Nos. 24-1820 & 24-1821

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

OPENING BRIEF FOR APPELLANT BRISTOL MYERS SQUIBB COMPANY

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, NY 10281

Jeffrey J. Greenbaum
Katherine M. Lieb
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102

Noel J. Francisco
Yaakov M. Roth
Brett A. Shumate
Charles E.T. Roberts
John Henry Thompson
Louis J. Capozzi III
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
(202) 879-3939

Counsel for Bristol Myers Squibb Company

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit LAR 26.1, Appellant Bristol Myers Squibb Company states that it has no parent corporation and no publicly held corporation holds 10% or more of its stock. Further, no publicly held corporation not a party to this proceeding has a financial interest in the outcome of this proceeding.

Dated: July 12, 2024

/s/ Jacob (Yaakov) M. Roth
Jacob (Yaakov) M. Roth

Counsel for Appellant Bristol Myers Squibb Company

INTRODUCTION

This is a constitutional challenge to the Medicare Drug Price Negotiation Program that Congress enacted in the Inflation Reduction Act (IRA). The Program's name suggests that Congress merely authorized Medicare to negotiate the prices it pays for prescription medicines. That is certainly how the Program was sold to the public.

Yet, in fact, the Program involves no real negotiations and no genuine agreements. Congress was not willing to risk that real negotiations would fail, leaving tens of millions of American seniors without their medicines. Instead, the Program uses the threat of enormous monetary penalties to compel manufacturers to provide Medicare with "access" to their leading medicines at steep discounts. It then forces manufacturers to "agree," in written public documents, that those discounts represent the "maximum fair prices" for their most valuable products. Doing so conceals the Program's central-planning approach, which the public would correctly recognize as a major impediment to life-saving pharmaceutical innovation.

This scheme violates the Constitution. Most obviously, it effects a taking of private property without just compensation, in violation of the Fifth Amendment. The whole point of the Program is to obtain medicines for Medicare beneficiaries without the need for the government to pay fair market value. It uses the threat of draconian penalties to force manufacturers, like Appellant Bristol Myers Squibb Co. (BMS), to transfer groundbreaking medicines for a fraction of their market price. This is a classic, *per se*, physical taking.

More subtly, the Program compels speech in violation of the First Amendment. Instead of authorizing Medicare to set prices for covered medicines, Congress required a regime of faux "negotiations" that ends with the manufacturer signing an "agreement" publicly professing that the government-dictated price is the "maximum fair price" for its medicine. This convoluted regime serves only to deceive the public and obscure the reality of an unprecedented, top-down government takeover of the U.S. pharmaceutical industry. But the First Amendment prohibits the government from forcing companies to carry its political water. The Program is thus unconstitutional twice over.

The district court upheld it nonetheless. To justify the government's conscription of property and speech, the court primarily reasoned that manufacturers could avoid the Program's penalties by withdrawing *all* their medicines (not merely the selected one) from Medicare and Medicaid. The district court thought that rendered the Program "voluntary" and thus immune from constitutional scrutiny altogether. That is deeply mistaken. Congress cannot leverage distinct government benefits, even "voluntary" ones, to extort the abandonment of constitutional rights; that is the core of the venerable "unconstitutional conditions" doctrine. The IRA exploits the government's dominant (nearly 50%) share of the U.S. pharmaceutical market to force manufacturers to turn over their property and parrot government talking points. That "condition" is coercive and disproportionate. It is no more constitutional than telling retirees they can keep their "voluntary" Social Security benefits so long as they fly an American flag, turn their backyards into public parks, or endorse the President.

The implications of the ruling below are thus far-reaching and grave, for patients and non-patients alike. The Supreme Court has long warned that Congress's Spending Power, left unchecked, could be abused to coerce the surrender of constitutional rights. *E.g.*, *Frost v. R.R. Comm'n of Cal.*, 271 U.S. 583, 594 (1926). If mere acceptance of federal benefits renders submission to *any* supposed condition "voluntary," no right is safe. This Court should refuse to launder coercion into consent. It should reverse.

STATEMENT OF JURISDICTION

This Court has jurisdiction under 28 U.S.C. § 1291 because BMS timely appealed (JA.29) from a final judgment (JA.27). The district court had jurisdiction under 28 U.S.C. § 1331 because BMS's claims arise under the U.S. Constitution.

STATEMENT OF THE ISSUES

1. Whether the Program effects takings that require just compensation under the Fifth Amendment. JA.5-18, 44-46.

2. Whether the Program compels speech in violation of the First Amendment. JA.6-25, 46-51.

3. Whether a manufacturer's submission to the Program's demands is "voluntary" and immune from constitutional scrutiny. JA.13-18, 51-54.

STATEMENT OF RELATED CASES

This case has not previously come before this Court. Other challenges to the Program have been filed around the country; this Court has consolidated two of those with this one. *See* Doc.18 (docketing statement with full list).

STATEMENT OF THE CASE

A. The Federal Government Dominates the Prescription Drug Market.

The federal government "dominates" the prescription drug market, accounting "for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Medicare is the largest federal health insurance program, covering "nearly 60 million aged or disabled Americans." *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019). It comprises two major prescription drug programs relevant to this case: Part B covers drugs administered by a physician, 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A), while Part D allows beneficiaries to enroll in privately operated but federally subsidized plans for self-administered prescription drugs, *see Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852, 854 (D.C. Cir. 2007).

Historically, both Medicare programs relied on market-based pricing to reimburse the cost of prescription drugs. Part B reimbursement rates are based on an "average sales price" methodology. 42 U.S.C. § 1395w-3a. And when Congress enacted Part D, it expressly prohibited HHS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [private plan] sponsors," *id.* § 1395w-111(i), which already bring market forces to bear. This served as a "fundamental protection" against "price fixing by … CMS." 149 Cong. Rec. S15624 (Nov. 23, 2003) (Sen. Grassley). Without it, Congress worried, the government's new "market power" would enable it to "dictate" drug prices, *id.* at S15707 (Nov. 24, 2003) (Sen. Santorum), which in turn would "destroy" innovation, *id.* at S15631 (Sen. Frist).

Medicaid is the second major federal drug benefit program; it provides coverage to more than 76 million low-income Americans. *See* Medicaid.gov, *March 2024 Medicaid & CHIP Enrollment Data Highlights*. The States jointly administer Medicaid programs. *See Equal Access for El Paso, Inc. v. Hawkins*, 562 F.3d 724, 725 (5th Cir. 2009).

B. The Program Requires Manufacturers To "Agree" To Sell Their Most Valuable Medicines at Steep Government-Dictated Discounts, and To "Agree" That Those Prices Are "Fair."

The Program revolutionizes how Medicare pays for certain prescription medicines. The Department of Health and Human Services (HHS) and its sub-agency, the Centers for Medicare & Medicaid Services (CMS), select the medicines that will be subjected to the Program. In September 2023, CMS selected the first 10 medicines; in 2025 and 2026, HHS will add 15 new medicines per year; in 2027 and beyond, the agency must add 20 new drugs annually. 42 U.S.C. §§ 1320f(b)(3), 1320f(d), 1320f-1(a). HHS is supposed to select medicines based on their total historical cost to Medicare. *Id.* § 1320f-1(b)(1)(A). Once selected, the medicines remain subject to the Program until HHS determines that a generic or biosimilar version of the drug is approved and marketed. *Id.* § 1320f-1(c)(1).

Once medicines are selected for the Program, their manufacturers must "enter into agreements" to participate in an orchestrated "negotiation" geared towards agreeing on an ostensible "maximum fair price" (MFP) for their products. *Id.* § 1320f-2(a). For the first round of selected medicines, the manufacturers had until October 1, 2023, to enter those initial agreements. *See id.* § 1320f(d)(2)(A).

CMS developed a so-called contract (the Template Agreement) that manufacturers must sign to satisfy this obligation. JA.299. The Template Agreement represents that "CMS and the Manufacturer agree" that they "shall negotiate to determine" and "agree to a maximum fair price for the selected drug." JA.300.

Once the manufacturer "agrees" to participate, the agency initiates the supposed "negotiation" by issuing a "written initial offer." 42 U.S.C. § 1320f-3(b)(2)(B). The IRA sets a ceiling price that HHS may not exceed under any circumstances. This ceiling ranges from 75% of a benchmark market-based price for the most recently approved medicines, down to just 40% of the benchmark for medicines approved longer ago. *Id.* § 1320f-3(b)(2)(F), (c)(1)(C). In other words, the Program mandates a discount of at least 25%. There is no floor on the price HHS may set; it need only consider certain non-exclusive factors in deciding how low of a price is "fair." *Id.* § 1320f-3(b)(2)(C)(ii), (e). There is no formal procedure for setting the price, and the IRA purports to shield the agency's pricing decisions from judicial review. *Id.* § 1320f-7.

For the first round of chosen medicines, the "negotiations" must end by August 1, 2024. *Id.* §§ 1320f(d)(5)(C), 1320f-3(b)(2)(E). By then, the manufacturer must "respond in writing" to the agency's "final offer," to either accept or reject it. JA.368. CMS has developed an "Addendum" to the Template Agreement, which manufacturers must sign to formalize their agreement on the "maximum fair price" for their medicine. JA.305. HHS will publicly "publish" the MFP it "negotiated with the manufacturer," along with its "explanation" for the final price. 42 U.S.C. § 1320f-4(a); JA.261-62.

Under this "agreement," the manufacturer is required to provide "access to such price to" Medicare beneficiaries, starting in 2026 for the first round of medicines. 42 U.S.C. § 1320f-2(a)(1). Violations of that "access" mandate are punished by a monetary penalty of 10 times the difference between the price the manufacturer charges and the MFP, for each unit sold, *id.* § 1320f-6(a), plus a $1 million daily penalty for violating the manufacturer's "agreement," *id.* § 1320f-6(c).

Critically, although the IRA speaks of "agreements"—both initially to participate in the negotiations, and ultimately to accept the MFP—manufacturers who decline to enter the "agreements" face draconian penalties. Refusal to sign an agreement to "negotiate," or refusal to "agree" to CMS's final MFP offer, triggers a daily "excise tax" beginning at 186% and escalating to 1,900% of the medicine's total daily revenues from *all* sources (not just from Medicare). 26 U.S.C. § 5000D; Cong. Rsch. Serv., R47202, *Tax Provisions in the Inflation Reduction Act of 2022* 4 tbl. 2 (2022). For a manufacturer like BMS, these immense penalties could reach $1 billion per day. JA.87.

As those figures suggest, Congress designed this scheme to ensure "agreement"—the confiscatory penalties make it irrational *not* to agree, because they capture the entire economic value of the medicine and then some. In recognition that no manufacturer could afford to pay the confiscatory penalty, Congress projected that this "tax" would raise "no revenue." 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).

The IRA offers only one way to avoid these prohibitively high penalties while still refusing to sign an "agreement": A manufacturer may terminate Medicare and Medicaid coverage of all of its products (not just the selected medicine). The IRA's excise tax is "suspend[ed]" on days when a manufacturer is not a party to a Medicare or Medicaid agreement for *any* of its products. 26 U.S.C. § 5000D(c). So a manufacturer could avoid the Program only by forfeiting access to nearly half of the U.S. prescription drug market for all of its products—leaving millions of Americans without their medications.[1]

C. The Government Misrepresents the Program as Voluntary.

Despite the IRA's penalty structure, the government has consistently characterized the Program as merely enabling a "negotiation" resulting in "voluntary" "agreements." When he signed the bill, the President stated that the IRA simply gave the government "the power to negotiate lower prescription drug prices."[2] In his 2024 State of the Union address, he said "Medicare is negotiating lower prices for some of the costliest drugs."[3]

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[1] Even this supposed option is illusory, at least as Congress designed it. Under the IRA, a manufacturer that gives notice to terminate its Medicare participation must wait between 11 and 23 months (depending on when this occurs during the calendar year) before that termination takes effect. *See* 42 U.S.C. § 1395w-114a(b)(4)(B). To avoid penalties for refusing to sign an initial agreement by October 1, 2023, a manufacturer would have had to act by January 31, 2022—before the IRA was even enacted. CMS has purported to fix this problem by inventing an expedited exit option. *See* JA.219-20.

[2] Remarks by Pres. Biden on Medicare and the Inflation Reduction Act (Sept. 27, 2022), https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/27/remarks-by-president-biden-on-medicare-and-the-inflation-reduction-act/.

[3] *See* Pres. Biden's State of the Union Address (Mar. 7, 2024), https://www.whitehouse.gov/state-of-the-union-2024/.

In a pre-address fact sheet, the White House boasted that manufacturers had come to "the negotiating table," and promised "negotiated prices for the first 10 prescription drugs."[4] CMS, too, has continued to pretend that "entering into an Agreement"—even under pain of penalties—"is voluntary." JA.338; *see also* JA.228.

D. CMS Selects Eliquis, and BMS Challenges the Program.

One of BMS's medicines, Eliquis, is used to treat and prevent blood clots and strokes. JA.3. CMS selected Eliquis for the Program in August 2023 (*id.*)—a function not of its price, but of its widespread utilization. Opdivo, a BMS cancer medicine, is projected to be swept up in a later Program cycle. *See* JA.407.

By October 1, 2023, BMS was thus required to "agree" to "negotiate" a "maximum fair price" for Eliquis—or incur taxes exceeding $1 billion per day. JA.87, 91-92. In light of those penalties, BMS was forced to sign the "agreement." The "negotiation" is now underway. But everyone knows how it will end: BMS must "accept" the price CMS sets for Eliquis, despite its belief that any such price—which will reflect *at least* a 25% discount from market value—will not be "fair." JA.86-90. BMS will thus be forced to provide Medicare with "access" to Eliquis at steep discounts while conveying the misimpression that it had previously charged a price above what is "fair." *See id.*

[4] https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/06/fact-sheet-president-biden-takes-new-steps-to-lower-prescription-drug-and-health-care-costs-expand-access-to-health-care-and-protect-consumers/

In anticipation of Eliquis's selection, BMS sued in June 2023, seeking declaratory and injunctive relief. The district court (Quraishi, J.) granted summary judgment to the government. JA.27-298 *First*, the court rejected BMS's Takings Clause claim, mistakenly believing that manufacturers could refuse to sell their medicines to Medicare without paying fines or withdrawing from Medicare and Medicaid coverage altogether. JA.5-13. *Second*, the court rejected BMS's First Amendment challenge, incorrectly concluding that the Program's "agreements" do not compel speech. JA.18-25. *Third*, the court erroneously held that participation in Medicare is voluntary, no matter what conditions Congress adds, and thus the Program is immune from constitutional scrutiny. JA.13-18, 25-26.

SUMMARY OF ARGUMENT

I. Under the Takings Clause, the government must pay fair market value if it takes private property for public use. *Cedar Point Nursery v. Hassid*, 594 U.S. 139 (2021). Forced sales of property are physical takings that require fair-market compensation. In *Horne v. Department of Agriculture*, 576 U.S. 351 (2015), the Supreme Court found a taking where the government required raisin growers to transfer a portion of their crop to a federal agency, with only a prospect of partial payment in return. By the same logic, the government cannot force manufacturers to sell their products for less than fair market value. Compelling transfers at dictated discounts is a straightforward violation of the Fifth Amendment, no different from appropriating the property.

That is what the Program does. Under this unprecedented regime, BMS must sell Eliquis for less than its fair market value—provide Medicare beneficiaries with "access" to deeply discounted medicines. That is a *per se* taking under *Horne*.

The district court held that no taking occurs because BMS has "options" to avoid it. Each is inadequate or illusory. *First*, the district court's assertion that the Program permits manufacturers to refuse to sell the selected medicine to Medicare while continuing to sell all of their *other* medicines to Medicare and Medicaid is wrong. That fictitious "option" disregards the IRA's plain text, makes nonsense of its structure, and is incompatible with the prescription-medication supply chain, as the government itself has recognized in implementing the Program. *Second*, a manufacturer's theoretical ability to avoid the Program's penalties by withdrawing *all of its products* from Medicare and Medicaid coverage does not immunize the Program from constitutional review. That is, instead, a classic "unconstitutional condition."

II. Under the First Amendment's compelled-speech doctrine, the government cannot force businesses to communicate messages against their will. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018); *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 585 U.S. 878, 892 (2018). Again, the Program does just that. Under threat of enormous penalties, the IRA compels BMS to publicly endorse the government's false message that BMS freely negotiated a "maximum fair" price for Eliquis, to which it has voluntarily "agree[d]." The IRA does so for an illegitimate purpose—to give the government political cover.

The district court's contrary reasoning is wrong in several respects. It conflated the IRA's *direct* speech compulsion with the merely *incidental* speech effects that accompany ordinary price regulation. It assumed that the "agreements," entered under duress, are non-expressive "commercial contracts" despite their objective substance and manifest purpose. And it asserted that BMS's ability to spread its *own* message about the Program eliminates the First Amendment harm wrought by the government co-opting its speech. Each of these conclusions flouts established doctrine.

III. The government cannot sweep these constitutional violations under the rug merely because BMS accepts Medicare and Medicaid coverage for its other medicines. That leveraging of distinct, pre-existing revenue streams does not make the Program *voluntary*; it makes it *coercive*. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 585 (2012) (*NFIB*). Plus, threatening BMS's access to half the pharmaceutical market to extort discounted sales of one medicine and compel government-friendly speech violates the unconstitutional-conditions doctrine by any measure.

The district court believed that accepting Medicare coverage categorically precludes constitutional challenges to the Program, since participating in Medicare is "voluntary." That flies in the face of longstanding Supreme Court precedent and would dangerously allow the Spending Clause to consume the rest of the Constitution.

STANDARD OF REVIEW

This Court reviews the grant of summary judgment *de novo*. *Mabey Bridge & Shore, Inc. v. Schoch*, 666 F.3d 862, 867-68 (3d Cir. 2012).

ARGUMENT

I. THE IRA VIOLATES THE FIFTH AMENDMENT BY TAKING MEDICINES FOR PUBLIC USE WITHOUT PAYING JUST COMPENSATION.

The Program takes medicines without paying just compensation. That is its whole point. The government promised Medicare beneficiaries it would cover the cost of their prescription medicines, like Eliquis, but it does not want to pay market price. The IRA's "solution" is to coerce BMS to transfer Eliquis to Medicare beneficiaries at a cut-rate discount to the government. That is an unvarnished taking.

A. The Takings Clause Requires the Government To Pay Just Compensation When It Appropriates Private Property for Public Use.

The Fifth Amendment's Takings Clause provides: "[N]or shall private property be taken for public use, without just compensation." U.S. CONST. amend. V. This provision "saves individual property owners from bearing 'public burdens which, in all fairness and justice, should be borne by the public as a whole.'" *Sheetz v. Cnty. of El Dorado*, 601 U.S. 267, 273-74 (2024). It establishes a "simple, *per se* rule: The government must pay for what it takes." *Cedar Point*, 594 U.S. at 148.

The government thus "has a categorical duty to pay just compensation" when it "appropriat[es] personal property." *Horne*, 576 U.S. at 358. A "classic" or *per se* taking occurs when the government forces a property owner to transfer possession or title, whether to "itself or someone else," *Cedar Point*, 594 U.S. at 149, because the owner loses the "rights to possess, use and dispose of" his property, *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982); *see also Sheetz*, 601 U.S. at 274.

A forced transfer of private property dressed up as a "sale" is equally a taking. *See, e.g.*, *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307-08 (1989); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (where businesses "are compelled to employ their property to provide services to the public, the Fifth Amendment requires" just compensation). The fact that the transferor may receive some money from the forced sale does not erase the taking; it affects only the *amount* of compensation owed. In *Horne*, for example, the Court found a taking of "personal property" where a statute directed farmers to "turn over a percentage of their raisin crop," under pain of penalties, even though the farmers retained a contingent right to recover partial payment if the raisins were later resold. 576 U.S. at 358, 361-62, 368-69.

Notably, a forced transfer of property is not the same as a price cap. The latter *forbids* any sales exceeding certain prices but does not *compel* sales at any price, and thus leaves open other uses of the property. *See Yee v. City of Escondido*, 503 U.S. 519, 527-28 (1992) (rent-control law that did not "compel[ ]" owners "to continue" renting was not a taking, since owner retains "voluntar[y]" choice about how to use property, including by living in it); *Bowles v. Willingham*, 321 U.S. 503, 517 (1944) (rent-control law had "no requirement that the apartments … be used for purposes which bring them under the Act"). A forced transfer is fundamentally different because it leaves the property owner with no meaningful choice but to submit to the "appropriation" of private property by the government-favored buyer. *Horne*, 576 U.S. at 362.

B. By Requiring Discounted Sales to Medicare, the IRA Takes Property for Public Use Without Paying Just Compensation.

The IRA flouts these constitutional principles by forcing manufacturers to sell their medicines to Medicare at prices far below market value. That is a taking, akin to forcing homeowners to rent their basements to the homeless at below-market rents, or compelling supermarkets to sell bread to seniors for 50% off.

To start, as the district court agreed, patented medicines are property protected by the Takings Clause, like all other personal property. *Horne*, 576 U.S. at 358; *United States v. Gen. Motors*, 323 U.S. 373, 383-84 (1945); JA.8.

The Program compels manufacturers to transfer that private property to Medicare beneficiaries. If a medicine is selected for the Program, its manufacturer must "agree" to "negotiate" an MFP and ultimately "agree" to the MFP that the agency dictates—or else pay ruinous financial penalties. *See supra* at p.7. And, under the "agreement" the manufacturer must sign, it is obligated to provide Medicare beneficiaries with "access" to the MFP. 42 U.S.C. § 1320f-2(a)(3). By its plain terms, that "access" mandate forces BMS, for instance, to make Eliquis available to those third parties at the price demanded by the government—BMS cannot refuse to deal on those dictated terms. This "requires physical surrender" of Eliquis, and BMS "lose[s] any right to control [its] disposition." *Horne*, 576 U.S. at 364. That effectuates a classic, *per se* taking of the medicines. *See id.* at 362; *Cedar Point*, 594 U.S. at 149 (treating "access" mandate as physical taking).

That the IRA launders these forced transfers through the façade of an "agreement" is immaterial. The Takings Clause does not care how an appropriation "comes garbed." *Cedar Point*, 594 U.S. at 149. BMS is penalized if it does *not* sign the "agreement" to transfer the medicines. That is tantamount to compelling the transfer; it therefore counts as a taking. *See E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998) (plurality op.) (statute effected taking by using "severe penalty" to coerce exactions); *Horne*, 576 U.S. at 356 (demand for raisins enforced via penalties was taking). "[O]therwise, the government could avoid … the Takings Clause by purporting to 'simply give the owner a choice of either surrendering [property] or making a payment equal to the [property's] value.'" *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1235 (D.C. Cir. 2023).

The IRA's scheme operates differently than a price cap. It does not set maximum prices beyond which covered medicines may not be sold. Nor does it set the maximum prices Medicare will pay for those medicines. Either of those regimes would have been simpler to set up, but politically toxic: The former would be transparent price controls, and the latter would create the risk that Medicare beneficiaries might lose access to their medicines if sellers refused the offered terms. Instead the Program mandates "access" for a preferred class of buyers—to prevent manufacturers from refusing to sell to them on the dictated terms. That special "access" requirement amounts to a taking. *Cedar Point*, 594 U.S. at 149 (law granting union "access" to property was *per se* taking). It is effectively an obligation to use private "property to provide [medicines] to the public," and that implicates the Fifth Amendment. *Garelick*, 987 F.2d at 916.

Because it effects a taking, the IRA triggers the government's obligation to pay the "fair market value" of the property. *United States v. Reynolds*, 397 U.S. 14, 16 (1970); *see also United States v. 564.54 Acres of Land*, 441 U.S. 506, 511 n.6 (1979). But the IRA is written precisely to *save* the government from paying fair market value. It sets the ceiling price at no more than 75% of a genuinely negotiated market price. 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C). CMS cannot exceed the ceiling in any circumstances, but is free to impose even steeper discounts with no judicial review. *Id.* § 1320f-7. By definition, then, the IRA does not provide just compensation for the seized property, because the statute mandates prices that deliberately fall *far below* fair market value. *See Horne*, 576 U.S. at 368-69. The government did not argue otherwise below.

All told, *Horne* is controlling here. Like the IRA, the law in *Horne* used penalties to coerce owners to turn over their property, triggering the government's "categorical duty to pay just compensation." 576 U.S. at 358, 362. The government in *Horne* took a fraction of the farmer's raisins, while here the government is taking BMS's medicines for a fraction of their fair value, but that distinction is not material. Both are physical appropriations; seizing 50% of a company's inventory is no different from seizing that inventory at a 50% discount. And Medicare's partial payments in the form of the MFP bear only on the amount of damages, just like the partial proceeds the farmers stood to earn from resale of their raisins seized by the government. *See id.* at 364. Accordingly, here as there, "[t]he government must pay for what it takes." *Cedar Point*, 594 U.S. at 148. Because the Program does not, it violates the Takings Clause.

C. The District Court's "Options" Are Illusory.

The district court did not dispute that forced sales of Eliquis must be compensated at fair market value. JA.8. But the court denied that the Program compels such sales, on the ground that BMS has "options" to avoid them. JA.12. Each ostensible "option," however, is either inadequate or imagined.

The principal "option"—that BMS could withdraw all its products from Medicare and Medicaid—is at least theoretically real, but it does not cure the constitutional evil. The Supreme Court's voluntariness and unconstitutional-conditions doctrines limit the government's power to demand the abandonment of constitutional rights in exchange for benefits. It is both *coercive* and *disproportionate* to hold hostage all Medicare and Medicaid coverage for all products—in practice, access to nearly 50% of the market—to coerce the transfer of discounted Eliquis. Since this cuts across both constitutional claims, it is addressed in detail in Part III, *infra*.

The district court also suggested, albeit in cursory fashion, that BMS can "divest [its] interest in the selected drug" before forced sales take place. JA.12. That too is true, but obviously legally insufficient. The "option" of selling property on the one hand, or divesting it on the other, is illusory—either way, the owner must give up the property. Indeed, divesting Eliquis (to a buyer who would remain subject to the taking) would strip BMS of all the same property rights as the threatened taking itself: BMS would transfer "title" and "lose any right to control" its property. *Horne*, 576 U.S. at 364. This is simply a redirection of the forbidden taking—not a way out of it.

That leaves the court's final "option": It accepted bare assertions by government litigators that BMS can decline to sell Eliquis to Medicare while continuing to sell it to privately insured patients at market prices—and do so *without* forfeiting Medicare coverage for its other medicines *or* paying any penalties. JA.14 (citing only government's brief for this). That notion rewrites the IRA's text, makes a hash of its structure, and creates yet another illusory "option" that does not exist in the real world—which is why other courts have not accepted it. *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:23-cv-01103, 2024 WL 3292657, at *11 (D. Conn. July 3, 2024).

1. Start with plain text. Congress commanded manufacturers to provide "access" to the MFP for the selected medicine. 42 U.S.C. § 1320f-2(a)(3) (ordering that "access to the maximum fair price … shall be provided"). That "access" command means what it says: BMS *must* sell Eliquis at the dictated price.

The government conceded this much in its initial briefing below. *See, e.g.*, ECF 38-1 at 34 (manufacturers must "provide *their drugs* at the negotiated prices"); *id.* at 27 (IRA "limits the prices at which *drugs* are to be made available") (emphases added). Other agencies have likewise appreciated that the IRA mandates that manufacturers provide "access to selected drugs." IRS, Notice 2023-52, at 2 (Aug. 4, 2023). Indeed, until relatively late in this litigation, neither HHS nor anyone else had ever doubted this.[5]

[5] Public analyses of the Program never mentioned this supposed loophole either. *See, e.g.*, Juliette Cubanski, *FAQs About the Inflation Reduction Act's Medicare Drug Price Negotiation Program*, Kaiser Family Foundation (Jan. 31, 2024) (mentioning only paying excise tax and withdrawing from Medicare and Medicaid as alternatives to Program).

As a matter of the IRA's plain text, if BMS were to *refuse* to sell Eliquis to Medicare beneficiaries, while continuing to sell it to others (at higher prices), that would plainly violate the "access" mandate central to the "agreement" it must sign. It would be like a car dealership agreeing to give a 60% discount to a customer, but then barring that customer from the sales lot. The dealer could not shrug and insist that it promised only access to the *discount*, not access to the *car itself*. One necessarily implies the other. But that is the government's revisionist account of the IRA in a nutshell.

In embracing the government's theory, the district court never analyzed the IRA's language. It simply repeated the assertion that the Program's access mandate is a "fairly thin read [*sic*] on which to infer that actual commercial transactions need to take place." JA.11 (quoting government's oral argument); *see also* JA.13 (citing government brief).[6] But the "access" requirement is not a "thin reed" at all. It is how the Program effectuates its core purpose: to ensure that Medicare beneficiaries retain "access" to leading medicines, without Medicare paying fair value for them. The way to guarantee "access" is to compel manufacturers to provide it. That is what the Program does.

2. The IRA's structure confirms its plain-text meaning. Indeed, reading the statute to allow a manufacturer to withhold the selected medicine from Medicare purchasers—without fully withdrawing or paying penalties—makes nonsense of the scheme.

[6] Puzzlingly, the district court also claimed BMS conceded this point—citing only a comment by the government's attorney. *See* JA.12 (citing Oral Arg. Tr. 72). There was no concession.

Most obviously, that renders the IRA's *actual* exit option irrelevant. As explained above, the statute provides only one way for a manufacturer to avoid crippling penalties: withdraw *all of its medicines* from federal healthcare programs. *See* 26 U.S.C. § 5000D(c). But according to the district court, manufacturers can circumvent that all-or-nothing choice by holding back the selected medicine while preserving Medicare coverage for their other medicines. On that telling, the IRA thus contains two exit options: an *explicit* one that requires abandoning half the U.S. market (*i.e.*, abandoning Medicare/Medicaid coverage for all products), and an *implicit* one that avoids nearly all those consequences (*i.e.*, refusing to sell a single covered medicine to Medicare). Manufacturers can escape the Program by cutting off an arm—or maybe while keeping it.

Neither the district court nor the government ever explained how this makes any sense. Nor could they. After all, courts must construe statutory provisions to work "in harmony" rather than "at cross-purposes." *Jones v. Hendrix*, 599 U.S. 465, 478 (2023). They cannot presume that "Congress intended to enact a statutory rule" while "with the other hand it created an exception that would destroy that very rule." *United States v. One (1) Palmetto State Armory PA-15 Machinegun Receiver/Frame, Unknown Caliber Serial No. LW001804*, 822 F.3d 136, 140-41 (3d Cir. 2016). The district court compounded both errors—vitiating an *express* rule by concocting an *implicit* workaround.

Confirming the point, the district court's rewrite renders yet another IRA provision nonsensical. In a statutory section outlining "beneficiary protections," and a subsection guaranteeing "[a]ccess to covered Part D drugs," the statute requires that all medicines

selected for the Program "shall" be included in every Medicare Part D formulary. 42 U.S.C. § 1395w-104(b)(3)(I)(i). That "protection" would be empty if manufacturers had the option to refuse a Medicare "beneficiary" with "access" to the medicine.

3. The only reason the government is even belatedly floating this "option"—so at odds with the IRA's text, structure, and purpose—is that it knows it is an impossibility in the real world. While *Medicare* could stop *covering* certain medicines, the government has never offered to cease coverage for Eliquis alone. Meanwhile, there is no way for a *manufacturer* to surgically prevent a medicine from *being sold* to Medicare beneficiaries—and ending up on the hook for guaranteeing the MFP discount. So even if this option did "exist in theory" (and it does not), there is no way "any manufacturer can realistically make use of it." *Boehringer Ingelheim*, 2024 WL 3292657, at *11 n.10.

As background, manufacturers like BMS do not sell prescription medications *directly* to patients; they sell to intermediaries in the distribution chain. *See* A. Mulcahy & V. Kareddy, *Prescription Drug Supply Chains*, Rand Res. Report, at vi (2021) (Rand Report). Indeed, for drugs classified as controlled substances, they are only *permitted* to sell to DEA-registered intermediaries. *City of Huntington v. AmerisourceBergen Drug Corp.*, 609 F. Supp. 3d 408, 421 (S.D. W.Va. 2022). It is dispensers (like pharmacies or hospitals) who then seek reimbursement from insurers (like Medicare). Rand Report vi.

Congress structured the IRA around these supply-chain realities. To comply with the Program, manufacturers must provide "access" to the MFP not only to Medicare beneficiaries, but also to "dispenser[s] at the point-of-sale," including "pharmac[ies],"

"hospitals, physicians, and other providers," and their "suppliers." 42 U.S.C. § 1320f-2(a)(3). As CMS has acknowledged, the manufacturer must "[e]nsure[ ] the MFP is made available to all … dispensers." CMS, *Medicare Drug Price Negotiation Program: Draft Guidance*, at 28, 38 (May 3, 2024). So if a selected medicine is dispensed to a Medicare beneficiary, the manufacturer must guarantee that its cost is no more than the MFP—including by providing, if necessary, a back-end rebate relative to the market price that the pharmacy, hospital, or supplier had paid. *See id.* at 36-37.

These operational realities expose the government's "option" as another fiction. If Medicare chose to stop covering a medicine—or if the manufacturer withdrew from Medicare coverage for all its products—then patients could still be dispensed the drug; Medicare simply would not reimburse its cost. But manufacturers do not (and cannot) control how a medicine is later dispensed. And if a covered medicine happens to be dispensed to a Medicare beneficiary, the Program saddles the manufacturer with the duty to effectuate the MFP in that transaction. As a consequence, contrary to the district court's hypothesis, a manufacturer cannot simply "decline" to sell a selected medicine to Medicare and thereby avoid the Program's burdens. Rather, once a covered medicine has entered the stream of commerce, the Program requires the manufacturer to guarantee the MFP as to any Medicare beneficiary who ends up being dispensed the medicine. That impairs the manufacturer's right to control disposition of its property, by effectively compelling a retroactive transaction on terms to which the manufacturer only agreed under threat of the IRA's monetary penalties.

Accordingly, the only way a participating manufacturer could even theoretically "decline" to sell to Medicare at the MFP would be to stop selling the medicine *entirely*—so it never enters the stream of commerce and is never "dispensed." CMS appears to recognize as much; recent guidance clarifies that manufacturers are "not obligated to make sales of the selected drug," *period*—that is, *to anyone*. May 2024 Guidance 35-36.[7]

But the "option" to pull a product from the entire market gets the government nowhere. Even the district court acknowledged that an entitlement "to stop selling … altogether" cannot obviate a taking. JA.11. *Horne* rejected a similar argument. The government claimed there was no taking because the growers could "plant different crops" or "sell their raisin-variety grapes as table grapes or for use in juice or wine." 576 U.S. at 365. That was misguided, because "basic and familiar uses of property" cannot be recharacterized as "special … benefit[s] that the Government may hold hostage, to be ransomed by the waiver of constitutional protection." *Id.* at 365-66; *see also Loretto*, 458 U.S. at 439 n.17 (rejecting argument that "landlord could avoid" taking "by ceasing to rent the building"). So, even assuming the IRA preserves BMS's option to pull Eliquis from the market entirely, that does not matter. Property rights "cannot be so easily manipulated." *Loretto*, 458 U.S. at 439 n.17.

[7] Indeed, after suggesting that manufacturers can end "sales of the selected drug," the next sentence of the CMS guidance reiterates their "obligation to timely report any changes to [National Drug Codes] for the selected drug." May 2024 Guidance 35-36. Those codes are required to market and sell prescription medications to *anyone*. *See* 21 C.F.R. § 207.33. The implication of this pairing is that manufacturers are entitled to pull the selected medicine from the U.S. market altogether.

* * *

Congress tried to dress it up, but at bottom the Program is a simple appropriation of private property. The legislation's objective was to ensure that Medicare beneficiaries maintain unbroken access to their medicines, while reducing the price the government pays for them. The IRA is perfectly tailored to that goal. It directs manufacturers to ensure Medicare's special "access" to whatever bargain-basement price CMS picks, and then guarantees compliance by deploying "taxes" so extreme that Congress admitted no manufacturer could ever pay them. This is a classic taking of property without just compensation. The district court erred in concluding otherwise.

II. THE IRA VIOLATES THE FIRST AMENDMENT BY FORCING MANUFACTURERS TO EXPRESS THE GOVERNMENT'S POLITICAL MESSAGES.

Adding insult to injury, the IRA forces manufacturers to peddle a political narrative under the cover of coerced "agreements." Takings Clause aside, Congress could have simply directed manufacturers to sell their medicines at HHS-dictated prices. That would have fully satisfied Congress's *economic* goals. But it would also have undermined Congress's *political* goals by exposing the Program as top-down government control. So, instead, Congress routed the Program's obligations through so-called "agreements" under which the manufacturers must publicly characterize HHS's mandated discounts as the "maximum fair prices" for their medicines. That circuitous regime succeeds in obscuring the Program's true nature. But the First Amendment forbids these efforts to conscript BMS to engage in political spin.

A. The First Amendment Protects Individuals and Businesses from Being Forced To Spread Government Messages.

Freedom of speech "necessarily compris[es] the decision of both what to say and what not to say." *Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781, 796-97 (1988). The government thus cannot "compel the endorsement of ideas that it approves." *Knox v. SEIU*, 567 U.S. 298, 309 (2012). It "may not compel affirmance of a belief with which the speaker disagrees," *Hurley v. Irish-American Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573 (1995), or "compel a person to speak its own preferred messages," *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023).

The compelled-speech doctrine serves two purposes. *First*, it protects citizens from being forced to betray their convictions. "At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994). Forcing citizens to spread government messages destroys their "right to present their [own] message undiluted by views they d[o] not share." *303 Creative*, 600 U.S. at 585-86. *Second*, the First Amendment's ban on compelled speech ensures an "open marketplace in which differing ideas about political, economic, and social issues can compete freely for public acceptance without improper government interference." *Knox*, 567 U.S. at 309. When Congress "requires the utterance of a particular message favored by the Government," that "manipulate[s] the public debate through coercion rather than persuasion." *Turner*, 512 U.S. at 641.

The government thus cannot "compel speakers"—individuals or corporations—"to utter or distribute speech bearing a particular message." *Id.* at 642. No speaker can be forced to feign "agree[ment] with the Government's polic[ies]." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213 (2013) (*AID*). Laws that compel speech are subject to strict scrutiny, *id.*, which requires the government to prove that the law is "narrowly tailored" to achieve a "compelling" interest, *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 19 (1986) (plurality op.).

B. The IRA's Forced "Agreements" Coopt Manufacturers To Convey the Government's Political Narrative.

The IRA offends these principles, and runs afoul of the compelled-speech doctrine, by forcing manufacturers to convey the government's viewpoint. Manufacturers must sign onto the premise that the HHS discounts reflect the "maximum fair prices" for the selected medicines—or else pay immense penalties. This scheme serves no functional purpose; it is designed solely to facilitate the misimpression that manufacturers "agree" with the IRA's mandates, thereby providing the government with political cover.

As described above, manufacturers must first "enter into" a public "agreement" promising to "negotiate" toward a "maximum fair price" for their medicines. 42 U.S.C. § 1320f-2(a); JA.299. After the pretend "negotiation" concludes, the manufacturer must publicly "agree to" the "maximum fair price" CMS dictated. 42 U.S.C. § 1320f-2(a)(1); JA.305. Refusal to sign on either dotted line triggers massive penalties. *See* 26 U.S.C. § 5000D.

Signing these documents communicates unmistakable messages to the public: that these are good-faith negotiations; that this voluntary give-and-take will end in genuine "agreement"; and that the final price set by HHS is the "maximum fair" one for Eliquis. This is an inevitable consequence of the IRA's novel "agreement" framework. *See John Doe No. 1 v. Reed*, 561 U.S. 186, 194-95 (2010) (recognizing that a "signature will express" messages conveyed by signed document). And CMS has designed ostensible form "contracts" to drive the messages home: The Template Agreement recites that the parties will "negotiate to determine a price" and the manufacturer contemplates reaching "agreement with CMS." JA.299. Across 12 pages, the document characterizes itself as an "Agreement" nearly 50 times, and states over 20 times that the parties do or will "agree." At the second step, the Addendum likewise communicates that the parties "negotiated" and "agree" to a price that is the "maximum fair" one. JA.305.

Of course, BMS does not genuinely "agree" with any of this. BMS disagrees that the Program involves a real "negotiation" because BMS has no leverage and would face punishment for walking away. BMS disagrees that its participation is voluntary because the threat of penalties coerces BMS to sign up. Most importantly, BMS fundamentally rejects the political view, embedded in the agreements, that HHS's dictated price—as opposed to the real market price genuinely negotiated among private parties—will be the "maximum fair price" for Eliquis. To the contrary, drastically discounting crucial medicines like Eliquis below that real market price will severely harm the public by undermining BMS's ability to develop new life-saving medications. JA.88.

In this way, the IRA uses the "threat of punishment" to compel BMS to broadcast, in writing, a viewpoint and value judgment that it vehemently rejects. *303 Creative*, 600 U.S. at 589. This is reminiscent of the regime that the Supreme Court invalidated in *AID*. There, a law barred funding "to any group … that does not have a policy explicitly opposing prostitution and sex trafficking." 22 U.S.C. § 7631(f). Regulations implemented that requirement by directing the recipient of the funds to "agree in the award document that it [was] opposed to" those activities. *AID*, 570 U.S. at 210 (citing 45 C.F.R. § 89.1(b)); USAID, Acquisition & Assistance Policy Directive 12-04 at 11 (Feb. 15, 2012) (standard contract stating that recipient "agree[d] that it is opposed to the practices of prostitution and sex trafficking"). This "plainly violate[d] the First Amendment" by "mandat[ing]" that parties "explicitly agree with the Government's policy." *AID*, 570 U.S. at 213. Here too, the IRA requires the manufacturer to "agree," in a "contract" signed under duress, with the statute's contested premises. Here too, that conscription "plainly violate[s] the First Amendment." *Id.*

The IRA's novel system of coerced "agreements" also implicates both purposes of the compelled-speech doctrine. For one, forcing BMS to "agree" with HHS on what constitutes a "fair price" compels the company to parrot messages inimical to its own—including that it has long been price-gouging by charging more than the "maximum fair price" for Eliquis. *See Cent. Illinois Light Co. v. Citizens Util. Bd.*, 827 F.2d 1169, 1173 (7th Cir. 1987) (First Amendment forbids turning businesses "into involuntary solicitors for their ide[o]logical opponents"). It is thus akin to a forced confession.

For another, these sham "agreements" corrupt "the processes through which political discourse or public opinion is formed." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 49 (2017) (Breyer, J., concurring). By forcing its targets to dress themselves up as willing participants, the IRA helps insulate from criticism the message that HHS's prices are "fair" and have been "agree[d] to" by BMS. That strikes at the heart of the First Amendment. While the government is entitled to persuade the public that prices would be "unfair" but for the IRA, it cannot compel BMS to say that it agrees.

Yet that political misimpression is not merely an unintended effect of the Program; it is its central feature and only evident purpose. After all, Congress could have achieved the IRA's economic aims merely by empowering HHS to set the prices it will pay for the selected medicines. That would have been a far simpler statute to implement; it would not have required manufacturers to "agree" to anything. Conversely, enlisting BMS in the government's messaging campaign does nothing to reduce prices or protect the public fisc (let alone foster innovation). All it provides is political cover. Congress had good reason to hide the Program's mandates behind a façade: Polls showed broad support for allowing Medicare to negotiate prices, but little appetite for a regime that "effectively allow[s] the federal government to set the prices of drugs." National Tracking Poll, Morning Consult 13, 17 (Sept. 2021). By compelling manufacturers to sign "agreements" professing that negotiations yielded a "fair price," the IRA lets the government boast that it is doing the popular thing (real negotiations) and obscure the unpopular reality.

The proof is in the pudding: When manufacturers signed the IRA's "agreements," the government immediately used those signatures to promote its deceptive narrative. The President announced that manufacturers "are coming to the negotiating table," and the White House bragged that all ten had "signed agreements to participate."[8] Media took the cue: "The manufacturers of 10 expensive medications have agreed to negotiate with the federal government for lower prices." Michael D. Shear, *Drug Makers Agree to Negotiate With Medicare on Prices of 10 Medications*, N.Y. Times, Oct. 3, 2023. The government compelled speech to score political points—and it worked.

Tellingly, the government has never offered an alternative justification for the IRA's roundabout structure. Below, it did not even argue that its speech mandate served any legitimate purpose sufficient to satisfy heightened scrutiny, instead contending solely that the IRA does not implicate the First Amendment at all.

In sum, the IRA enlists manufacturers in a public-relations campaign on behalf of the Program. That is the only reason to launder the IRA's mandates through a series of public "agreements" rather than simply allowing the U.S. Code to do this work itself. But the First Amendment prohibits any scheme forcing the regulated to carry political water for their regulators.

[8] President Biden, X (Oct. 3, 2023, 8:05 AM), https://twitter.com/POTUS/status/1709177956285759844?s=20; The White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023).

C. The District Court Misapplied Basic First Amendment Doctrine.

The district court upheld the Program's "agreement" framework on four grounds. It first reasoned that BMS's acceptance of Medicare coverage rendered its participation "voluntary," foreclosing any constitutional challenge. That profoundly flawed holding is addressed in Part III, because it applies to both constitutional claims. The court's other rationales badly distort settled First Amendment doctrine.

1. The district court thought the Program only "regulates conduct," with "merely incidental" effects on BMS's speech. JA.20. In reality, the IRA directly mandates BMS to sign a public document that communicates obvious messages opportunistically selected by the government. That is central, not "incidental."

True, "the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011). But that principle has no application here. It applies where the law regulates conduct but affects speech downstream. For example, anti-discrimination laws incidentally prohibit "White Applicants Only" signs, and bans on "outdoor fires" incidentally forbid flag burning. *Id.* In the same way, "typical price regulation" regulates the "seller's conduct" by placing certain prices off-limits—affecting speech "indirectly" by barring the offering or advertising of those prices. *Expressions Hair*, 581 U.S. at 47. In such cases, the regulation targets non-speech conduct (discrimination, fires, prices); speech is burdened only as an incident. These laws do not directly "dictate the content of the speech *at all*." *Rumsfeld v. FAIR*, 547 U.S. 47, 62 (2006) (emphasis added).

The IRA does—for example, by directly requiring BMS to proclaim "agree[ment]" with the "maximum fair price" imposed by the government. 42 U.S.C. § 1320f-2(a). Had Congress simply capped the price of Eliquis, that would, as a practical matter, bar BMS from communicating sales at higher prices. *See, e.g.*, *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 78 (1st Cir. 2013) (holding that First Amendment does not protect "offers to engage in banned activity"). Instead, the IRA orders BMS to speak *about* the price HHS has imposed—to express "agree[ment]," admit it is the "maximum fair price" for Eliquis, and describe it as the product of a "negotiation." Unlike price caps, laws directly "regulating the *communication* of prices" have speech as their *object* and thus trigger scrutiny. *Expressions Hair*, 581 U.S. at 48 (emphasis added).

The district court deemed the IRA a conduct regulation because "[t]he primary purpose of the Program is to" set prices, whereas its "agreements and negotiations are incidental mechanisms the government is using to set those prices." JA.22. That has the law backwards: While Congress can regulate *conduct* in ways that affect downstream *speech*, it cannot mandate *speech* as a way to regulate *conduct*. Congress's "purpose" in enacting a speech mandate goes to whether the mandate can survive strict scrutiny (an issue the government forfeited); it does not immunize the mandate from scrutiny in the first place. Regardless, routing the IRA's mandates through "agreements" has *zero* conduct-based justification. Again, a direct price regulation would have equally served Congress's economic goals. The only marginal benefit of an intervening "agreement" is to deceive the public for political ends.

2. The district court next reasoned that the Program's "agreements" are not "expressive," because the "agreements are ordinary commercial contracts" that merely incorporate "statutory terms of art." JA.23. That is mistaken on multiple levels.

First, the Program's "agreements" are nothing like run-of-the-mill commercial contracts. They do not memorialize transactions or record promises to act. (Indeed, they would not be enforceable under ordinary contract law, given the pervasive duress built into the process.) Instead, like the contracts in *AID*, they require manufacturers to agree "with the Government's policy." 570 U.S. at 213. They are "inten[ded] to convey a particularized message," *Spence v. Washington*, 418 U.S. 405, 410-11 (1974) (per curiam): that BMS and CMS have "agreed" on a "maximum fair price" by sitting down and engaging in "negotiations." Through the agreements, BMS must proclaim that the price dictated by CMS is the "maximum fair price" for Eliquis—a declaration that will inevitably be used against BMS in the marketplaces for both medicines and ideas. Once more, the agreement's expressive nature—and concomitant political value—is the only reason why Congress structured the Program in such a convoluted way.

The court was wrong to suggest that the legally binding nature of BMS's agreement makes it less expressive. The Supreme Court has rejected the idea that "adding … legal effect to an expressive activity somehow deprives that activity of its expressive component, taking it outside the scope of the First Amendment." *Reed*, 561 U.S. at 195. Anyway, beyond documenting certain facts about BMS's legal duties, the agreement forces BMS to represent *agreement* to those mandates. That part is pure fiction.

Second, the district court thought that the agreements cannot be expressive because their terms are "ported over from the statute," and thus carry only their defined legal meanings. JA.23-24. For this theory, it relied solely on *Meese v. Keene*, 481 U.S. 465 (1987). That decision offers no support for the remarkable position that Congress can compel any speech it likes so long as it appends a statutory glossary insisting that the speech does not mean what any ordinary person would understand it to mean.

Keene involved a challenge to the Foreign Agents Registration Act, which imposed "registration, filing, and disclosure requirements" on certain expressive conduct offered by, or on the behalf of, foreign governments. *Id.* at 467. The plaintiff did not dispute "[t]he constitutionality of those underlying requirements." *Id.* Instead, he claimed the First Amendment prohibited Congress from "using the term 'political propaganda' as the *statutory name* for the regulated category of expression." *Id.* (emphasis added). The challenge was thus to Congress's use of words in a statute.

The Supreme Court rejected that claim. Congress's label "place[d] no burden on protected expression"; its statutory definition "ha[d] been on the books for over four decades" and "had [not] actually interfered with the exhibition of a significant number of foreign-made films." *Id.* at 480, 483-84. More fundamentally, the only entity that employed the phrase "political propaganda" was *Congress itself*. As the Court was careful to emphasize, "the term … does not appear on the form" that individuals must submit to comply with the statute. *Id.* at 471.

Keene is inapposite. BMS is not challenging "Congress' use of the term" "maximum fair price" in the IRA itself, *id.* at 484; nor has it alleged that the presence of those words in the U.S. Code imposes a "reputational injury" or chills speech, *id.* at 474-76. Instead, BMS is challenging the Program's *speech mandate*, including the requirement to attest that whatever price CMS sets is the "maximum fair price." Nothing like that existed in *Keene*, which would have surely come out the other way had Congress tried to force FARA registrants to publicly label their films as "propaganda." In short, *Keene* "did not suggest, much less hold," that Congress can "skew public debate by forcing companies to use [its] preferred language" merely by assigning that language a "statutory definition." *Nat'l Ass'n of Manufacturers v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015) (cleaned up).

3. Finally, the court suggested that BMS's freedom to spread its own views about the Program cured any "constitutional problems." JA.24. This too is manifestly erroneous. Even absent any speech restriction, Congress cannot "require speakers to affirm in one breath that which they deny in the next." *Pac. Gas*, 475 U.S. at 15 n.11 & 16 (plurality op.); *Hurley*, 515 U.S. at 576. Otherwise, the Supreme Court's foundational compelled-speech decisions would make no sense. New Hampshire drivers were free to "disavow" the "Live Free or Die" license-plate motto using "a conspicuous bumper sticker." *Wooley v. Maynard*, 430 U.S. 705, 722 (1977) (Rehnquist, J., dissenting). That did not change the result. So too, the government cannot compel BMS to attest that the price for Eliquis would be "unfair" if not for the IRA—even if BMS remains free to broadcast the truth "on its own time and dime." *AID*, 570 U.S. at 218.

After BMS sued, the government tried implementing a workaround by allowing manufacturers to include a misleading disclaimer in their "agreement." JA.24 n.12. The disclaimer purports to say that the agreement does not reflect an "endorsement of CMS' views" or that "fair" means "fair" in the "colloquial" sense. JA.302. The manufacturer is supposedly only agreeing on a "maximum fair price" as those words are "specified in the statute." *Id.* But this disclaimer only underscores the problem. It "does not suffice" to cure the First Amendment problems for the same reason counterspeech does not: It still distorts the party's message by forcing him to speak out of both sides of his mouth. *See Pac. Gas*, 475 U.S. at 15 n.11 & 16 (plurality op.).

This Court held as much in *Circle Schools v. Pappert*, 381 F.3d 172 (3d Cir. 2004), where private schools challenged a law mandating recital of the Pledge of Allegiance and the State responded that the schools could issue a disclaimer. "[T]hat the schools can issue a general disclaimer along with the recitation does not erase the First Amendment infringement," this Court said, as "the schools are still compelled to speak the Commonwealth's message." *Id.* at 182. "Otherwise," governments could "infringe on anyone's First Amendment interest at will." *Id.*

"[S]o too would a disclaimer here be inadequate." *Telescope Media Grp. v. Lucero*, 936 F.3d 740, 757 (8th Cir. 2019). By forcing it to sign agreements promising to "negotiate," purporting to "agree," and communicating that an HHS-dictated price for Eliquis is "fair," the IRA impermissibly compels BMS to express viewpoints it rejects.

* * *

When the government has two equally effective options to achieve its substantive goals, one that requires a regulated party to speak and one that does not—and it picks the former—the First Amendment violation is as obvious as the government's motive. Forcing manufacturers to peddle a public-relations narrative on the government's behalf is unconstitutional. This Court should say so, and reject the district court's dangerous doctrinal distortions.

III. THE GOVERNMENT CANNOT USE ITS MARKET LEVERAGE TO COERCE THE ABANDONMENT OF CONSTITUTIONAL RIGHTS.

The district court also held that the IRA does not violate the Constitution because manufacturers "voluntarily" submit to its mandates by accepting Medicare coverage for their other medicines. In other words, the court construed the Program as a *condition* on "voluntary" Medicare participation. This is a common argument by the government, but it has not met with much success in the Supreme Court. *See, e.g.*, *Cedar Point*, 594 U.S. at 161-62 (rejecting argument that government could "require property owners to cede a right of access as a condition of receiving certain benefits" because access was not "germane to any benefit provided"); *Horne*, 576 U.S. at 366 (rejecting argument that taking was permissible "condition" because it could not "reasonably be characterized as part of a … voluntary exchange"); *AID*, 570 U.S. at 214 (rejecting argument that speech compulsion was permissible "condition on the receipt of [federal funds]"); *see also Valancourt*, 82 F.4th at 1235-36 (rejecting argument that requirement to send works to Library of Congress was voluntary condition on copyright protection).

Reframing statutory mandates as "conditions" is no constitutional panacea. Courts must still assess whether demands embedded in federal spending programs comply with the Supreme Court's voluntariness and unconstitutional-conditions doctrines.

The Program flunks both. The only off-ramp that the IRA gives manufacturers is to terminate the agreements that allow their medicines—all of their medicines—to be covered by Medicare and Medicaid. If the manufacturer withdraws *all of its products* from *both* programs, the excise tax for "noncompliance" with the Program's mandates is "suspen[ded]." 26 U.S.C. § 5000D(b), (c). That is not a legitimate option giving rise to a voluntary choice. The Constitution does not permit the government to force BMS to choose between complying with unconstitutional mandates backed by vast penalties, or destroying its business by abandoning almost half of all patients in the United States. No matter how that stark choice is framed, it is unconstitutional.

The implications of the district court's contrary holding are profound: If framing a mandate as a condition of a governmental benefit is enough to insulate the regime from scrutiny, the government could readily exercise its Spending Clause authority to coerce the surrender of constitutional rights. It could take property, compel speech, restrict speech, or impair any other rights simply by promising to release those mandates if the target withdraws from a "voluntary" spending program. But the government cannot do indirectly what it cannot do directly. Core constitutional principles and precedent confirm that submission to such extortion is not "voluntary."

A. The IRA's Mandates Are Unconstitutionally Coercive.

Congress may impose conditions on federal funding, but if those conditions impair constitutional rights, they cannot be unduly coercive. Conditions cross the line when "persuasion gives way to coercion." *NFIB*, 567 U.S. at 585. Congress must offer a *genuine* choice; it 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. Only then can the recipient "voluntarily … accept[]" the terms. *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Put simply, Congress cannot make "offers" that are, "for practical purposes, impossible to refuse." *Texas v. Yellen*, __ F.4th __, 2024 WL 3159081, at *6 (5th Cir. June 25, 2024).

NFIB illustrates an unconstitutionally coercive funding condition. The Court held that Congress could not force a State to expand Medicaid by "threatening to withhold all of [its] Medicaid grants." 567 U.S. at 575. Three features rendered that condition too coercive. *First*, Congress "threaten[ed] to withhold … *existing* Medicaid funds" from States that did not accept "*new* conditions," which showed that Congress was using its spending power as a "means of pressuring" recipients. *Id.* at 575-76, 579-580 (emphases added). *Second*, the pressure was unconstitutionally coercive because of its size: It threatened about 10% of a State's budget. *Id.* at 581-82. *Third*, Congress upset reliance interests developed over "many decades" by imposing "post-acceptance retroactive conditions" that States "could hardly [have] anticipate[d]." *Id.* at 581, 583-84.

In sum, *NFIB* rejected the government's attempt to leverage large, pre-existing funding streams—on which recipients had relied and which they could not afford to lose—to pressure them to take actions the government could not mandate directly. The IRA likewise leverages Medicare and Medicaid funds to coerce manufacturers to submit to the government's property and speech mandates.

First, the IRA threatens to remove *existing* coverage for *all* of BMS's medicines unless BMS surrenders its rights to one product (Eliquis)—just as Congress threatened to strip *all* of a State's *existing* Medicaid funding to induce agreement to *new* conditions. Instead of simply refraining from covering Eliquis absent mutual agreement on a price, Congress "threaten[ed] to terminate other significant independent grants." *Id.* at 580. *Second*, the IRA's threats are enormously consequential. The supposed choice is merely "illusory," *Butler*, 297 U.S. at 71, because Congress knew that manufacturers could not jeopardize their survival by refusing to deal with the payor responsible "for almost half the annual nationwide spending on prescription drugs," *Sanofi*, 58 F.4th at 699. This is a choice "merely in theory," not "in fact." *NFIB*, 567 U.S. at 581. *Third*, the IRA "surpris[es]" manufacturers with "post-acceptance conditions" that "transform[]" the nature of the deal brokered "decades" earlier. *Id.* at 581, 583-84. Congress expressly assured manufacturers that the government would "not interfere" in manufacturers' pricing negotiations for Medicare Part D, 42 U.S.C. § 1395w-111(i)(1); *supra* at p.4. The Program thus effects a bait and switch: The IRA does not merely *interfere* with private pricing—it *replaces* it with compelled transfers at government-set prices.

While the statute in *NFIB* coerced *States* to abandon their rights, 567 U.S. at 577-78, the IRA's coercion of *private companies* to surrender their rights is unconstitutional for all the same reasons. As this Court has observed, private entities too can suffer "'economic dragooning' and a 'gun to the head'" when the government threatens the "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). If anything, protection for private parties must be *more* robust—for they lack the "political powers" and "institutional resources" to resist federal encroachment. *Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002); *see also Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 219 (2022) (applying same voluntariness approach to Spending Clause in context of private recipients).

For these reasons, the IRA puts BMS to an unconstitutional choice under *NFIB*, and the Program's impositions therefore cannot be disregarded as "voluntary."

B. The IRA's Mandates Are Unconstitutionally Disproportionate.

Even aside from *NFIB*, the IRA violates the unconstitutional-conditions doctrine, which "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). Like *NFIB*, this doctrine "is based on the proposition that government incentives may be inherently coercive." *Koslow*, 302 F.3d at 174. The IRA bears all the hallmarks of an unconstitutional condition. It pressures manufacturers by leveraging *other* medicines and transactions, abusing the federal government's market power to extort the abandonment of constitutional rights.

1. The Court has developed a framework "modeled on" the unconstitutional-conditions doctrine to police "extortion" in the context of real property. *Sheetz*, 601 U.S. at 275. It ensures that the government cannot eviscerate "the Fifth Amendment right to just compensation." *Koontz*, 570 U.S. at 604. Under that framework, benefits may be conditioned on the surrender of property rights only if the condition (1) has an "essential nexus" to the benefit and (2) is "rough[ly] proportiona[l]" to it. *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994); *see also Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 834-37 (1987). That *Nollan-Dolan* test is a more flexible version of the ordinary unconstitutional-conditions standard, yet the IRA still fails both parts of it.

First, since the Program seeks to extract a favorable price for Eliquis by threatening funding for *other* BMS medicines, there is no "essential nexus." *Dolan*, 512 U.S. at 386. It would be one thing to condition Medicare coverage for a medicine on the manufacturer's agreement to a mutually acceptable price for that medicine; in that scenario, the condition (agreeing to the price) would have a direct nexus to the benefit (coverage). But, tellingly, the Program operates differently. "The nexus requirement ensures that the government is acting to further its stated purpose, not leveraging its … monopoly to exact private property without paying for it." *Sheetz*, 601 U.S. at 275. The government here is doing the latter—using Medicare's monopsony to broadly hold other medicines hostage in order to "exact" a particular product "without paying for it." *Id.*; *see also Cedar Point*, 594 U.S. at 162 (holding that "access" mandate was not sufficiently "germane to any benefit provided").

Scholars call a condition that takes this form—unrelated to the benefit withheld—"cross-collateralized," and treat it as a "powerful indicator the condition" is unlawful. P. Hamburger, PURCHASING SUBMISSION 69 (2021). For its part, the Supreme Court called this sort of condition "extortion." *Nollan*, 483 U.S. at 837-38; *Sheetz*, 601 U.S. at 268. That is not hyperbole. It can be *criminal* to threaten unrelated financial harm as a means to obtain property to which one has no lawful right. *See Buster v. George W. Moore, Inc.*, 783 N.E.2d 399, 411-12 (Mass. 2003); *Care One Mgmt. LLC v. United Healthcare Workers E.*, 43 F.4th 126, 147 (3d Cir. 2022) (asking whether there is a "reasonably close relationship" or "nexus" between "alleged extortionate acts and the objective sought").

Second, at minimum, the threat to terminate coverage for *all* of a manufacturer's medicines is not "rough[ly] proportiona[l]," *Dolan*, 512 U.S. at 391, to the requirement to transfer a *single one* at a discount. Hinging all access to the Medicare and Medicaid markets on an agreement to sell one medicine at a discount is a perfect illustration of a coercive condition, not a proportional one. It thus fails the second *Dolan* requirement, too. *See FCC v. League of Women Voters*, 468 U.S. 364, 400 (1984) (invalidating condition that required radio station receiving government grants accounting for "only 1% of its overall income" to abstain "from all editorializing").

An antitrust analogy is instructive here. The FTC has claimed that a pharmaceutical manufacturer would engage in unlawful "tying" by conditioning rebates for its portfolio of popular drugs on granting access to a single other product. *See* Compl., *FTC v. Amgen, Inc.*, No. 23-cv-3053 (N.D. Ill. May 16, 2023). Yet the Program is a mirror image.

The government wields immense "market power" as the ultimate payor for Medicare and Medicaid. *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45 (2006). It is leveraging its control over the "tying" market (Medicare and Medicaid) to "force" BMS to hand over the "tied" product (Eliquis) at a preferred price.

As one Fifth Circuit judge recently observed at oral argument in a related appeal, the Program would be "beyond" an "antitrust violation" if committed by a private party. Oral Arg. at 29:30-30:10, *Nat'l Infusion Cntr. Ass'n v. Becerra*, No. 24-50180 (5th Cir. May 1, 2024). If such behavior by a private monopolist is unlawfully coercive under the antitrust laws, it stands to reason that the same behavior undertaken by the government is also unlawfully coercive under the unconstitutional-conditions doctrine.

2. The violation is even more obvious for the IRA's speech mandate. 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. 327, 359 (1976) (plurality op.). In particular, the First Amendment forbids "compel[ling] a grant recipient" to profess "the Government's view on an issue," since such a requirement "by its very nature affects protected conduct outside the scope of the federally funded program." *AID*, 570 U.S. at 218; *see also Speiser v. Randall*, 357 U.S. 513 (1958).

Compelling BMS to publicly "agree" that CMS prices are the "maximum fair" ones is plainly not a lawful condition. While it is central to the Program's practical operation, it does not limit how federal money is spent; it merely forces BMS "to pledge allegiance to the government's policy." *AID*, 570 U.S. at 220. That is impermissible.

C. The District Court's Holding That All Medicare Conditions Are Automatically "Voluntary" Was Profoundly Wrong.

The district court did not engage with these arguments. It did not apply the tests outlined in *NFIB*, *Dolan*, or *AID*. Instead, it held that participation in Medicare—no matter what new conditions Congress imposes—is always "voluntary" because BMS can abandon Medicare and "continue to sell [its] drugs to any purchaser other than the federal government." JA.17; *see also* JA.20 (rejecting First Amendment challenge because "the Court has already concluded that the Program is voluntary"). That is not the law. The district court's decision bypasses the unconstitutional-conditions doctrine—and thus poses a dangerous threat to *all* rights.

Congress's Spending Clause power is extraordinarily potent. *See NFIB*, 567 U.S. at 533. HHS alone "spends an average of more than $100 billion per month, which means about $3.3 billion per day or nearly $138 million per hour," allowing "the federal government [to] lean heavily on participants." Hamburger, *supra*, at 6. The Spending Clause also allows Congress to regulate beyond its enumerated powers, *South Dakota v. Dole*, 483 U.S. 203, 206-08 (1987), creating the risk of evading crucial limits on federal authority. *See NFIB*, 567 U.S. at 533. Long ago, the Supreme Court recognized this risk—and cautioned that it would not allow federal spending to be used to coerce individuals and businesses into giving up their constitutional rights. *Frost*, 271 U.S. at 594. The Court's doctrines refuse to permit unchecked spending authority to subsume "the Constitution's structures of power as well as its rights." Hamburger, *supra*, at 6.

Specifically, the Court's voluntariness and unconstitutional-conditions doctrines implement these limits. Applying them, courts ensure that the government does not abuse the power of the purse to "do indirectly what [it] is barred from doing directly." *NRA v. Vullo*, 602 U.S. 175, 190 (2024); *see also Pac. Co. v. Johnson*, 285 U.S. 480, 501 (1932) (articulating same principle nearly a century ago).

The district court ignored these fundamental limits, reasoning that since Medicare is "voluntary," any conditions must be permissible. JA.13-18. That does not follow. Participating in Medicare may be voluntary, but that does not mean the government can condition that participation on the waiver of constitutional rights. To the contrary, as the Supreme Court has noted, "[v]irtually all of our unconstitutional conditions cases involve a gratuitous governmental benefit"—in other words, one that the recipient can *voluntarily* accept or reject—"[y]et we have repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights." *Koontz*, 570 U.S. at 608.

If the law were otherwise, nothing would prevent the government from forcing Social Security recipients to grant property easements, quarter soldiers, or even pledge loyalty to the President. HHS could condition Affordable Care Act subsidies on the recipients' display of "I Love Obamacare" bumper stickers. Given that "the finances of most Americans include much government aid," Hamburger, *supra*, at 6, the district court's account would leave no rights secure, and leave *NFIB* and the unconstitutional-conditions doctrines with no function.

Nor can those doctrines be bypassed simply by characterizing the government's actions here as within its capacity as a "market participant." JA.17. The district court cited no authority suggesting that the unconstitutional-conditions doctrine goes out the window whenever the government buys or sells things. Anyway, the Program is a quintessential exercise of sovereign power, not ordinary market forces. Only the government can tax private parties who decline to obey its terms, as the IRA threatens. Only the government can legislate its own market dominance, as Congress did by enacting Medicare Part D and acquiring monopsonistic market control. And only the government can punish obstreperous private parties by shutting them out of other markets without fearing antitrust sanctions, as the Program purports to do.

Finally, the cases that the district court cited for the proposition that any condition on Medicare is voluntary and thus constitutional are manifestly inapposite. JA.15. Most obviously, none involved mandates to turn over property, let alone engage in speech, as a condition of participating in Medicare or another program.

In *Baptist Hospital East v. HHS*, hospitals challenged a rule denying reimbursement for "free health care" they *volitionally* provided "to non-Medicare patients." 802 F.2d 860, 862 (6th Cir. 1986). There was no constitutional problem, since the hospitals were "adequately compensate[d] for services to Medicare patients, and the Act neither requires nor permits more." *Id.* at 869. This was simply a limit on what the government subsidizes—not even arguably a taking of any property—and participating in Medicare subject to those limits was indeed "wholly voluntary." *Id.* Not so here.

Likewise, in *Minnesota Association of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare*, nursing homes that participated in Medicaid challenged a cap on the rates they could charge non-Medicaid patients. 742 F.2d 442, 444 (8th Cir. 1984). That was an ordinary price cap that "d[id] not involve a forced taking of property," *id.* at 446, and infringed "no constitutional right," *id.* at 447. So imposing that rate regulation as a condition of Medicaid participation necessarily did not require the nursing homes "to relinquish" any "constitutional right" either, and could not violate the unconstitutional-conditions doctrine. *Id.* This case is fundamentally different because the government *cannot* directly force manufacturers to provide "access" to their medicines, or to convey falsehoods about those prices. *See supra* Parts I & II. That is the necessary predicate, absent elsewhere, for application of the unconstitutional-conditions doctrine.

Finally, the court cited *Livingston Care Center, Inc. v. United States*, 934 F.2d 719 (6th Cir. 1991), the least relevant of them all. That case held that a nursing home could not sue to challenge its termination from Medicare, because the Act provided an exclusive alternative route for such claims. *See id.* at 720-723.

The district court erred by invoking snippets of stray dicta from these facially inapt cases, instead of conducting the nuanced analysis called for by the Supreme Court's controlling standards under *NFIB*, *Horne*, *Dolan*, and *AID*.[9]

[9] The court also cited two district-court decisions upholding the IRA. As the court acknowledged, however, those cases involved distinct challenges focused on procedural due process. JA.14 & n.10. To the extent they included broader "voluntariness" dicta, they are wrong for all of the reasons discussed above.

* * *

Accumulating dominance over the national market for prescription medicines, and then exploiting that legislated market power to extort manufacturers to give up their property and betray their convictions, is anathema to the Constitution. Far from a way around the constitutional defects with this Program, it is the type of abuse of the Spending Clause that the Supreme Court has been warning against for 100 years. This Court should not countenance it.

CONCLUSION

The Court should reverse the decision below.

Respectfully submitted,

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, NY 102811

Jeffrey J. Greenbaum
Katherine M. Lieb
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, NJ 07102

/s/ Jacob (Yaakov) M. Roth
Noel J. Francisco
Yaakov M. Roth
Brett A. Shumate
Charles E.T. Roberts
John Henry Thompson
Louis J. Capozzi III
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
(202) 879-3939

Counsel for Appellant
Bristol Myers Squibb Company

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 12,999 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.

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Dated: July 12, 2024

/s/ Jacob (Yaakov) M. Roth
Jacob (Yaakov) M. Roth

Counsel for Appellant Bristol Myers Squibb Company

CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2024, this brief was electronically filed with the Clerk of Court using the appellate CM/ECF system.

Dated: July 12, 2024

/s/ Jacob (Yaakov) M. Roth
Jacob (Yaakov) M. Roth

Counsel for Appellant Bristol Myers Squibb Company