting any of this, the government rests its defense of the Program solely on the “option” to withdraw from Medicare and Medicaid altogether. Govt.39. (That “option” appears to be what the government means when it says repeatedly that manufacturers are not forced to “sell their drugs” to Medicare. Govt.38-39.) In doing so, the government abandons key parts of the district court’s rationale. While that court suggested that BMS could refuse to sell Eliquis *alone* to Medicare while continuing to retain coverage for its *other* medicines (JA.14), the government does not defend that reasoning or address BMS’s showing that this “option” does not exist in law or fact. *Compare* BMS.18-24, *with* Govt.30-36; *see NICA*, 2024 WL 4247856, at *5 (recognizing that an opt-out manufacturer “must remove *every* drug that it produces from Medicare coverage, not just the drug that is the subject of the negotiation”).¹ Nor does the government defend the clearly erroneous view that BMS’s option to “divest” its Eliquis business somehow absolves the government of liability. *Compare* JA.12, *with* Govt.39.

¹ Despite not otherwise pressing the point, the government does parrot the court’s claim that BMS “conceded at oral argument” that a manufacturer is not required to “physically transmit” its drugs. Govt.29. As BMS pointed out, the court erroneously cited a comment by the *government’s* attorney. JA.12 (citing Tr. 58); BMS.20 n.6. The government’s reliance on a fictional concession is baffling.

The parties thus agree that a manufacturer cannot simply refuse to sell the selected drug to Medicare, while avoiding other adverse consequences. The government's brief makes clear that this case instead reduces to whether BMS's "option" of withdrawing entirely from Medicare and Medicaid cures the constitutional problem. As explained next, it does not. It instead runs headlong into the unconstitutional-conditions doctrine and well-established limits on the Spending Power.

B. The "Option" To Withdraw All Medicines from Federal Insurance Coverage Does Not Save the Program.

It is true that, in lieu of handing over its property at deep discounts or paying vast tax penalties, a manufacturer can accept a different sort of sanction: exclusion of every medicine in its portfolio from coverage under Medicare and Medicaid. The core issue is whether that option automatically renders the transfer of property "voluntary" and therefore immune from takings liability. On appeal, the government goes all-in on the notion that there are no limits on how it can "use its leverage" to "define" the terms of spending programs. Govt.51, 60-62. But as this Court has recognized, "government incentives" enabled by the Spending Clause "may be inherently coercive." *Koslow v. Commonwealth*, 302 F.3d 161, 174 (3d Cir. 2002). And given the government's dominant role in many economic sectors, adopting its position would give Congress nearly unlimited authority to circumvent constitutional rights simply by framing its demands as "conditions" on existing spending programs. Two related strands of Supreme Court jurisprudence confirm that the government's absolutist position is wrong.

1. The Program violates the unconstitutional-conditions doctrine.

Whenever the government claims a constitutional right has been voluntarily waived in exchange for a benefit, the unconstitutional-conditions doctrine is implicated, and the supposed exchange must be tested under that framework. Even under the most lenient variant of the doctrine, the government may condition a benefit on the forfeiture of a property right only if the condition has an “essential nexus” to the benefit and is “rough[ly] proportiona[l]” to it. *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994); *Nollan v. Cal. Coastal Comm’n*, 483 U.S. 825, 834-37 (1987).² Neither condition is satisfied by the Program’s attempt to leverage *other* sales to Medicare and Medicaid to coerce BMS’s submission to the conscription of *one* product. *Accord* NCLA.Amicus.21-33.

To start, there is no “essential nexus” because the Program seeks to extract a below-market price for *Eliquis* by threatening funding for *other* medicines. *Dolan*, 512 U.S. at 386; BMS.43-44. The Program could have conditioned Medicare coverage for *Eliquis* on BMS’s agreement to a mutually acceptable price for that medicine in particular. That way, BMS would have had a choice whether to sell at the government’s price, and the government would have had a choice whether to buy at BMS’s price. Instead, the

² The government suggests *Nollan-Dolan* applies only in the land-use context. Govt.57 n.6. But in a recent decision that the government ignores, the Supreme Court clarified that the nexus-and-proportionality test is “rooted” in, and was “modeled on[,] the unconstitutional conditions doctrine.” *Sheetz v. Cnty. of El Dorado*, 601 U.S. 267, 275, 278 (2024). And that doctrine applies *whenever* Congress tries to infringe “enumerated rights [by] coercing people into giving them up” through conditions. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013).

Program leverages *unrelated* benefits—coverage for other BMS medicines under both the Medicare and Medicaid programs—to coerce consent to the requisition of Eliquis alone. *See NICA*, 2024 WL 4247856, at *5 (noting that a noncompliant manufacturer must “remove *every* drug that it produces from Medicare coverage, not just the drug that is the subject of the negotiation”). That cross-collateralized setup is a “powerful indicator [that] the condition” is unlawful. P. Hamburger, PURCHASING SUBMISSION 69 (2021). Withholding distinct, preexisting benefits to secure acceptance of a new, unrelated condition strongly suggests the government is “leveraging its ... monopoly to exact private property without paying for it.” *Sheetz*, 601 U.S. at 275.

Nor is the threat to terminate Medicare and Medicaid coverage for all of BMS’s medicines “rough[ly] proportiona[l],” *Dolan*, 512 U.S. at 391, to the demand to transfer a single medicine at a discount. The government controls “almost half [the Nation’s] annual nationwide spending on prescription drugs.” *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Being barred from selling to half the national market would crush a manufacturer (and its patients), which is why the Program’s demands cannot rationally be resisted. *See NICA*, 2024 WL 4247856, at *5 (“[T]he penalties the Program imposes make reaching an agreement all but certain.”); IWF.Amicus.9-10.

The government largely glosses over this all-or-nothing aspect of the Program. But that is its core constitutional defect: Using power over *A* to force concessions on *B* is “extortion,” just like using power over zoning changes to extract “unrelated” property rights without paying for them. *Nollan*, 483 U.S. at 837.

The government presses two arguments for why the Program does not violate the unconstitutional-conditions doctrine. Both fail.

First, the government argues that the unconstitutional-conditions doctrine applies only to *gratuitous* benefits, not to situations where the government is *buying or selling*. Govt.56-59. In the latter scenario, the government insists, it has a blank check to exert economic pressure of any kind, and to any degree, to secure its desired outcomes. That is plainly wrong—as a matter of both precedent and logic.

To start, Supreme Court precedent proves that the unconstitutional-conditions doctrine applies even where the party receiving government funds provides services in exchange. For example, in *Agency for International Development v. Alliance for Open Society International*, grant recipients entered a contractual agreement under which they received federal funds in exchange for work combating HIV. 570 U.S. 205, 209-10 (2013) (*AID*). That the government “procure[d]” public-health services (Govt.57) did not immunize its conditions from scrutiny. To the contrary, the Court invalidated those conditions. *See* 570 U.S. at 214-15. Likewise, even though public employees sell their labor to the state, the doctrine restricts the government’s ability “to leverage the employment relationship to restrict, incidentally or intentionally, the liberties [its] employees enjoy.” *Garcetti v. Ceballos*, 547 U.S. 410, 419 (2006); *see also Perry v. Sindermann*, 408 U.S. 593, 597 (1972). As the Court explained in rejecting a similar request for “a special exception,” the unconstitutional-conditions doctrine “span[s] a spectrum” of “relationship[s]” between the government and those who receive its funds. *Bd. of Cnty. Comm’rs. v.*

Umbehr, 518 U.S. 668, 680-81 (1996); *see also Planned Parenthood of Greater Ohio v. Hodges*, 188 F. Supp. 3d 684, 691-93 (S.D. Ohio 2016) (finding likelihood of success on unconstitutional-conditions challenge to law excluding abortion provider from receiving state grants and contracts). This Court should not break new ground by categorically excluding “procurement” from the doctrine’s domain.

The government’s novel “procurement” exception is also deeply illogical. Again, this doctrine exists to prevent the government from leveraging its spending power to coerce individuals into giving up their constitutional rights. *See, e.g., Koontz*, 570 U.S. at 604. The government says that entities selling goods or services enjoy “bargaining power” and thus the ability to walk away. Govt.58-59. But that is equally true of the funding recipients in heartland unconstitutional-conditions cases. The landowners in *Nollan* and *Dolan*, the contractors in *AID*, and the employees in *Garvetti* had the leverage to deny the government their property or services. But the unconstitutional-conditions doctrine appreciates that the government almost always has *far more* leverage thanks to its unique sovereign authority to tax and spend—and that protecting individual rights requires policing the government’s use of that leverage.

Second, the government posits that its threat to Medicare and Medicaid coverage is acceptable because it falls within the Program’s “scope.” Govt.60-64. This wordplay is a favorite government tactic, because “the definition of a particular program can always be manipulated to subsume the challenged condition.” *AID*, 570 U.S. at 215; *see id.* at 214 (rejecting theory that a condition is unconstitutional only if “not relevant to

the objectives of the program”). That is why the Supreme Court has warned that the government “cannot recast a condition on funding as a mere definition of its program in every case, lest [the doctrine] be reduced to a simple semantic exercise.” *Id.* at 215.

With that warning in mind, it is apparent that threatening coverage for all medicines under Medicare and Medicaid is not within the “scope” of the Program. Govt.62. The government’s power to set conditions on a program’s “scope” is just another way of saying that the government gets to decide how its funds will be spent. *See Gruver v. La. Bd. of Supervisors*, 959 F.3d 178, 183 (5th Cir. 2020). That is not what is happening here. The Program’s “scope” concerns *selected drugs*—here, Eliquis. All agree that the Constitution would permit the government to withhold payment for Eliquis until BMS agrees to a price; that is inherent in any bargained-for exchange, and an appropriately targeted condition. But that arrangement would give bargaining power to *both* sides. To strip BMS’s leverage, the Program goes much further—withholding not only Eliquis coverage but also *all federal payments for every other BMS product* until BMS “agrees” to the government’s demand to transfer Eliquis at a discount.

In sum, the Program conditions the government’s purchases of products A through Y on the manufacturer’s “agreement” to sell it product Z on favorable terms. As BMS explained and the government ignores, the government’s own antitrust enforcers call that illegal “tying,” and even sued a pharmaceutical manufacturer for allegedly doing it. BMS.44-45. The Program does the same basic thing to achieve the same basic result. It is an unconstitutional exploitation of the Spending Clause.

2. The Program’s funding “offer” is unconstitutionally coercive.

Treated as a condition on Medicare and Medicaid coverage, the Program’s “offer” is also unconstitutionally coercive. Spending Clause legislation must present a truly “voluntary” exchange, even in the context of private funding recipients. *See Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219-20 (2022). Conditions on receipt of government funds are unlawful when “persuasion gives way to coercion.” *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 585 (2012) (*NFIB*). Congress must offer a *genuine* choice; the option to decline cannot be “illusory,” *United States v. Butler*, 297 U.S. 1, 71 (1936), and must exist “not merely in theory but in fact,” *NFIB*, 567 U.S. at 581.

It is hard to imagine a closer analogy to *NFIB* than the Program. BMS.40-42. As in *NFIB*, manufacturers face the loss of existing funding streams if they do not bow to the Program’s new demands. As in *NFIB*, those preexisting funding streams are crucial to the manufacturers’ viability, leaving them with only the illusion of choice. *See NICA*, 2024 WL 4247856 at *5 (submission “all but certain”). And as in *NFIB*, the new “conditions” work a major revision to the original bargain. Medicare Part D forbade government interference in negotiations between manufacturers and plan sponsors—a feature its proponents called a “fundamental protection” against “price fixing by the CMS bureaucracy.” 149 Cong. Rec. S15624 (Nov. 23, 2003) (Sen. Grassley). The Program breaks that promise. All told, the IRA coerces compliance with its new Program just as the Affordable Care Act coerced States to expand Medicaid.

The government does not dispute *any* of those obvious parallels to *NFIB*. Instead, it argues that this limit on Congress’s authority simply does not exist in this context. Here too, the government presses two distinctions; here too, both fail.

First, the government argues that the restrictions enforced in *NFIB* only apply when Congress makes a funding offer to a *State*. Govt.40-41, 52-53. Not so. In *NFIB*, the Tenth Amendment’s guarantee of State sovereignty provided the substantive check on Congress’s ability to mandate Medicaid expansion *directly*—that would have violated the anti-commandeering doctrine. *NFIB*, 567 U.S. at 577-78. But the lack of *direct* authority is what raised the next question: whether Congress could “us[e] financial inducements” to achieve the same result—*i.e.*, to “*indirectly* coerce[] a State to adopt a federal regulatory system as its own.” *Id.* (emphasis added). The Court’s relevant analysis focused on that distinct second question, assessing whether the funding offer amounted to “economic dragooning” that left States “no real option but to acquiesce.” *Id.* at 578, 582.

Here, the substantive bar to direct federal action comes from the Fifth Amendment, not the Tenth. The Takings Clause, not federalism, bars Congress from simply ordering BMS to turn over its property. *See* Part I.A, *supra*. But the next question—whether the Spending Clause allows the government to do *indirectly* what it cannot do *directly*—is the same. It asks whether “persuasion [has] give[n] way to coercion.” *NFIB*, 567 U.S. at 585. And private entities, no less than States, can face a “gun to the head” when the government threatens “ruinous” “loss of federal funds.” *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (quoting *NFIB*, 567 U.S. at 581-82).

NFIB thus simply represents a specific application of the same test the Supreme Court has applied for over a century in reviewing unconstitutional conditions: asking whether rights have been abridged “by the indirect ... process of requiring a surrender, which, though, in form voluntary, in fact lacks none of the elements of compulsion.” *Frost v. R.R. Comm’n of Cal.*, 271 U.S. 583, 593 (1926); *see also Koontz*, 570 U.S. at 607; *Koslow*, 302 F.3d at 174 (“The ‘unconstitutional conditions’ doctrine is based on the proposition that government incentives may be inherently coercive.”); *Pace v. Bogalusa City Sch. Bd.*, 403 F.3d 272, 286-87 (5th Cir. 2005) (en banc) (“[T]he unconstitutional-conditions doctrine ... is anchored at least in part in a theory of coercion.”). These two lines of precedent—cases like *NFIB* policing inducements that lead States to forfeit their sovereignty, and cases like *Koontz* and *Frost* policing inducements that lead private parties to forfeit their rights—stand for the same proposition: “what cannot be done directly because of constitutional restriction cannot be done indirectly.” *Pac. Co. v. Johnson*, 285 U.S. 480, 501 (1932). And to identify that circumvention, the Court seeks to distinguish coercion from voluntary acceptance. Kathleen Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413, 1428-34 (1989).³ That inquiry cannot be bypassed here.

³ *See also, e.g., Frost*, 271 U.S. at 593 (“compulsion”); *Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937) (“undue influence”); *Speiser v. Randall*, 357 U.S. 513, 518-19 (1958) (“coercing”); *Butler*, 297 U.S. at 71 (“coercion by economic pressure”); *Union Pac. R.R. Co. v. Pub. Serv. Comm’n*, 248 U.S. 67, 70 (1918) (“duress”); *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (“compulsion”); *accord* Chamber.Amicus.14-18 (analyzing some of these cases in greater depth).

In response, the government’s only authority for its federalism limitation on *NFIB* is a footnote in which the Eighth Circuit *declined to address* an *NFIB* challenge to a regulation barring arbitration with nursing homes. *Northport Health Servs. of Ark. v. HHS*, 14 F.4th 856, 869 n.5 (8th Cir. 2021). No court has adopted the argument. This Court should not be the first to discard such a crucial protection for individual rights.

Second, the government claims it is allowed to engage in coercion whenever it acts as a “market participant” rather than a regulator. Govt.53-54. No authority supports that distinction. Most of the government’s cases stand for the unremarkable point that States sometimes act as market participants rather than regulators—which matters for some *preemption* doctrines. *See Chamber of Com. of U.S. v. Brown*, 554 U.S. 60, 70 (2008) (NLRA preemption); *Associated Builders & Contractors Inc. v. City of Jersey City*, 836 F.3d 412, 417-18 (3d Cir. 2016) (ERISA preemption). The government’s other cases hold only that States’ market activities—as opposed to regulations—are outside the scope of the Commerce Clause. *Reeves, Inc. v. Stake*, 447 U.S. 429, 435-37 (1980); *Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006). None of these cases has any relevance here.⁴ This is just another version of the claim that procurement is a Constitution-free zone—and fails for the same reasons: No case supports this exception to the limits on Congress’s power, and adopting it would gut those limits. *See supra* at 9-10.

⁴The Government also cites *Biden v. Missouri*, 595 U.S. 87 (2022) (per curiam), which rejected a challenge to HHS’s statutory authority to impose a vaccine requirement for hospitals participating in Medicare and Medicaid. The Court did not say that HHS was acting as a market participant, apply *NFIB*’s coercion test, or even cite *NFIB*.

More fundamentally, a spending-vs.-regulation distinction would prove too much, collapsing the Spending Clause framework that undergirds *NFIB* and many other cases. By definition, Congress is *never* engaged in regulation when it makes conditional funding offers—whether to States or private entities. It is instead exercising its *spending* power. “Unlike ordinary legislation, which ‘imposes congressional policy’ on regulated parties ‘involuntarily,’ Spending Clause legislation operates based on consent.” *Cummings*, 596 U.S. at 219. The dispositive question thus remains whether BMS *did* “consent”—*i.e.*, whether it could “voluntarily ... accept” the Program’s coercive terms. *Id.*

In any event, the government’s claim that it enacted the Program in its role as a “market participant” is fantastical. The Program is a quintessential exercise of *sovereign power*, not ordinary market participation. *See* NCLA.Amicus.22-23. Market participants cannot impose debilitating penalties on counterparties who reject their terms, as Congress provided in the Program. Nor can a market participant legislate its own monopsonistic leverage, as Congress did over the prescription market by enacting Medicare Part D. And only the government can punish counterparties by shutting them out of other markets: The antitrust laws prohibit private entities from abusing their market power that way—again, a point the government does not dispute.

In the end, these twin lines of Supreme Court precedent lead to the same bottom line: The Program uses sovereign power to coerce BMS to hand over Eliquis without just compensation. That violates the Constitution.

C. The Government’s Authorities Are Inapt.

At odds with first principles and Supreme Court precedent, the government tries to shield its sweeping “voluntariness” argument behind out-of-circuit cases rejecting challenges to other Medicare provisions. Govt.26-28, 35-36, 52. These authorities are inapposite. None holds that the government may punish a refusal to transfer property by imposing penalties or excluding the recalcitrant owner from other benefits.

Most merely uphold the government’s right to determine “the amount it will pay for ... services” (Govt.27), without *requiring* sellers to provide those services or *punishing* them for refusal to do so. *See, e.g., Whitney v. Heckler*, 780 F.2d 963, 968, 972 (11th Cir. 1986) (freeze on amounts physicians could “charge their Medicare patients,” whom they were “not required to treat”); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875-76 (7th Cir. 1983) (per curiam) (rejecting challenge to reimbursement rate that was allegedly “so low” as “to be confiscatory”); *Se. Ark. Hosp., Inc. v. Burwell*, 815 F.3d 448, 449-50 (8th Cir. 2016) (upholding statutory reimbursement cap for hospice care).

These decisions are irrelevant. BMS agrees that the government is free to cap “the amount it will pay” for Eliquis. Govt.27. There might be economic pressure to accept a low price, but that still would be a genuine choice—not an extortionate one—because it would not bring extrinsic leverage to bear in the form of penalties or exclusion from other government benefits. The problem is not that the Program limits the amount Medicare will pay for Eliquis, but rather that it subjects BMS to penalties or wholesale exclusion from Medicare and Medicaid coverage if it refuses to sell at that price.

In one cited case, a provider contended that a statute “impermissibly condition[ed]” Medicaid participation “on the relinquishment ... of constitutional rights.” *Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984). But that claim failed because the “condition”—that nursing homes could not charge non-Medicaid patients higher rates—did not implicate a constitutional right, as there is “no constitutional right to be free from state controls on [those] rates.” *Id.* at 446-47. Because the State may cap prices *directly*, it was free to do so *indirectly*. (So too in *Northport Health* and *Biden v. Missouri*: The arbitration and vaccine conditions could have been mandated directly, leaving no basis for an unconstitutional-condition claim.) Here, though, the Takings Clause forbids mandating that BMS *transfer* Eliquis to others. So, unlike those cases, the Program does “compel[] the relinquishment of constitutional rights that [BMS] would otherwise have.” *Minn. Ass’n*, 742 F.2d at 446.

Two other cases involved providers who claimed they were compelled to provide services at a discount. As one court observed, though, it is not clear “that professional services constitute property protected by the Takings Clause.” *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991). Regardless, both courts rejected the premise of compulsion, for factual reasons inapplicable here. *See id.* (compulsion fell on hospitals, not physician-plaintiffs); *Garellick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993) (“anesthesiologists can ... practic[e] on an outpatient basis”). Here, by contrast, the Program compels BMS to sell property for below-market value, with no way to refuse without triggering adverse consequences from the government (beyond merely loss of those sales).

All that aside, none of the government’s cases supports its claim that the Program is voluntary. The Supreme Court’s standards for coercion and proportionality are fact-intensive. And this case involves unprecedented facts: (1) threatened exclusion from nearly half the Nation’s prescription drug market; (2) calamitous financial penalties; and (3) a fundamental change to a preexisting funding relationship on which manufacturers have relied for decades. The government’s cases involved no such extremes. Nor did the other schemes the government notes in passing (Govt.9, 34), which is why—unlike the Program—they were accepted without protest and never challenged.

In the end, this Court must scrutinize the particular “condition” here under the frameworks set forth by the Supreme Court in cases like *Nollan*, *Dolan*, *Koontz*, *AID*, and *NFIB*. The Program cannot pass muster under those tests. And outdated, legally inapposite, factually distinguishable, out-of-circuit cases cannot save it.

* * *

The government’s position is sweeping and striking. On its view, hospitals could be forced to give union organizers access to their property, or lose Medicare and Medicaid reimbursements. Defense contractors could be compelled to endorse military aid to Ukraine, or lose their existing (and future) weapons contracts. *See infra* Part II.A. Public employees could be instructed to vote for the incumbent President, or be fired. All that and more would be *immune* from constitutional scrutiny, on the ground that these are “voluntary” conditions on government spending.

By contrast, BMS asks the Court to apply longstanding doctrines that impose modest limits on the government’s extraordinarily potent spending power. Enforcing those rules will *never* force the government to purchase “at prices [it] is unwilling to pay.” Govt.32. BMS agrees that the government can negotiate over the price of Eliquis, and is always free to walk away—with no punishment from BMS—if mutually agreeable terms cannot be found. All BMS wants is that same right. The Constitution guarantees it; the Program denies it.

II. THE PROGRAM COMPELS SPEECH BY REQUIRING MANUFACTURERS TO PUBLICLY “AGREE” TO CONTESTED POLITICAL PREMISES.

A straightforward edict to provide access to Eliquis at a discount would have served the government’s *economic* goals. But to better advance the government’s *political* goals, the Program instead effectuates a First Amendment violation by obscuring its “access” obligations using the charade of an “agreement.” Under threat of penalties, it obligates BMS to “agree” in a written, public document that it and CMS have determined through “negotiation” that the “maximum fair price” for Eliquis is a fraction of its market value. That unprecedented scheme compels BMS to speak and to betray its own beliefs. *See* BMS.25-38. Contrary to the district court and the government, this is not “voluntary” but instead the type of forced pledge-of-allegiance the Supreme Court has invalidated as a condition on receipt of federal funds. And the government’s fallback defenses rest on mischaracterizations of both the Program and the First Amendment.

A. The Program’s Compelled Speech Is Not Voluntary.

The government principally retreats to its theory that the Program is voluntary. Govt.42-43. But as explained, if BMS does not sign a document “agree[ing]” that it is turning over Eliquis at a “fair price,” it must pay steep penalties or accept banishment from the entire Medicare and Medicaid markets. This bears no resemblance to typical government contracting, in which the contractor can walk away with no consequences extrinsic to the transaction. *Contra* Govt.45-47. “Voluntariness” is no more a solution to the Program’s speech mandate than it is to the forced-access mandate.

In fact, the government’s argument is even *less* persuasive in the First Amendment context. BMS.45. The Supreme Court has “broadly rejected the validity of limitations on First Amendment rights as a condition to the receipt of a governmental benefit.” *Elrod v. Burns*, 427 U.S. 347, 359 (1976) (plurality op.). It has held that Congress may *never* use funding conditions to “requir[e] recipients to profess a specific belief” or express “the Government’s view on an issue of public concern.” *AID*, 570 U.S. at 218. And that is true even if the funding condition is *not* “actually coercive, in the sense of an offer that cannot be refused.” *Id.* at 214. Thus, even if BMS had an actual (as opposed to merely theoretical) escape route from the Program, its speech mandate would remain unconstitutional. *See* IFS.Amicus.7-13.

Again, the government insists the condition is permissible because it is sufficiently “connected to” the Program’s “contours.” Govt.62-64. Again, that is wrong. For one thing, that principle has never been employed to justify compelled speech. For another,

it does not apply on its own terms. Unlike the statutes in the government’s cases, the Program’s “agreement” mandate does not merely implement a congressional decision about what kinds of services, products, or speech to subsidize. *E.g., Rust v. Sullivan*, 500 U.S. 173, 178, 196-99 (1991). Proving the point, an alternative version of the Program that set prices *without* an “agreement” mandate would result in the *exact same* spending. Instead, the Program forces funding recipients to express “the Government’s view[s]” about the fairness of its prices—“by its very nature,” going “beyond defining the limits of [a] federally funded program.” *AID*, 570 U.S. at 218.

The government’s other authorities are equally inapt. It cites *Rumsfeld v. FAIR*, but the Court there held that the statute did not “dictate the content of ... speech at all.” 547 U.S. 47, 62 (2006). From this Court, the government invokes *C.N. v. Ridgewood Board of Education*, but the compelled survey there did not violate the First Amendment only because the school imposed no “disincentive or penalty if the survey was not completed.” 430 F.3d 159, 189 (3d Cir. 2005) (cleaned up). Here, BMS must pay an enormous “penalty,” *id.*, if it does not speak as the Program demands, *see NICA*, 2024 WL 4247856 at *1-2 (documenting “penalt[ies]”). And the prospect of being shut out of half the U.S. pharmaceutical market is a decisive “disincentive.”

The government does identify one on-point case, but it only proves BMS’s point. In *Miller v. Mitchell*, this Court found a First Amendment violation where a student was required to write an essay explaining that her actions were wrong. *See* 598 F.3d 139, 151-52 (3d Cir. 2010). The student could refuse to self-flagellate, but doing so would

not be “free of consequences.” *Id.* at 151. So too here: BMS must confess that all its past prices for Eliquis exceeded the “maximum fair price,” and refusal to do so carries severe “consequences.” That choice violates the First Amendment.

B. The Government’s Fallback Arguments All Fail.

The government has never claimed the Program can survive heightened scrutiny, so it instead offers a series of slapdash arguments to resist the need to apply *any* scrutiny to the Program’s “agreement” mandate. None of these arguments has merit.

First, the government insists that the Program imposes only “incidental burdens on speech,” like “typical price regulation.” Govt.45. Hardly. Price ceilings *indirectly* impact speech because they make certain offers unlawful; that effect is merely incidental to the conduct regulation. But the Program *directly* mandates that BMS express written assent to an “agreement” *about* the price of Eliquis, its “fair[ness],” and the process by which it was set. 42 U.S.C. § 1320f-2(a). As the government admits, the “agreements” are the very “mechanisms” for achieving the statute’s goals. Govt.49. That is exactly the point: Price regulations regulate *prices* (conduct), but the Program compels *agreements* (speech), and instrumentalizes that private speech to achieve other, public ends. That implicates the First Amendment. *See* BMS.32-33.

Second, citing *Meese v. Keene*, 481 U.S. 465 (1987), the government suggests that being forced to agree to “statutory terms” cannot be compelled speech. Govt.48. But the government never answers BMS’s explanation that *Keene* did not even imply, much less establish, that supposed limit on the compelled-speech doctrine. BMS.35-36.

Finally, the government denies that the agreements are “expressive.” Govt.44-46. But agreements are *speech*. Not all *conduct* is “expressive,” but—to state the obvious—“creation and dissemination of information are speech within the meaning of the First Amendment.” *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 570 (2011). Of course, “run-of-the-mill commercial contracts” do not implicate the First Amendment. BMS.34. But “run-of-the-mill commercial contracts” are not compelled by threat of sanctions. And, unlike “run-of-the-mill commercial contracts,” Congress mandated (and CMS drafted) these contracts to convey that manufacturers “agreed” on a “maximum fair price” in “negotiations.” Those points of “agreement” are expressive. *See New Hope Family Servs., Inc. v. Poole*, 966 F.3d 145, 177-78 (2d Cir. 2020) (requiring adoption agency to approve placement forced it to “communicat[e]” state’s “viewpoint” on child’s best interests).

Indeed, the contracts here serve no other purpose. The only reason for Congress to have infused the Program with manufacturer speech about “maximum fair prices” is to convince the public that the Program operates through bargaining rather than decree. The President, agencies, and media have relied on these “agreements” to promote that false narrative. BMS.8-9, 30-31. Grasping for an alternative theory, the government suggests Congress wanted “CMS to hear from manufacturers.” Govt.50. That cannot pass any smell test. If Congress wanted CMS to receive manufacturer input before setting a price, it could have simply directed CMS to pick up the phone. Or required a comment period. *E.g.*, 5 U.S.C. § 553. That would have compelled zero speech while allowing the government to “revise” decisions and “accept” suggestions. Govt.50.

The government also posits that the agreements serve the purpose of “committing the parties to a shared understanding of their contractual obligations.” Govt.49. Again, that proves BMS’s point. When Congress wants to impose “obligations,” it typically does so by writing them into the U.S. Code. But “shared understandings” make for a better campaign ad. So, once again, Congress took “a shorter cut than the constitutional way,” *Penn. Coal*, 260 U.S. at 416, this time by forcing BMS to serve as a mouthpiece for political messaging. The First Amendment forbids this conscripted theatre.

CONCLUSION

The Court should reverse the decision below.

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COMBINED CERTIFICATIONS

In accordance with the Federal Rules of Appellate Procedure and the Local Rules of this Court, I hereby certify the following:

1. I am a member in good standing of the Bar of this Court.
2. This Brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) because it contains 6,494 words, excluding the parts exempted by Fed. R. App. P. 32(f).
3. This Brief complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) & (a)(6) because it has been prepared using Microsoft Word in a proportionally spaced 14-point font (Garamond) in the text and the footnotes.
4. The text of the electronic Brief is identical to the text in the paper copies.
5. The electronic file containing the Brief was scanned for viruses using the most recent version of a commercial virus scanning program, and no virus was detected.

Dated: October 2, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on October 2, 2024, this brief was electronically filed with the Clerk of Court using the appellate CM/ECF system. Service on counsel for all parties in the district court has been accomplished via notice filed through the district court's CM/ECF system attaching a copy of this filing.

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